College of the Holy Cross

Bloodborne Pathogen

Safety Manual

Triumvirate Environmental, Inc.

Modified by Jamie Herrick, Biosafety Officer

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Reviewed annually

Exposure Incident

Report exposure immediately; you may need immediate therapy.

- **Needlesticks/puncture wounds:**

  Wash the affected area with antiseptic soap and warm water for 15 minutes.

- **Mucous membrane exposure:**

  Flush the affected area for 15 minutes using an eye wash.

For all exposure incidents:

- Notify Biosafety Officer or your supervisor to initiate accident or exposure incident report.

  Seek medical assistance immediately (within 1-2 hours) - College of the Holy Cross Health Services 508/793-2276.

College of the Holy Cross Biosafety Manual was prepared by Ronnie P. Souza, Life Sciences Consulting Manager, Triumvirate Environmental and edited by Jamie Herrick, Chemical Hygiene Officer, College of the Holy Cross

College of the Holy Cross Commitment to Safety

Holy Cross maintains a policy to provide their employees with a safe and healthy work environment. This Blood Borne Pathogens Program has been formulated around fundamental principles of accident prevention and possesses the strong commitment and support of senior management. Personnel at all levels are expected to comply with requirements of the Blood Borne Pathogens Program and participate in the safety program by reporting to their supervisor unsafe processes or conditions and ideas to improve the safety of the work environment at Holy Cross. The Blood Borne Pathogens Program complies fully with the OSHA Blood Borne Pathogens Standard as well as other safety and health standards established by federal, state and municipal laws, guidelines and regulations.

Contents

1. INTRODUCTION

Universal Precautions (developed by CDC) are protective measures employees use to eliminate or minimize exposure to infectious agents that may be present in human blood, tissues or certain body fluids. Universal Precautions are based upon the premise that all human blood, tissues and certain body fluids are treated as if known to be infectious for HIV, HBV and other bloodborne pathogens. Individuals who handle blood or these body fluids must wear appropriate personal protective equipment to prevent contact with potentially infectious materials.

The Occupational Safety and Health Administration (OSHA) incorporated many of CDC's Universal Precautions guidelines into a standard titled "Occupational Exposure to Bloodborne Pathogens". The standard was published on December 6, 1991 and a copy can be found in Appendix A of this manual. The OSHA standard outlines:

1. the criteria employers are to use to determine who is potentially exposed to bloodborne pathogens
2. the elements of an acceptable exposure control plan
3. the acceptable methods for reducing or eliminating potential exposure (engineering and work practice controls, personal protection equipment and housekeeping)
4. the information on bloodborne pathogen hazards that must be communicated to all potentially exposed employees
5. the special training and work practice requirements in HIV and HBV research laboratories and production facilities
6. the employer's obligation to provide Hepatitis B vaccination to all potentially exposed employees and post-exposure follow-up to employees exposed during incidents
7. the records that must be maintained

The bloodborne pathogen standard applies to all employers with "occupationally exposed" employees. OSHA's regulatory definition of "occupational exposure" in this standard departs from its use in other standards. In other standards, occupational exposure has referred to an actual exposure event. In the bloodborne pathogen standard, OSHA defined "occupational exposure" as reasonably anticipated skin, eye, mucous membrane, or parenteral contact with human blood or "other potentially infectious materials" that may result from performance of an

employee's duties. OSHA uses the term "exposure incident" to refer to an actual exposure. Therefore an individual is considered occupationally exposed even if he/she does not have direct contact with blood or other potentially infectious material.

In the regulation, OSHA defines "other potentially infectious materials" as: "...semen, vaginal secretions, cerebrospinal fluids, synovial fluids, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; any unfixed tissue or organ (other than intact skin) from a human (living or dead); and human immunodeficiency virus (HIV) – containing cell or tissue cultures, organ cultures, and HIV- or Hepatitis B virus (HBV) - containing culture medium or other solutions; and body organs, or other tissues from experimental animals infected with HIV or HBV." OSHA also considers all primary and continuous cell cultures as potentially infectious if not screened and shown negative for the presence of all bloodborne pathogens.

2. HOLY CROSS'S EXPOSURE CONTROL PLAN

The information in the Exposure Control Plan is intended to eliminate or minimize employee exposure to bloodborne pathogens and outlines how Holy Cross will comply with all provisions of the OSHA bloodborne standard. The Holy Cross Exposure Control Plan also identifies the job classifications of all "occupationally exposed" employees. This Exposure Control Plan is reviewed annually.

3. TRAINING REQUIRED BY OSHA'S BLOODBORNE PATHOGEN STANDARD

The bloodborne pathogens training required by OSHA's standard must be performed at the time of employment and at least annually thereafter. The specific elements of an acceptable training program are outlined in the OSHA standard [1910.1030 (g) (2)], which can be found in Appendix A. This training manual contains all of the required training information.

4. EXPOSURE CONTROL RESPONSIBILITIES

Each of us is partially responsible for our health and safety on the job. We share responsibility for the welfare of other people in our work environment. Responsibilities identified in the Exposure Control Plan are highlighted below for your reference.

4.1 Occupationally Exposed Employees

Occupationally exposed employees are in a position to exert enormous control over situations in their workplaces. Their actions can prevent or create exposure risks for other employees. Occupationally exposed employees shall:

- attend training seminars
- learn the information presented and apply it in the workplace
- ensure personal protective equipment and engineering controls are inspected periodically and function properly
- implement sign and label requirements, work practice controls and housekeeping duties
- correct deficiencies in control equipment if possible and report all safety deficiencies to their immediate supervisor
- follow emergency action, exposure incident and post-exposure procedures

4.2 Biosafety Officer

Biosafety Officer shall assure:

- all employees participate in a Bloodborne Pathogens "new hire" training before they are assigned tasks where occupational exposure occurs and receive annual "refresher" training thereafter
- employees receive additional training when changes (modification of tasks or institution of new tasks) affect the employee's occupational exposure
- engineering controls are used whenever possible to eliminate or minimize employee exposure
- engineering controls, signs and labels are examined, maintained and replaced as necessary
- employees implement work practice controls
- personal protective equipment worn is appropriate for the task, is inspected before use, and functions properly
- emergency action procedures are understood and followed by all employees

4.3 Principal Investigators

A. Principal investigators are responsible for entire laboratory. Principal investigators shall assure:

- all exposed employees and supervisors fulfill their responsibilities
- all shipping requirements are met
- all equipment and work surfaces are cleaned and properly decontaminated
- special requirements for HIV and HBV research laboratories are fulfilled
- new occupationally exposed employees have been offered the Hepatitis B vaccine

B. Use of Personal Protective Equipment

Identify tasks and procedures that may result in skin, eye, mucous membrane or parenteral contact with blood, and list the personal protective equipment that will be utilized to minimize the exposure potential.

List Procedure and Check Required Protective Clothing

Task /Procedure with Exposure	Lab Coat	Surgical Gloves	Face Shield Eye Wear & Surgical mask	Other

C. Engineering Controls

List the engineering controls that will be utilized to eliminate or minimize occupational exposure, and identify personnel responsible for maintaining or replacing on a regular schedule to ensure their effectiveness.

Engineering Control	Personnel Responsible	Maintenance Schedule
Sharps Container	All lab members	Replace when 2/3 - 3/4 full
Plexiglass bench shield	All users	Decontaminate after use
Biowaste bags	All lab members	Replace when 2/3 - 3/4 full
Biosafety Cabinet	All users	Decontaminate before and after use, and immediately following a spill of blood
Vacuum filters	All users	Replace when contaminated, wet or damaged
Plastic transport bins	All users	Decontaminate after use
Forceps and other mechanical means of sharps collection	All personnel	Decontaminate after use

D. Disinfection and Decontamination

The Principal Investigator/Lab Supervisor is responsible for ensuring that laboratory is kept neat and clean. Work surfaces and lab equipment must be decontaminated with a suitable disinfectant (such as ethanol or an EPA registered tuberculocidal disinfectant) after use and immediately after a spill of potentially infectious material or human blood.

5. BLOODBORNE PATHOGEN EPIDEMIOLOGY, SYMPTOMATOLOGY, TRANSMISSION

OSHA has determined that occupational exposure to human blood, tissues and body fluids poses a significant health risk because these may contain bloodborne pathogens such as:

- Human Immunodeficiency Virus
- Bloodborne Hepatitis Viruses (Hepatitis B Virus, Hepatitis D Virus, Hepatitis C Virus)

- Plasmodium species
- Treponema species
- Babesia species
- Brucella species
- Leptospira species
- Francisella species
- Streptobacillus moniliformis
- Spirillum minus
- Colorado Tick Fever Viruses (arboviruses- Colorado Tick fever viruses, Kemerovo, Lipovnik, Quaranfil,
- Bhanja, Ganjam, Thogoto and Dugbe viruses)
- Borrelia species
- Creutzfeldt-Jakob agent
- Human T-lymphotropic Virus Type I
- Hemorrhagic Fever Viruses (Ebola, Marburg, Lassa and Crimean-Congo viruses)

The greatest occupational exposure potential for the clinical and laboratory worker is a puncture wound from a sharp (such as needles, cutting instruments, broken glassware) contaminated with human blood, tissue or body fluid. Handling human specimens and direct contact (person to person) are also potential exposure routes. Direct and indirect contact with bloodborne pathogens enables them to enter the body through broken skin (parenteral entry) and through the mucous membranes of the eyes, nose, mouth and urogenital tract.

The bloodborne pathogens that cause malaria, tularemia, leptospirosis, relapsing fever, Lyme disease, brucellosis, babesiosis, viral hemorrhagic fever and Colorado tick fever can also be transmitted by insect bites or animal contacts.

The table in Appendix B, lists the most common bloodborne pathogens, initial symptoms, routes of entry and transmission information.

The following two sections review in detail the epidemiology, symptomatology and mode of transmission of AIDS and Viral Hepatitis.

5.1 AIDS: Human Immunodeficiency Virus (HIV)

HIV is a retrovirus that causes the Acquired Immune Deficiency Syndrome (AIDS) - a severe life-threatening illness which suppresses the body's ability to fight infection and can impede neurological function. There are two known strains, HIV-I and HIV-II. HIV-I is the etiologic agent of

AIDS in North and South America, Europe and Central and East Africa. HIV-II is endemic only in West Africa.

HIV replicates primarily in human macrophages and T4 lymphocytes. Invasion of these two vital components of the immune system gradually depletes the number of cells necessary for normal immune function. As a result, an infected individual's susceptibility to opportunistic infections is increased.

AIDS was first described in 1981 in New York and Los Angeles during an unusual incidence of Pneumocystis carinii pneumonia and Kaposi's sarcoma in homosexual men who had no known underlying immunodeficiency. In the United States, 51% of all AIDS cases have been men who reported sexual contact with other men. In central Africa and in some areas of the Caribbean, sexual transmission appears to be primarily heterosexual. Other sexually transmitted diseases such as herpes, syphilis, and chancroid may facilitate transmission of HIV through ulcerations in the mucous membranes.

Bloodborne pathogen transmission has occurred: (1) by transfusion of blood from HIV infected donors; (2) through receipt of clotting factors for treatment of hemophilia; (3) through the sharing of needles for injection of drugs; (4) through unprotected sexual intercourse with an HIV-infected person (5) through accidents in health care settings with needles or other sharps contaminated with HIV infected blood; and (6) accidental blood splashes on mucous membranes. Up to 30% of infants born to HIV infected mothers may be infected with HIV themselves. The exposure occurs either in utero or during labor and delivery. There are also reports of HIV virus transmission during breast-feeding.

Post-exposure prophylaxis is available for occupational exposure to HIV. The CDC recommends that workers who have an exposure incident must be evaluated within 1 hour for a risk assessment and possible prophylactic treatment with antiviral drugs. All potential HIV exposures must be reported and evaluated within 1 hour to insure optimal treatment.

Infection with HIV appears to be lifelong. The disease is characterized by a very long incubation period, which is the time of infection to the onset of life-threatening opportunistic infections, and malignancies that signal the development of full-blown AIDS. Disease progression with HIV is divided into several stages according to types of infections or symptoms reported and are associated with progressive decline in CD4+ cells.

- Acute Infection:
    - Within 1 to 4 weeks after infection, an individual may experience acute retroviral syndrome, which will manifest itself in a mononucleosis-like or flu-like illness. Unexplained fever, lymphadenopathy, myalgia (muscle pain), arthralgia (joint pain),

headache, sore throat, unexplained diarrhea, fatigue, loss of appetite and rash are signs and symptoms of this usually self-limiting stage.

- Asymptomatic Infection:
    - During this stage which occurs 4 to 12 weeks after infection, most individuals will develop HIV antibodies (seroconversion). These individuals may be asymptomatic for months to years but can transmit the virus to others.
- Symptomatic HIV infection/AIDS Related Complex (ARC):
    - During this stage which may last from months to several years after infection, many of the symptoms of acute infection reemerge. Oral candidiasis (oral thrush), oral hairy leukoplakia, Herpes zoster in individuals younger than 60 years and ulcerative Herpes simplex may also occur.
- AIDS:
    - Many HIV infected individuals go on to develop AIDS months to several years after initial infection. Their immune systems become severely weakened turning normally mild, opportunistic or rare infections into potentially fatal diseases. Indicator diseases of AIDS include: Pneumocystic carinii pneumonia, the most common cause of death; fungal diseases of the esophagus, trachea, bronchi or lungs especially with Candida or Cryptococcus; Cytomegalovirus (CMV) retinitis; Kaposi's sarcoma; primary brain lymphoma; extrapulmonary disseminated mycobacteria tuberculosis; any mycobacterial disease caused by mycobacteria other than Mycobacterium tuberculosis, especially Mycobacterium avium complex or Mycobacterium kansasii; pulmonary tuberculosis; recurrent pneumonia; invasive cervical cancer; brain toxoplasmosis; disseminated fungal diseases, especially coccidioidomycosis and histoplasmosis; HIV associated encephalopathy (AIDS dementia); HIV associated wasting syndrome (slim disease); HIV disease progression is often associated with decrease of CD4 + cell count throughout.

5.2 VIRAL HEPATITIS: Hepatitis B, Hepatitis D, and Hepatitis C Viruses

Viral hepatitis is an ancient disease. The liver, the major target organ in viral hepatitis, plays an essential role in metabolism and degradation and detoxification mechanisms. Cellular damage to the liver, either directly or indirectly, results in a broad range of individual symptoms.

Despite widespread diagnosis and knowledge of infection routes, hepatitis remains one of the leading viral diseases requiring hospitalization in the United States. Over 200,000 cases are reported annually to the CDC. The clinical manifestations of viral hepatitis vary widely from asymptomatic clinical

inapparent disease to severe acute symptoms of fatigue, nausea, anorexia, vomiting and fever to chronic and debilitating liver disease followed by cirrhosis and hepatocellular carcinoma.

5.2.1 Hepatitis B Virus (HBV)

HBV is a hepadnavirus. As the name indicates, it is a DNA virus, which infects the liver and replicates in liver cells (hepatocytes). HBV is released into the bloodstream from infected hepatocytes. HBV infection may result in a long term carrier state with either mild or severe chronic liver disease including primary hepatocellular carcinoma. The virus is found all over the world with over 200 million carriers worldwide. The carrier rate among "healthy" adults
in the United States varies from 0.02% to 0.1% with the pool of carriers increasing 2% to 3% annually. Total infection with HBV is 5 to 10 times the carrier rate since most infections result in clearance of viremia followed by immunity. More than 50% of foreign-born Asians in the United States are HBV antigen positive.

Blood and blood products are the most effective vehicles for the transmission of HBV. Hepatitis B surface antigen (HBsAg) has been found in virtually all body secretions and excretions, however, only blood, saliva, breast milk, semen and vaginal fluids have shown to be infectious.

Accidental direct percutaneous inoculation (needlestick or other sharp) is the most efficient HBV transmission method. Percutaneous transfer of HBV infected serum or plasma without direct puncture can occur through minute cutaneous scratches or abrasions and through contamination of mucous membranes. Indirect transfer of infective material to skin or mucous membranes can occur by way of contaminated medical devices, gloves or other environmental surfaces.

The efficiency of HBV transmission by the various methods is due to the extraordinary amount of circulating infectious HBV in the blood of infected individuals who are either in the acute phase of infection or who are HBAg carriers and are positive for Hepatitis B "e" antigen (HBeAg). The presence of HBsAg and HBeAg and of HBV viral DNA in an individual's serum is a sign of relatively high infectivity. HBsAg and HBeAg positive human serum can be diluted a hundred million times and still induce HBV infection in experimental animals. HBV is an extremely stable virus in the environment. Studies at the CDC demonstrated HBV in HBsAg and HBeAg positive sera remained infectious after drying on a surface at 42% relative humidity for at least a week.

5.2.2 Hepatitis D Virus (HDV)

First described in Italy in 1977, HDV (delta agent) is a defective RNA containing virus with HBsAg as a surface coating. HDV requires HBV for replication. It appears to be worldwide in distribution and is endemic in areas of Southern Europe, Africa, the Middle East and South America. The virus is found in HBsAg positive individuals from the same risk groups as in HBV infection.

Three types of infection may result from HDV:

- Acute HDV infection superimposed on chronic HBV infection is the most serious category. HDV can replicate indefinitely in the presence of HBV resulting in fulminate disease with high morbidity and mortality. If an individual survives this serious complication of HBV infection, the end result may be chronic hepatitis and cirrhosis.
- Chronic HDV superimposed on chronic HBV infection is often asymptomatic.
- Simultaneous HBV and HDV infection manifests itself as an acute viral hepatitis and usually resolves without complications.

5.2.3 Hepatitis C Virus (HCV)

HCV or parenterally transmitted hepatitis nonA-nonB (NANB) virus is an enveloped RNA virus. HCV infection is the most common chronic bloodborne infection and is a major cause of liver disease in the United States. An estimated 3.9 million Americans have been infected with HCV. There are 175,000 documented cases of HCV in US annually and an estimated 560 to 1120 occupationally transmitted cases. At least 85% of persons with HCV infection become chronically infected, and chronic liver disease with persistently elevated liver enzymes develops in approximately 70% of all HCV infected persons. Persons with chronic hepatitis C are at risk for cirrhosis and primary hepatocellular carcinoma.

Most HCV transmission is associated with direct percutaneous exposure to blood. Health care workers (HCW) are at occupational risk for acquiring this viral infection. However, no vaccine is available to prevent hepatitis C, and immune globulin and antiviral agents are not recommended for postexposure prophylaxis.

The severity of HCV infection ranges from inapparent cases to, in rare cases, fulminating fatal disease. Over 60% of HCV infections progress to chronic liver disease over a period of years. Symptomatic chronic HCV infection often improves within 3 to 5 years after infection but may progress to cirrhosis. In infected individuals, HCV antibody is not detected until an average of 15 weeks after the onset of hepatitis (22 weeks) and may even remain undetectable for a year. There exists a "healthy" carrier state since HCV viremia may persist throughout the course of disease and is not always cleared.

6. DOOR SIGNS, LABELS AND COLOR CODING

6.1 Wall and Door Signs

Entry ways to research and clinical areas that handle human blood and other potentially infectious materials must be posted with a Biosafety Level sign that contains the universal biohazard symbol, bears the legend “Biohazard” and BL2.

The sign includes the international biohazard symbol, bears the legend "Biohazard", and identifies the name of the infectious agent, any special entrance requirements, and the name and phone numbers of the principal investigator or any other responsible persons. The following elements must be included on the door sign:

BIOHAZARD

(Name of infectious agent)

(Special entrance requirements)

(Name, telephone number of the principal investigator or other responsible person)

The door signs shall be fluorescent orange-red (or predominantly so) with lettering or symbols in a contrasting color.

6.2 Labels and Color-coding

Inside the facility, warning labels shall be affixed to containers of medical waste, refrigerators, freezers, incubators, and centrifuges containing BL2 agents, human blood or "other potentially infectious material". Other equipment such as water baths, and biological safety cabinets do not require a permanent biohazard label if decontaminated after each use. In these situations, a biohazard label should be temporarily posted on the equipment while in use with human blood, other potentially infectious materials, or an infectious agent.

Warning labels shall also be affixed to other containers used to store, transport or ship BL2 or, human blood or "other potentially infectious material". Note: Shipping blood and “other potentially infectious materials” not suspected of harboring an infectious agent may not require the biohazard warning label, just the diagnostic specimen label (UN3373). Labels required must have the international biohazard symbol and bear the legend "Biohazard" (see figure below).

BIOHAZARD

The labels shall be fluorescent orange-red (or predominantly so) with lettering or symbols in a contrasting color. Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or any other method that prevents their loss or unintentional removal.

The use of warning labels may be waived if: (1) waste is placed in red bags or red containers; or (2) individual containers of blood or "other potentially infectious materials" are placed in a labeled secondary container during storage, transport, shipment or disposal.

6.3 Labeling Equipment Sent Out for Repair or Being Discarded

Potentially contaminated and contaminated equipment sent out for repair or disposal must be decontaminated as thoroughly as possible. Affix a biosafety notice tag to the equipment indicating when the equipment was decontaminated, what disinfectant was used, and the name of the person who performed the decontamination. Thorough decontamination of highly technical or sensitive equipment or equipment with limited access to contaminated areas may not be possible. Decontaminate the equipment to the degree possible (flushing lines or wiping down the exterior) and affix a biohazard label indicating which areas of the equipment remain contaminated before sending it out for repair. The biohazard label must include the biohazard symbol as well as the term "biohazard". The label must convey this information to all affected workers (service representatives, manufacturer, etc.).

7. ENGINEERING CONTROLS

Engineering controls include equipment, devices or supplies that reduce the risk of employee exposure by removing the hazard or isolating the worker from the hazard. Examples of engineering controls include biological safety cabinets, autoclaves, safety centrifuges, splash guards, mechanical pipetting devices.

Utilize appropriate engineering controls whenever possible. Good work practices are necessary to assure that engineering controls work effectively. Engineering controls require preventive maintenance or periodic replacement to provide employee protection. It is the direct responsibility of the supervisor to insure engineering controls operate properly.

Engineering controls such as biological safety cabinets, safety centrifuges and mechanical pipetting devices are to be decontaminated immediately (or as soon as feasible) when overtly contaminated, or after a spill of blood or other potentially infectious materials. Engineering controls shall also be decontaminated at the end of the work shift. Decontamination should be performed with a ethanol, 10% household chlorine bleach solution or an EPA registered tuberculocidal disinfectant. Engineering controls can be organized into four categories:

1. controls that reduce needlestick opportunities

2. controls that contain spills
3. controls that contain splashes and aerosols
4. controls that decontaminate

7.1 Controls That Contain Spills

7.1.1 Plastic Backed Towels, Bench Coats or Diapers and Spill Trays

Plastic backed towels, bench coats or diapers and spill trays used in conjunction with the biohazard warning label symbol provide a flexible, clear definition of work areas where potentially infectious materials are in use. They also absorb and/or contain potentially infectious materials in the event of a spill and facilitate clean up when work is completed. Because spill trays are reusable, the volume of medical waste generated each day may be reduced.

Long term use of spill trays may be more cost effective than the plastic backed towels or diapers.

Considerations and Limitations of Plastic Backed Towels, Bench Coats or Diapers and Spill Trays:

1. Towels, coats or diapers must be removed, decontaminated, discarded and replaced when visibly soiled or at the end of the work shift.
2. Notebooks, pens and other common use items must not be placed in the defined biohazard work area.
3. Infectious materials spilled on spill trays may splatter or aerosolize.

7.2 Controls That Contain Splashes and Aerosols

Controls that contain splashes and aerosols include splash guards, biological safety cabinets (BSCs), mechanical pipetting devices, safety centrifuges, vacuum line trap and filter systems, safety blenders and safety sonicators. The following types of controls should be incorporated into protocols whenever possible.

7.2.1 Vacuum Line Chemical Traps and Filters

Vacuum line chemical traps and filters prevent suction of human blood and other potentially infectious materials into the vacuum lines. The trap systems also prevent vacuum lines from clogging with non-infectious material. A vacuum filter is located between the overflow flask and the vacuum line.

Considerations and Limitations of Vacuum Line Chemical Traps and Filters:

1. The collection flasks should be monitored and emptied or replaced before they are filled. All connections or seals shall be tight to assure the vacuum is adequate.
2. Add full strength chemical disinfectant to collection flasks and allow the aspirated fluids to dilute disinfectant to appropriate concentration. (For example: Start with 100 ml household chlorine bleach, aspirate 900 ml fluids and discard.) Vacuum line filters shall be examined and replaced if

clogged or if liquid makes contact with the filter. Used filters shall be discarded in the medical waste stream.

7.2.2 Splash Guards

Splash guards are clear plastic shields that prevent potentially infectious material from splashing onto laboratory workers.

Considerations and Limitations of Splash Guards:

1. Splash guards protect against splashes - not aerosols.

7.2.3 Biological Safety Cabinets

Biological Safety Cabinets (BSCs) offer personal, product and environmental protection. A BSC isolates biohazards from the worker by confining the contaminant within the cabinet and removing the contaminants through High Efficiency Particulate Air (HEPA) filters. The cabinet's intake and exhaust air is filtered through a HEPA filter before flowing into or out of the BSC work area. Any aerosols generated within the cabinet work area are contained within the BSC. See Appendix E for a discussion of the proper use of the class II BSC.

Considerations and Limitations of Biological Safety Cabinets:

1. Many BSCs are equipped with germicidal ultra-violet (UV) lamps. The germicidal effect of the UV lamp is affected by time of exposure, distance, presence of dust or debris and the UV lamp intensity. Therefore UV lamp intensity must be monitored. Even though UV lamps maintain a blue visible glow throughout their lifetime, it does not mean the lamps still have a germicidal effect. Routine surface decontamination of the BSC is more effective then the use of UV lamps.
2. Biological Safety Cabinets (BSCs) must be certified after installation and before use, after being relocated and on an annual basis.
3. BSCs must be professionally decontaminated before the unit is relocated, stored or if service to the interior of the unit is required.

7.2.4 Mechanical Pipetting Devices

Mechanical pipetting devices must be used in place of mouth pipetting or mouth aspiration. Mechanical pipetting devices prevent:

(1) oral contamination by aspiration of infectious fluids or aerosols;

(2) transfer of infectious material from fingers to the mouth by the proximal end of the pipette;

(3) contamination of the work environment; and

(4) possible injuries from sharp or broken pipettes.

Considerations and Limitations of Mechanical Pipetting Devices:

1. Even though mechanical pipetting devices used with biohazards are decontaminated after use, they should be labeled with the biohazard symbol. When using mechanical pipetting devices, be careful not to create aerosols while dispensing liquids.

7.2.5 Centrifuge Safety Cups or Buckets

Safety cups or buckets with covers are designed to retain the contents of the centrifuge tube in the event of breakage or leakage.

Considerations and Limitations of Safety Cups or Buckets:

1. A centrifuge tube that leaks or breaks is likely to be under pressure. Routinely open safety cups inside a BSC to contain the release of any potential aerosols.

7.2.6 Safety Centrifuges

Safety centrifuges such as centrifuges with automatic locking mechanisms or solid lids prevent the centrifuge lid from being opened while the rotor is still in motion, thereby preventing the release of aerosols. The locking device is released after the centrifuge head has stopped revolving. Centrifuges without automatic locking mechanisms or solid lids shall be replaced by those with automatic locking mechanisms and solid lids as soon as possible.

Small table top centrifuges may be operated within a biological safety cabinet to protect workers from any aerosols generated. Place the centrifuge to the rear of the biological safety cabinet and do not perform any work in the biological safety cabinet while the centrifuge is in operation.

7.3 Controls That Decontaminate

Physical decontamination controls use low temperature, incineration, high temperature (either dry or moist heat), osmotic pressure, sonic and ultrasonic waves, ultraviolet light, x-rays and gamma rays to achieve their effect. Decontamination renders an item safe for further handling. Moist heat has greater penetrating power than dry heat.

One of the most effective physical decontamination controls is steam sterilization (autoclaving) which generates moisture and high temperature (pressurized steam) within a sealed chamber. Autoclaves can sterilize all items that are heat stable (not damaged by steam or high temperature). In gravity autoclaves, cycles of 250°F (121°C), 15 to 18 lbs. pressure for one hour may be required for decontamination. In the newer vacuum autoclaves, decontamination may require 270°F (132°C), 27 to 30 lbs. pressure for 45 minutes. Use a biological indicator to verify your autoclave technique.

Personal protective equipment (PPE) such as rubberized aprons, full face shields and heat and liquid resistant gloves must be worn when operating autoclaves. When autoclaves cannot be used, an alternative method such as chemical decontamination may be employed. Items must be soaked in a

tuberculocidal disinfectant or a 10% bleach solution for at least 30 minutes. Heavily soiled items must be cleaned first.

Considerations and Limitations of Autoclaves and Hot Air Ovens:

1. Whatever the temperature and time requirement for decontamination, the contents of each load must be positioned so that steam penetrates into, or heated air flows freely among all items to be decontaminated. Tightly sealed or stoppered materials may not be effectively decontaminated and may become dangerously pressurized causing injury when removed.
2. A routine autoclave maintenance program is recommended. Regular chemical "tape" monitoring of temperature and periodic biological monitoring should be performed to evaluate the effectiveness of the autoclave. Place biological indicators at locations inside the load, the area slowest to heat up, throughout the autoclave are the best indication of sterilization. Autoclaves should be tested periodically.
3. Items containing chemicals (such as phenol-chloroform) should not be placed in an autoclave or a hot air oven (remove chemicals first).

8. WORK PRACTICE CONTROLS

Work practice controls reduce the likelihood of employee exposure to infectious agents by altering the manner in which a task is performed. The protection provided by work practice controls is based upon employee behavior and attitude.

Proper work practice controls ensure that engineering controls and personal protective equipment are used effectively. Proper work practice controls protect others from exposure to pathogens in the work area or facility, reduce possible cross contamination and improve the quality of the work performed. Routine use of safe work practices also provides a margin of safety for unrecognized hazards.

REMEMBER: Safety is a shared responsibility. Your attitude and work practices are critical for your own health and safety, and for the welfare of those around you. A work practice essential to reducing employee exposure to bloodborne pathogens is the practice of Universal Precautions. According to the concept of Universal Precautions, all human blood and certain fluids are treated as if known to be infectious for HIV, HBV and other bloodborne pathogens.

8.1 General Work Practices

Organize and plan work procedures with your safety and the safety of others in mind and keep an uncluttered work space. Always make sure all necessary safety materials and exposure control equipment are available and in good working order. Keep tuberculocidal disinfectant or 10% household

chlorine bleach and paper towels nearby in case of a spill. Know the location of the eyewash and know how to use it. Test the eyewash once a week to flush the system. Always remove laboratory coats when leaving laboratory areas for general access areas such as lunchrooms and administrative offices.

Beards or mustaches may be undesirable in work places with potential airborne contamination. Facial hair retains particulate contamination more persistently than clean shaven skin. Clean shaven faces enhance the fit of facial masks and are required when respirators are used.

Eating, drinking, smoking, applying cosmetics and lip balm and handling contact lenses are prohibited in potentially contaminated work sites. Hand creams and lotions are permitted because they are not considered to be cosmetics. Use non-petroleum based hand creams only. Petroleum based hand creams can compromise the integrity of some brands of gloves.

Food and drink must never be stored in refrigerators, freezers, cabinets or bench tops where blood or other potentially infectious materials may be present.

8.2 Handwashing

Handwashing removes microorganisms that may have contaminated hands during manipulation of specimens, equipment and supplies or while treating patients or contacting environmental surfaces. Each clinical or laboratory area must have readily accessible handwashing facilities. Wash hands with soap and running water immediately, or as soon as feasible, after removing gloves and other personal protective equipment. Wash hands when leaving the laboratory area for general access areas such as lunchrooms, libraries, and administrative offices. Wash any other skin areas with soap and water, and flush mucous membranes with water immediately, or as soon as feasible, following contact with blood or other potentially infectious materials.

8.3 Reusable Sharps

Contaminated reusable sharps must be placed in special containers as soon as possible after use and stored or processed in a way that does not require employees to reach into the reprocessing container by hand and risk a needlestick or other injury.

Unlike disposable sharps that are immediately discarded within a leak-proof puncture-resistant container after use, procedures involving reusable sharps (such as razor blades and fine tip forceps) may present additional opportunities for needlestick or other injuries. Employees may face potential exposure to contaminated reusable sharps during collection, transport, decontamination, or while removing or changing blades.

According to the OSHA, “reusable sharps must be immediately placed in a leakproof puncture-resistant (sides and bottom) container that is labeled with a biohazard symbol or colored red.” Containers must be

maintained and used in a manner that prevents an employee from manually handling contaminated sharps.

The following precautions will help minimize your risk of percutaneous injuries from contaminated sharps.

- Place a leak proof puncture-resistant tray that contains a suitable disinfectant (such as 10% household bleach) in the immediate work area. Label the collection tray with the biohazard symbol label. Reusable sharps may also be autoclaved.
- Place reusable sharps in the collection tray immediately following use. Lay sharps in the same direction within the collection tray.
- Allow a sufficient contact time for disinfection (at least 20 minutes). If items are covered with debris, wipe clean with a small bristle brush, keeping your hands away from the blade. Decontaminate the brush after use,
- After decontamination, remove reusable sharps from the container with tongs or forceps. If bleach is used as a disinfectant, rinse items with ethanol or water to remove any corrosive residues.
- Substitute plastic for glass wherever feasible.

8.4 Footwear

Wear close-toed shoes at all times. Sandals or open-toed shoes do not provide adequate foot protection and are inappropriate laboratory. A dedicated pair of work shoes may reduce the amount and type of contamination introduced into the workplace by street shoes. This practice can also minimize the possibility of bringing microbial contamination from the workplace into the home.

8.5 Splash and Aerosol Control

All procedures involving blood or other potentially infectious materials must be performed in a manner that minimizes splashing, spraying, spattering and generation of droplets. This precaution decreases the chances of direct personal exposure and reduces the contamination of bench tops, instruments or other surfaces in the work area. Liquid cultures of infectious material, sealed ampoules and vacutainers are best opened in a biological safety cabinet (BSC). If a BSC is not available, use a splash guard.

Avoid mixing biohazardous materials by drawing and expulsion through pipettes. When delivering pipette contents into a container, allow the contents to run down the container wall or deliver the contents as close as possible to the fluid or agar level. Avoid dropping pipette contents from a height. Mix covered solutions by swirling, inverting or vortexing.

8.6 Housekeeping for Laboratory Workers - Surface/Equipment Decontamination

Laboratory workers are responsible for certain housekeeping activities. Work surfaces are to be decontaminated immediately (or as soon as feasible) when overtly contaminated, or after a spill of blood or other potentially infectious materials. Work surfaces must also be cleaned at the end of the work shift.

Equipment that may become contaminated with blood or other potentially infectious materials must be decontaminated:

1. when visibly contaminated
2. at the end of the work shift
3. prior to servicing or shipping.

Heavily soiled equipment that is also contaminated must be prewashed before being decontaminated. Most disinfectants or sterilants can not effectively penetrate organic material present on heavily soiled equipment. OSHA requires EPA registered tuberculocidal disinfectants or 10% household chlorine bleach be used to disinfect surfaces contaminated with human blood or other potentially infectious materials. Household chlorine bleach sold commercially has a concentration of 5.25 w/v (52,500 ppm) available chlorine. A 10% solution results in a 0.5 w/v (5,250 ppm chlorine) which inactivates bloodborne pathogens. The list of EPA registered tuberculocidal disinfectants is available on the web at http://www.epa.gov/oppad001/list_b_tuberculocide.pdf

Ethanol or isopropanol (70%) are effective disinfectants, but are not accepted by OSHA as being tuberculocidal. These alcohols are effective cleansers, and may be used in conjunction with a tuberculocidal disinfectant. Quaternary ammonium compounds are not believed to be effective against HBV- even though they are considered to be tuberculocidal. Products registered by EPA as HIV effective are not necessarily tuberculocidal, and are not necessarily effective against agents such as HBV, which is more resistant to inactivation than HIV.

Contaminated broken glassware must not be picked up directly by hand. Use mechanical devices (brush and dust pan, tongs or forceps) to facilitate clean up. Decontaminate the mechanical devices with a tuberculocidal disinfectant. Vacuum cleaners are not appropriate for clean up of broken contaminated glass.

Waterbaths and waterbath sonicators used for inactivating, incubating or testing of infectious substances should contain a disinfectant or other microstatic agent to minimize bacterial, fungal or algae growth. Change the water periodically or whenever growth is observed.

Freezers and refrigerators shall be checked periodically. Promptly remove any broken vials, ampoules or tubes containing human material or other potentially infectious materials and decontaminate the inside of the freezer or refrigerator.

General trash receptacles must be inspected daily to insure that regulated sharps are not inadvertently discarded in the general waste stream. Improperly discarded sharps can result in puncture wounds and cuts to custodians and other support staff.

Custodians are responsible for activities such as sweeping or mopping floors, removing general trash, and cleaning general environmental surfaces such as floors and walls. Custodians are instructed not to touch any laboratory, materials, supplies or special wastes unless instructed by their supervisor to do so. Custodians are instructed not to remove general trash if they find medical waste in the trash receptacle or to pick up medical waste from the floor. Custodians are not responsible for cleaning and decontaminating laboratory spills.

9. PERSONAL PROTECTIVE EQUIPMENT (PPE)

Engineering and work practice controls provide the first level of protection against exposure to bloodborne pathogens. Personal protective equipment (PPE) is used to provide additional protection when the potential for an occupational exposure remains after engineering and work practice controls have been instituted. PPE is used to prevent blood or other potentially infectious materials from making direct contact with an employee's clothing or body.

The type and amount of PPE required depends upon the task to be performed and the type of anticipated exposure. The types of PPE utilized to prevent exposure to potentially infectious materials include disposable (single use) gloves, rubber utility gloves, protective body clothing (gowns, coats, jumpsuits, aprons), face and eye protection (face shield or surgical mask and protective eyewear), emergency ventilation devices, surgical caps, hoods or head covers, and shoe protection. Supervisors must discuss with their employees the type and proper use and limitations of PPE needed to perform job tasks safely.

9.1 General Guidelines for Personal Protective Equipment

The PPE must be easily accessible and of proper size and must not permit blood or other potentially infectious materials to pass through or to reach the employee's outer or inner clothing (including uniforms), skin, eyes, mouth, or other mucous membranes. Garments penetrated by blood or other potentially infectious materials must be removed immediately or as soon as feasible.

Hypoallergenic gloves, latex free gloves, glove liners, powderless gloves or different glove brands must be provided to employees who exhibit allergic reactions to the gloves normally provided. It is important to note that latex gloves have proved effective in preventing transmission of many infectious diseases to health care workers, but for some workers, exposures to latex may result in skin rashes; hives; flushing; itching; nasal, eye, or sinus symptoms;
asthma; and (rarely) shock. Reports of such allergic reactions to latex have increase in recent years – especially among health care workers.

All PPE must be removed prior to leaving the work area for common areas such as cafeterias, offices, etc. PPE must be placed in an appropriately designated area or container, for storage, washing, decontamination or disposal.

Don't touch clean surfaces, such as phones, door knobs or computers, with gloved hands. Supervisors are responsible for taking necessary measures to insure their employees wear the PPE outlined for specific tasks.

9.2 Considerations and Limitations of Personal Protective Equipment

1. Gloves must be inspected prior to use for holes or tears. Glove quality can vary with age, manufacturer and elastomeric materials used in fabrication.
2. Gloves must be replaced as soon as feasible if contaminated, torn, punctured or the integrity of the glove barrier is compromised.
3. Gloves do not protect against injuries from needles or other sharp objects.
4. Contaminated gloves must be discarded in the medical waste stream. Uncontaminated gloves may be discarded in the general trash.
5. Rubber utility gloves may be more desirable than disposable gloves when performing certain procedures such as cleaning. Rubber utility gloves may be washed and reused as long as the integrity of the glove is not compromised. Take care not to contaminate the inside of the gloves. Avoid grasping the outside of a contaminated glove with bare hands.
6. Always wash hands thoroughly with soap and water after glove removal.
7. Gowns, lab coats and jumpsuits protect the wearer's clothing and skin from contamination. As with all PPE, the type of clothing needed will depend on the task being performed and the degree of exposure anticipated.
8. Long sleeved protective clothing with snug fitting cuffs are preferred over open or short sleeves. Snug fitting cuffs prevent splashes, splatters and aerosols from making contact with exposed skin on the lower arms. Longer single use gloves can be pulled over snug fitting cuffs to seal out any infectious materials.

9. Plastic, vinyl or rubber aprons are usually worn over other protective body clothing when extra protection is desired. Aprons are generally used for protection against liquid spills, splashes or soiling of blood or other potentially infectious materials. Plastic, vinyl or rubber aprons may also be used to provide protection from steam and hot water in locations such as animal handling facilities, autoclave rooms and laboratory glass washing rooms.
10. Protective clothing must be removed as soon as feasible if contaminated or penetrated by blood or other potentially infectious materials and autoclaved before being discarded or laundered.
11. Face and mucous membrane protection must be worn whenever there is potential for the generation of splashes, spray, splatter or droplets of blood or other potentially infectious material in the eyes, nose, mouth or other facial areas.
12. Eye protection may prevent damage to the eye in addition to preventing exposure to bloodborne pathogens. Certain disinfectants and other chemicals can damage the eye or cause blindness if splashed in the eye.
13. Surgical masks are generally protective against droplets, splashes and sprays. Masks must cover both the nose and the mouth. Masks must fit the face closely, so the air passes through the mask before being inhaled. Some surgical masks are available with attached eye shields. Moisture from expired air may eventually saturate the mask, making breathing difficult. Change the mask once it has been compromised. Surgical masks do not protect the worker from aerosol exposure.
14. Shoe covers or boots shall be worn when gross contamination is reasonably anticipated. Circumstances where shoe protection may be necessary include animal rooms, surgery and autopsy rooms, etc. Shoe covers are required to prevent contamination migration and direct and indirect transmission.
15. Contact lenses provide no protection in the laboratory and should not be substituted for required eye protection. The use of contact lenses may increase the risk of eye damage because infectious agents and other microbes may become trapped between the contact lens and the cornea. The liquid between the contact lens and cornea is an excellent growth medium for microorganisms. If contact lenses must be worn, barrier eye protection shall be worn.

9.3 Decontamination of Personal Protective Equipment

Disposable gloves must not be washed or decontaminated for re-use. Disinfecting agents (including soap and water) often cause deterioration of glove material (e.g., latex). Washing with surfactants can result in "wicking" or enhanced penetration of liquids through the gloves. Wicking can transport potentially infectious materials to the skin inside the glove.

Rubber utility gloves may be decontaminated and discarded in the general waste stream. Contaminated utility gloves shall be discarded in the medical waste stream. Contaminated laboratory clothing must be autoclaved or 10% household chlorine bleach treated before being discarded. Reusable face and mucous membrane protection (face shields, goggles, safety glasses, surgical masks) must be decontaminated with 10% household chlorine bleach or an EPA registered tuberculocidal disinfectant when visibly soiled.

10. HEPATITIS B VACCINE INFORMATION

Hepatitis B vaccination provides the most effective protection from Hepatitis B virus. "Occupationally exposed" employees are strongly encouraged to receive the Hepatitis B vaccine. The Hepatitis B vaccine is offered free of charge by Holy Cross Pre-exposure vaccination is preferred. If an "occupationally exposed" employee initially declines the vaccine, he/she can choose to be vaccinated at a later time. The vaccine is also offered to unvaccinated employees who experience an "exposure incident". Employees who have already received the vaccine should have a blood test to demonstrate immunity to the virus.

10.1 Hepatitis B Vaccine

Hepatitis B vaccine is 96-99% effective in preventing HBV infection. Booster doses of hepatitis B vaccine are not necessary. If a routine booster dose of Hepatitis B vaccine is recommended by the US Public Health Service at a future date, the employer must make the booster dose available to its employees. The vaccine also protects against Hepatitis D viral (HDV) infection, as HDV requires the co-existence of HBV infection for viral replication.

The vaccine is a series of three injections given intramuscularly. The second dose is given 1 month after the first. The third dose is given 5 months after the second. Remember: All three shots must be given for the vaccination to be complete. Employees must be tested for antibody to Hepatitis B surface antigen 1 to 2 months after the completion of the series. Employees who do not respond to the primary vaccination series must be revaccinated with a second three-dose vaccine series and retested. Non-responders must be medically evaluated.

The first Hepatitis B vaccine (licensed in 1982) was made from inactivated human sera from people with chronic HBV infections. This vaccine is no longer available in the United States. The newer synthetic vaccines (first licensed in 1987) are much safer. Recombinant DNA technology enabled the Hepatitis B surface antigen (HBsAg) gene to be inserted into common baker's yeast cell DNA. These altered yeast cells produce HBV protein markers, but no complete virus particles. It is virtually

impossible to become infected with bloodborne pathogens from the vaccine. No whole or live virus particles or human sera are used in the vaccine preparation.

10.2 Medical Considerations

The only medical reason for not receiving the vaccine is a history of allergy to yeast or any of the vaccine components. Employees with a history of chronic illness or immunosuppression should consult their personal physician before receiving the vaccine. Pregnant women or nursing mothers should not receive the vaccine until it has been discussed with the physician. Vaccine administration should be delayed if possible in persons with a current febrile illness or other active infections. The most commonly reported side effects are local redness and soreness at the injection site, low grade fever, headache or dizziness in 1-10% of those vaccinated.

11. EMERGENCY ACTIONS

A bloodborne pathogen emergency is an unplanned release of human blood or "other potentially infectious materials". This release may be the result of: (1) a spill; (2) an aerosol release; (3) an injured co-worker; or (4) an unanticipated encounter with human blood or "other potentially infectious materials". If an "exposure incident" occurs in conjunction with an emergency, follow the exposure incident procedures outlined in section 12.0 in addition to the emergency action procedures described here.

11.1 Decontamination procedures for a spill or other release

Only "occupationally exposed" employees can perform decontamination procedures. Protective clothing and equipment appropriate for the situation must be worn. Household chlorine bleach or an appropriate tuberculocidal disinfectant shall be used to clean all spills of human blood and "other potentially infectious materials". Make up a fresh dilution of household chlorine bleach as follows - mix 1 part chlorine bleach with 4 parts water (For example: 1 cup chlorine bleach mixed with 4 cups water). Mix up a fresh dilution of an appropriate EPA registered tuberculocidal disinfectant following the manufacturer's instructions.

11.2 Emergency Actions to Take - Spills of Blood or Other Potentially Infectious Materials

Stop work immediately. Presume the spilled material is contaminated with bloodborne pathogens. Inform others in the immediate area that a spill has occurred. Employees who are not considered "occupationally exposed" must leave the area and not attempt to clean up the spill. These individuals must notify their supervisors and obtain assistance from employees who are considered

"occupationally exposed". If the spill occurred in a public access area (hallways, restrooms, etc.), or if you do not know how to proceed, notify Biosafety Officer or dial x2222 (508/793-2222) after hours.

If you will be cleaning up the spill, first contain it to prevent it from spreading to uncontaminated areas. Place paper towels or other absorbent materials over the spill. Pour enough disinfectant into the spill puddle to double its size (if possible). Allow the disinfectant to remain in contact with the spilled material for at least 15 minutes. Carefully mop up the liquid, or soak it up with paper towels or disposable pads. Pick up any glass (or other sharps) with tongs. Discard the towels or pads in a red bag. Remove all spilled materials and decontaminate the area again with an appropriate disinfectant. If a mop is used, soak the mop in fresh disinfectant for 20 minutes before rinsing for reuse. Wash reusable gloves with the disinfectant. Wash hands thoroughly with soap and water afterward. See Appendix F, Universal Precautions Spill Response Guide for further information on spill response to BL2 and blood spills.

11.3 Emergency Actions to Take - Aerosol Generation

Stop work immediately. Presume the aerosolized material is contaminated with bloodborne pathogens. Inform all others in the area that an aerosol may have been generated. All persons shall evacuate the room immediately for at least 30 minutes. Notify Biosafety Officer or call x2222 (508/793-2222). Label the area off-limits for at least 30 minutes. Decontaminate all exposed environmental surfaces after 30 minutes have passed and before releasing the room for normal use.

11.4 Emergency Actions to Take - Injured Co-worker

Assess the situation. If the injured worker can provide his or her own first aid, assist the person only by supplying bandages and dressings. The injured person will clean and decontaminate any contaminated work surfaces, if possible. If further assistance is needed, persons who are not considered "occupationally exposed" shall notify their supervisors and obtain assistance from workers who are considered "occupationally exposed".

Workers who assist injured co-workers must follow Universal Precautions while performing Good Samaritan acts. Employees must use their best judgment if the injury is life threatening. Employees who incur an exposure incident during a Good Samaritan act will notify their supervisor and seek treatment from a Medical Center.

11.5 Emergency Actions to Take - Unanticipated Encounters

A situation may arise where an unanticipated occupational exposure to human blood or "other potentially infectious materials" may occur. In all likelihood, employees experiencing an unanticipated encounter will not have previously been considered "occupationally exposed". These employees must attempt to avoid contact with human blood and "other infectious materials". They must notify their supervisors and Biosafety officer. Dial x2222 after normal working hours. If the employees at the scene

are considered "occupationally exposed" they shall follow the instructions for spills or aerosols as appropriate.

12. EXPOSURE INCIDENT RESPONSIBILITIES/PROCEDURES

An "exposure incident" is specific contact (eye, mouth, other mucous membrane, non-intact skin, or parenteral) with blood or "other potentially infectious materials" that results from the performance of an employee's duties.

12.1 Employee’s Responsibilities

An employee who sustains a known or potential "exposure incident" must wash the area immediately with soap and water. When hand washing sinks are not available, antiseptic hand cleanser or towelettes may be used for skin only. The exposed area must be washed with soap and running water as soon as possible. The employee must report the incident to his/her supervisor, and seek medical assistance at a Medical Center immediately.

12.2 Supervisor's Responsibilities

The supervisor must complete a Report of Injury form, documenting the route of exposure and the circumstances under which the incident occurred.

12.3 Medical Centers' Responsibilities

The Medical Center will provide the post-exposure evaluation and follow-up at no cost to employees who experience "exposure incidents".

12.4 Post-Exposure Evaluation and Follow-Up

All employees who have an "exposure incident" will be offered a confidential post-exposure medical evaluation and follow-up through the Medical Center.

13. UNIVERSAL PRECAUTIONS SPILL RESPONSE GIUDE

Prepare and maintain a spill response kit. Basic equipment is some concentrated disinfectant (chlorine bleach), a package of paper towels, household rubber gloves, full face protection, biohazard bags, and dust pan/brush, forceps to pick up broken glass. The contents of the kit can be kept in a small sharps container or plastic container.

Biosafety Level 2 (BL2) Spill

- Avoid inhaling airborne material, while quickly leaving the room. Notify others to leave. Close door, and post with a warning sign.
- Remove contaminated clothing, turn exposed areas inward, and place in a biohazard bag.
- Wash all exposed skin with disinfectant.

- Inform Supervisor, and, if assistance is needed, consult Biosafety Officer

Clean-up of BL2 Spill:

- Allow aerosols to disperse for at least 30 minutes before reentering the laboratory. Assemble clean-up materials (disinfectant, paper towels, biohazard bags, and forceps).
- Put on protective clothing (lab coat, face protection, utility gloves, and booties if necessary).
- Cover the area with disinfectant-soaked towels, and then carefully pour disinfectant around the spill. Avoid enlarging the contaminated area. Use more concentrated disinfectant as it is diluted by the spill. Allow at least a 20 minute contact time.
- Pick up any sharp objects with forceps and discard in a sharps container. Soak up the disinfectant and spill using mechanical means, such as an autoclavable broom and dustpan, since there may be sharps under the paper towels, and place the materials into a sharps container. Smaller pieces of glass may be collected with cotton or paper towels held with forceps. If no sharps were involved in the spill discard the materials into an autoclave bag.
- Wipe surrounding areas (where the spill may have splashed) with disinfectant.
- Soak up the disinfectant and spill, and place the materials into a biohazard bag.
- Spray the area with 10% household bleach solution and allow to air dry (or wipe down with disinfectant-soaked towels after a 10-minute contact time). Place all contaminated paper towels and any contaminated protective clothing into a biohazard bag and autoclave.
- Wash hands and exposed skin areas with disinfectant or antiseptic soap and water.

Blood Spills (For blood or other material with a high organic content and low concentration of infectious microorganisms)

- Wear gloves, eye protection, and a lab coat.
- Absorb blood with paper towels and place in a biohazard bag. Collect any sharp objects with forceps or other mechanical device and place in a sharps container.
- Using a detergent solution, clean the spill site of all visible blood.
- Spray the spill site with 10% household bleach and allow to air dry for 15 minutes.
- After the 15 minute contact time, wipe the area down with disinfectant-soaked paper towels.
- Discard all disposable materials used to decontaminate the spill and any contaminated personal protective equipment into a biohazard bag.
- Wash your hands.

14. PROPER USE OF BIOLOGICAL SAFETY CABINETS

1. A properly balanced and properly used Biological Safety Cabinet (BSC) will do an excellent job of controlling airborne contaminants only if appropriate contamination control procedures and aseptic techniques are also employed.
2. Position the BSC away from doorways, high traffic areas, room ventilation systems, air conditioners, and low ceilings. Common room air currents can disrupt the protective air barrier of a BSC. The minimum distance from the top of the BSC to the ceiling is ten inches; this will allow for proper airflow and repairs when needed.
3. All BSCs shall be professionally certified at the time of installation and annually thereafter. If a BSC is to be moved, it shall be professionally formaldehyde decontaminated before moving, and recertified before work commences. Keep the insides and tops of BSCs free of unnecessary equipment or supplies. Clutter inside and on top of the BSC may affect proper air flow or damage the exhaust HEPA filter.
4. Some BSCs are equipped with ultraviolet (UV) lights. If good procedures are followed, UV lights are not needed. All UV lights shall be turned off whenever the laboratory is occupied.
5. Avoid using toxic, explosive, flammable, or radioactive substances unless a safety professional has approved them for work in your BSC.
6. To begin the BSC operation, turn on the fluorescent lights, confirm the air intake and exhaust grills are clear, and turn on the blower. If a drain valve is present, make certain it is closed.
7. Wash hands and arms with germicidal soap before and after work in the BSC. Operators shall wear long sleeved gowns with tight fitting cuffs, and gloves. This measure protects the operator's hands and arms from contamination, and minimizes the shedding of skin flora into the work area.
8. Disinfect interior surfaces of the work area using freshly prepared 10% household chlorine bleach or an
9. EPA registered tuberculocidal disinfectant. Use a contact time appropriate for the agent in use. If bleach is used in the BSC, follow up with a wipe down of surfaces with 70% ethanol to remove any corrosive residues from work surface.
10. Everything needed for the complete procedure shall be placed in the BSC before starting work. Nothing shall pass in or out through the air barrier until the procedure is completed. Place a pan containing an appropriate disinfectant into the BSC for discarding contaminated materials. Avoid overloading the work area, and thereby compromising the efficacy of the BSC.

11. Work supplies are best arranged to segregate clean from dirty materials.
12. Set the view screen at the proper height.
13. Wait five minutes after all materials have been placed in the BSC before beginning work. This will enable the BSC to purge airborne contaminants from the work area.
14. Work as far to the back of the BSC workspace as possible.
15. Always use mechanical pipetting aids.
16. Avoid using open flames inside BSCs. Flames disrupt the unidirectional airflow and contribute to the heat load inside the BSC. Flames have shortened the lifetime of HEPA filters, burned holes through HEPA filters and have caused explosions in BSCs.
17. Do not work in a BSC while a warning light or alarm is signaling.
18. After completion of work, enclose or cover all equipment and materials. Wipe down items such as flasks and bottles with an appropriate disinfectant prior to removal from the BSC. Allow the BSC to run for five minutes to purge airborne contaminants from the work area.
19. Decontaminate interior surfaces with freshly prepared 10% household chlorine bleach or an EPA registered tuberculocidal disinfectant after removal of all materials, cultures and apparatus. Use a contact time appropriate for the agent in use. If bleach is used in the BSC, follow up with a wipe down of surfaces with 70% ethanol to remove any corrosive residues from work surface.
20. Periodically decontaminate under work grills and work surfaces if these parts are removable.
21. When the blower is shut off, the air barrier is destroyed. Within seconds, the inside of the cabinet becomes contaminated with microorganisms from the laboratory. For this reason, some manufacturers recommend that BSCs be left operating continuously (24 hours a day).
22. ACCIDENTS OR SPILLS: In the event of a spill, all surfaces and items shall be surface decontaminated before being removed from the BSC. If the spill results in puddles, flood the area with an appropriate disinfectant for a sufficient time to achieve a complete kill. If a drain system is involved, consult the BSC manufacturer's specific instructions regarding decontamination. After a spill is decontaminated, the area shall be thoroughly cleaned and dried. Residual materials can support the growth and multiplication of microorganisms, and can jeopardize the product protection normally provided by BSCs.

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APPENDIX A: OSHA BLOODBORNE PATHOGEN STANDARD

The Standard

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 ß1910.1030 is added:

Authority: Secs. 6 and 8. Occupational Safety and Health Act. 29 U.S.C.655, 657, Secretary of Labor's Orders Nos.12-71 (36 FR 8784), 8-76 (41 FR 25059). or 9-83 (48 FR 35736). as applicable: and 29 CFR part 1911.

……..

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

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2. Section 1910.1030 is added to read as follows:

1910.1030(a)

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

1910.1030(b)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

HBV means hepatitis B virus.

HIV means human immunodeficiency virus.

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

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

(2) The administration of medication or fluids; or (3) Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

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

Other Potentially Infectious Materials means (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBVcontaining culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

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

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

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

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

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

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

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

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

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

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

1910.1030(c)

Exposure Control --

1910.1030(c)(1)

Exposure Control Plan.

1910.1030(c)(1)(i)

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

1910.1030(c)(1)(ii)

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

1910.1030(c)(1)(ii)(A)

The exposure determination required by paragraph (c)(2),

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

The schedule and method of implementation for paragraphs

(d) Methods of Compliance, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, (g) Communication of Hazards to Employees, and (h) Recordkeeping, of this standard, and

1910.1030(c)(1)(ii)(C)

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

1910.1030(c)(1)(iii)

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

1910.1030(c)(1)(iv)

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

1910.1030(c)(1)(iv)(A)

Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and

1910.1030(c)(1)(iv)(B)

Document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.

1910.1030(c)(1)(v)

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

1910.1030(c)(1)(vi)

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

1910.1030(c)(2)

Exposure Determination.

1910.1030(c)(2)(i)

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

1910.1030(c)(2)(i)(A)

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

1910.1030(c)(2)(i)(B)

A list of job classifications in which some employees have occupational exposure, and

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

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

1910.1030(c)(2)(ii)

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

1910.1030(d)

Methods of Compliance --

1910.1030(d)(1)

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

1910.1030(d)(2)

Engineering and Work Practice Controls.

1910.1030(d)(2)(i)

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

1910.1030(d)(2)(ii)

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

1910.1030(d)(2)(iii)

Employers shall provide handwashing facilities which are readily accessible to employees.

1910.1030(d)(2)(iv)

When provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or

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

1910.1030(d)(2)(v)

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

1910.1030(d)(2)(vi)

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

1910.1030(d)(2)(vii)

Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B) below. Shearing or breaking of contaminated needles is prohibited.

1910.1030(d)(2)(vii)(A)

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

1910.1030(d)(2)(vii)(B)

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

1910.1030(d)(2)(viii)

Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be:

1910.1030(d)(2)(viii)(A)

Puncture resistant;

1910.1030(d)(2)(viii)(B)

Labeled or color-coded in accordance with this standard;

1910.1030(d)(2)(viii)(C)

Leakproof on the sides and bottom; and

1910.1030(d)(2)(viii)(D)

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

1910.1030(d)(2)(ix)

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

1910.1030(d)(2)(x)

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

1910.1030(d)(2)(xi)

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

1910.1030(d)(2)(xii)

Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.

1910.1030(d)(2)(xiii)

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

1910.1030(d)(2)(xiii)(A)

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

1910.1030(d)(2)(xiii)(B)

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

1910.1030(d)(2)(xiii)(C)

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

1910.1030(d)(2)(xiv)

Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated

as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible.

1910.1030(d)(2)(xiv)(A)

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

1910.1030(d)(2)(xiv)(B)

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

1910.1030(d)(3)

Personal Protective Equipment --

1910.1030(d)(3)(i)

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

1910.1030(d)(3)(ii)

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

1910.1030(d)(3)(iii)

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

1910.1030(d)(3)(iv)

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

1910.1030(d)(3)(v)

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

1910.1030(d)(3)(vi)

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

1910.1030(d)(3)(vii)

All personal protective equipment shall be removed prior to leaving the work area.

1910.1030(d)(3)(viii)

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

1910.1030(d)(3)(ix)

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

1910.1030(d)(3)(ix)(A)

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

1910.1030(d)(3)(ix)(B)

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

1910.1030(d)(3)(ix)(C)

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

1910.1030(d)(3)(ix)(D)

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

1910.1030(d)(3)(ix)(D)(1)

Periodically reevaluate this policy;

1910.1030(d)(3)(ix)(D)(2)

Make gloves available to all employees who wish to use them for phlebotomy;

1910.1030(d)(3)(ix)(D)(3)

Not discourage the use of gloves for phlebotomy; and

1910.1030(d)(3)(ix)(D)(4)

Require that gloves be used for phlebotomy in the following circumstances:

1910.1030(d)(3)(ix)(D)(4)(i)

When the employee has cuts, scratches, or other breaks in his or her skin;

1910.1030(d)(3)(ix)(D)(4)(ii)

When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and

1910.1030(d)(3)(ix)(D)(4)(iii)

When the employee is receiving training in phlebotomy.

1910.1030(d)(3)(x)

Masks, 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.

1910.1030(d)(3)(xi)

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

1910.1030(d)(3)(xii)

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

1910.1030(d)(4)

Housekeeping --

1910.1030(d)(4)(i)

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

1910.1030(d)(4)(ii)

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

1910.1030(d)(4)(ii)(A)

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

1910.1030(d)(4)(ii)(B)

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

1910.1030(d)(4)(ii)(C)

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

1910.1030(d)(4)(ii)(D)

Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up

using mechanical means, such as a brush and dust pan, tongs, or forceps.

1910.1030(d)(4)(ii)(E)

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

1910.1030(d)(4)(iii)

Regulated Waste --

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

Contaminated Sharps Discarding and Containment.

1910.1030(d)(4)(iii)(A)(1)

Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:

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

Closable;

1910.1030(d)(4)(iii)(A)(1)(ii)

Puncture resistant;

1910.1030(d)(4)(iii)(A)(1)(iii)

Leakproof on sides and bottom; and

1910.1030(d)(4)(iii)(A)(1)(iv)

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

1910.1030(d)(4)(iii)(A)(2)

During use, containers for contaminated sharps shall be:

1910.1030(d)(4)(iii)(A)(2)(i)

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

1910.1030(d)(4)(iii)(A)(2)(ii)

Maintained upright throughout use; and

1910.1030(d)(4)(iii)(A)(2)(iii)

Replaced routinely and not be allowed to overfill.

1910.1030(d)(4)(iii)(A)(3)

When moving containers of contaminated sharps from the area of use, the containers shall be:

1910.1030(d)(4)(iii)(A)(3)(i)

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

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

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

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

Closable;

1910.1030(d)(4)(iii)(A)(3)(ii)(B)

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

1910.1030(d)(4)(iii)(A)(3)(ii)(C)

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

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

Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.

1910.1030(d)(4)(iii)(B)

Other Regulated Waste Containment --

1910.1030(d)(4)(iii)(B)(1)

Regulated waste shall be placed in containers which are:

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

Closable;

1910.1030(d)(4)(iii)(B)(1)(ii)

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

1910.1030(d)(4)(iii)(B)(1)(iii)

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

1910.1030(d)(4)(iii)(B)(1)(iv)

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

1910.1030(d)(4)(iii)(B)(2)

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

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

Closable;

1910.1030(d)(4)(iii)(B)(2)(ii)

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

1910.1030(d)(4)(iii)(B)(2)(iii)

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

1910.1030(d)(4)(iii)(B)(2)(iv)

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

1910.1030(d)(4)(iii)(C)

Disposal of all regulated waste shall be in accordance with

applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.

1910.1030(d)(4)(iv)

Laundry.

1910.1030(d)(4)(iv)(A)

Contaminated laundry shall be handled as little as possible with a minimum of agitation.

1910.1030(d)(4)(iv)(A)(1)

Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.

1910.1030(d)(4)(iv)(A)(2)

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

1910.1030(d)(4)(iv)(A)(3)

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

1910.1030(d)(4)(iv)(B)

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

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

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

1910.1030(e)

HIV and HBV Research Laboratories and Production Facilities.

1910.1030(e)(1)

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

1910.1030(e)(2)

Research laboratories and production facilities shall meet the following criteria:

1910.1030(e)(2)(i)

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

1910.1030(e)(2)(ii)

Special Practices.

1910.1030(e)(2)(ii)(A)

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

1910.1030(e)(2)(ii)(B)

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

1910.1030(e)(2)(ii)(C)

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

1910.1030(e)(2)(ii)(D)

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

1910.1030(e)(2)(ii)(E)

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

1910.1030(e)(2)(ii)(F)

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

1910.1030(e)(2)(ii)(G)

Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with other potentially infectious materials is unavoidable.

1910.1030(e)(2)(ii)(H)

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

1910.1030(e)(2)(ii)(I)

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

1910.1030(e)(2)(ii)(J)

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

1910.1030(e)(2)(ii)(K)

All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.

1910.1030(e)(2)(ii)(L)

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

1910.1030(e)(2)(ii)(M)

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

1910.1030(e)(2)(iii)

Containment Equipment.

1910.1030(e)(2)(iii)(A)

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

1910.1030(e)(2)(iii)(B)

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

1910.1030(e)(3)

HIV and HBV research laboratories shall meet the following criteria:

1910.1030(e)(3)(i)

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

1910.1030(e)(3)(ii)

An autoclave for decontamination of regulated waste shall be available.

1910.1030(e)(4)

HIV and HBV production facilities shall meet the following criteria:

1910.1030(e)(4)(i)

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

1910.1030(e)(4)(ii)

The surfaces of doors, walls, floors and ceilings in the work

area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.

1910.1030(e)(4)(iii)

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

1910.1030(e)(4)(iv)

Access doors to the work area or containment module shall be self-closing.

1910.1030(e)(4)(v)

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

1910.1030(e)(4)(vi)

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

1910.1030(e)(5)

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

1910.1030(f)

Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up --

1910.1030(f)(1)

General.

1910.1030(f)(1)(i)

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

1910.1030(f)(1)(ii)

The employer shall ensure that all medical evaluations and procedures including the hepatitis B vaccine and vaccination series and post-exposure evaluation and followup, including prophylaxis, are:

1910.1030(f)(1)(ii)(A)

Made available at no cost to the employee;

1910.1030(f)(1)(ii)(B)

Made available to the employee at a reasonable time and place;

1910.1030(f)(1)(ii)(C)

Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and

1910.1030(f)(1)(ii)(D)

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

1910.1030(f)(1)(iii)

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

1910.1030(f)(2)

Hepatitis B Vaccination.

1910.1030(f)(2)(i)

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

1910.1030(f)(2)(ii)

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

1910.1030(f)(2)(iii)

If the employee initially declines hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time.

1910.1030(f)(2)(iv)

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

1910.1030(f)(2)(v)

If a routine booster dose(s) of hepatitis B vaccine is recommended by the U.S. Public Health Service at a future

date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii).

1910.1030(f)(3)

Post-exposure Evaluation and Follow-up. Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements:

1910.1030(f)(3)(i)

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

1910.1030(f)(3)(ii)

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

1910.1030(f)(3)(ii)(A)

The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.

1910.1030(f)(3)(ii)(B)

When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.

1910.1030(f)(3)(ii)(C)

Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

1910.1030(f)(3)(iii)

Collection and testing of blood for HBV and HIV serological status;

1910.1030(f)(3)(iii)(A)

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

1910.1030(f)(3)(iii)(B)

If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

1910.1030(f)(3)(iv)

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

1910.1030(f)(3)(v)

Counseling; and

1910.1030(f)(3)(vi)

Evaluation of reported illnesses.

1910.1030(f)(4)

Information Provided to the Healthcare Professional.

1910.1030(f)(4)(i)

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

1910.1030(f)(4)(ii)

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

1910.1030(f)(4)(ii)(A)

A copy of this regulation;

1910.1030(f)(4)(ii)(B)

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

1910.1030(f)(4)(ii)(C)

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

1910.1030(f)(4)(ii)(D)

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

1910.1030(f)(4)(ii)(E)

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

1910.1030(f)(5)

Healthcare Professional's Written Opinion. The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.

1910.1030(f)(5)(i)

The healthcare professional's written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.

1910.1030(f)(5)(ii)

The healthcare professional's written opinion for postexposure evaluation and follow-up shall be limited to the following information:

1910.1030(f)(5)(ii)(A)

That the employee has been informed of the results of the evaluation; and

1910.1030(f)(5)(ii)(B)

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

1910.1030(f)(5)(iii)

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

1910.1030(f)(6)

Medical Recordkeeping. Medical records required by this standard shall be maintained in accordance with paragraph (h)(1) of this section.

1910.1030(g)

Communication of Hazards to Employees --

1910.1030(g)(1)

Labels and Signs --

1910.1030(g)(1)(i)

Labels.

1910.1030(g)(1)(i)(A)

Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F) and (G).

1910.1030(g)(1)(i)(B)

Labels required by this section shall include the following legend:

Biohazard

1910.1030(g)(1)(i)(C)

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

1910.1030(g)(1)(i)(D)

Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

1910.1030(g)(1)(i)(E)

Red bags or red containers may be substituted for labels.

1910.1030(g)(1)(i)(F)

Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements of paragraph (g).

1910.1030(g)(1)(i)(G)

Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.

1910.1030(g)(1)(i)(H)

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

1910.1030(g)(1)(i)(I)

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

1910.1030(g)(1)(ii)

Signs.

1910.1030(g)(1)(ii)(A)

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

Biohazard

(Name of the Infectious Agent)

(Special requirements for entering the area)

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

1910.1030(g)(1)(ii)(B)

These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color.

1910.1030(g)(2)

Information and Training.

1910.1030(g)(2)(i)

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

1910.1030(g)(2)(ii)

Training shall be provided as follows:

1910.1030(g)(2)(ii)(A)

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

1910.1030(g)(2)(ii)(B)

Within 90 days after the effective date of the standard; and

1910.1030(g)(2)(ii)(C)

At least annually thereafter.

1910.1030(g)(2)(iii)

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

1910.1030(g)(2)(iv)

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

1910.1030(g)(2)(v)

Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

1910.1030(g)(2)(vi)

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

1910.1030(g)(2)(vii)

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

1910.1030(g)(2)(vii)(A)

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

1910.1030(g)(2)(vii)(B)

A general explanation of the epidemiology and symptoms of bloodborne diseases;

1910.1030(g)(2)(vii)(C)

An explanation of the modes of transmission of bloodborne pathogens;

1910.1030(g)(2)(vii)(D)

An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan;

1910.1030(g)(2)(vii)(E)

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

1910.1030(g)(2)(vii)(F)

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

1910.1030(g)(2)(vii)(G)

Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment;

1910.1030(g)(2)(vii)(H)

An explanation of the basis for selection of personal protective equipment;

1910.1030(g)(2)(vii)(I)

Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;

1910.1030(g)(2)(vii)(J)

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

1910.1030(g)(2)(vii)(K)

An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available;

1910.1030(g)(2)(vii)(L)

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

1910.1030(g)(2)(vii)(M)

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

1910.1030(g)(2)(vii)(N)

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

1910.1030(g)(2)(viii)

The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.

1910.1030(g)(2)(ix)

Additional Initial Training for Employees in HIV and HBV

Laboratories and Production Facilities. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements.

1910.1030(g)(2)(ix)(A)

The employer shall assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.

1910.1030(g)(2)(ix)(B)

The employer shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.

1910.1030(g)(2)(ix)(C)

The employer shall provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The employer shall assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.

1910.1030(h)

Recordkeeping --

1910.1030(h)(1)

Medical Records.

1910.1030(h)(1)(i)

The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020.

1910.1030(h)(1)(ii)

This record shall include:

1910.1030(h)(1)(ii)(A)

The name and social security number of the employee;

1910.1030(h)(1)(ii)(B)

A copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination as required by paragraph (f)(2);

1910.1030(h)(1)(ii)(C)

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

1910.1030(h)(1)(ii)(D)

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

1910.1030(h)(1)(ii)(E)

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

1910.1030(h)(1)(iii)

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

1910.1030(h)(1)(iii)(A)

Kept confidential; and

1910.1030(h)(1)(iii)(B)

Not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by this section or as may be required by law.

1910.1030(h)(1)(iv)

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

1910.1030(h)(2)

Training Records.

1910.1030(h)(2)(i)

Training records shall include the following information:

1910.1030(h)(2)(i)(A)

The dates of the training sessions;

1910.1030(h)(2)(i)(B)

The contents or a summary of the training sessions;

1910.1030(h)(2)(i)(C)

The names and qualifications of persons conducting the training; and

1910.1030(h)(2)(i)(D)

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

1910.1030(h)(2)(ii)

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

1910.1030(h)(3)

Availability.

1910.1030(h)(3)(i)

The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

1910.1030(h)(3)(ii)

Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee representatives, to the Director, and to the Assistant Secretary.

1910.1030(h)(3)(iii)

Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.1020.

1910.1030(h)(4)

Transfer of Records.

1910.1030(h)(4)(i)

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

1910.1030(h)(4)(ii)

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

1910.1030(h)(5)

Sharps injury log.

1910.1030(h)(5)(i)

The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum:

1910.1030(h)(5)(i)(A)

The type and brand of device involved in the incident,

1910.1030(h)(5)(i)(B)

The department or work area where the exposure incident occurred, and

1910.1030(h)(5)(i)(C)

An explanation of how the incident occurred.

1910.1030(h)(5)(ii)

The requirement to establish and maintain a sharps injury log shall apply to any employer who is required to maintain a log of occupational injuries and illnesses under 29 CFR 1904.

1910.1030(h)(5)(iii)

The sharps injury log shall be maintained for the period required by 29 CFR 1904.6.

1910.1030(i)

Dates --

1910.1030(i)(1)

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

1910.1030(i)(2)

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

1910.1030(i)(3)

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

1910.1030(i)(4)

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

[56 FR 64004, Dec. 06, 1991, as amended at 57 FR 12717, April 13, 1992; 57 FR 29206, July 1, 1992; 61 FR 5507, Feb. 13, 1996; 66 FR 5325 Jan., 18, 2001]

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 vaccination 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.

[56 FR 64004, Dec. 06, 1991, as amended at 57 FR 12717, April 13, 1992; 57 FR 29206, July 1, 1992; 61 FR 5507, Feb. 13, 1996]

APPENDIX B: SYMPTOMS, ROUTES OF ENTRY AND TRANSMISSION OF COMMON BLOODBORNE PATHOGENS

AGENT	DISEASE	INCUBATION PERIOD (initial infection)	PRINCIPAL METHOD OF SPREAD (TRANSMISSION)	SYMPTOMS TO WATCH FOR	IMMUNITY	CARRIER STATE
Plasmodium Species	malaria	10-35 days	Arthropod bite, transfusion	weakness, sweating, headache, fever, chills, muscle pain	gradual	no
Treponema pallidum	acquired syphilis	9-90 days	Sexual	sore in genital area	no	no
HIV	AIDS	2 mos-10 yrs	Sexual, broken skin/mucous membrane, Transfusion	flu-like illness	no	yes
HBV	viral bloodborne hepatitis	40-180 days	Sexual, broken skin/mucous membrane, transfusion	fatigue, vomiting, fever	yes	yes
HDV	Same as HBV	2-10 weeks	Same as HBV	Same as HBV	yes	no
HCV	Same as HBV	2 wks-6 mos	Transfusion	same as HBV	?	yes
Leptospira interrogans	leptospirosis	4-20 days	Broken skin/mucous membrane, inhalation	impaired senses, headache, fever, chills, muscle pain, rash	no	no
Borrelia species	relapsing fever	2-15 days	Arthropod bite	sudden fever, severe headache, chills, nerve and muscle pain	yes	no
Borrelia burgdorferi	Lyme disease	2-30 days	Arthropod bite	spread red rash, swollen glands, stiff neck	no	no

HBV is the only bloodborne pathogen that has an approved vaccine.

AGENT	DISEASE	INCUBATION PERIOD (initial	PRINCIPAL METHOD OF SPREAD (TRANSMISSIO	SYMPTOMS TO WATCH FOR	IMMUNITY	CARRIER STATE

		infection)	N)			
Brucella species	brucellosis	5-60 days	Broken skin/mucous membrane, inhalation, ingestion	sudden fever night sweats, chills, severe headache, body aches	yes	no
Francisella tularensis	tularemia	1-10 days	Arthropod bite, ingestion, inhalation	flu-like illness	yes	no
Babesia species	babesiosis	1 wk to 12 mos	Insect bite, transfusion	same as malaria	no	no
Streptobacillusmo n iliformis	streptobacillary ratbite fever	3-20 days	Rat bite, ingestion	rash, headache, chills, fever, arthritic symptoms	no	no
Spirillum minus	spirillary (rat-bite) fever	1-3 weeks	Arthropod bite	same as streptobacillus	no	no
Creutzfeldt-Jakob virus	Creutzfeldt-Jakob disease	15 mos-20 yrs	Broken skin/mucous membrane	confusion, madness	?	?
Marburg virus Ebola virus	hemorrhagic fever	3 days-2 weeks	Broken skin/mucous membrane	sudden fever, weakness, severe leg pain, rash, stomach pain	?	no
Junin virus Machupo virus	hemorrhagic fever	7-16 days	Scratched or broken skin/mucous membrane, inhalation of dried infected rodent feces and urine	same as Marburg/Ebol a and sweats, sore throat	yes	no
Crimean-Congo Virus	hemorrhagic fever	3-12 days	Arthropod bite, also infected rodents and domesticated	same as Marburg/Ebol a	some	no

			animals, broken skin/mucous membrane			
HTLV-I	leukemia/lymphoma (T-cell origin)	Unknown	Transfusion		no	yes
Several arboviruses	Colorado tick fever	3-12 days	Arthropod bite, transfusion	fever, headache, stiff neck, confusion	yes	no

APPENDIX C: SAMPLE EQUIPMENT DECONTAMINATION TAG

BIOSAFETY NOTICE

This equipment's exterior and interior surfaces were decontaminated, and are free of Biological Hazards. This notice does not apply to radiation or chemical hazards (if any).
This equipment is released for: (circle one) Service/Repair Relocation Discard
Decontamination performed by:

Chemical or disinfectant used:

Date of decontamination:

Location of equipment:

Lab telephone number:

Note: The following areas of this equipment remain contaminated and a biohazard warning label has been attached near the contaminated area.

APPENDIX D: SHARP SAFETY DEVICE EVALUATION RECORD AND FORM

Sharps Safety Device Evaluation Record

Evaluation performed due to:

- □ Follow-up to an injury/exposure involving a contaminated sharp
- □ Proactive review of sharps use with human material, other potentially infectious materials (e.g. human or animal pathogens)

Evaluation Date: Principal Investigator:

Department: Building/Room#:

Contact Employee: Phone:

Fax: Email:

Procedure involving a contaminated sharp:

Type/Brand of sharp currently in use:

Recommendation:

- □ Elimination of sharp from procedure
- □ Substitution with a safe sharps device
- □ Use of engineering controls
- □ Implementation of safe work practices
- □ Personal Protective Equipment
- □ No recommendation needed at this time, effective safety device(s) currently in use.

Device(s) in use:

Results of training and evaluation of new device:

- □ Type/Brand of sharp(s) evaluated:
- □ List employees involved in formal evaluation of safe sharps device(s):
- □ Training date for work with new safe sharps device(s):
- □ Device(s) formally in use following evaluation (selection/use date):

Complete and return all forms to:

Biosafety Officer

APPENDIX E: HEPATITIS B VACCINE NOTIFICATION FORM

Holy Cross

HEPATITIS B VACCINE NOTIFICATION FORM

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 have declined Hepatitis B vaccination 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.

 Yes, I wish to be vaccinated against Hepatitis B

 I have already received the Hepatitis B vaccine.

Name (Please Print) Signature

Work address

Date

Please return completed copy to: Biosafety Officer

Bloodborne Pathogen Program