
I. OVERVIEW OF OSHA STANDARD AND INFORMATION AND TRAINING REQUIREMENTS

Notes:

A. Introduction

On December 6, 1991, the federal Occupational Safety and Health Administration (OSHA) enacted regulations concerning occupational exposure to bloodborne pathogens. On January 8, 1993, CAL/OSHA published its final Bloodborne Pathogens Rule (Title 8 CCR GISO 5193). The primary goal of this regulation is to minimize occupational exposure to hepatitis B (HBV), human immunodeficiency virus (HIV), and other potentially infectious bloodborne agents. While the regulation is directed primarily toward hospital, clinical, and other patient care facilities, it also covers *all* occupations where exposure to human blood or other potentially infectious materials may occur.

Past experience regarding the potential for transmission of HBV and HIV in health care settings has resulted in an approach to infection control termed **Universal Precautions** (MMWR, August 21, 1987), a safety concept that assumes all blood, blood products, and certain body fluids to be contaminated with HIV, HBV, or other bloodborne pathogens, and requires that appropriate safety precautions be taken when handling or working with these materials. A description of Universal Precautions can be found in Appendix A.

The **Universal Precautions** concept continues to be the fundamental premise of working with these materials. However, implementation of the new OSHA regulation also places additional requirements on Stanford University. These additional requirements include:

- specific identification of all employees who are “occupationally exposed” (Criteria for determining the risk of occupational exposure to Hepatitis B or other bloodborne pathogens can be found in Appendix B);
- development of a written exposure control plan that requires specified work practices and personal protective equipment to be used;
- offering HBV vaccinations to any employee considered to be “occupationally exposed”;
- development of post-exposure follow-up procedures;
- mandatory training programs, initial and annual update; and
- recordkeeping to document compliance with the regulation.

This manual, along with Stanford’s bloodborne pathogen training program, is intended to help you learn more about preventing transmission of bloodborne diseases in the workplace and the requirements of the OSHA standard.

B. Information and Training Requirements of the OSHA Standard

Notes:

The OSHA standard requires every employer to provide information and training to all employees who are occupationally exposed. In general,

- employers must ensure that all employees with occupational exposure participate in a training program,
- training must be provided at the time of employment and at least annually thereafter, and
- material appropriate in content and vocabulary to the educational level, literacy, and language of employees must be used.

OSHA also requires specific elements be covered in the training program. These include:

- ensuring a copy of the standard is accessible to all employees and explaining the contents of the standard to ensure employees know their rights under the standard,
- providing information to employers regarding the epidemiology and symptoms of bloodborne diseases,
- discussion of the modes of transmission of bloodborne pathogens,
- review of the contents of the employer's Exposure Control Plan,
- discussion of appropriate methods for recognizing activities that may involve exposure to blood and other potentially infected materials,
- use and limitations of practices that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment,
- types, proper use, location, removal, handling, decontamination and/or disposal of personal protective equipment,
- basis for selection of personal protective equipment,
- information on the hepatitis B vaccination, including its efficacy, safety, and the benefits of being vaccinated,
- appropriate actions to take and persons to contact in an emergency involving human blood or other potentially infectious materials,
- procedures to follow if an exposure incident occurs, and
- explanation of the signs and labels and/or color coding required by the standard.

At Stanford, these provisions apply to anyone potentially exposed to blood or bloodborne pathogens, including students, visitors, volunteers, etc.

II. BLOODBORNE PATHOGEN TRAINING PROGRAM

Notes:

A. Availability of the OSHA Standard and Overview of its Contents

A copy of the OSHA Standard entitled Bloodborne Pathogens (Title 8 CCR GISO 5193), is available at Stanford's Department of Environmental Health and Safety (EH&S). A copy is also included as Appendix C. The OSHA Bloodborne Pathogen standard includes the sections listed below with a brief description of the requirements or contents of each section.

B. Sections of the OSHA Bloodborne Pathogen Standard

1. Scope and Application - specifies the workplaces that are covered by this standard. All workplaces where occupational exposure to blood or other potentially infectious materials, as defined in the next section, are covered by the standard.

2. Definitions - includes 28 definitions, the most important being the definition of *blood, other potentially infectious materials, and occupational exposure*.

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

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

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.

3. Exposure control - has two primary requirements: the development of an Exposure Control Plan, designed to eliminate or minimize employee exposure; and the requirement to prepare an exposure determination, a description of how employees are designated as having an "occupational exposure".

4. Methods of compliance - describes the specific methods employers must use to comply with the OSHA standard. In general, Universal Precautions, found in Appendix C, are to be used when appropriate. In addition, the section describes, in detail, the engineering and work practice controls the employer must utilize to eliminate or minimize exposure. These are described in the Exposure Control Plan.

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5. HIV and HBV research laboratories and production facilities - this section specifies additional requirements for 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. Laboratories falling in this designation must adopt special practices and must have specific biosafety procedures written for the lab.

6. Hepatitis B vaccination and post-exposure evaluation and follow-up - describes the requirements for making HBV vaccine available to occupationally exposed employees and the requirements to provide for post-exposure medical evaluation and follow-up.

7. Communication of hazards to employees - describes the requirements for labeling containers, and the types of identifying signs and labels to be used to indicate the possible presence of a bloodborne pathogen. Also, this section contains the specific requirements for the information and training that **must** be provided to employees.

8. Recordkeeping - this section covers two areas related to documentation and maintenance of medical and training records. Occupational medical records are maintained by Stanford University in accordance with applicable regulations regarding content and confidentiality. Training records will be maintained in accordance with applicable regulations.

9. Dates of Implementation - The effective implementation dates for the components of the standard are:

- An exposure determination was completed by March 8, 1993.
- An Exposure Control Plan was completed on March 8, 1993.
- The provisions for information and training were in effect by April 8, 1993.
- The provision for recordkeeping was in effect by April 8, 1993.
- The schedule and implementation for Engineering and Work Practice Controls, Personal Protective Equipment, Housekeeping, HIV and HBV Research Laboratories and Production Facilities, Hepatitis B Vaccination and Post-Exposure Follow-up, and labels and signs were completed by May 8, 1993.

10. Appendix A: Hepatitis B vaccine declination - requires employees who decline to accept the hepatitis B vaccination offered by the employer to sign a specified statement. A copy of the Stanford declination statement is may be found in Appendix B of this document.

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C. Infectious Diseases and Modes of Transmission

A **microorganism** is a living organism which is usually visible only with a microscope. Disease producing microorganisms include viruses, bacteria, parasites, and fungi.

A **virus** is a microorganism usually only visible with the aid of an electron microscope. Viruses normally reside within other living (host) cells and cannot reproduce outside of a living cell. Thus, if a virus is present on a surface or object, it cannot reproduce.

Bacteria are types of living microorganisms that can produce disease in a suitable host. Bacteria can self-reproduce and some produce toxins that are harmful to their host.

Since bacteria can multiply outside the cell, i.e., on surfaces or objects, the proper cleaning of equipment is critical. Items, such as bag-valve masks, have been implicated in the spread of disease from one person to another.

Infection is the growth of pathogenic organisms in the tissues of a host, with or without detectable signs of injury. A pathogen is a microorganism that can cause disease. Typically, infection occurs when the body is invaded by a pathogenic organism, such as a virus or bacteria, which reproduces, causing illness or disease.

An **antibody** is a component of the immune system that eliminates or counteracts a foreign substance (antigen) in the body.

Infection control efforts are designed to prevent infection from occurring in either persons who work with material that might be infectious or transmission of infectious agents to patients.

Effective infection control procedures (such as the use of personal protective equipment (PPE), proper cleaning / decontamination practices, immunizations, etc.) are the main focus of preventing the transmission of infectious agents, and are covered in detail under discussion of *Universal Precautions* in Section F of this training guide.

Infectious disease results from invasion of a host by disease-producing (pathogenic) organisms such as bacteria, viruses, fungi, or parasites.

Several infectious diseases are foodborne, i.e., transmitted by the ingestion of contaminated food. For example, mayonnaise can contain staph bacteria. Unrefrigerated food containing mayonnaise provides an effective growth medium for the bacteria, allowing them to multiply over time. When this occurs, those who eat the food may get ill. Similarly, eggs that are cracked or broken often contain salmonella bacteria which can be transmitted during ingestion.

Notes:

A communicable disease is a disease that can be transmitted from one person to another. It is also known as a contagious disease. Not all infectious diseases are communicable. As noted above, salmonella is a highly infectious disease, but it is not communicable — it is not normally transmitted from one person to another. On the other hand, chicken pox is an infectious disease that is also communicable — it can easily be transmitted from one person to another. A communicable disease can be spread two ways; by direct or indirect transmission.

Direct transmission occurs when an organism passes directly from one person to another due to direct contact with infected blood or other body fluids. For example, you are trying to control bleeding in a person with a lacerated arm. The person's blood drips onto your hand and you have a cut on your palm. This direct contact with a person's blood can result in the transmission of the organism that can cause disease.

Indirect transmission occurs without direct person-to-person contact. The organism passes from one person to another indirectly, i.e., via some contaminated object. The infected person leaves blood or other body fluids on some object; another person gets the disease-causing organism upon contact with the contaminated object. For example, a laboratory worker cuts his hand on a glass shard contaminated with an infected person's blood during clean-up operations and later develops hepatitis B. The disease is indirectly transmitted to the lab worker through the glass shard contaminated with blood.

Not All Pathogen Exposure Results in Infection. The body's immune system is designed to provide protection from disease. An antigen is a substance that the body recognizes as foreign, including many pathogens. The immune system then creates protective antibodies to fight the invading antigen. The presence of antibodies in the blood may indicate exposure to a disease-causing organism. This is the basis of tests for HBV and HIV infection. A person who develops antibodies after an exposure is said to seroconvert.

Seroconversion is a term used to describe a change in the status of

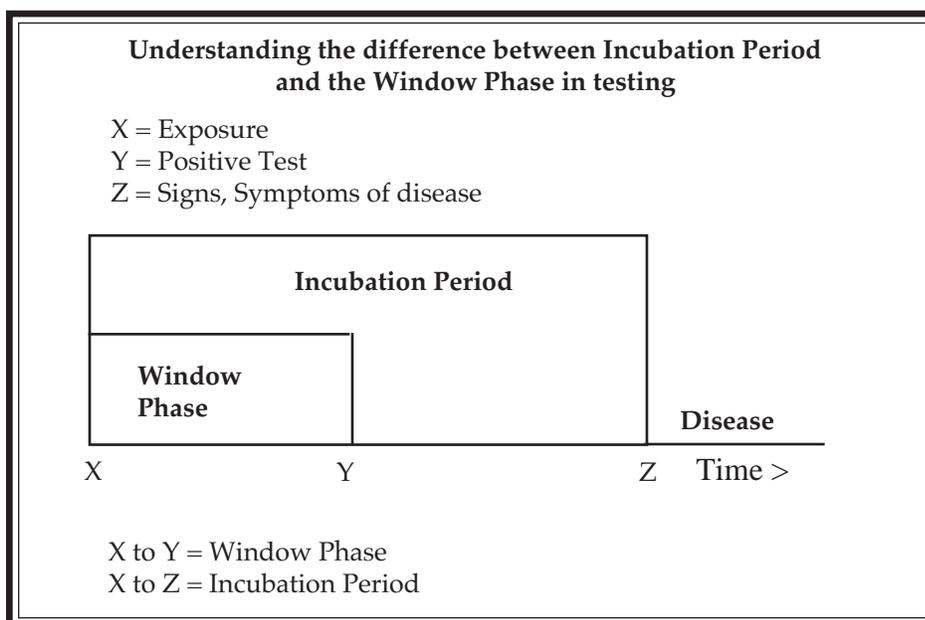
one's serum. It means that a test result for a specific component which was previously negative is now positive. For example, a person is exposed to the HIV virus. He is tested and the results are negative. Six weeks later, the person is again tested and the test is now positive. The person has seroconverted.

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Post-Exposure Terminology and Concepts

The window phase is the time from exposure to the organism until one tests positive for the infection. This time will vary from one individual to another, depending on the response by the individual's immune system. Someone in the window phase may test negative but actually be positive and able to spread the organism. For example, with HIV testing, the window phase is from one to twelve weeks. In other words, from the time the person is exposed to the virus, it may take twelve weeks from the blood test to show positive. If a person is exposed to HBV, the window phase or the time to positive test is one to four weeks.

Incubation is the time period from exposure to the organism until the first appearance of signs or symptoms of disease. This varies with each disease. For example, the incubation period for HBV is up to 200 days post-exposure, while for HIV the incubation period is up to ten years post-exposure. Thus, simply testing personnel immediately after an exposure is not always enough. Follow-up testing — based on the incubation period and window phase of the specific disease — is also required. The following figure illustrates this concept.



The transmission of communicable disease takes place primarily by direct or indirect contact with contaminated blood or other body fluids.

Bloodborne transmitted diseases are spread by direct contact with the blood or other body fluids of an infected person. Bloodborne diseases include, but are not limited to: HIV / AIDS, HBV, hepatitis C, and syphilis. Bloodborne diseases may be spread by either virus or bacteria. For example, HIV, HBV and non-A and non-B hepatitis are caused by viruses. However, syphilis is a sexually transmitted infectious disease that is caused by bacteria.

Airborne transmitted diseases are spread by contact with droplets of the disease-producing organism that have been expelled into the air by a productive cough or sneeze. Direct contact with infected secretions may also play a role. Airborne diseases include, but are not limited to, tuberculosis (TB), meningitis, mumps, rubella, and chicken pox. For example, the disease-producing organism that causes tuberculosis lives in the lungs. To spread the disease, the person may cough up aerosols containing the organism and another person must be close enough to inhale the aerosols.

Health Effects

Many communicable diseases have potential for causing serious long-term effects. For example, most childhood diseases acquired by adults result in more severe symptoms and often are accompanied by serious complications, such as pneumonia. Hepatitis B and C may result in chronic hepatitis, liver cancer, cirrhosis of the liver or death. HIV currently has a very high mortality rate; however, new drug therapies are resulting in a prolonged life span. TB is a treatable disease and, historically, minimal long-term effects have been reported. However, in recent years health care workers have been infected with a strain of TB that is resistant to standard antibiotics. This may have some significant long-term effects.

Assessing Risk of Infection

Any exposure to a bloodborne pathogen carries a certain amount of risk. An exposure occurs whenever there is contact with blood or other body fluids through open wounds, mucous membranes, or parenteral routes. The degree of risk depends on the degree of exposure and evaluation of other risk. Four factors critical in assessing one's personal risk potential in an exposure situation are the organism, dosage, virulence, and host resistance.

1. Organism Identification - Identification of the causative agent is critical. As noted previously, a virus cannot reproduce outside of a living cell; on the other hand, bacteria can self-reproduce. Also, some organisms are more readily transmitted than others.

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2. Dosage of the Organism - Dosage refers to the number of viable (live) organisms received during an exposure. Each illness requires a certain number of infectious agents to be present in order to cause disease/illness. For example, 10 hepatitis B viruses in one milliliter of blood may be all that is needed to spread the infection, while 100,000 HIV viral particles per milliliter may be needed.

3. Virulence of the Organism - Virulence is the disease-evoking power of the organism - the strength or ability of the bacteria or virus to infect or overcome bodily defenses. This will vary from one organism to another.

4. Host Resistance - Host resistance is the ability of the host to fight infection. Infection occurs as a result of an interruption in the body's normal defense mechanisms. Typically, the healthier you are, the less likely you will become ill.

Nature of Exposure in Bloodborne Disease

Risk of infection by bloodborne pathogens varies according to the type of exposure. The list below was published by the Centers for Disease Control and Prevention (CDC) to help evaluate risk levels. Risk level increases from top to bottom.

- Blood/body fluid contact to intact skin (low risk).
- Blood/body fluid contact to the mucous membrane surface of the eyes, nose, or mouth (low risk).
- Blood/body fluid contact with an open area of the skin (medium risk).
- Cuts with sharp objects covered with blood/body fluid (medium risk).
- Contaminated needle-stick injury (high risk).

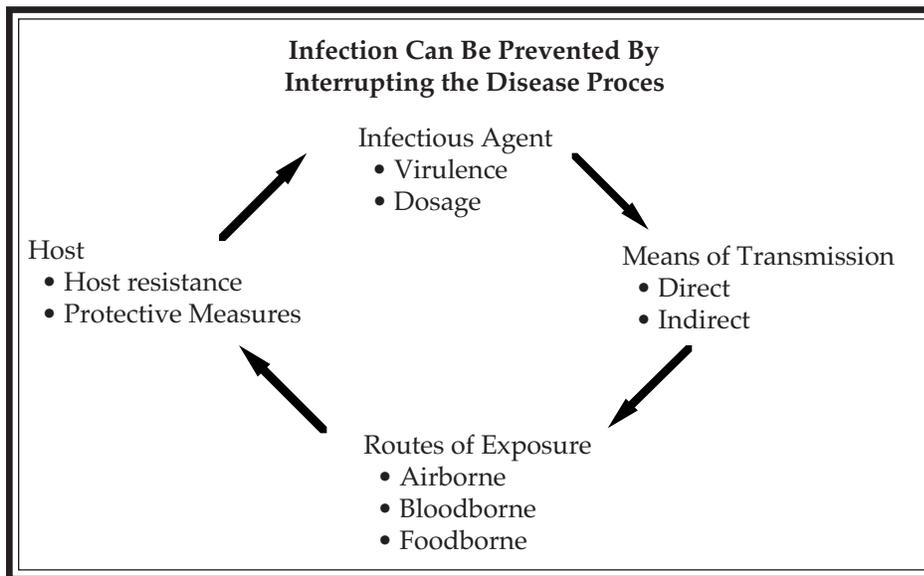
Laboratory workers handling and working with blood, body fluids, and tissue cultures of disease organisms will always face exposure risks. Although we can use measures to reduce risk, we cannot create a 100% risk-free environment. Supervisors need to review work-associated risks with personnel, especially newly hired employees.

Exposure Assessment Summary

Exposure does not mean infection. However, avoiding exposure does mean avoiding infection. Personnel can avoid exposure by practicing effective infection control practices.

The disease process has four components; the infectious agent, the means of transmission, the route of exposure, and the host carrier. All of these components must be present for disease to occur. Infection can be prevented by interrupting the disease process at any of these points. This can be accomplished by following good infection control practices and having an understanding of diseases and their transmission. This enables you to ensure that the risk of infection remains low.

Notes:



D. Epidemiology and Symptoms of Bloodborne Diseases¹

Certain pathogenic microorganisms can be found in the blood of infected individuals. For purposes of this standard, OSHA refers to these microorganisms as “bloodborne pathogens” and to the diseases that they cause as “bloodborne diseases”. These bloodborne pathogens may be transmitted from the infected individual to other individuals by blood or certain other body fluids, for example, when blood-contaminated needles are shared by intravenous drug users. Because it is the exposure to the blood or other body fluids that carries the risk of infection, individuals whose occupation duties place them at risk of exposure to blood or other potentially infectious materials are also at risk of becoming infected with these bloodborne pathogens, developing disease, and in some cases, dying. Infected individuals are also capable of transmitting the pathogens to others.

Communicable diseases, those capable of being transmitted from person-to-person, are not new and include many commonly known diseases such as:

- Pneumonia
- Hepatitis
- Influenza
- Chicken pox
- Measles
- Tuberculosis
- Meningitis
- Rubella

1. Extracted from "Occupational Exposure to Bloodborne Pathogens", FR Vol 56 No. 235, Dec. 6, 1991.

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- Human Immunodeficiency Virus (HIV)

Notes:

Communicable diseases include not only those pathogens capable of being transmitted by a bloodborne route, but also those capable of transmission through airborne or foodborne routes.

For purposes of the OSHA-required training, this program will focus primarily on discussion of two of the most significant bloodborne pathogens; hepatitis B virus, and human immunodeficiency virus. Included is a discussion of each of the viruses, the disease each causes, modes of transmission, and documented risk of infection resulting from occupational exposure.

Hepatitis Virus

Hepatitis means “inflammation of the liver” and can be caused by a number of agents or conditions including drugs, toxins, autoimmune disease, and infectious agents including viruses. The most common causes of hepatitis are viruses. There are four types of viral hepatitis that are important as occupational health risks in the U.S.

Hepatitis A, formerly called “infectious” hepatitis, is spread by fecal contamination and is not generally considered to be a significant risk in the occupational setting.

Hepatitis B, formerly called “serum” hepatitis, is a major risk to healthcare workers and others in occupations that involve the handling and manipulation of human blood and certain other body fluids. It is often referred to as HBV.

Hepatitis D, or delta hepatitis, may co-infect with hepatitis B or may infect persons already infected with HBV, and can increase the severity of acute and chronic liver disease in these individuals.

Non-A, Non-B hepatitis is caused by viral agents other than hepatitis A and hepatitis B. Two that have been identified are hepatitis E, previously known as enterically transmitted (ET) non-A, non-B hepatitis and hepatitis C, previously known as parenterally transmitted non-A, non-B hepatitis.

Hepatitis E is transmitted by the fecal-oral route and has occurred both in epidemic and sporadic forms in parts of Asia, North and West Africa, and Mexico. It is not known whether the virus is present in the United States or western Europe.

Hepatitis C is known to be efficiently transmitted by blood transfusion

and by needle sharing among IV drug users. There have been some reports of occasional transmission of HCV to health care workers.

Notes:

Hepatitis B Virus (HBV)

Hepatitis B virus is the major infectious bloodborne occupational hazard to healthcare workers. The CDC estimates that there are approximately 8,700 infections in healthcare workers with occupational exposure to blood and other potentially infectious materials in the United States each year. These infections cause over 2,100 cases of clinical acute hepatitis, 400-440 hospitalizations, and approximately 200 deaths each year in healthcare workers alone.

Hepatitis B is caused by the hepatitis B virus that attacks and replicates in liver cells. The virus has an inner core and an outer shell structure. The inner core contains DNA, enzymes, and various proteins, including the hepatitis B core antigen (HBcAg) and hepatitis B e antigen (HBeAg). The outer shell is composed of lipoprotein called hepatitis B surface antigen (HBsAg) which is produced in great excess by liver cells replicating the virus, and is found in the form of small spheres and larger tubular particles in the blood of infected persons. There is a readily available laboratory test for HBsAg and its presence in blood indicates that an individual is currently infected with the HBV, and is potentially infectious to others.

Infection with the hepatitis B virus in a susceptible person can produce two types of outcomes: self-limited acute hepatitis B and chronic HBV infection. The most frequent response seen in healthy adults is development of self-limited acute hepatitis and the production of an antibody against HBsAg, called anti-HBs. The production of the antibody coincides with the destruction of liver cells containing the virus, elimination of the virus from the body, and signifies lifetime immunity against reinfection.

Unfortunately, the destruction of liver cells in an attempt to rid the body of this infection often leads to clinically apparent acute hepatitis B. About one third of infected individuals have no symptoms when infected with the virus, one third have a relatively mild clinical course of a flu-like illness which is usually not diagnosed as hepatitis, and one third have a much more severe clinical course with jaundice (yellowing of the eyes and skin), dark urine, extreme fatigue, anorexia, nausea, abdominal pain, and sometimes joint pain, rash, and fever. These symptoms require hospitalization in about 20% of jaundiced cases, and often cause several weeks to months of work loss even in those cases that do not require hospitalization. Fulminant hepatitis, which is about 85% fatal with even the most advanced medical care, develops in about 1-2% of reported acute hepatitis B cases, and in an

estimated 1 per 1,000 HBV infections.

Notes:

The second type of response-development of chronic HBV infection-has more severe long-term consequences. About 6-10% of newly-infected adults cannot clear the virus from their liver cells and become chronic HBV carriers. These individuals continue to produce HBsAg form many years, usually for life. HBV carriers are at high risk of developing chronic persistent hepatitis (25%), chronic active hepatitis (25%), cirrhosis of the liver, and primary liver cancer, called primary hepatocellular carcinoma (PHC). Chronic HBV infection has been estimated to cause 10% of the 25,000-30,000 deaths that occur due to cirrhosis in the U.S. each year, and about 25-33% of all PHC cases, or 750-1,000 PHC cases annually result from HBV infection.

HBV: Modes of Transmission

In the workplace, HBV is spread via parenteral (by direct inoculation through the skin) or mucous membrane (blood contamination of the eye or mouth) routes. The most efficient mode of transmission is direct inoculation of infectious blood, such as might occur during blood transfusion, needle sharing by IV drug users, or needlestick or other sharp instrument injury in occupationally exposed workers. Direct inoculation of infectious blood may occur in less apparent ways. Preexisting lesions on hands from injuries incurred at the workplace or at home, or from dermatitis, may provide a route of entry for the virus. In addition, transfer of contaminated blood via inanimate objects or environmental surfaces has been shown to cause infection in the healthcare workplace.

One milliliter (ml) of HBsAg positive blood may contain 100 million infectious doses of virus; thus exposure to extremely small inocula of HBV-positive blood may transmit infection. In different studies, 7-30% of susceptible healthcare workers sustaining needlestick puncture injuries from HBsAg positive patients became infected if they did not receive post-exposure prophylaxis.

While there has been concern about the potential infectivity of aerosols generated by dental, medical, and laboratory equipment, and although HBsAg may be found in large particles of "spatter" that travel short distances, there is no known data that links HBV transmission with aerosols through inhalation.

HBV: Epidemiology

HBV infection does not occur uniformly in the U.S. population. There is a substantial difference in the reported numbers of hepa-

titis B cases by geographic region. The presence of certain populations with a high percentage of individuals who are carriers may result in higher prevalence rates for certain defined areas, such as parts of Alaska and the U.S. Trust Territories. HBV infection is more prevalent in certain ethnic and racial groups, and is especially prevalent in certain "high risk" groups defined by occupation and lifestyle. The prevalence of HBV antibodies in the general population, reflecting the percentage of the population ever infected, is 3-4% for whites and 13-14% for blacks. Foreign born Asians have a prevalence of antibody of greater than 50%. The HBsAg prevalence, reflecting the percentage of the population who are HBV carriers, is 0.2% for whites, 0.7% for blacks, and up to 13% for foreign born Asians. The high prevalence rate in the last group is a reflection of the fact that most HBV infections in Asia occur in childhood.

Approximately 1% (or more) of hospitalized patients are HBV carriers; most HBV carriers seen in the healthcare setting are not symptomatic, are unaware that they are carriers, and their medical charts do not contain this information. Workers may take extraordinary precautions when dealing with a known carrier, but are often unaware that they may treat five carriers for each one they recognize. This is a key point in understanding the rationale for the concept of "Universal Precautions" and for the use of the hepatitis vaccine in workers with exposure to blood.

Hepatitis B Vaccine

In 1982, a safe, immunogenic, and effective hepatitis B vaccine derived from human plasma was licensed in the U.S. and was recommended for use in healthcare workers with blood or needle exposure in the workplace. A second vaccine, produced in yeast by recombinant technology was first licensed in 1987. The hepatitis B vaccination is the most important part of any HBV control program, because gloving and other protective devices cannot completely prevent puncture injuries from needles and other sharp instruments.

The yeast derived vaccines contain no human plasma and there is no possibility that they could be infectious for HIV, a concern that was raised regarding the earlier plasma derived vaccine. Although the concerns about the earlier plasma derived vaccines were studied and addressed, the plasma derived vaccine is no longer available in the U.S. since the yeast derived vaccines have been verified as effective, safe, and more economical to produce. Only the recombinant DNA derived vaccines are used in the U.S.

Hepatitis B vaccines are given intramuscularly in the deltoid (upper arm), in three doses over a six month period. These vaccines, when

given according to manufacturers directions, induce protective antibody levels in 85-97% of healthy adults.

Notes:

Protection against both the illness and development of the carrier state lasts at least nine years (the duration of the follow-up studies) and perhaps longer. Although antibody in many individuals will decay below detectable levels within seven years after immunization, if these individuals are exposed to HBV, they develop a rapid (anamnestic) antibody response and do not become ill or develop the HBV carrier state.

For persons with normal immune status, it is not recommended that a booster dose of hepatitis B vaccine be given after the initial series, although this may be recommended in the future if it appears that immunity conferred by the vaccine wanes after some time period.

Pre-exposure vaccination is the most effective method for preventing HBV infection. However, if an individual declines vaccination, and has a subsequent exposure, effective post-exposure prophylaxis exists if appropriate protocols are followed. A copy of the vaccination request/ declination form can be found in Appendix D.

Non-A, Non-B Hepatitis

Non-A, Non-B hepatitis in the U.S. is caused by more than one viral agent. Studies have shown that parenterally transmitted (PT) non-A, non-B hepatitis accounts for 20-40% of acute viral hepatitis in the U.S. and has epidemiological characteristics similar to those of hepatitis B.

Because the primary mode of transmission is blood to blood contact, and a large asymptomatic carrier reservoir exists, precautions to prevent non-A, non-B hepatitis in the workplace are identical for those of other bloodborne viruses, such as HBV.

Human Immunodeficiency Virus (HIV)

In June of 1981, the first cases were reported in the U.S. of what was to become known as Acquired Immunodeficiency Syndrome (AIDS). During 1983 and 1984, French and American scientists independently isolated a human virus associated with AIDS. This virus was identified as human T-cell lymphotropic virus type III (HTLV). Eventually, human immunodeficiency virus type I (HIV-1) became the universally accepted term for the virus.

The CDC estimates that in the U.S. between 1 million and 1.5 million persons are infected with HIV. As of July 1991, 186,895 cases of AIDS had been reported to the CDC, 3,199 of whom are children under the

age of 13. At least 63.5% of the adult/adolescent cases had died, as well as 57% of the pediatric cases. Although the rate of spread of HIV in the future is unknown, scientists with the U.S. Public Health Service have estimated that in the U.S. alone, a cumulative total of more than 365,000 cases of AIDS will have been reported by the end of 1992 with 80,000 new cases diagnosed during that year.

Notes:

Of perhaps greater importance for workers is the 1.0 to 1.5 million persons who are infected with HIV, often unknowingly so, and who require medical treatment for related or unrelated conditions.

There are reports of at least 30 healthcare workers who apparently were infected with HIV through occupational exposure to blood or other potentially infectious materials. Of these cases, five occurred outside the U.S. The number of known work-related HIV seroconversions among healthcare workers is approximately 24 at present.

The increasing number of individuals with AIDS, the large number of unidentified HIV infections, and the reports of occupational infection all indicate that healthcare workers are at risk for occupationally acquired HIV infections.

HIV: Biology

HIV is a member of a group of viruses known as human retroviruses. Its genetic material is ribonucleic acid (RNA) rather than deoxyribonucleic acid (DNA), the genetic material found in most living organisms. The virus particle is comprised of a core containing the RNA and viral enzymes surrounded by an envelope consisting of lipids and proteins.

Because they lack the cellular machinery necessary to reproduce, all viruses must reproduce intracellularly, that is within the host cell. HIV replicates in human macrophages and T4 lymphocytes, two types of human cells that are vital components of the immune system. T4 lymphocytes and a few other cell types have protein molecules on their surfaces called CD4 antigens or receptors. HIV particles bind with the CD4 receptor sites of the host's cells and then release their viral RNA. The RNA is then transcribed by viral enzymes into double-stranded DNA that is incorporated into the DNA of the host cell. The viral DNA then serves as a template to produce more virus particles. The transcription of RNA to DNA is the reverse of what occurs in most organisms and thus HIV is called a retrovirus. The process occurs with the aid of the viral enzyme reverse transcriptase, which is considered to be a marker for retrovirus production. HIV gradually depletes the number of cells

which are essential for host immune function, rendering the infected individual increasingly susceptible to opportunistic infections.

Notes:

Circulating macrophages are also considered a reservoir as well as another target for HIV infection. Since some macrophages can circulate freely throughout the body, they may actually transport HIV to the brain which may lead to neurological complications.

HIV: Serological Testing

Infection with HIV may be identified through testing the blood for the presence of HIV antibodies. Although the antibodies do not appear to defend or protect the host against HIV, they serve as markers of viral infection. Most people infected with HIV have detectable antibodies within 6 months of infection, with the majority generating detectable antibodies between 6 and 12 weeks after exposure.

The enzyme-linked immunosorbent assay (ELISA or EIA) technique used to detect HIV antibodies is sensitive, economical, and easy to perform. However, as with all laboratory determinations, this test can produce a false positive result when the HIV antibody is not present. Therefore, current recommendations include repeating the ELISA test if the first test is positive. If the second test is also positive, another test, usually employing the Western blot technique, is used to validate the ELISA results. A positive ELISA test and a positive Western blot result indicate the presence of HIV antibodies and HIV infection.

HIV: Transmission

Although HIV has been isolated from blood and many other body fluids, epidemiologic evidence implicates only blood, semen, vaginal secretions, and breast milk in the transmission of the virus. Documented modes of HIV transmission include:

- engaging in sexual intercourse with an HIV-infected person;
- using needles contaminated with the virus;
- having parenteral, mucous membrane, or non-intact skin contact with HIV-infected blood, blood components, or blood products;
- receiving transplants of HIV-infected organs and tissues including bone, or transfusions of HIV-infected blood;
- through semen used for artificial insemination; and
- perinatal transmission (from mother to child around the time of birth).

HIV is not transmitted by casual contact. Studies have produced

no evidence that HIV is transmitted by shaking hands or talking, by sharing food, eating utensils, plates, drinking glasses or towels, by sharing the same house or household facilities, or by “personal interactions expected of family members” including hugging and kissing on the cheek or lips. Other studies have shown that HIV is not transmitted by mosquitoes or other animals.

Notes:

Some types of exposures are clearly more efficient at transmission than others. The risk of infection following receipt of transfused blood from an HIV-infected donor is approximately 90%. The risk of perinatal transmission from an HIV-infected mother is estimated to be 30-50% or higher. Besides the particular types of exposure, other variables contributing to the likelihood of transmission may include:

- susceptibility of the host;
- the virulence of the particular strain;
- the stage of infection of the source; and
- the size of the inoculum the individual is exposed to.

This last factor, the actual amount of virus, may be very important in the likelihood of transmission since, it appears, there is greater probability of infection from HIV-contaminated blood transfusions (890 infections per 1,000 persons transfused with contaminated blood) than from accidental needlesticks with needles contaminated with HIV (3-5 infections per 1,000 persons injured with contaminated needles).

HIV: Clinical Manifestation of Disease

HIV adversely affects the immune system, rendering the infected individual vulnerable to a wide range of clinical disorders. These conditions, some of which tend to recur, can be aggressive, rapidly progressive, difficult to treat, and less responsive to traditional modes of treatment. They usually lead to the death of the HIV infected patient. The CDC has divided disease progression into several stages according to types of infections or symptoms reported:

Group I: Within a month after exposure, an individual may experience acute retroviral symptoms, the first clinical evidence of HIV infection. This is a mononucleosis-like syndrome that can include fever, lymphadenopathy, myalgia, arthralgia, diarrhea, fatigue, and rash. Acute retroviral syndrome is usually self-limiting and followed or accompanied by the development of antibodies.

Group II: Although most persons infected with HIV develop antibodies to the virus within 6-12 weeks after exposure, most of these individuals are asymptomatic for months to years following infection. However, they can transmit the virus to others throughout

this time.

Notes:

Group III: Although no other signs or symptoms are experienced, some HIV-infected patients will develop a persistent, generalized lymphadenopathy that lasts more than 3 months.

Group IV: Epidemiological data indicates that most persons who are infected with HIV will eventually develop AIDS. AIDS can result in severe opportunistic infections that an individual with a normal immune system would only rarely experience, as well as a wide range of neurologic and oncogenic or neoplastic processes.

HIV: Workplace Transmission

Occupational transmission of HIV has been documented in healthcare workers. As of May 1990, there are at least 65 case reports of healthcare workers whose HIV infections are associated with occupational exposure. Eighteen of these cases seroconverted following a documented exposure incident. Thirteen of the seroconversions were caused by parenteral exposure to blood or blood containing fluids (11 by needlesticks and 2 by cuts with a sharp object). Five seroconversions involved blood contamination of mucous membranes or non-intact skin and one was due to parenteral exposure to concentrated HIV-I.

HIV: Epidemiology

A number of prospective studies and surveys have been conducted to determine occupational risks for HIV infection. The CDC has been conducting a national prospective study which began in 1983, to assess initially the risk of AIDS and later, with the advent of HIV-antibody testing, the risk of HIV seroconversion among healthcare workers exposed to the blood or body fluids of persons with HIV infection. Of those subjects who had sustained either a needlestick injury or a cut with a sharp instrument contaminated with blood or body fluid from an HIV-infected patient, the seroconversion rate was determined to be 0.35%.

Weiss and co-workers conducted a prospective study to assess the risk of HIV infection in laboratory workers. Of 225 laboratory workers, 10 reported one or more episodes of parenteral exposure to HIV, including needlesticks or cuts, and 35 reported one or more episodes of skin contact with HIV. One individual who worked with concentrated HIV-1 was seropositive for the virus upon entering the study. The HIV isolated from the subject's blood was shown to be genetically identical to a strain of HIV

used in the laboratory, thus strongly implicating occupational exposure as the source of infection. No seroconversions were identified in the other study participants during the period of prospective follow-up. The authors calculated that the rate of HIV infection was 0.48 per 100 person-years for laboratory personnel in this study.

Notes:

Other Bloodborne Pathogens

Several additional infectious diseases are characterized by a phase in which the causative agent may circulate in blood for a prolonged period of time. With the exception of syphilis and malaria, these diseases are rare in the U.S.

Syphilis

Syphilis is caused by infection with *Treponema pallidum*, a spirochete. Syphilis is a sexually transmitted disease that is increasingly prevalent in the U.S. Although syphilis is primarily transmitted sexually and in utero, a few cases of transmission by needlestick, by tattooing instruments, and by blood transfusion have been documented. Preventive treatment of an exposed healthcare worker with an antibiotic during the incubation period would be expected to prevent serological test positivity and the potential for permanent reactivity on treponemal testing, as well as preventing the manifestations of infection.

Malaria

Malaria is a potentially fatal mosquito-borne parasitic infection of the blood cells characterized by paroxysms of fever, chills, and anemia. Malaria is an important health risk to immigrants from numerous malaria endemic areas of the world and to Americans who travel to such areas. Malaria is characterized by a prolonged erythrocytic phase during which the causative agent, one of several species of the *Plasmodium* genus, is present in the blood. In many nations, malaria is among the most common transfusion related infectious diseases. In temperate countries, it is only occasionally reported. Malaria has also been transmitted by needlestick injury; in one incident, malaria was transmitted to a child who received a unit of blood and to the recipient's physician, who stuck himself with a needle.

E. Stanford University Exposure Control Plan

Two *Exposure Control Plans* are maintained by the University. One *Exposure Control Plan* is maintained by the Biosafety Office at EH&S and contains specific procedures applicable to all operating

units at the University, including the School of Medicine Blood Center but excluding the Stanford Health Services. Stanford Health Services maintains a second *Exposure Control Plan* which contains specific procedures applicable to clinical and patient care operations.

Notes:

The *Exposure Control Plan* describes Stanford University policy regarding handling and working with human blood and other potentially infectious materials covered by the OSHA Bloodborne Pathogen standard. The *Exposure Control Plan* describes the specific materials covered by the policy, assigns responsibility for compliance with the policy, provides detailed information regarding the work practices to be followed, and personal protective equipment to be used at Stanford, references existing biological waste disposal policies, and provides information regarding post-exposure follow-up. Some of this information is summarized in the discussion below, however, each Stanford University employee is responsible for complying with the requirements and procedures detailed in the *Exposure Control Plan*.

F. Universal Precautions

There is no way to tell by looking at a person whether or not that person is carrying a bloodborne pathogen. Anyone of any age, race, or gender can be infected with hepatitis B, HIV, or other bloodborne disease and still appear perfectly healthy.

As a result, all exposure control plans are based upon the concept of *Universal Precautions*. Staying healthy depends upon always following safe work practices whenever you may be exposed to bloodborne pathogens.

Applying *Universal Precautions* means you must always assume that blood or other potentially infectious material is carrying a disease, and always take the necessary measures to protect yourself. To avoid infection with a bloodborne disease, you must maintain an attitude of continual self-protection.

The specific procedures you must follow may vary, depending upon your particular job or the particular situation that you face. But applying *Universal Precautions* will always involve the same basic safe work practices.

Personal Protective Equipment (PPE)

Wearing personal protective equipment is usually an important

part of applying *Universal Precautions*. The PPE worn must always be appropriate to the situation.

Notes:

Gloves

Whenever hands might come into contact with blood or any other potentially infectious material or with contaminated surfaces, gloves are required. They should be made of latex or some other impermeable materials that will not allow fluids to pass through.

Disposable (Single Use) Gloves

In normal situations, surgical or examination type gloves are used. Where exposure to a large quantity of blood is likely, or where gloves might be damaged during a procedure, wearing two pairs (double gloving) is recommended. These gloves may not be decontaminated for re-use. They must always be discarded as soon as possible.

When removing disposable gloves, care must be taken not to allow the outside surfaces to come into contact with bare skin. The following procedure will minimize this potential exposure.

1. Grasp the top or wrist of one glove, being careful not to touch anything but the glove.
2. Pull the glove off, turning it inside out. Continue holding the glove.
3. Insert a finger into the top of the other glove, being careful not to touch its outside surface.
4. Pull the glove off, turning it inside out and pulling it over the first glove. Both gloves should now be inside out, one inside the other.
5. Discard both gloves into an approved waste container.
6. Wash your hands.

Utility Gloves

For some tasks, like cleaning up and decontaminating after a blood spill, household type utility gloves are acceptable. These gloves may be decontaminated and re-used provided they are not cracked, peeling, torn, punctured, discolored, or deteriorating in any way. If they are not in perfect condition, they should be discarded. When removing these gloves, make certain that their outside surfaces do not come into contact with bare skin.

When wearing any type of possibly contaminated gloves, avoid touching any surfaces unnecessarily to limit the spread of contamination.

Notes:

To avoid infection, never touch your face or rub your eyes with contaminated gloves.

Eye Protection, Masks, and Face Shields

Whenever blood or other potentially infectious material can splash, spray, or spatter and might contaminate the eyes, nose, or mouth, additional protection is required. A mask may be used in combination with goggles or glasses that have solid side shields. A chin length face shield may also be used.

In some situations, a gown or apron may be required to keep contamination away from the body and clothing. **Use the PPE that will protect you from any reasonably anticipated exposure.**

Safe Handling and Disposal

Applying the *Universal Precautions* also involves following safe work practices at all times. Potentially infectious materials and any contaminated materials must always be handled safely and disposed of correctly.

Warning Labels

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.

Labels shall include either the following legend:



BIOHAZARD

or in the case of regulated waste the legend:

BIOHAZARDOUS WASTE

The Biohazard Symbol - Everyone should be able to recognize the biohazard warning symbol and know that it indicates contaminated or potentially infectious material.

The symbol itself must be fluorescent orange or orange-red, or predominantly so with lettering and symbols in contrasting color.

Notes:

The biohazard symbol should also be used as a warning on any contaminated equipment until the equipment can be decontaminated.

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.

Needles and Sharp Objects

A sharp object that has been contaminated with blood or other potentially infectious material is extremely hazardous. A puncture wound can introduce bloodborne pathogens directly into the bloodstream.

Personnel must be especially careful with needles and syringes. Needles must never be recapped nor deliberately bent or broken, but are to be discarded as soon as possible in a sharps disposal container.

Remember, rubber or latex gloves will not provide protection against a puncture wound.

Other Contaminated Materials

Anything that has come into contact with blood or other potentially infectious material should be considered to be contaminated. This can include work surfaces, machinery, materials used during first aid procedures, clothing, and personal protective equipment. To avoid infection, and to keep from spreading contamination further, safe work practices are essential. Never handle possibly contaminated materials without wearing gloves and any other appropriate PPE. Avoid letting your gloves or any other contaminated material come into contact with uncontaminated surfaces.

Dispose of all contaminated materials following Stanford University's Biohazardous Waste Disposal Guidelines.

Decontamination

When blood or other potentially infectious material has come into contact with a work surface, machinery, or the surfaces of sinks and other fixtures, use an approved disinfectant to decontaminate the affected areas.

A one to ten dilution of ordinary household bleach and water is an effective disinfectant - approximately 1 1/2 cups of bleach added to 1 gallon water.

If possible, begin by covering the contaminated area with paper towels (or an absorbent cloth). Pour the bleach solution over the paper towels, allow it to soak through, and wipe the area. Then pour more bleach solution over the area and use fresh paper towels to wipe it clean and dry.

Some equipment may be damaged by bleach, and another disinfectant may be required. Remember that not all disinfectants will destroy HBV. A summary of disinfectants and their effective use is found in Appendix B of the Exposure Control Plan and is available from the Biosafety Officer at 5-1473.

Wash Your Hands

Hand washing after handling possibly infectious or contaminated materials is a very important part of Universal Precautions. Even if you have been wearing gloves, washing your hands vigorously and thoroughly with soap and warm water is a vital part of avoiding infection. You should not eat, smoke, or touch your face with your hands until they have been washed.

Always wash your hands thoroughly after handling any possibly contaminated material!

G. Procedures to Follow if an Exposure Occurs

If you are ever directly exposed to blood or other potentially infectious material, wash the area contacted with bacteriocidal soap and warm water as soon as possible. Washing should be very thorough, including, for example, under the fingernails if hands have been exposed.

If material has splashed into your eyes, immediately use an emergency eyewash or another source of clean running water to flush them for **at least 15 minutes**. Hold the eyes open and roll them around to make certain that water reaches their entire surface.

All employees of the Medical Center and medical students are to report exposures as soon as possible. Between the hours of 7:00 a.m. and 3:30 p.m., report to the Stanford University Hospital Employee Health Office for post-exposure evaluation and follow-up medical consultation. If an exposure occurs after these hours,

on holidays or weekends, please report to the Stanford University Hospital Emergency Department for post-exposure follow-up. Always report any exposure to blood or other potentially infectious materials to your supervisor or to EH&S as soon as possible. Treatment is most effective if exposed personnel can be seen on the same day that the exposure occurred. Exposures reported after the first 24 hours are not considered to be urgent.

Notes:

H. Post-Exposure Evaluation and Follow-Up

Post-Exposure Follow-Up

After any occupational exposure to blood or other potentially infectious materials, a confidential medical evaluation and counseling will be made available at no cost to you. The exposed individual will be provided with post-exposure medical treatment (e.g., hepatitis B vaccine), counseling and evaluation as appropriate and in accordance with CDC recommendations. All test results and medical records will be available to you, but otherwise they will be kept strictly confidential.

Treatment and follow-up are dependent upon the specific exposure. Post-exposure medical protocols are maintained by the Stanford University Hospital Emergency Department and may be reviewed upon request.

Employee information

The exposed employee will be provided with a written opinion that will include: HBV vaccination status and recommendations; results of the post-exposure evaluation; and discussion of any medical conditions resulting from exposure to blood or other potentially infectious materials that require further evaluation or treatment. **All other findings or diagnoses shall remain confidential and shall not be included in the written report.**

I. Conclusions

Avoiding occupational exposure to bloodborne disease is not difficult.

Apply UNIVERSAL PRECAUTIONS whenever you might be exposed to blood or other potentially infectious materials:

- Always wear the appropriate personal protective equipment.
- Always handle and dispose of any contaminated materials safely.

-
- Always wash your hands, even if you have been wearing gloves.

Notes:

Maintain an attitude of continual self-protection and always follow safe work practices.

J. Questions and Answers

Appendices

APPENDIX A: Universal Precautions

**APPENDIX B: Criteria for Determining the Risk of Exposure to the Hepatitis B Virus
or Other Bloodborne Pathogens**

**APPENDIX C: OSHA Bloodborne Pathogen Standard. Title 8, California Code of
Regulations, General Industry Safety Order 5193**

APPENDIX D: Hepatitis B Virus Vaccination Declination Form

APPENDIX A: Universal Precautions

Universal Precautions apply to blood, body fluids, and all human tissues. Body fluids include: semen, vaginal secretions, cerebrospinal fluid (CSF), synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid; feces, urine, sputum, nasal secretions, saliva, tears, and vomitus.

Handwashing

Universal Precautions are designed to supplement important routine infection control, such as handwashing.

- Hands and other skin surfaces that are contaminated with blood or body fluids must be immediately and thoroughly washed.
- Gloves must be changed and hands must be washed between patient contacts involving blood or body fluids.
- Hands must be washed between patient contacts not involving blood or body fluids.

Use of Protective Barriers

Protective barriers will be worn to prevent exposure to blood or body fluids during procedures where splashing or aerosolization may occur. Individual departments/units will specify the type of protective barrier(s) to be used during any specific procedure, according to the type of exposure anticipated. Barriers such as gloves, gowns, plastic aprons, masks, protective eyewear or face shields may be required. These policies will be reviewed by the Infection Control Committee.

Gloves

Gloves will be worn during phlebotomy, finger or heel sticks, when starting or manipulating intravascular lines, or during any procedure involving a potential exposure to blood. Gloves will be worn in situations where exposure to body fluids may occur.

- Use sterile gloves for procedures involving contact with normally sterile areas of the body.
- Use examination gloves for procedures involving contact with mucous membranes and for other patient care.
- Change gloves between patient contacts.
- Do not wash or disinfect surgical or exam. gloves for reuse as this may cause deterioration.
- Use general-purpose utility gloves (e.g., rubber household gloves) for housecleaning chores and for instrument cleaning and decontamination procedures. Utility gloves may be decontaminated and reused, but should be discarded if peeling, cracked, torn or damaged.

Preventing Penetrating Injuries

Gloves should reduce the incidence of contamination of the hands, but they cannot prevent penetrating injuries due to needles or other sharp instruments.

- Do not recap needles by hand; do not remove used needles from disposable sy-

ringes by hand; and do not bend, break, or otherwise manipulate used needles by hand.

- ❑ Place used disposable syringes, needles, scalpel blades, and other sharp items in red puncture-resistant containers for disposal. Containers should be located at the bedside or as close to the use area as practical.
- ❑ Take care, both during and after procedures, to prevent injuries from needles, scalpels, or other sharp instruments or devices.

APPENDIX B: Criteria for Determining the Risk of Occupational Exposure to Hepatitis B Virus or other Bloodborne Pathogens

Does the employee ever:

- a) work with animals, such as primates that are infected with hepatitis B or other bloodborne pathogens OR perform tasks where such animals are housed?
- (b) work with hepatitis B virus or other bloodborne pathogens or with preparations, such as liquid solutions or powders containing the hepatitis B virus?
- (c) handle human blood products such as whole blood, plasma, serum, platelets, or white cells?
- (d) handle human body fluids such as semen, cerebrospinal fluid, vaginal secretions, joint fluid, pleural fluid, peritoneal fluid, pericardial fluid, or amniotic fluid?
- (e) handle unfixed human tissue or organs? (Tissues and organs soaked in chemical preservatives such as alcohol or formaldehyde are “fixed”)
- (f) handle blood, blood products, body fluids or unfixed tissues or organs of animals infected with the hepatitis B virus or other bloodborne pathogens?
- (g) handle sharp instruments such as knives, needles, scalpels, or scissors which have been used by others working with human blood or other potentially infectious materials to include human organs, tissues or body fluids OR used by others working with similar body parts and fluids from animals infected with the hepatitis B virus or other bloodborne pathogens?
- (h) enter areas where other individuals work with human or animal blood, body fluid, tissues or organs which are infected with the hepatitis B virus or other bloodborne pathogens AND perform tasks where any of the forementioned body substances may come into contact with the laboratory worker’s unbroken skin, broken skin, or mucous membranes?
- (i) perform tasks which may potentially result in the lab workers exposed skin or mucous membranes coming in contact with human or animal blood, body fluids, organs, or tissues which are infected with the hepatitis B virus or other bloodborne pathogens?

IF THE ANSWER TO ANY OF THE ABOVE QUESTIONS IS “YES”, THEN THE LAB WORKER IS CONSIDERED TO BE AT OCCUPATIONAL RISK OF CONTRACTING HBV OR OTHER BLOODBORNE PATHOGENS

**APPENDIX D:
Stanford University
Occupational Exposure to Bloodborne Pathogens or
Other Potentially Infectious Materials
(in compliance with Title 8, CCR, GISO 5193)**

Name: _____
(please print)

Phone: _____

Title: _____

Dept.: _____

PLEASE CHECK THE APPROPRIATE BOX:

- I have already received the Hepatitis B vaccine.
Approximate date of vaccine _____.
I received the vaccine at _____.
- I wish to receive the Hepatitis B vaccine.
- I do not wish to receive the Hepatitis B vaccine at this time.
(Please read and sign the statement below.)

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 this opportunity to be vaccinated with hepatitis B vaccine at no charge to myself. However, I decline the 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.

SIGNATURE: _____

DATE: _____

For additional information, please contact the Biosafety Officer at 725-1473.

Please return this form to:
The Department of Environmental Health and Safety
Biosafety Office
Mail Code 8007

APPENDIX C: OSHA Bloodborne Pathogen Standard. Title 8, California Code of Regulations, General Industry Safety Order 5193

Bloodborne Pathogens.

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

Exception: This regulation does not apply to the construction industry.

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

Biological Cabinet" means a device enclosed except for necessary exhaust purposes on three sides and top and bottom, designed to draw air inward by means of mechanical ventilation, operated with insertion of only the hands and arms of the user, and in which virulent pathogens are used. Biological cabinets are classified as:

(1) Class I: A ventilated cabinet for personnel protection with an unrecirculated inward airflow away from the operator and HEPA filtered exhaust air for environmental protection.

(2) Class II: A ventilated cabinet for personnel, product, and environmental protection having an open front with inward airflow for personnel protection, HEPA filtered laminar airflow for product protection, and HEPA filtered exhaust air for environmental protection.

(3) Class III: A total enclosed, ventilated cabinet of gas-tight construction. Operations in the cabinet are conducted through attached protective gloves.

"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).

"Chief" means the Chief of the Division of Occupational Safety and Health of the California Department of Industrial Relations or designated representative.

"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 a surface or in or on an item.

"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. Decontamination includes procedures regulated by Health and Safety Code Section 25090.

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

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

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

"HBV" means hepatitis B virus.

"HIV" means human immunodeficiency virus.

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

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

"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.

"One-Hand Technique" means procedure wherein the needle of a reusable syringe is capped in a sterile manner during use. The technique employed shall require the use of only the hand holding the syringe so that the free hand is not exposed to the uncapped needle.

"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 other body fluid that is visibly contaminated with blood such as saliva or vomitus, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids such as emergency response;

- (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and
- (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

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

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

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

"Regulated Waste" means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials. Regulated Waste includes "medical waste" regulated by Health and Safety Code Chapter 6.1.

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

"Source Individual" means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clinics 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. Sterilization includes procedures regulated by Health and Safety Code Section 2S090.

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

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

c) Exposure Control.

(1) Exposure Control Plan.

(A) Each employer having an employee(s) with occupational exposure as defined by subsection (b) of this section shall establish a written Exposure Control Plan, which is designed to eliminate or minimize employee exposure and which is also consistent with Section 3203.

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

1. The exposure determination required by subsection (c)(2);
2. The schedule and method of implementation for each of the applicable subsections: (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
3. The procedure for the evaluation of circumstances surrounding exposure incidents as required by subsection (f)(3) (A)-

(C) Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with Section 3204(e).

(D) 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, to reflect new or revised employee positions with occupational exposure and to review the exposure incidents which occurred since the previous update.

(E) The Exposure Control Plan shall be made available to the Chief or NIOSH or their respective designee upon request for examination and copying.

(2) Exposure Determination.

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

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

2. A list of job classifications in which some employees have occupational exposure; and
3. 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 subsection (c)(2)(A)2. of this standard.

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

(d) Method of Compliance

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

(2) Engineering and Work Practice Controls.

(A) 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.

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

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

(D) 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.

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

(F) 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.

(G) Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in subsections (d)(2)(G)1. and (d)(2)(G)2. below. Shearing or breaking of contaminated needles is prohibited.

1. 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.

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

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

1. Puncture resistant;
2. Labeled in accordance with this section;
3. Leakproof on the sides and bottom; and
4. In accordance with the requirements set forth in subsection (d)(4)(B)5. for reusable sharps.

(I) 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.

(J) 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.

(K) 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.

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

(M) 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.

1. The container for storage, transport, or shipping shall be labeled or color-coded according to subsection (g)(1)(A), 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 subsection (g)(1)(A) is required when such specimens/containers leave the facility.

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

3. 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.

(N) 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.

1. A readily observable label in accordance with subsection (g)(1)(A)8. shall be attached to the equipment stating which portions remain contaminated.

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

(3) Personal Protective Equipment.

(A) 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. NOTE: For fire fighters, these requirements are in addition to those specified in Sections 3401-3411, and are intended to be consistent with those requirements.

(B) 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 judgment, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future. The employer shall encourage employees to report all such instances without fear of reprisal in accordance with Section 3203.

(C) 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.

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

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

(F) 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.

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

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

(I) 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 subsection (d)(3)(I)4.; and when handling or touching contaminated items or surfaces. These requirements are in addition to the provisions of Section 3384.

1. 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.

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

3. 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.

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

a. Periodically reevaluate this policy;

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

c. Not discourage the use of gloves for phlebotomy; and

d. Required- that gloves be used for phlebotomy in the following circumstances:

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

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

iii. When the employee is receiving training in phlebotomy.

(J) 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. These requirements are in addition to the provisions of Section 3382. Where respiratory protection is used, the provisions of Section 5144 are required.

NOTE: Surgical masks are not respirators.

(K) 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. These requirements are in addition to the provisions of Section 3383.

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, orthopedic surgery). These requirements are in addition to the provisions of Section 3383.

(4) Housekeeping.

(A) 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.

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

1. 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.

2. 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.

3. 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.

4. 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.

5. 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.

(C) Regulated Waste.

1. Contaminated Sharps Discarding and Containment.

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

i. Closable;

ii. Puncture resistant;

iii. Leakproof on sides and bottom; and

iv. Labeled in accordance with subsection (g)(l)(A) of this section.

b. During use, containers for contaminated sharps shall be:

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);

ii. Maintained upright throughout use; and iii. Replaced routinely and not be allowed to overfill.

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

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

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

A. Closable;

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

C. Labeled according to subsection (g)(l)(A) of this section.

d. 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.

2. Other Regulated Waste Containment.

a. Regulated waste shall be placed in containers which are:

i. Closable;

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

iii. Labeled and color-coded in accordance with subsection (g)(l)(A) of this section; and

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

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

i. Closable;

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

- iii. Labeled and color-coded in accordance with subsection (g)(l)(A) of this section; and
- iv. Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping

3. Handling, storage, treatment and disposal of all regulated waste shall be in accordance with Health and Safety Code Chapter 6.1 and other applicable regulations of the United States, the State, and political subdivisions of the State.

(D) laundry.

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

a. 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.

b. Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with subsection (g)(l)(A) 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.

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

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

3. 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 subsection (g)(l) (A)-

e) HIV and HBV Research Laboratories and Production Facilities.

(1) General.

This subsection applies in addition to the other requirements of this section to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV.

EXCEPTION: This subsection does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs.

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

(A) Standard Microbiological Practices. All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens. Such methods are further specified in Health and Safety Code Chapter 6.1.

(B) Special Practices.

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

2. 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.

3. 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.

4. 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 subsection (g)(l)(B) of this standard.

5. 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.

6. 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.

7. 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.

8. 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.

9. 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.

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

11. 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.

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

13. Written biosafety procedures shall be prepared and adopted into the Exposure Control Plan of subsection (c)(l). Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, And shall be required to follow them.

(C) Containment Equipment.

1. 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.

2. Biological safety cabinets shall be certified by the employer that they meet manufacturers' specifications when installed, whenever they are moved and at least annually.

3. HIV and HBV research laboratories shall meet the following criteria:

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

(B) An autoclave for decontamination of regulated waste shall be available.

NOTE: Autoclaves should meet the requirements of Health and Safety Code Section 25090.

4. HIV and HBV production facilities shall meet the following criteria:

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

(B) 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.

(C) 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.

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

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

NOTE: Autoclaves should meet the requirements of Health and Safety Code Section 25090.

(F) 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). The ventilation system shall conform to the requirements of Article 107.

(5) Training Requirements.

Training requirements for employees in HIV and HBV research laboratories and HIV and HBV production facilities are specified in subsection (g)(2) and they shall receive in addition the following initial training:

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

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

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

f) Hepatitis B Vaccination and Post-Exposure- Evaluation and Follow-up.

(1) General.

(A) 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.

When an employer is also acting as the evaluating healthcare professional, the employer shall advise an employee following an exposure incident that the employee may refuse to consent to post-exposure evaluation and follow-up from the employer healthcare professional. When consent is refused, the employer shall make immediately available to exposed employees a confidential medical evaluation and follow-up from a healthcare professional other than the exposed employee's employer.

EXCEPTION: Designated first aid providers who have occupational exposure are not required to be offered pre-exposure hepatitis B vaccine if the following conditions exist:

1. The primary job assignment of such designated first aid providers is not the rendering of first aid.

a. Any first aid rendered by such persons is rendered only as a collateral duty responding solely to injuries resulting from workplace incidents, generally at the location where the incident occurred.

b. This provision does not apply to designated first aid providers who render assistance on a regular basis, for example, at a first aid station, clinic, dispensary, or other location where injured employees routinely go for such assistance, And emergency or public safety personnel who are expected to render first aid in the course of their work.

2. The employer's Exposure Control Plan, Subsection (c)(1), shall specifically address the provision of hepatitis B vaccine to all unvaccinated first aid providers who have rendered assistance in any situation involving the presence of blood or other potentially infectious material (regardless of whether an actual exposure incident, as defined by Subsection (b), occurred) and the provision of appropriate post-exposure evaluation, prophylaxis and follow-up for those employees who experience an exposure incident as defined in subsection (b), including:

a. Provisions for a reporting procedure that ensures that all first aid incidents involving the presence of blood or other potentially infectious material shall be reported to the employer before the end of the work shift during which the first aid incident occurred.

i. The report must include the names of all first aid providers who rendered assistance, regardless of whether personal protective equipment was used and must describe the first aid incident, including time and date.

A. The description must include a determination of whether or not, in addition to the presence of blood or other potentially infectious material, an exposure incident, as defined in subsection (b), occurred.

B. This determination is necessary in order to ensure that the proper post-exposure evaluation, prophylaxis and follow-up procedures required by subsection (f)(3) are made available immediately if there has been an exposure incident, as defined in subsection (b).

ii. The report shall be recorded on a list of such first aid incidents. It shall be readily available to all employees and shall be provided to the Chief upon request.

b. Provision for the bloodborne pathogens training program, required by subsection (g)(2), for designated first aiders to

include the specifics of the reporting requirements of subsection (f)(3) and of this exception.

c. Provision for the full hepatitis B vaccination series to be made available as soon as possible, but in no event later than 24 hours, to all unvaccinated first aid providers who have rendered assistance in any situation involving the presence of blood or other potentially infectious material regardless of whether or not a specific exposure incident, as defined by subsection (b), has occurred.

3. The employer must implement a procedure to ensure that all of the provisions of subsection 2. of this exception are complied with if pre-exposure hepatitis B vaccine is not to be offered to employees meeting the conditions of subsection 1. of this exception.

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

1. Made available at no cost to the employee;
2. Made available to the employee at a reasonable time and place;
3. Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and
4. 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 Subsection (f).

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

(2) Hepatitis B Vaccination.

(A) Hepatitis B vaccination shall be made available after the employee has received the training required in subsection (g)(2)(G)9. 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.

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

(C) 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.

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

(E) 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)(B).

(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:

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

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

1. 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.

2. 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.

3. 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.

(C) Collection and testing of blood for HBV and HIV serological status;

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

2. 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.

3. Additional collection and testing shall be made available as recommended by the U.S. Public Health Service.

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

(E) Counseling; and

(F) Evaluation of reported illnesses.

(4) Information Provided to the Healthcare Professional.

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

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

1. A copy of this regulation;

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

3. Documentation of the route(s) of exposure and circumstances under which exposure occurred, as required by subsection (f)(3)(A);

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

5. All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer's responsibility to maintain, as required by subsection (h)(1)(B)2.

(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.

(A) 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.

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

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

2. 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.

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

(6) Medical Recordkeeping.

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

(g) Communication of Hazards to Employees

(1) Labels and Signs.

(A) Labels.

1. 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 subsection (g)(1)(A)5., 6. and 7 .

2. Labels required by this section shall include either the following legend as required by Section 6004:



BIOHAZARD

or in the case of regulated waste the legend: BIOHAZARDOUS WASTE

as described in Health and Safety Code Sections 25080-25082.

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

4. Labels required by subsection (g)(1)(A) shall either be an integral part of the container or shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

5. Red bags or red containers may be substituted for labels except for sharp containers or regulated waste red bags. Bags used to contain regulated waste shall be color-coded red and shall be labeled in accordance with subsection (g)(1)(A)2. Labels on red bags or red containers do not need to be color-coded in accordance with subsection (g)(1)(A)3.

6. 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 subsection (g).

7. 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.

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

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

(B) Signs.

1. The employer shall post signs at the entrance to work areas specified in subsection (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.)

2. These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color, and meet the requirements of Section 6003.

(2) Information and Training.

(A) 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.

(B) Training shall be provided as follows:

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

2. At least annually thereafter.

(C) 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.

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

(E) 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.

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

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

1. An accessible copy of the regulatory text of this standard and an explanation of its contents;
 2. A general explanation of the epidemiology and symptoms of bloodborne diseases;
 3. An explanation of the modes of transmission of bloodborne pathogens;
 4. An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan;
 5. An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;
 6. 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;
 7. Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment;
 8. An explanation of the basis for selection of personal protective equipment;
 9. 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;
 10. Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;
 11. 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;
 12. Information on the post-exposure evaluation and followup that the employer is required to provide for the employee following an exposure incident;
 13. An explanation of the signs and labels and/or color coding required by subsection (g)(1); and
 14. An opportunity for interactive questions and answers with the person conducting the training session.
- NOTE: Additional training is required for employees of HIV and HBV Research Laboratories and Production Facilities, as described in subsection (e)(5).

(H) 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.

h) Recordkeeping

(1) Medical Records.

(A) The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with Section 3204.

(B) This record shall include:

1. The name and social security number of the employee;
2. 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 subsection (f)(2);
3. A copy of all results of examinations, medical testing, and follow-up procedures as required by subsection (f)(3);
4. The employer's copy of the healthcare professional's written opinion as required by subsection (f)(5); and

5. A copy of the information provided to the healthcare professional as required by subsections (f)(4)(B)2., 3. and 4.

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

1. Kept confidential; and

2. 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.

(D) The employer shall maintain the records required by subsection (h) for at least the duration of employment plus 30 years in accordance with Section 3204.

(2) Training Records.

(A) Training records shall include the following information:

1. The dates of the training sessions;

2. The contents or a summary of the training sessions;

3. The names and qualifications of persons conducting the training; and

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

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

(3) Availability.

(A) The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Chief and NIOSH for examination and copying.

(B) Employee training records required by this subsection final be provided upon request for examination and copying to employees, to employee representatives, to the Chief, and to NIOSH.

(C) Employee medical records required by this subsection shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Chief, and to NIOSH in accordance with Section 3204.

(4) Transfer of Records.

(A) The employer shall comply with the requirements involving transfer of records set forth in Section 3204.

(B) 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 NIOSH, at least three months prior to their disposal and transmit them to the NIOSH, if required by the NIOSH to do so, within that three month period.

(i) Dates

(1) The Exposure Control Plan required by subsection (c)(1) of this section shall be completed within 60 days of the effective date of this standard.

(2) Subsection (g)(2) Information and Training and (h) Recordkeeping shall take effect within 90 days of the effective date of this standard.

(3) Subsections (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 120 days after the effective date of this standard.

(j) Appendix

Appendix A to this section is incorporated as a part of this section and the provision is mandatory.

NOTE: Authority cited: Section 142.3, Labor Code. Reference: Section 142.3, Labor Code and Chapter 6.1, Health and Safety Code.

APPENDIX A - Hepatitis B Vaccine Declination

(MANDATORY)

The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the following statement as required by subsection (f)(2)(D):

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.

NOTE: Authority cited: Section 142.3, Labor Code. Reference: Section 142.3, Labor Code.