ABSTRACT

RICHARD K. MATTICK. Development of an Occupational Audit System for OSHA's Proposed Bloodborne Pathogens Standard. (Under the Direction of Dr. ALVIS G. TURNER)

OSHA's proposed bloodborne pathogen rule will be the agency's first and most costly attempt at regulating biological hazards, namely HIV and HBV, in the occupational environment. Lifetime risk of infection to healthcare workers from HIV and HBV can be significantly reduced with adherence to the OSHA standard. In this study, an audit system was developed to provide research and clinical laboratories and production facilities with a means of assessing compliance with the rule. In addition, a fault tree analysis added the ability to classify facilities on the basis of exposure risk to bloodborne pathogens. Database software offers the ability to store collected audit information and disseminate risk management strategies and remedial information to audited facilities.

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CHAPTER I

INTRODUCTION

On May 30, 1989, the Occupational Safety and Health Administration (OSHA) issued a proposed rule to regulate workers' exposures to blood and body fluids potentially contaminated with bloodborne pathogens. The proposal, which covers close to 5.7 million workers, aims to protect health-care workers and public service personnel against the diseases associated with these agents, primarily the serious liver disease associated with the hepatitis B virus (HBV) and the often fatal acquired immunodeficiency syndrome, or AIDS, caused by the human immunodeficiency virus (HIV). The proposed standard is the Agency's first effort at trying to regulate a biological hazard rather than a physical or chemical one. OSHA held five public hearings (27), the last one convening in San Francisco, January 9-17, 1990, and set the closing date for the public comment period at May 21, 1990. The comment period for the proposed rule was "the largest substantive record in agency history" with 4,500 separate entries (29). The final rule was expected to be published one year later. As of January 9, 1991, it was announced that the rulemaking record closed December 10, 1990, and that the final rule was still due out sometime in May of 1991. Currently, however, the rule is still under

review with no mention as to when it will be issued. As of November, the proposed rule will be four years in the making since its inception.

The objective of this report is to critically analyze the proposed bloodborne standard. It will track the developmental history of the standard, define its scope and impact on industry, and review some of the specific bloodborne pathogens affecting the general population and occupational workforce. It will also discuss the risk management techniques used to control bloodborne pathogens in the workplace, including the development of an audit system. Lastly, this paper will identify the potential advantages and disadvantages of this standard to industry and the worker once promulgated.

CHAPTER II

BLOODBORNE PATHOGENS

The Human Immunodeficiency Virus (HIV)

Infectious Agent/Etiologic Pathway/Clinical Manifestations

The human immunodeficiency virus (HIV), formerly referred to as the human T-lymphotrophic virus type III (HTLV-III) or lymphadenopathy-associated virus (LAV), was discovered in 1983 and is the etiologic agent of acquired immune deficiency syndrome (AIDS). It is a retrovirus, containing RNA instead of DNA for its genetic code. Two types have been identified, type 1 (HIV-1) and type 2 (HIV-2). Both these viruses are serologically and geographically relatively distinct, but have similar epidemiologic and pathologic characteristics. HIV attacks a subpopulation of T-lymphocytes known as the T4 or CD4 cell, the white blood cell that influences the function of many other cells in the immune system, by multiplying within them, and eventually destroying them. The process of T-cell destruction leads to immune system imbalance and dysfunction. Without a properly functioning immune system, the body becomes susceptible to opportunistic infection and disease from organisms that normally pose no or minimal threat to healthy humans with

normally functioning immune systems. Generally, the severity of the HIV-related illness is directly correlated with the degree of immune system dysfunction. The spectrum of diseases range from totally asymptomatic infection to full-blown immunodeficiency accompanied by opportunistic infection and cancer (4,5,58).

Within several weeks to several months after infection with HIV, many persons develop an acute, self limited, flu-like illness lasting for a week or two. Evidence that such symptoms occur is best ascertained by documented occupational exposure. Detectable antibodies (seroconversion) to the virus usually occurs within 4 to 12 weeks after initial infection with the virus; occasionally this period is prolonged. The standard serologic tests for antibody to HIV are the enzyme-linked immunosorbent assay (ELISA) and the confirmatory Western Blot HIV antibody test performed in succession (4,5). Infected persons may be free of clinical signs or symptoms of infection for many years; the median length of time before symptoms appear is now estimated to be in excess of 9 years (49). Onset of clinical illness is usually insidious with non-specific symptoms such as lymphadenopathy (swollen lymph nodes), anorexia, chronic diarrhea, weight loss, fever and fatigue. These symptoms along with HIV antibody confirmation are referred to as AIDS related complex (ARC) or "symptomatic HIV infection", but are not sufficient for a diagnosis of AIDS (4).

More than a dozen opportunistic infections and several cancers are considered by the CDC to be specific indicators of uderlying immunodeficiency and thus, if diagnosed by standard histological and/or culture techniques, are used in case definition of AIDS. These opportunistic infections include: Pneumocystis carnii pneumonia, which 60% of AIDS patients have as their first manifestation of the disease, chronic cryptosporidiosis, toxoplasmosis of the CNS, esophageal or lower respiratory tract candidiasis, disseminated or CNS cryptococcosis, disseminated atypical mycobacteriosis, pulmonary, GI, CNS, or ocular cytomegalovirus (CMV) infection, chronic ulcerative mucocutaneous or disseminated herpes simplex infection, and progressive multifocal leukoencephalopathy. The cancers include Kaposi's sarcoma, primary B-cell lymphoma limited to the brain and non-Hodgkin's lymphoma. Additional indicators of AIDS are wasting syndrome, extrapulmonary tuberculosis and varied neurologic symptoms such as AIDS dementia or sensory neuropathy (4).

The proportion of HIV-infected persons who will ultimately develop AIDS is not precisely known although cohort studies of HIV-infected adults carried out before specific antiviral therapy was available indicated that about 15-20% developed AIDS within 5 years, and about 50% within 7-10 years. Beyond 10 years, it was projected that the vast majority of infected persons may develop AIDS within another 5 to 10 years. Without specific therapy, 80-

90% of AIDS patients have died within 3-5 years after the diagnosis of AIDS was made. With modern day drug therapy such as Zidovudine better known as AZT, these incubation periods and time-to-death are thought to be extended by a couple of years (4).

Transmission

The reservoir for the virus is found in man and is spread almost entirely through direct contact with an infected person's blood, blood products, semen, vaginal secretions, and tissues. While the virus on occasion has been found in saliva, tears, urine, cerebrospinal fluid, pleural fluid, amniotic fluid, and breast milk, transmission after contact with these fluids, with the exception of perinatal transmission to a mother's infant through breast milk, has not been reported (4,11,37,47). The major route of transmission is sexual, both homosexual and heterosexual. Other important routes of exposure are parenteral (entry into the body other than through the GI tract) such as by shared needles among drug abusers and accidental percutaneous needlestick injuries or other contaminated skin-penetrating objects; through blood transfusions of infected blood or its components, and by contact of infected body fluid with mucous membranes of the nose, mouth, and eyes or with open wounds/sores (non-intact skin) (4,11,47). The virus can cross mucous membranes but cannot cross the skin barrier and is not transmitted by casual contact,

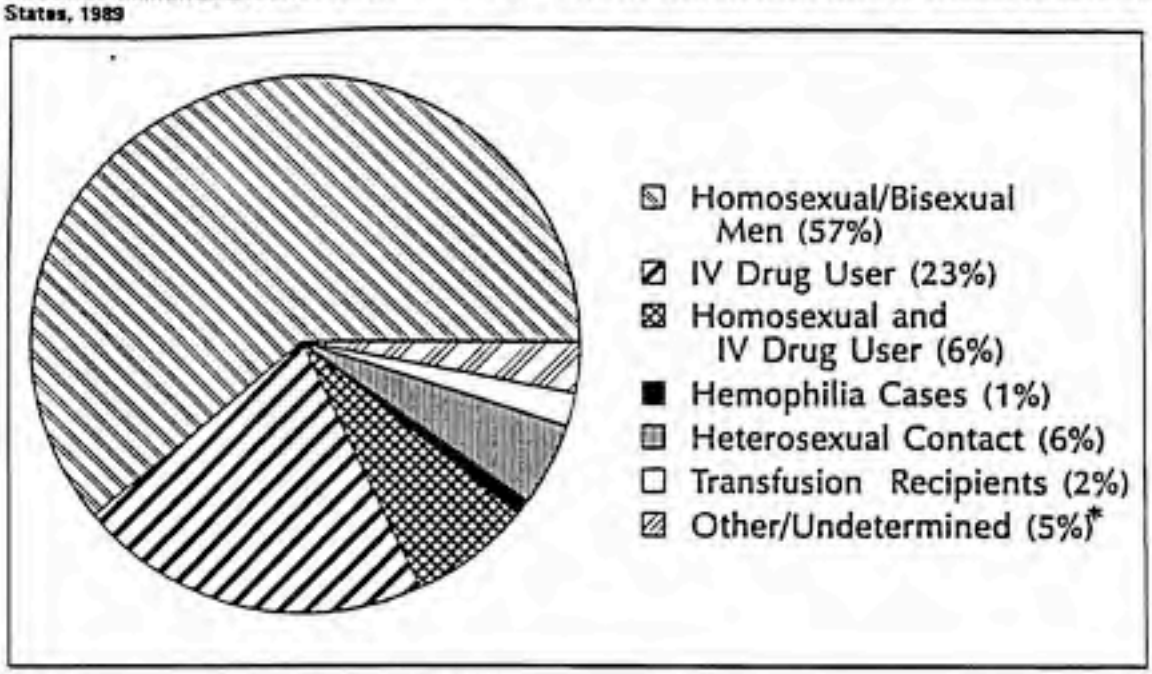
fecal-oral or airborne routes, or by contaminated food or drinking water (13). The infectious dose, or number of HIV viral particles needed to cause infection in man is unknown, although the number of viral particles found in seroconverted blood ranges from 0-3,000/ml (55).

Epidemiology: General Population

AIDS was first recognized in New York and Los Angeles in 1981 and was used to describe a disease complex of young, seemingly healthy men with a severe cellular immune deficiency (35). From 1981 to mid 1990, over 130,000 AIDS cases have been reported in the U.S (4). (See Figure 1 for reported cases by state) That number is expected by the CDC to triple to 365,000 cases by the end of 1992 (47). As of July 1990, the majority of U.S. AIDS cases (86%) were homosexual or bisexual men (57%), IV drug users (23%), and those who were homosexual and used IV drugs (6%). The remainder of the cases were hemophiliacs (1%), heterosexual contacts of infected partners (6%), transfusion recipients (2%), children born to infected mothers (1%), and undetermined/other (4%) (11,47). (See Figure 2) Ninety - one percent of these cases are male and approximately that same percentage are between 20-49 years of age (4,47). It is estimated that currently between 1.0-1.5 million Americans have been infected with the HIV virus, and 6 to 8 million world-wide (4,41).

FIG 1

ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) — Reported adult/adolescent cases, by exposure category, United States, 1989

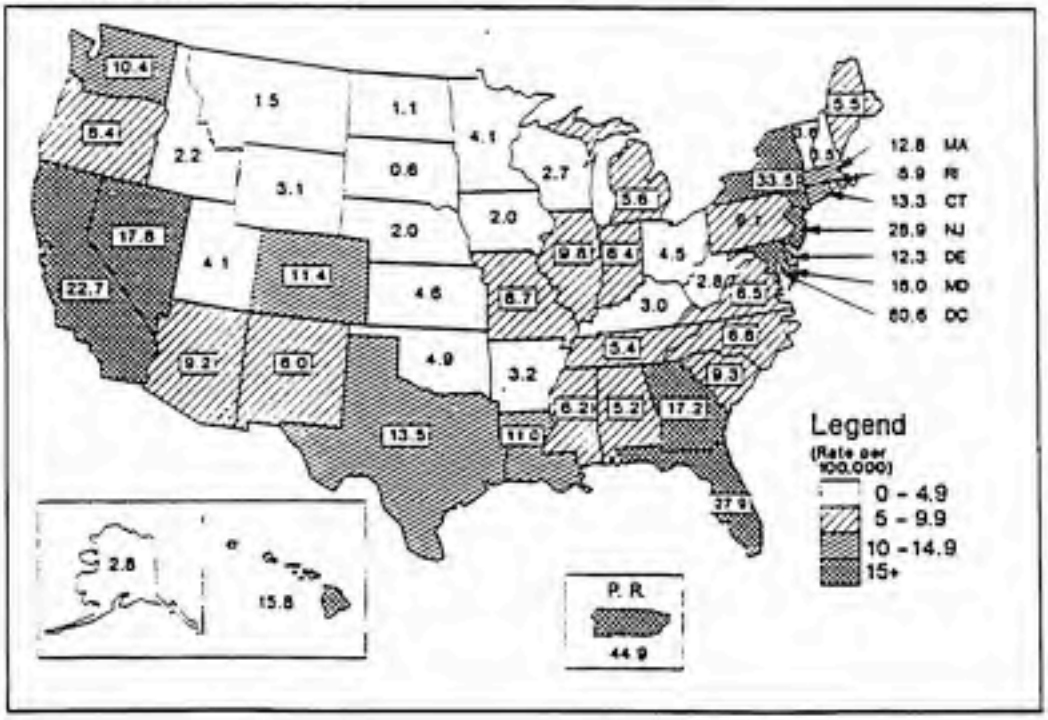


*Includes patients under investigation; patients who died, were lost to follow-up, or refused interview; and patients whose mode of exposure to human immunodeficiency virus (HIV) remains undetermined after investigation.

Source : Centers for Disease Control, MMWR: Summary Report, 1990

FIG 2

ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) — Cases per 100,000 population, reported to CDC by state, United States, 1989.



Source: Centers for Disease Control, MMWR: Summary Report, 1990

Epidemiology: Health-Care Workers

Several prospective epidemiologic studies show that needlestick injuries are the leading cause of occupational HIV exposure in the health-care setting. In 1988, an updated review of the CDC Cooperative Needlestick Study, an ongoing, nationwide prospective survey, found that 89% of all HIV exposures resulted from percutaneuos inoculation, while 6.5% resulted from contamination of open wounds, and 4.7% from contamination of mucous membranes (41). Several prospective surveillance studies, in addition to the CDC study, have been initiated to estimate the risk of infection following an exposure that meets the following criteria: (1) documented exposure to HIV; (2) no other established risk factors; (3) negative pre-exposure HIV serology; and (4) positive post-exposure HIV serology. Through November 1989, of the more than 2,000 exposed health-care workers who enrolled in 9 different prospective surveys, 8 workers had been found to have occupationally acquired HIV infection (41,43). Of the 8 infected workers, 7 were exposed through the percutaneous route and the eighth case through blood contact with non-intact skin. The risk of HIV infection from an occupational exposure, as calculated by the review of these studies, was less then .5%, or more specifically .36% or 3.6 per 1000 exposures (41). This coincides with the approximate .5 % risk estimated by the CDC (55). In addition to these studies, there have been an additional 19 case reports of HIV-infected health-care workers in the

scientific literature (13 with documented seroconversion and 6 without documented seroconversion).

Hepatitis B Virus (HBV)

Infectious Agent/Etiologic Pathway/Clinical Manifestations

The term hepatitis means inflammation of the liver. One of the causes of hepatitis besides bacteria, toxins, drugs, and excess alcohol intake is by the hepatitis B virus (HBV). HBV is a double-stranded DNA virus which attacks and replicates in liver cells. There have been 3 HBV antigens identified: a nucleocapsid core (HBcAg), surrounded by an outer lipoprotein coat (HBsAg), and a third soluble antigen and a subset of the core antigen without cross reactivity, the e antigen (HBeAg). Antibodies are made specific to these antigens and are referred to as anti-HBc, anti-HBs, and anti-HBe (4). Diagnosis of infection is usually confirmed by demonstration of HBsAg. HBV infection may also be confirmed by the presence of HBV viral DNA in the serum or the demonstration of recent antibody development to core and/or surface antigens (anti-HBc and anti-HBs) (4). In combination with HBsAg, the detection of HBeAg is associated with relatively high infectivity (acute infection); conversely, presence of anti-HBe correlates with a relative lack of infectivity. The presence of HBeAg at the time of delivery indicates a very high risk of infection in a newborn infant. Commercial kits including ELISA and

radioimmunoassy (RIA) are available for detection of all markers except HBcAg (58).

HBsAg can be detected in the serum from several weeks before onset of symptoms to days, weeks or months after onset; it is persistent in chronic infections. Anti-HBc appears at the onset of illness and persists indefinitely. IgM Class anti-HBc is present in high concentration (high titer) during acute infection and usually disappears within 6 months (4).

Approximately 50% of the patients that are infected with HBV have symptoms of some type; the rest are subclinical or asymptomatic (36). Usual incubation period is about 45 days (36). Clinical symptoms may start between one week to six months after exposure. These symptoms are flu-like and include fatigue, fever, lose of appetite, nausea, vomiting, abdominal pain, diarrhea, rash, and muscle and joint aches. Approximately 25% of individuals, however, will suffer more acute symptoms with the involvement of the liver, and develop jaundice and dark urine. One-half to two percent of patients with severe liver involvement, called fulminant liver disease, will die (36).

Although most infected individuals recover with no serious complications, approximately 10% of infected adults do not develop resistance to the virus and develop what is known as chronic hepatitis. These individuals become carriers of the virus and can actively transmit it. Usually chronic hepatitis persists for more then 4 to 6 months, sometimes as

long as a lifetime. During the chronic state, the carrier may be asymptomatic or continue to have symptoms. Other complications include "chronic active" hepatitis which has the potential to progress to cirrhosis of the liver and a much increased risk of developing liver cancer. About 25% of the carriers, whether they have symptoms or not, eventually will develop liver cancer (36). The relative risk of liver cancer for active carriers is 273 times greater than for non-carriers (1).

Transmission

HBsAg has been found in virtually all body secretions and excretions; however, only blood and serum derived fluids, saliva, semen, and vaginal fluids have been shown to be infectious (4). The virus is found in the highest concentrations in the blood, where it may reach levels of 1×10^8 viral particles per milliliter (36). Transmission occurs by percutaneous (intravenous, intramuscular, subcutaneous or intradermal) and mucous membrane exposure to infective body fluids, as may occur in needlestick accidents, perinatal exposure, transfusions, contaminated needle sharing among IV drug users, tattooing, earpiercing, acupuncture, and by sexual exposure, both heterosexual and homosexual. Personal hygiene items such as razors and toothbrushes have been implicated as occasional transmitters of HBV (4). The virus is not transmitted by casual contact, touching or shaking hands, eating food prepared by an

infected person or by contact with inanimate objects, such as toilet seats, or telephones. All stages of the disease, including the pre-clinical state (many weeks before symptoms are seen), the clinical period, as well as the chronic carrier state are considered infectious and communicable periods.

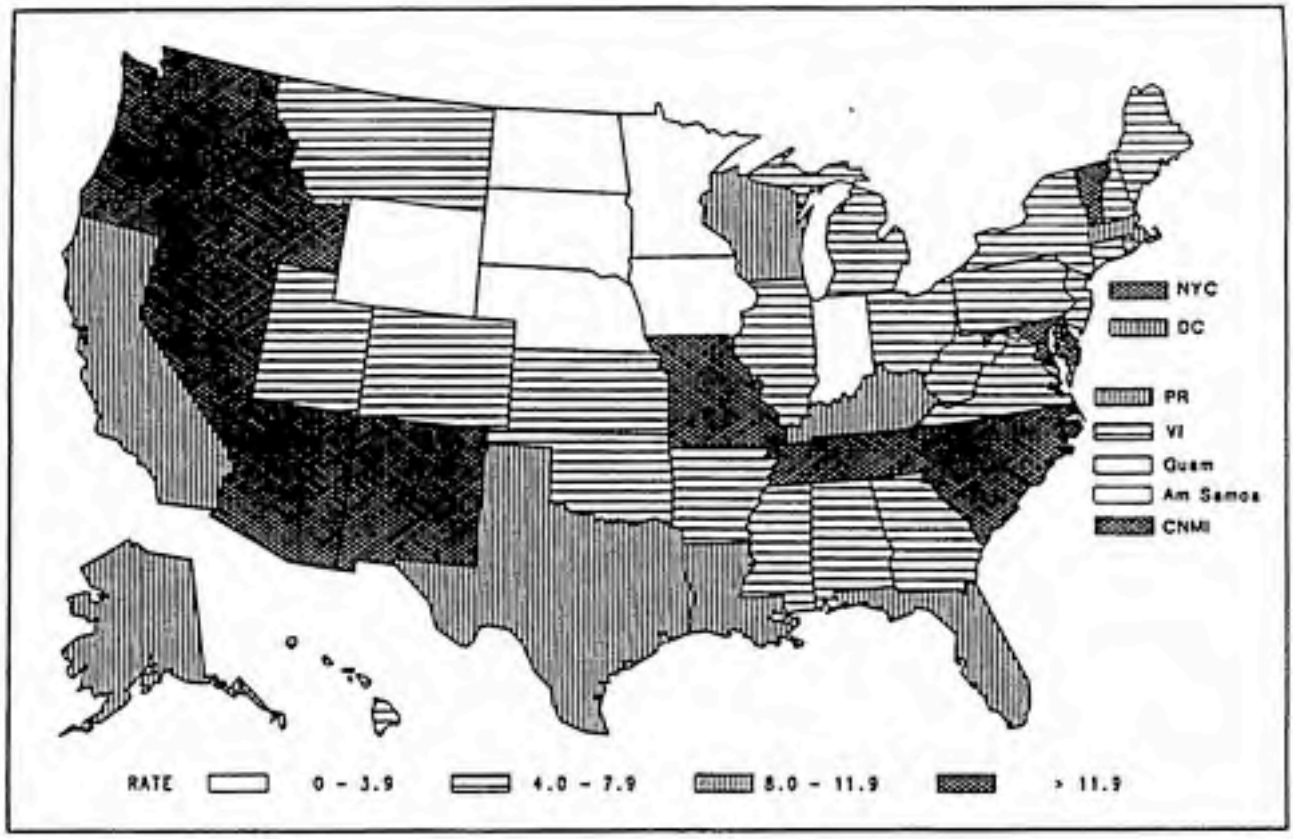
In the health-care occupations, the most important sources of transmission are accidental needle-sticks and infected fluid contact with mucous membranes of the eyes and mouth, and non-intact skin such as cuts, skin lesions and dermatitis (55). The only reservoir in nature is man, although chimpanzees are susceptible to infection (4). Despite the similarities in the modes of transmission, the risk of HBV infection in health-care settings far exceeds that for HIV infection. This is thought to occur due to the number of infectious particles per milliliter of blood in infected persons, up to 8 logs for HBV compared with 3 logs for HIV, as well as the infectious dose (number of viral particles needed to cause infection), an average of only 10 particles intravenously for HBV (36,55). For example, it has been estimated that the risk of acquiring HBV infection following a puncture with a contaminated needle ranges from 6% to 30% - far in excess of the risk of HIV infection under similar circumstances (<1%) (11,55).

Epidemiology: General Population and Health-Care Occupations

Two to nine-tenths of a percent of the adult population in the United States are carriers of HBV (HBsAg), and 5% have anti-HBs. In Asia the antigen carrier rate may be as high as 10-15% (4). HBV infection is common in high risk groups where exposure to blood and body fluids is high. This includes parenteral drug abusers, heterosexuals with multiple partners, homosexual men, clients and staff in institutions for the retarded, and health-care and public safety occupations. The CDC has estimated the total number of HBV infections to be 300,000 in the U.S. each year, leading to 15,000 hospitalizations, 375 deaths due to fulminant hepatitis, 6,000 deaths due to hepatitis related cirrhosis, and 1,200 deaths due to hepatitis-related primary liver cancer (11). (See Figure 3 for reported cases by state) CDC also believes that as many as 18,000 health-care workers per year may be infected by HBV, approximately 12,000 of these cases through occupational exposure. The Hepatitis Branch of the CDC has further estimated that between 500-600 health-care workers are hospitalized annually due to acute occupational infection and illness with over 200 deaths (12-15 due to fulminant hepatitis, 170-200 from cirrhosis, and 40-50 from liver cancer) (11). Studies have also shown that 10% to 30% of health-care workers have demonstrated past or present hepatitis B

FIG 3

***HEPATITIS B* — Reported cases, per 100,000 population, United States, 1989**



Source: Centers for Disease Control, MMWR: Summary Report, 1990

Table 1 Percentage of Health-Care Workers Demonstrating Previous HBV Infection When Screened

What is my risk of acquiring hepatitis?

Health care professionals, especially those who are exposed to or handle blood frequently, are at significantly greater risk of contracting hepatitis B than the general population. The following chart indicates the percentage of various health care workers who demonstrate previous hepatitis B infection when screened for serological markers of the disease:

Emergency Room Nurses[2]	30%	Internal Medicine Practitioners[3]	18%
Surgeons[3]	28%	Anesthesiologists[3]	17%
Dialysis Personnel[3]	27%	Oncology Staff[3]	17%
Pathologists[3]	27%	Obstetricians/ Gynecologists[3]	16%
Blood Bank Workers[2]	26%	Family Practitioners[3]	16%
Laboratory Technicians[2]	24%	Dentists[4]	14%
Intravenous Teams[2]	22%	Intensive Care Nurses[2]	10%
Oral Surgeons[4]	21%	Hospital Workers with no patient contact[5]	4%
Pediatricians[3]	21%		

Source: Reference #1, pp. 1-2

infection when screened for serologic markers of the disease (1). (See Table 1)

Other Bloodborne Pathogens

There are many other pathogens carried in the blood and body fluids that could cause potential infection to those who come in contact with them. While many of these agents are not common in the U.S. or perhaps quite as infectious or devastating as HBV and HIV, they can cause a myriad of disease, some quite serious, and are included under the scope and application of the proposed blood-borne pathogen rule as "pathogenic microorganisms that are present in human blood and can cause disease in humans (58)." A few of the more significant agents, where occupational infection is a potential or documented risk, will be discussed.

Hepatitis C (HCV)

Although there is evidence for several types of agents, a candidate virus with a RNA genome has been detected and suggested as the major HCV virus. It is estimated that HCV viruses cause between 15-35% of community-acquired acute hepatitis cases in the U.S. (58). The principal mode of transmission is bloodborne. Major risk groups are IV drug users, transfusion recipients and dialysis patients. Health-care workers who come in frequent contact with blood and household or sexual contact with infected persons have also been documented to be at risk, although the extent to

which these modes of transmission are important has not yet been well defined. It is known, however, that the number of virus present in the blood of infected persons is much lower than HBV and the relative infectivity is 100 to 100,000 fold lower (58). This suggests a lower risk of infection to health-care workers, whose contact with blood, relative to the defined high risk group, is small. HCV is the most common post-transfusion hepatitis in the U.S., accounting for approximately 90% of this disease (4). HCV viruses cause both acute and chronic hepatitis: 40-60% of infections lead to development of the chronic state, with potential for progression to cirrhosis and lifetime infectivity (58). A serologic test for antibodies to HCV (anti-HCV) has just been developed, however, current diagnosis depends on the exclusion of Hepatitis A, B, D, and other causes of liver damage. Currently there is no available vaccine, and the value of immune globulin for post-exposure prophylaxis is undetermined.

Cytomegalovirus (CMV)

CMV is a herpesvirus that affects most persons at some point in their lives. It rarely produces symptomatic disease in normal children and adults, although in immunocompromised hosts and infants, it acts as an opportunistic pathogen and causes serious illness and death involving the liver, spleen and central nervous system (13). It is usually a good indicator of clinically diagnosed AIDS.

The virus persists in a latent form after a primary infection, and reactivation may occur years later, especially during an immunocompromised state. CMV is excreted in urine, saliva, semen, cervical secretions, breast milk, and to a lesser degree associated with the leukocytes in the blood. Transmission occurs most commonly by mucosal contact with the above fluids, usually through sexual contact. Transmission by blood transfusions can also occur; however, since the virus is found in such low concentration in the blood, infection is more likely to occur after multiple transfusions. There have been no documented reports of CMV transmission via blood in the occupational setting. The fetus may be infected in utero from a primary or reactivated maternal infection. Postnatal infection occurs more commonly in infants of mothers who are actively shedding the virus in their cervical secretions during birth. Intrauterine infection of the infant is thought to occur in .4% to 2.3% of all live births (58). The virus can also be transmitted to the infant through the breast milk. Although most neonatal infections are asymptomatic at birth, 10% of these infections display some neurosensory disorder. Of the 5-10% of those born who are symptomatic, the most severely affected are those with cytomegalic inclusion disease (CID) manifested by hepatosplenomegaly, jaundice, petechial rash, chorioretinitis, cerebral calcifications, and microcephaly (58). Death may occur in-utero or neonatal. Survivors may

exhibit mental retardation, motor disabilities, hearing loss, and evidence of chronic liver disease. Similar symptoms of hepatitis retinitus, and pnemonitis can be seen in immunocompromised individuals. Infection acquired later in life is usually inapparant, but may produce similar symptoms to infectious mononucleosis. Although the risk of occupational infection would be low, there is some potential threat to pregnant and immunocompromised health-care workers.

Syphilis

Syphilis is caused by an infection with Treponema pallidum, a spirochete, and is a sexually transmitted disease whose incidence is increasing in the U.S.; 14.6 cases per 100,000 in 1987, is the highest rate since 1950 (58). Syphilis is characterized by three stages, primary, secondary, and tertiary with a latency period in between the stages. The primary stage is characterized by the eruption of a chancre usually in the genital area; the secondary by rash involving the palm and soles, fever, and secondary eruptions; and the tertiary stage, with high morbidity and mortality, with involvement of the skin and rubbery tumors called gummas, the cardiovascular system, with lesions on the aorta, and the central nervous system with an acute meningitis. Syphilis is most readily transmitted during the primary and secondary stages, although transmission has occurred throughout the course of the illness. Syphilis is

primarily transmitted by direct contact with exudates from lesions; sexually, through contact with the infectious body fluids and secretions (saliva, semen, blood, and vaginal discharges); and in utero. Transmission has also been documented through blood transfusion, tattooing instruments, and an occupational needlestick with blood from the early stages of the disease (58). Transmission rarely occurs through kissing. Treatment is very effective, especially in the early stages, with antibiotics.

CHAPTER III

REGULATION OF BIOLOGICAL AGENTS

Before the announcement by the Occupational Safety and Health Administration (OSHA) in July of 1987 that the Agency would adopt a permanent rule to protect health-care workers from bloodborne diseases, there was no regulation by the government of biological agents, of any type, in the workplace (15). At best, there was a myriad of guidelines, publications, and reference manuals published over the years that covered every aspect of work with biological agents. These included everything from specific safety issues and the etiologic agents associated with activities such as animal handling, recombinant deoxyribose nucleic acid (rDNA) research, oncology research, HIV/HBV prevention to guidance in biological safety, laboratory safety and technique, quality control and safety management, disinfection and sterilization, facilities and equipment and packaging/transport of etiologic specimens (3). As R.M. Pike reported in his 1979 review, Laboratory-associated Infections: Incidence, Fatalities, Causes, and Prevention, "the knowledge, the techniques, and the equipment to prevent most laboratory infections are available (52)." There was not, however, at this time, any single code of practice, standards, guidelines, or other publication that provided a

detailed summary of the many safety issues and risk management strategies associated with biological agents and their use in the workplace.

This changed in the 1980's with the publication of two comprehensive references. The first of these, Biosafety in Microbiological and Biomedical Laboratories (BMBL), published by the CDC and National Institute of Health (NIH) branches of the Public Health Service, categorized biohazardous agents into four classes or levels based on their risk as an occupational hazard (56). This concept was originally presented in a 1969 publication, Classification of Etiologic Agents on the Basis of Hazard, which served as a general reference for some laboratories utilizing infectious agents and as the basic format for BMBL (56). BMBL, however, is a much more comprehensive guide, providing "specific descriptions of combinations of microbiological practices, laboratory facilities and safety equipment, and recommendations for use in four categories or biosafety levels of laboratory operation with selected infectious agents of man (56)."

The second publication, prepared by the American Industrial Hygiene Association Biohazards Committee in 1985, was titled the Biohazards Reference Manual. It too collected a lot of the loose and current information on biological hazards but it was much more comprehensive than BMBL, covering such issues as control methods, and decontamination and disposal issues in much more detail as

well as addressing newer issues such as allergies, current bioaerosol sampling methodologies and equipment and immunoprophylaxis. (3)

While both of these references made noble attempts at organizing biological safety issues and were (and still are) significant sources of information for safety professionals, no need was seen by the federal government to regulate the workplace and officially safeguard the individuals working with biological agents. It was not until the increase in the incidence of HIV and HBV in the general population, along with the petitioning of several unions, that OSHA felt the need to promulgate a standard to protect health-care workers against these bloodborne diseases. Currently OSHA Instruction CPL 2-2.44B, issued February 27, 1990 which revised OSHA Instruction 2-2.44A of August 15,1988, regulates blood-borne pathogens in the workplace until the proposed regulation, that was specifically designed to reduce occupational exposure to these viruses, is promulgated. The directive basically relies on updated CDC guidelines for HBV and HIV for reflecting an appropriate and widely recognized and accepted standard of protection to be followed by health-care employers in carrying out their responsibilities under the Occupational Safety and Health Act (OSH Act) of 1970. Its purpose is to provide uniform inspection procedures and guidelines to be followed when conducting inspections of health-care facilities and issuing

citations (51). Citations can be issued for regulations that already exist under the OSH Act. These include:

- 29 CFR 1910.132; personal protective equipment
- 29 CFR 1910.22 (a)(1) and (a)(2); general housekeeping requirements
- 29 CFR 1910.141 (a)(94)(i) and (ii); waste disposal provisions of the sanitation standard
- 29 CFR 1910.145 (f); specifications for accident prevention signs and tags
- Section 5(a)(1) and Executive Order 12196, Section 1-201(a); OSHA's General Duty Clause (51).

CHAPTER IV

PROPOSED REGULATION OF BLOODBORNE PATHOGENS

History of the Proposed Blood-Borne Pathogens Standard

The official involvement of OSHA in recognizing bloodborne pathogens as an occupational hazard began with the release of hepatitis B guidelines for health-care workers in November 1983. The guidelines, set forth in OSHA Instruction CPL 2-2.36, were disseminated to health care professionals by the Agency's regional and area offices as part of OSHA's outreach program. The recommendations were largely drawn from guidelines prepared by the CDC, and included a description of the disease, proper work practices and personal protection, and the recommended use of hepatitis B immune globulin and the hepatitis B vaccine (13). This was OSHA's only official recognition of biological hazards in the workplace. On September 19, 1986, The American Federation of State, County and Municipal Employees (AFSCME) petitioned OSHA for an emergency temporary standard (ETS) covering infectious bloodborne diseases, including the human immunodeficiency virus (HIV) and the hepatitis B virus (HBV), under section 6(C) of the Occupational Safety and Health Act (10). They maintained that current guidelines, including those issued by the CDC,

the American Hospital Association, the American Occupational Medical Association, and the Department of Health and Human Services for reducing occupational exposure to HIV, were not fully or rigorously implemented in many health-care settings and that "OSHA has completely neglected establishing legal remedies to force health care employers to comply with commonly accepted infectious disease precautions (10)." The Union further reasoned that the health care industry, the industry most at risk of significant exposures to infectious bloodborne diseases, is the largest and fastest growing industry in the United States. Besides requesting an ETS, the petitioners asked OSHA to require employers to provide the HBV vaccine at no cost to employees at high risk for HBV infection and that the Hazard Communication Standard be amended to require a training program for employees exposed to infectious diseases. Just three days later, on September 22, three AFL-CIO unions, Service Employees International Union (SEIU), National Union of Hospital and Health Care Employees (NUHHCE) and RWDSU Local 1199-Drug, Hospital, and Healthcare Union also petitioned OSHA to promulgate a standard to protect health-care employees from the hazard posed by HBV (9). They requested that the standard contain all of the provisions in OSHA's 1983 guidelines with an emphasis on making workers aware of the benefits of the HBV vaccine. In addition, they too wanted OSHA to issue an immediate directive stating that employers must provide the HBV vaccine free of charge to high risk employees.

On July 23, 1987, after reviewing these petitions and available data, OSHA denied the request for an emergency temporary standard, but did announce that the Agency would develop a permanent rule to protect the Nation's health-care workers from exposure to bloodborne pathogens (15). An advanced notice of proposed rulemaking (ANPR) was published four months later on November 27, 1987, requesting information and comments on the health effects, technological and economic feasibility, and other relevant provisions that should be considered for inclusion in the standard. Interested parties had until January 26, 1988 to submit such information (13).

Approximately one year and two months later, a draft copy of the proposed bloodborne standard was made available for discussion by Secretary of Labor Ann McLaughin to the attendes at the January 8-10, 1989 conference, "AIDS: Frontline Healthcare" in Washington D.C. OSHA had planned to publish it's proposed rule in December 1988, but the Office of Management and Budget had yet to approve it (18). Finally, on Tuesday May 30, 1989, the full text of the proposed bloodborne pathogen regulations were printed in the Federal Register, vol. 54, No. 102. The new regulations proposed to amend Part 1910 of Title 29 of the Code of Federal Regulations with its addition as Section 1910.1030 (58). (See Appendix A) OSHA was hoping after a 90 day public comment period, to publish a final rule within one year (18). The final rule has still not been issued.

Impact of Proposed Bloodborne Standard on Industry

When the proposed bloodborne standard is promulgated, its impact will affect a large number of occupations. Paragraph (a) of the proposed regulation, establishes the scope of section 1910.1030 to apply to "all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b) of this section." Paragraph (b) continues by defining occupational exposure as "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. This definition excludes incidental exposures that may take place on the job, and that are neither reasonably nor routinely expected and that the worker is not required to incur in the normal course of employment." Other potentially infectious materials is further defined to mean: "(1) The following body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid saliva in dental procedures, and any body fluid that is visibly contaminated with blood.

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

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

with HIV or HBV (58)."

The impact of the proposed regulations will be felt the hardest in the health-care industries and the emergency medical services where an approximate 5.7 million workers at 620,000 sites have frequent contact with blood, body fluids, and tissues (18,58). This includes such professions as nurses, physicians, dentists and other dental workers, emergency room personnel, paramedics, emergency medical technicians, advanced life support personnel, diagnostic and research laboratory personnel, blood-bank personnel, phlebotomists, dialysis personnel, medical examiners, morticians, institutional facility personnel, and other workers such as housekeepers and laundry workers in health care facilities. Other occupations that can be interpreted to fall with the scope of the proposed regulations are the Public Safety Services which would include firefighters, law-enforcement officers and correctional-facility workers (13,55,58). (See Table 2)

The proposed bloodborne pathogen standard will also be, by far, OSHA's most expensive standard to implement. The costs of first year compliance are estimated to be about $800 million, with hospitals having the highest annual compliance costs of $33,035 per facility, funeral establishments the lowest at $141, and the average being $1,379 (18,58). By comparison, OSHA's next most expensive regulation is the hazard communication standard which had a $500 to $600 million implementation cost. Usually most OSHA

Table 2 Summary of Population at Risk of Exposure to Bloodborne Pathogens

[Number of affected workers]

	Hospitals	Dental offices	Physicians offices	Med./dent. labs	Research labs	Police depts.	Fire & rescue	Nursing homes	Residential care	Outpatient care	Funeral homes	Personnel services	Correctional institutions	Blood/tissue collection	Industrial clinics	Equipment repair	Total
Physicians	100,450	1,194	208,929	2,223				2,294	579	50,566					2,251		368,516
Dentists	1,938	74,679	451	233				295		2,371							79,967
Registered nurses	756,838	1,505	97,515	534				10,366	1,074	119,877		43,455					1,031,162
Lic. pract. nurses	301,951	466	52,759	248				116,565	6,125	33,530		28,556					542,220
Occupational nurse															8,492		8,492
Therapists	83,730	136	5,815	228				23,297	1,460	14,124		2,235					131,025
Therapy assistants	16,998		1,191							3,760							21,949
Dental hygienists	620	84,332	495	164				50		890							86,551
Laboratory tech.	132,619	566	30,075	28,065		7,820		233		14,281							213,659
Emerg. med. tech.	12,921		239				25,550			11,621							50,331
Surgical tech.	31,497	77	664							317							32,775
Other health prof.	54,327	866	6,026	2,399			302	2,809	4,387	27,359	357	38,466					137,338
Dental asst.	1,390	148,556	564	211				185		3,983							154,889
Nursing aids/ orderlies	325,743		1,641					509,573	40,262	60,814		43,112					981,165
Psychiatric aids	52,042							2,836	850	(in above)							55,528
Other health service	41,792	465	929	1,932				4,876	2,885	7,747					27,564		88,190
Physician asst.	4,792		11,207					705		5,004							21,708
Medical asst.	16,204	1,104	68,621	423				1,190		7,930							115,472
Ambulance drivers	2,830						5,382	119		1,322	754						10,407
Janitors & cleaners	206,450	8,690	28,801	1,313				103,182	20,927	4,998	4,375			692			379,428
Life scientists				2,849													2,849
Lab researchers					98,715												98,715
Police officers						200,873											200,873
Fire fighters							170,515										170,515
Embalmers											20,921						20,921
Corrections staff													97,945				97,945
Nurses/ phlebotomists														9,300			9,300
Blood bank lab workers														6,510			6,510
Plasma center workers														5,600			5,600
Tissue bank workers														96			96
Emergency personnel															234,536		234,536
Unpackers/ cleaners																1,882	1,882
Total affected	2,145,140	322,676	536,122	40,822	98,715	208,693	201,749	778,375	80,569	370,514	26,407	155,844	97,945	22,198	223,903	1,882	5,311,554

Source: Reference #58, p. 23077

standards carry first year costs of approximately $100 million (18).

CHAPTER V

MANAGEMENT OF OCCUPATIONAL RISK TO BLOODBORNE PATHOGENS

Risk, as defined in the environmental sciences, is the probability of an adverse effect or event happening that presents some possibility of harm to human health, the ecology, the economic system, or the quality of human life. Thus, risk management is the process by which this risk is reduced (53). In the specific environment of the workplace, risks take on many forms: there are physical risks such as those posed by machinery and moving parts, environmental conditions such as slippery floors, dangerous stairs, and there are other physical forms such as heat, cold, radiation, and noise; there are chemical risks posed by the various compounds and solvents utilized in the workplace; and there are biological risks, risks posed by contact with potentially infectious and disease causing agents such as bacteria, viruses, fungi, and protozoans. Collectively, these risks can be identified as occupational; risks encountered by the worker in the occupational setting.

The Occupational Safety and Health Administration's (OSHA) role, as defined in the Occupational and Safety Health Act of 1970, is to manage the risks found in the workplace by adopting regulations and providing guidelines for various industries to follow. These regulations are no

more than lists of risk control methods, procedures, and programs designed to eliminate or minimize hazardous working conditions. Historically, OSHA has managed the risk posed by physical and chemical hazards in the workplace. However, with the advent of the proposed bloodborne pathogen regulations, OSHA has made a determination that certain employees face a significant health risk as the result of occupational exposure to blood and other potentially infectious materials because they may contain bloodborne pathogens, including HBV, which causes a serious liver disease, and HIV, which causes AIDS (58). These employees include health-care and public service occupations.

Employees incur risk each time they are exposed to bloodborne pathogens; any one exposure incident may result in infection and subsequent illness. Since it is possible to become infected from a single exposure, incidents should be prevented whenever possible. It is therefore the goal of the proposed standard to reduce significant risk by minimizing or eliminating exposure to blood or other infectious materials. This is accomplished through a general infection control plan which is developed to minimize the risk of patient acquisition of infection through exposure incidents from contact with contaminated devices, objects or surfaces, or transmission of an infectious agent from health-care workers to patients (55). It consists of three main parts:

1. Identification of tasks or procedures that involve occupational exposure to blood and other potentially infectious materials. This is usually broken down further into three categories; category I, those with actual blood exposure, category II, those tasks which, by themselves, entail no blood exposure, though the individual assigned to the task may be called upon to perform an unplanned category I task, and category III, those with no blood exposure (11).

2. Identification and documentation of the actual positions whose duties include the tasks (categories) identified above without taking into account any protective measures, such as personal protective equipment.

3. It must state when and how it will implement protection and prevention to the positions defined in number 2. This is usually accomplished using a combination of engineering controls, work-practice controls, personal protective clothing and equipment, containment and disposal, training, safety inspection and audits, labelling and signs, medical follow-up of exposure incidents, and vaccinations. The risks are defined in parts 1 and 2 of the infection control plan. Part 3 identifies risk management strategies.

Risk Management Strategies

Engineering Controls

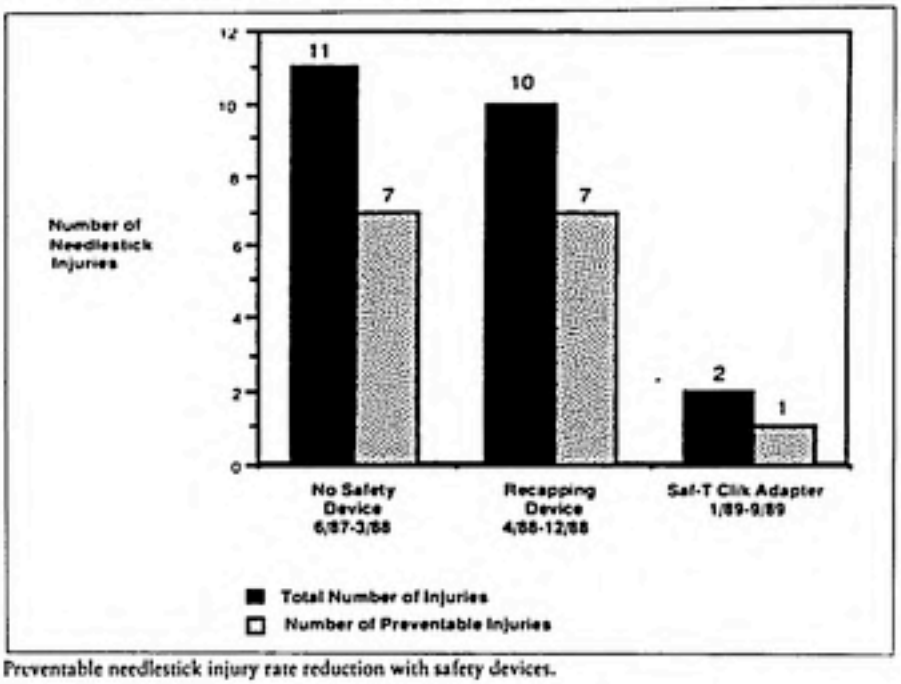
It is generally recognized among safety professionals, especially industrial hygienists, that protection of the

employee is most effectively attained by elimination or minimization of the hazard at its source, i.e., engineering controls (50). Engineering controls do not rely on the uncertainties and infallibility of human behavior and therefore have always been preferred when feasible. Examples of engineering controls that would protect employees from exposure to bloodborne pathogens include sharps disposal containers, biological safety cabinets, or other types of vented enclosures, splashguards, needle-recapping devices, or self-sheathing needles, which prevent hand contact with the needle at all times (6,56). These controls embody the principles of process or equipment redesign, process or equipment enclosure, and employee isolation (58). An example of how engineering controls can work is nicely portrayed in Vanderbilt University Medical Center's laboratory liaison services study of two phlebotomy devices designed to reduce needlestick injuries in phlebotomy (6). (see Figure 4)

Work Practice Controls

Work practice controls reduce the likelihood of exposure through alteration of the manner in which a task is performed. Unlike engineering controls, the protection they provide is based upon employer and employee behavior, however, like engineering controls, work practice controls act on the source of the hazard. In many instances the two methodologies are reliant on one another for protection as

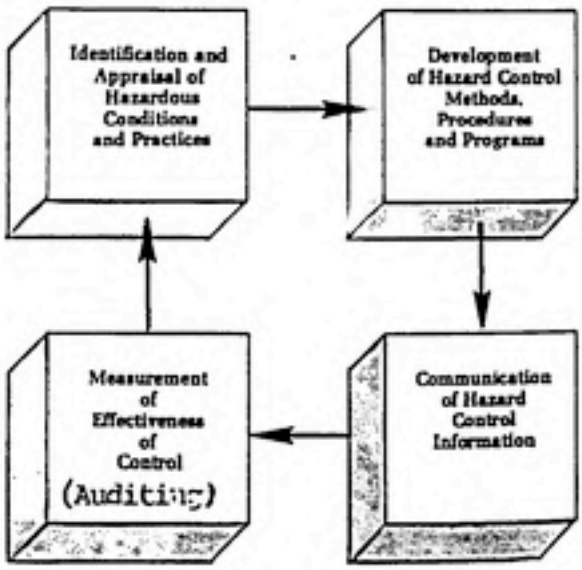
FIG 4 Preventable Needlestick Injury Rate Reduction with Safety Devices



Preventable needlestick injury rate reduction with safety devices.

Source: Reference #6, p. 123

FIG 5 Role of Safety Auditing in the Scheme of Risk Management



Source: Reference #50, p. 586

it is often necessary to employ work practice controls to assure effective operation of engineering controls, and better employee protection. Examples of work practice controls that would protect employees from exposure to bloodborne pathogens include no re-capping of contaminated needles, no drinking, smoking, putting on cosmetics or putting in contact lenses while in the laboratory, hand washing, spill cleanup, using techniques that minimize aerosolization of potentially infectious materials, working with known biohazards in a biosafety cabinet, and wearing personal protection correctly. (see biological safety audit checklist, Appendix A) However, one of the most important work practices pertaining to bloodborne pathogens is the implementation of "universal precautions" as recommended by the CDC. "Universal precautions" require employees to assume that all blood and other body fluids are infectious for HIV, HBV, and other bloodborne pathogens, and handle them accordingly (37). Quite often, training is an effective means of teaching and learning good work practices. However, it takes inherent concentration and consistency of practice on the employees part to make work practices operative.

Personal Protective Equipment and Clothing

There are situations where neither engineering controls nor work practice controls are feasible and thus employee protection must be achieved through the use of personal

protective equipment. Personal protective equipment ranges from gloves, protective shoe coverings, gowns, smocks, and laboratory coats, to protective eyewear, and face shields. In order for them to be effective, the following conditions must be met. First, the employee must be trained to use the equipment properly. Secondly, the equipment must be used each time the task is performed and must be appropriate for the task and fit properly. Lastly, it must be free of physical flaws that could compromise protection. Personal protection, like work practice controls, again relies on the behavior and attitude of the employee. An employer can provide the equipment and training but cannot completely ensure that the employee is meeting the above prescribed conditions. Also, in many cases, employees must exercise their professional judgment as to whether a situation dictates the use of personal protective equipment, especially when other engineering controls and work practices are available, or in cases of life and death emergencies as encountered by many public service personnel.

Containment and Disposal

Waste disposal and containment are an unlikely but possible source of occupational exposure to potentially infectious materials and therefore need to be considered. The disposal of broken contaminated glass and needles pose the greatest risk since they lend themselves to auto-inoculation. Also of concern would be the leakage of

infectious materials into work areas from a containment device or onto the outside of a containment device that is handled, or an over-filled container. At greatest risk are waste handlers and transporters. Examples of proper waste containment and disposal for employee protection to bloodborne pathogens would be disposal of sharp items in a puncture-proof container and other blood-contaminated items into leak-proof plastic bags. This waste should then either be incinerated or be decontaminated by autoclaving before disposal into a sanitary landfill. An infectious waste management plan is recommended by OSHA for the identification, collection, handling, transport, treatment, and disposal of potentially infectious waste (58).

Training

Effective training is a critical element of every health and safety program. It will ensure that employees understand the occupational risks presented to them and the control measures used to manage them. It can also inform them of appropriate actions to take in the case of an emergency, existing regulation/guidelines applicable to the occupation, and inform them of surveillance and prophylaxis programs they can/should participate in. In addition, a bloodborne pathogen training program should include an explanation of the epidemiology, symptomatology, and modes of transmission of the diseases to ensure that the worker has a basic understanding of the diseases and the need to

observe precautions to prevent disease transmission. Training for bloodborne pathogens should also include an explanation of "universal precautions". The infection control plan should be explained and the appropriate methods for recognizing tasks that may include exposure to blood and other potentially infectious materials should be emphasized. Special training consideration, such as standard microbiology practices and techniques, may also be presented to those workers in research and production facilities where concentrated HIV and HBV cultures are handled and manipulated. (58)

Hazard Communication: Signs and Labels

Signs and labels serve many important purposes in risk management, first and foremost to warn employees of the hazards to which they are exposed. They can also act as an important "memory-jog" for trained employees as well as a warning for those not aware of a hazard. They also alert employees of possible exposure to materials, contents or work areas that can not be readily identified. For bloodborne pathogens, labels reading Biohazard with the universal biohazard symbol in black should be affixed to refrigerators and freezers storing blood or potentially infectious materials, containers used to store or transport the same, and non-red bags and non-red containers storing potentially infectious waste (58). Biohazard warning signs should also be posted at all entrances to research

laboratories or production facilities with the name of the infectious agent, special provisions for entry into the area, and name and telephone number of the laboratory director on the sign. This assures that employees are aware of the specific biohazard involved, that authorized individuals who enter the area are properly protected, and that, in the event of an emergency or other unforeseen event, a trained and knowledgeable individual can be contacted and consulted. (58)

Vaccination

The goal of the aforementioned occupational risk management options is to minimize or eliminate significant risks. However, accidents do happen, equipment may fail or be defective, employees may have unsuspecting cuts or dermatitis and work-practice behavior is far from infallible. Thus if the risk of infection is high enough, the manifestations of the infection are serious, and the effective treatment of the infection is low (ie.. viruses), a vaccine should be administered to further reduce or eliminate occupational infection. For the bloodborne pathogens, one such vaccine has been available since 1982. The hepatitis vaccine induces protective antibody levels in 85% to 97% of healthy adults (36,55) and provides protection against HBV infection for at least 7 years (4). The vaccine is by far the most important part of HBV prevention among workers who come in contact with blood and other body

fluids. It is estimated, however, that only 30 to 40% of high-risk health-care workers have been vaccinated in this country (58).

Post-Exposure Determination, Documentation and Surveillance

The route of exposure, the source patient's antibody status, the circumstances under which the exposure occurred, and the surveillance of the exposed employee for sero-conversion are important parts of any infection control plan. First, such information gives the employer some feedback regarding the most prevalent circumstances and routes of exposure of employees so that greater effort can be concentrated on decreasing or eliminating the causes of the exposure. Secondly, post-exposure surveillance ensures that the employee will receive proper medical attention after an exposure. Early testing of the employees blood as soon as possible after exposure to determine baseline serological status, appropriate prohylaxis and counseling if needed, and further screening of the blood to identify possible occupational infection are important steps in reducing the risk of infection and preventing further transmission should infection occur. (55,58)

Safety Inspection/Auditing

The final element integral to successful occupational risk management is measurement and evaluation of these risk control methods. Are they effective? Are guidelines,

regulations and policies complied with? Are further modifications of an infection control plan needed to develop optimum results? These are some of the questions answered by conducting an audit or safety inspection. Besides the more obvious compliance aspects, the audit can also act as a means of prevention and identification. It helps eliminate causative factors associated with the loss problem, before a loss occurs (50) and can identify new or other potential problems that have not been addressed by present risk management techniques. (See figure 5) In addition to improved compliance and reduced risk, auditing can also demonstrate to potential investors that safety and health liabilities are under control while improving corporate image and employee confidence.

Auditing can take many forms; however in the occupational environment it usually means assessing all levels of management, policies, guidelines and attitudes. This can be achieved by physically inspecting a facility and observing engineering controls, work-practice techniques, personal protection use, etc.. utilized and performed by the employees and by reviewing policies and programs on paper to make sure they are complete. The latter form of auditing is often the most important form. For example, when inspecting a facility for bloodborne pathogen hazards, OSHA Instruction CPL 2-2.44B dictates that a facility's infection control plan is the first item to be audited, before a physical walk-around occurs (51). If the plan is incomplete, the

auditor knows that certain parts of the missing plan will not be carried out in the workplace.

Auditing is usually best achieved with an audit team that is well-staffed and appropriately trained. Strong consideration should be given to an outside auditor who is likely to be more objective, would not inconvenience or intrude on the time of the organization's staff, and usually adds expertise. Procedures developed in creating the audit should also be consistent and provide reproducible results throughout all facilities involved in the auditing program. It is also essential that one confront the consequences of the knowledge that may be revealed after inspection. This requires the need to document audit findings as well as insure proper communication and implementation of corrective actions. (See figure 5)

Lastly, it is important that management recognize auditing as an important tool in measuring the success of a compliance or preventative program. Frequent measurement and review of a program success will help to assure that it is successful. For bloodborne pathogens, the development of an comprehensive audit program for assessment of the risk management issues encountered in OSHA's proposed standard is recommended.

CHAPTER VI

BLOODBORNE PATHOGEN AUDIT SYSTEM

Background and Scope

The scope of OSHA's blood-borne pathogen standard is to regulate all occupational environments where exposure of a worker HIV and/or HBV is a potential threat. While this includes a number of health-care and emergency response professions, to develop an efficient audit that incorporates the unique environment and procedures found in each setting would be an arduous and lengthy task as well impractical. Instead the audit system developed by this researcher is designed to evaluate the specific environment of two of the more important potential sources of biological bloodborne hazards, research/clinical laboratories and production facilities. It is based on a typical occupational setting, taking into account such laboratory elements as facility design, equipment used, work practice and techniques performed, and engineering controls. More than 150 laboratories and production facilities were evaluated for biological hazards in the development of this audit protocol. It has been refined to provide an efficient and timely instrument to identify occupational risks to bloodborne pathogens. (See Appendix B)

The computer software program, PC File, is recommended for managing the information generated from this audit system. This program was used to store audit data and generate individual reports for each laboratory or facility, noting deficiencies and providing risk management strategies. Examples of these reports are included in Appendix C. The database can also be used to manipulate data into graphs and tables as well as provide emergency response capabilities.

Applications

This audit system will be particularly useful for the following applications.

a) The first and most obvious one is to insure that a facility or laboratory is in compliance with the proposed and soon to be promulgated blood-borne pathogen standard

b) Avoid a citation if inspected by OSHA

c) Improve laboratory safety and awareness

d) evaluate the effectiveness of existing or newly adopted Biological Safety (BS) or Infection Control (IC) Programs.

e) Identify BS or IC program deficiencies when compared with the new federal standard.

f) Identify and correct exposure pathways

g) Classify facilities as high, medium or low risk on the basis of potential occupational exposures to bloodborne pathogens

This audit system offers a range of applications that can be utilized by both private companies and governmental agencies. Safety professionals including industrial hygienists, biological safety officers, laboratory managers, laboratory personnel, consultants, and contractors should benefit from it's use. (See Appendix D for an outline of the audit instrument) However because of it's comprehensive nature, it is of little use to an OSHA inspector who by the current standard instructive (OSHA Instruction CPL 2-2.44B, paragraph J, inspections procedures #7) is directed to inspect using a spot-check approach. "....It is not expected that a comprehensive walkaround inspection of the workplace will be necessary (51)."

Risk Classification of Facilities Using Fault Tree Analysis

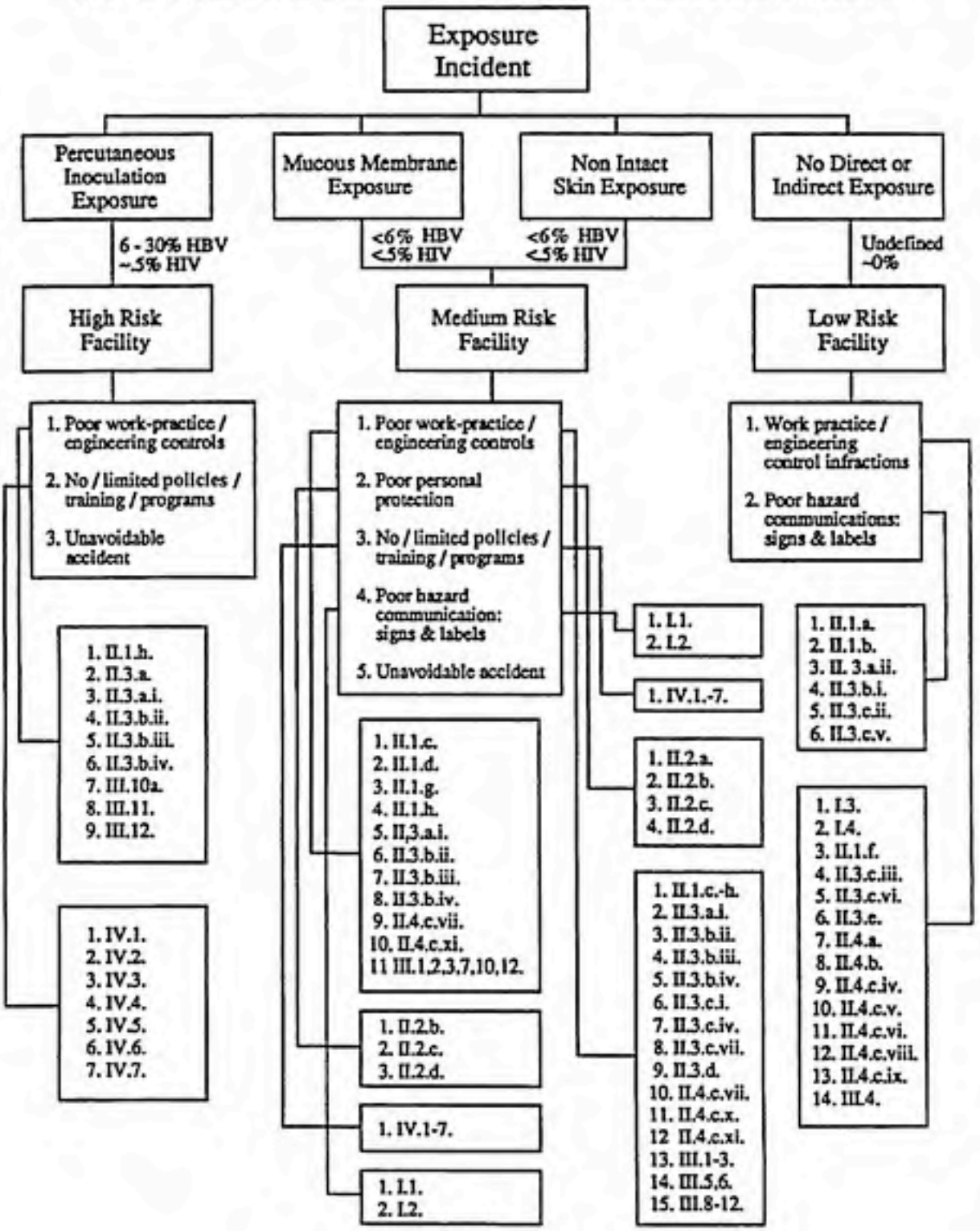
Fault trees can be used to analyze and evaluate the fallibility of complex systems, or the failure of a system in the absence or low occurrence of an actual failure experience. The first step in this analysis is to identify an undesirable event and reason back to determine how it might have happened. Most fault trees determine actual failure rates or probabilities for each factor that may contribute to the undesirable event. The fault tree method has been evolving for the last 20 years and is one of the

most widely used techniques for quantitative prediction of system failure. (40)

Using the proposed audit instrument as a guide, a fault tree analysis was prepared to rank facilities on the basis of occupational risk to bloodborne pathogens. The single most important risk or "fault" in the laboratory setting was identified as an exposure incident to blood or other potentially infectious materials. There was insufficient quantitative data to determine actual failure rates or probabilities leading to an exposure incident, however, a qualitative evaluation of the contributing factors in occupationally acquired HIV or HBV infection was possible. (See Figure 6) The contributing factors were classified into four general groups: engineering and work practice controls, personal protection, hazard communication such as signs and labels, and policies/training/programs. These factors, if disregarded or poorly implemented, can lead to four outcomes: percutaneous inoculation, mucous membrane exposure, non intact skin exposure, or no direct or indirect exposure. Each of these exposure routes have different probabilities of infection associated with them. Percutaneous inoculation presents the highest risk of infection, 6% to 30% of percutaneous inoculations with a known HBV source acquired infection, whereas, with a known HIV positive source, approximately 0.5% seroconverted (55,58). Any single contributing factor or combination of factors elements that can lead to percutaneous inoculation

FIG 6

FAULT TREE ANALYSIS AND RISK CLASSIFICATION OF AN OCCUPATIONAL EXPOSURE IN THE CLINICAL / RESEARCH LABORATORY OR PRODUCTION FACILITY



were considered high risk activities or practices. These factors, when discovered, place a facility at high risk. These elements are identified in the first column of the fault tree and are coded by reference to the audit instrument.

The risk of infection from mucous membrane exposure or non intact skin exposure, while inadequately quantified, is considered to be far less then percutaneous inoculation by the CDC (55). Thus, any contributing factors or combination of factors that potentially could lead to this type of exposure were classified as medium risk relative to the risk of percutaneous inoculation. These activities placed a facility in the medium risk category.

There are also factors shown in the audit that do not contribute directly or even indirectly to exposure, but may play some tertiary role or have a cumulative effect that leads to an exposure incident. Facilities delinquent in these areas present no immediate risk to the health of the worker and are therefore considered low risk relative to percutaneous inoculation, mucous membrane exposure, or non intact skin exposures.

It should be pointed out that the fault tree analysis only identifies one type of risk involved in an exposure incident scenario. This is the risk posed by the audit factors lead to high, medium and low risk types of exposure. They appropriately can be defined as contributory or exposure risk. However, there are many tiers of risk

involved in an occupational exposure scenario. First, once an exposure incident occurs, one must identify if the source of the exposure is HIV/HBV positive. This can be defined as source risk. If the source is known positive, one is at a higher risk of infection then if the source is unknown. If the source is a known negative for HIV/HBV, one is at no to low risk of infection. There is still some risk associated with a negative source since it may be a false negative. If the source is identified as HBV positive, one has a much higher chance of infection then if the source was identified as HIV positive due to the relative viral concentrations in the blood between the two. Source risk can be altered, however, depending on the type of infected material involved. For example, an exposure to a concentrated laboratory culture of HIV or HBV can severely increase the risk of infection over that of infected blood. The virulence of the organism, or the degree to which an organism can cause disease may also play a role. If someone is exposed to the antigen of a virus instead of the complete virus, or exposed to a culture that has been heat inactivated or partially treated in some form, the risk of infection is again altered. Finally, the risk of clinical manifestations of an infection depends on the specific immune system status of the individual infected, which further relies on such factors as age, sex, diet, stress, and the presence of protective antibodies as created by vaccination. Thus, while the OSHA standard is intended to

prevent and eliminate the risks involved with an exposure incident, there are a myriad of risks after exposure occurs that can alter the outcome, an infectious disease.

CHAPTER VII

ADVANTAGES AND DISADVANTAGES OF THE OSHA BLOODBORNE PATHOGEN REGULATIONS

The impact the bloodborne pathogens standard will have on human health and the economics of the health-care industry is considerable. Whether this impact will be positive or negative is widely debated. The public comment period on the proposed regulations, OSHA's largest substantive record in its history, brought to light many of these advantages and disadvantages of the standard in its current form. What effect these comments will have in altering the rule before it is promulgated is still unknown. However, when asked about changes to the rule before it is finalized, OSHA Health Standards Director Adkins said, "We don't expect a large number of changes, but there could be some (33)."

Two elements of the proposed standard brought the sharpest and by far the most reiterated criticism. The first of these was the issuing of a free HBV vaccine by employers to workers who are exposed to the virus an average of one or more times a month. Many argue, especially labor organizations, that any worker at risk to exposure in the course of duty should receive the vaccine (20,24,25) and that with OSHA'S proposal, many employees who may not

receive an average of one exposure a month may receive a few massive exposures to blood a few times a year. These workers, such as public safety personnel, would fall through the cracks and not be vaccinated. Other groups, such as hospitals, argued that offering the vaccine is unnecessary and too costly, adding between $30,000 to $60,000 initial expense per 500 employees (30). Other arguments maintained that an employee exposed an average of one time a month is certainly not high risk, especially with the use of personal protection and universal precautions.

The second most criticized element of the standard was the way OSHA established the hierarchy of controls. Many felt that the proposed rule does not emphasize engineering controls over personal protective equipment and work practices as the most effective means of preventing exposure(21,32). Among the engineering controls most commonly discussed were the mandatory use of safer needles and syringes, provided by redesign or by other items as self-sheathing devices. A standard that mandates this would encourage manufacturers to produce safer instruments (33). OSHA's proposed regulation states that needles should not be recapped, should be completely discarded, and complete needle/syringe unit type should be required. Janine Jagger, assistant professor of neurosurgery at University of Virginia, declared that needlestick injuries are distressingly common among health-care workers and may be the "single most preventable hazard that health-care workers

face," and that improved product designs are being "largely overlooked as a method for preventing the spread of bloodborne pathogens in the health-care setting (22)."

Other criticisms attack the extensiveness of OSHA's proposed infection control plan which requires that employers identify and document tasks and procedures where occupational exposure to potentially infectious materials may take place. To do this, especially in large health-care facilities, would be a monumental administrative burden and very costly. As John D. Brinsko, an industrial hygienist with Vanderbilt University, stated "certainly this requirement is not in line with the federal reduction of paperwork guidelines you are hopefully trying to follow (19,31)."

Another issue which was consistently brought up was that of personal protection. Many feel that the rule, as written, would interfere with a worker's mobility and manual dexterity, discouraging its use. Specifically, barrier clothing and gloves are hot and uncomfortable and do not protect against needlesticks, and unless covering an open wound or non-intact skin, provide no significant reduction in risk (19,25,30). The American Hospital Association states that the OSHA proposed provisions "do not provide useful criteria for selecting equipment that reduces possible exposures without interfering with the workers ability to perform (19)".

Other issues debated were compliance costs (28), OSHA's cost benefit analysis (32), the scope of the regulations excluding raw sewage workers and students (20,26), and a request for clearer definitions (23).

While many of the above comments had justifiable, definitional problems with the proposed standard, many are unfounded when looked at in the light of one of the biggest inherent properties of the proposed regulation, that it is written as a performance standard, allowing for some interpretation. One of the elements that tends to make the proposed standard of the performance type, is the incorporation of CDC's universal precautions, which urges workers to treat all fluids they come in contact with as if they were infected with HIV or HBV and take proper precautions. Regulatory backing of the CDC guidelines is looked at as one of the major advantages of the rule because it allows new information on HIV to be automatically incorporated into an enforceable standard, instead of establishing fixed regulations that would become obsolete over time (21,24). Others praise the new standard which would finally unify all existing guidelines and work practices in the health-care setting that are currently uneven in their effectiveness and application (25).

The most convincing advantage of the proposed standard is the protection it will provide to the health of health-care employees. In the proposed standard, OSHA has presented quantitative estimates of risk of death and

clinical illness from occupational exposure to HBV-infected blood and other potentially infectious materials (58). The Agency estimates the lifetime risk of infection from HBV to be from 75 to 119 cases per thousand and the risks of material impairment of health or functional capacity (clinical hepatitis) to be from 20 to 31 per thousand. The risk of death from HBV is 2 to 3 per 1000. These estimates are based on the assumption of exposure to HBV for the period of a working lifetime of 45 years. This translates to 12,000 hepatitis B infections and approximately 260 deaths annually among health-care workers (11,58). Moreover, OSHA's risk assessment shows that if every employee were to receive the HBV vaccine, there would still be a remaining lifetime risk of material impairment of health of 2 to 3 per 1000 workers and 2 to 3 deaths per 10,000 workers based on the 90% efficacy of the vaccine. These numbers could be further reduced with the adherence to a standard which included the elements of personal protection, engineering controls, and work practice controls. The number of occupationally acquired infections from HIV and the risks involved are hard to currently quantify because of the lack of sufficient data. Recently, the CDC estimates there are some 6000 U.S. health-care workers infected with HIV, about 40 of them infected through known work-related causes (34), and many others with no defined risk. As the number of AIDS cases continues to rise in the general population, the rate of occupational risk is

also expected to increase as well, but by how much is unknown.

Besides risks to health, there are economic risks involved with occupational infection. It is estimated that health-care costs for HBV and HCV in health-care workers is $10 to 12 million annually (11). Estimates of average lifetime costs for the care of an AIDS patient have varied considerably, but recent evidence suggests the amount is probably in the range of $50,000 to $75,0000 dollars (11). In addition, the cost of postexposure follow-up, including vaccination, screening, treatment, and counselling is estimated at $405 per needlestick (32). Companies may also want to consider potential litigation costs for suits brought by workers who contract bloodborne disease through negligence in the workplace. These costs, coupled with the more intangible costs of lost productivity, lost time, quality of life, and mental/emotional suffering, could be seriously reduced or avoided by compliance with the proposed regulations.

In light of the devastating health effects by HIV and HBV and the economic costs to support an occupationally infected individual, it certainly seems there is a need for regulation of bloodborne pathogens in the workplace, especially for those at high risk. Two of the workplaces at high risk are research laboratories and production facilities where concentrated cultures of HIV and HBV, much higher than that found in the blood, are often worked with.

An audit system, designed especially to assess these types of environments, is key in preventing occupational infection. Such a instrument is an effective way of achieving compliance with the bloodborne standard as well as a method which can be used to identify facilities at risk.

As the final rule nears promulgation, it was announced that the nation's first health-care worker infected with HIV on the job has died in her home on June 6, 1991 (34). With approximately 40 more workers likewise infected with HIV in the workplace and the incidence of HIV infection increasing rapidly in the general population, with 1.5 million people currently infected, HIV is becoming an increasingly important hazard in the health-care industry that needs to be addressed. This coupled with the known hazard of HBV that results in 12,000 occupational health-care worker infections and 200 to 300 health-care worker deaths each year, and the emergence and recognition of other important bloodborne pathogens such as HCV, regulation is sorely needed. Publication of the final rule will mark the completion of a long and extensive process undertaken by OSHA, to regulate a hazard that has traditionally been ignored in the occupational setting, a biological hazard.

APPENDIX A

this address. All timely submissions will be part of the record of the proceeding.

Information on Hepatitis B Vaccination Issues for the Public Hearing

OSHA seeks to gather additional information related to hepatitis B vaccination during the written comment period and the public hearing. Since the employee's participation in the hepatitis B vaccination program is voluntary, OSHA is particularly interested in existing HBV vaccination programs that have achieved a high degree of voluntary employee compliance. The Agency will attempt to identify those elements that are common to successful programs and will provide this information to all employers. In addition, we are also seeking information on other issues including availability, cost and any potential distribution problems that are associated with initiating the vaccination of large numbers of employees within the 150 day period following the effective date of the standard.

The Agency intends to designate several days of the Washington, DC hearing to focus on the issues surrounding HBV vaccination. We encourage hearing participants whose primary testimony will involve hepatitis B vaccination to indicate this in their Notice of Intention To Appear, and OSHA will attempt to schedule these participants on the days of the hearing that are set aside to focus on Hepatitis B vaccination. Other participants whose testimony will not be primarily on HBV vaccination issues but who wish to address HBV vaccination will be scheduled on another day, but they may enter a separate statement in the record during this period. In any case, participants are free to discuss hepatitis B vaccination or any other issue related to this standard whenever they present their testimony.

Certification of Record and Final Determination After Hearing

Following the close of the hearing, the presiding Administrative Law Judge will certify the record of the hearing to the Assistant Secretary of Labor for Occupational Safety and Health. The Administrative Law Judge does not make or recommend any decisions as to the content of the final standard.

The proposed standard will be reviewed in light of all testimony and written submissions received as part of the record, and a standard will be issued, based on the entire record of the proceeding, including the written comments and data received from the public.

XI. Authority and Signature

This document was prepared under the direction of Alan C. McMillan, Acting Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210.

Accordingly, pursuant to sections 6(b), 8(c) and 8(g) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655, 657), 29 CFR Part 1911 and Secretary of Labor's Order No. 9-83 (48 FR 35736), 29 CFR Part 1910 is proposed to be amended as set forth below.

List of Subjects in 29 CFR Part 1910

AIDS, Hepatitis B, Human Immunodeficiency Virus, Blood, Blood diseases, Communicable disease, Health, Healthcare, Health professions, Hospitals, Protective equipment, Immunization, Medical research, Occupational safety and health.

Signed at Washington, DC on this 19th day of May, 1989.

Alan C. McMillan,

Acting Assistant Secretary of Labor.

XII. The Proposed Standard

General Industry

Parts 1910 of Title 29 of the Code of Federal Regulations are proposed to be amended as follows:

PART 1910—[AMENDED]

Subpart Z—[Amended]

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

Authority: Secs. 6 and 8, Occupational Safety and Health Act, 29 U.S.C. 655, 657, Secretary of Labor's Orders Nos. 12-71 (36 FR 8754), 8-76 (41 FR 25059), or 9-83 (48 FR 35736), as applicable; and 29 CFR Part 1911.

* * * * *

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

* * * * *

2. Section 1910.1030 is added to read as follows:

§ 1910.1030 Bloodborne pathogens.

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

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

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

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

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

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

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

"Disinfect" means to inactivate virtually all recognized pathogenic microorganisms but not necessarily all microbial forms (e.g. bacterial endospores) on inanimate objects.

"Engineering Controls" means controls that isolate or remove the 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.

"Infectious Waste" means blood and blood products, contaminated sharps, pathological wastes, and microbiological wastes.

"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. This definition excludes incidental exposures that may take place on the job, and that are neither reasonably nor routinely expected and that the worker is not required to incur in the normal course of employment.

"Other Potentially Infectious Materials" means

(1) The following body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid , amniotic fluid, saliva in dental procedures, and any body fluid that is visibly contaminated with blood.

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

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

"Parenteral" means exposure occurring as a result of piercing the skin barrier (e.g. subcutaneous, intramuscular, intravenous routes).

"Patient" means any individual, living or dead, whose blood, body fluids, tissues, or organs may be a source of exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the mentally retarded; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains prior to embalming; and individuals who donate or sell blood or blood components.

"Personal Protective Equipment" is specialized clothing or equipment worn by an employee to protect him/her from a hazard.

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

"Research Laboratory" means a laboratory producing research-laboratory-scale amounts of HIV or HBV.

"Sharps" means any object that can penetrate the skin including, but not limited to, needles, scalpels, and broken capillary tubes.

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

"Universal precautions" is a method of infection control in which 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.

(c) *Infection control*— (1) *Exposure Determination.* (i) Each employer who has employees with occupational exposure as defined by paragraph (b) of this section shall identify and document those tasks and procedures where occupational exposures may take place.

(ii) Each employer shall identify and document all positions with occupational exposure.

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

(2) *Infection Control Plan.* (i) Each employer having employees whose reasonably anticipated duties may result in occupational exposure shall establish a written infection control plan designed to minimize or eliminate employee exposure.

(ii) This infection control plan shall contain the following as a minimum:

(A) The exposure determination required by paragraph (c)(1) and

(B) The schedule and method of implementation for each of the applicable paragraphs of this standard.

(iii) This infection control plan shall be reviewed and updated as necessary to reflect significant changes in tasks or procedures.

(iv) The infection control plan shall be made available to the Assistant Secretary and the Director for examination and copying.

(d) *Methods of Compliance*— (1) *General.* Universal precautions shall be observed to prevent contact with blood and other potentially infectious materials, unless those precautions would interfere with the proper delivery of health care or public safety services in a particular circumstance, or would create a significant risk to the personal safety of the worker.

(2) *Engineering and work practice controls.* (i) Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.

(ii) Employees shall wash their hands immediately or as soon as possible after removal of gloves or other personal protective equipment and after hand contact with blood or other potentially infectious materials.

(iii) All personal protective equipment shall be removed immediately upon leaving the work area or as soon as possible if overtly contaminated and placed in an appropriately designated area or container for storage, washing, decontamination or disposal.

(iv) Used needles and other sharps shall not be sheared, bent, broken, recapped, or resheathed by hand. Used needles shall not be removed from disposable syringes.

(v) Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a potential for occupational exposure.

(vi) Food and drink shall not be stored in refrigerators, freezers, or cabinets where blood or other potentially infectious materials are stored or in other areas of possible contamination.

(vii) All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, and aerosolization of these substances.

(viii) Mouth pipetting/suctioning is prohibited.

(3) *Personal protective equipment*— (i) *Provision and Use.* When there is a potential for occupational exposure, the employer shall provide and assure that the employee uses appropriate personal protective equipment such as, but not limited to, gloves; gowns, fluid-proof aprons, laboratory coats, and head and foot coverings; face shields or masks and eye protection; and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices.

(ii) *Accessibility.* The employer shall assure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the worksite or issued to employees. Hypoallergenic gloves shall be readily accessible to those employees who are allergic to the gloves normally provided.

(iii) *Cleaning.* The employer shall provide for the cleaning, laundering or disposal of personal protective equipment required by paragraphs (d) and (e) of this standard.

(iv) *Repair and replacement.* The employer shall repair or replace required personal protective equipment as needed to maintain its effectiveness.

(v) *Gloves.* Gloves shall be worn when the employee has the potential for the hands to have direct skin contact with blood, other potentially infectious materials, mucous membranes, non-intact skin, and when handling items or surfaces soiled with blood or other potentially infectious materials.

(A) Disposable (single use) gloves, such as surgical or examination gloves, shall be replaced as soon as possible when visibly soiled, torn, punctured, or when their ability to function as a barrier is compromised. They shall not be washed or disinfected for re-use.

(B) Utility gloves may be disinfected for re-use if the integrity of the glove is not compromised, however they must be discarded if they are cracked, peeling, discolored, torn, punctured, or exhibit other signs of deterioration.

(vi) *Masks, Eye Protection, and Face Shields.* Masks and eye protection or chin-length face shields shall be worn whenever splashes, spray, spatter, droplets, or aerosols of blood or other potentially infectious materials may be generated and there is a potential for eye, nose, or mouth contamination.

(vii) *Gowns, Aprons, and Other Protective Body-Clothing.* Appropriate protective clothing shall be worn when the employee has a potential for occupational exposure. The type and characteristics will depend upon the task and degree of exposure anticipated; however, the clothing selected shall form an effective barrier.

(A) Gowns, lab coats, aprons, or similar clothing shall be worn if there is a potential for soiling of clothes with blood or other potentially infectious materials.

(B) Fluid-resistant clothing shall be worn if there is a potential for splashing or spraying of blood or other potentially infectious materials.

(C) Surgical caps or hoods shall be worn if there is a potential for splashing or splattering of blood or other potentially infectious materials on the head.

(D) Fluid-proof clothing shall be worn if there is a potential for clothing becoming soaked with blood or other potentially infectious materials.

(E) Fluid-proof shoe covers shall be worn if there is a potential for shoes to become contaminated and/or soaked with blood or other potentially infectious materials.

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

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

(A) Work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; when surfaces are overtly contaminated; immediately after any spill of blood or other potentially infectious materials; and at the end of the work shift.

(B) Protective coverings such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper may be used to cover equipment and environmental surfaces. These coverings shall be removed and replaced at the end of the work shift or when they become overtly contaminated.

(C) Equipment which may become contaminated with blood or other potentially infectious materials shall be checked routinely and prior to servicing or shipping and shall be decontaminated as necessary.

(D) All bins, pails, cans, and similar receptacles intended for reuse which have a potential for becoming contaminated with blood or other potentially infectious materials shall be inspected, cleaned, and disinfected on a regularly scheduled basis and cleaned and disinfected immediately or as soon as possible upon visible contamination.

(E) 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, a vacuum cleaner, tongs, cotton swabs or forceps.

(F) Specimens of blood or other potentially infectious materials shall be placed in a closable, leakproof container labeled or color-coded according to paragraph (g)(1)(ii) prior to being stored or transported. If outside contamination of the primary container is likely, then a second leakproof container that is labeled or color-coded according to paragraph (g)(1)(ii) shall be placed over the outside of the first and closed to prevent leakage during handling, storage, or transport. If puncture of the primary container is likely, it shall be placed within a leakproof, puncture-resistant secondary container.

(G) Reusable items contaminated with blood or other potentially infectious materials shall be decontaminated prior to washing and/or reprocessing.

(iii) *Infectious Waste Disposal.* (A) All infectious waste destined for disposal shall be placed in closable, leakproof containers or bags that are color coded or labeled as required by paragraph (g)(1)(ii) of this standard.

(1) If outside contamination of the container or bag is likely to occur then a second leakproof container or bag which is closable and labeled or color-coded as described in paragraph (g)(1)(ii) shall be placed over the outside of the first and closed to prevent leakage during handling, storage, and transport.

(2) Disposal of all infectious waste shall be in accordance with applicable Federal, state, and local regulations.

(B) Immediately after use, sharps shall be disposed of in closable, puncture resistant, disposable containers which are leakproof on the sides and bottom and that are labeled or color-coded according to paragraph (g)(1)(ii).

(1) These containers shall be easily accessible to personnel and located in the immediate area of use.

(2) These containers shall be replaced routinely and not allowed to overfill.

(iv) *Laundry.* (A) Laundry from workplaces with employees covered under paragraph (a) of this section that is contaminated with blood or other potentially infectious materials or may contain contaminated sharps shall be treated as if it were contaminated and shall be handled as little as possible and with a minimum of agitation.

(1) Contaminated laundry shall be bagged at the location where it was used and shall not be sorted or rinsed in patient-care areas.

(2) Contaminated laundry shall be placed and transported in bags that are labeled or color-coded as described in paragraph (g)(1)(ii). Whenever this laundry is wet and presents the potential for soak-through of or leakage from the bag, it shall be placed and transported in leakproof bags.

(B) The employer shall ensure that laundry workers wear protective gloves and other appropriate personal protective equipment to prevent occupational exposure during handling or sorting.

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

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

(i) *Standard microbiological practices.* All infectious liquid or solid waste shall be decontaminated before being disposed of.

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

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

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

(D) When 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 the provisions outlined in paragraph (g)(1)(i) of this standard.

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

(F) Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work

area and shall be decontaminated before being laundered.

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

(H) All waste from work areas including animal rooms shall be decontaminated before disposal.

(I) Vacuum lines shall be protected with high-efficiency particulate air (HEPA) filters and liquid disinfectant traps.

(J) Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of potentially infectious fluids. Extreme caution shall be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. 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 decontaminated, preferably by autoclaving, before being discarded or reused.

(K) Spills and accidents that result in overt exposures of employees to potentially infectious materials shall be immediately reported to the laboratory director or other responsible person.

(L) A biosafety manual shall be prepared or adopted. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

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

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

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

(i) Each laboratory shall contain a sink for hand washing.

(ii) An autoclave for decontamination of infectious laboratory waste shall be available.

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

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

(ii) The interior surfaces of walls, floors and ceilings 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 of the work area.

(iii) Each work area shall contain a sink for washing hands. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.

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

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

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

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

(f) Hepatitis B Vaccination and Post Exposure Follow-up—(1) General. (i) The employer shall make available hepatitis B vaccination to all employees who have occupational exposure on average one or more times per month and post-exposure follow-up for all employees with an occupational exposure incident.

(ii) The employer shall assure that all medical evaluations and procedures are performed by or under the supervision of a licensed physician and that all laboratory tests are conducted by an accredited laboratory.

(iii) The employer shall assure that all evaluations, procedures, vaccinations, and post-exposure management are provided to the employee at a reasonable time and place, and according to standard recommendations for medical practice.

(2) *HBV Vaccination.* (i) HBV vaccination shall be offered to all employees occupationally exposed on an average of one or more times per month to blood or other potentially infectious materials, unless the employee has a previous HBV vaccination or unless antibody testing has revealed that the employee is immune. If the employee initially declines HBV vaccination but at a later date while still covered under the standard decides to accept the HBV vaccine, the employer shall provide the vaccine at that time. Should a booster dose(s) be recommended at a future date, such booster dose(s) shall be provided according to standard recommendations for medical practice.

(ii) HBV antibody testing shall be made available to an employee who desires such testing prior to deciding whether or not to receive HBV vaccination. If the employee is found to be immune to HBV by virtue of adequate antibody titer, then the employer is not required to offer the HBV vaccine to that employee.

(3) *Post exposure evaluation and follow-up.* Following a report of an exposure incident, the employer shall make available to each employee covered by paragraph (a) a confidential medical evaluation and follow-up, including at least the following elements:

(i) Documentation of the route(s) of exposure, HBV and HIV antibody status of the source patient(s) (if known), and the circumstances under which the exposure occurred.

(ii) If the source patient can be determined and permission is obtained, collection of and testing of the source patient's blood to determine the presence of HIV or HBV infection.

(iii) Collection of blood from the exposed employee as soon as possible after the exposure incident for the determination of HIV and/or HBV status. Actual antibody or antigen testing of the blood or serum sample may be done at that time or at a later date if the employee so requests.

(iv) Follow-up of the exposed employee including antibody or antigen testing, counseling, illness reporting, and safe and effective post-exposure

prophylaxis, according to standard recommendations for medical practice.

(4) *Information provided to the physician.* The employer shall provide the following information to the evaluating physician:

(i) A copy of this regulation and its appendices and

(ii) A description of the affected employee's duties as they relate to the employee's occupational exposure.

(5) *Physician's written opinion.* For each evaluation under this section, the employer shall obtain and provide the employee with a copy of the evaluating physician's written opinion within 15 working days of the completion of the evaluation. The written opinion shall be limited to the following information:

(i) The physician's recommended limitations upon the employee's ability to receive hepatitis B vaccination.

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

(iii) Specific findings or diagnoses, which are related to the employee's ability to receive HBV vaccination. Any other findings and diagnoses shall remain confidential.

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

(g) *Communication of Hazards to Employees*—(1) *Signs and Labels*—(i) *Signs.* The employer shall post signs at the entrance to work areas specified in paragraph (e) of this standard 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.]

(ii) *Labels.* (A) Warning labels shall be affixed to containers of infectious waste; refrigerators and freezers containing blood and other potentially infectious materials; and other containers used to store or transport blood or other potentially infectious materials except as provided in paragraph (g)(1)(ii) (E) and (F).

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

BIOHAZARD

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

(D) Labels required by paragraph (g)(1)(ii) shall either be an integral part of the container or shall be affixed as close as safely possible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

(E) Red bags or red containers may be substituted for labels on containers of infectious waste.

(F) Containers of blood or blood components that are labeled as to their contents and have been released for distribution are exempted from the labeling requirements of paragraph (g).

(2) *Information and Training.* (i) Employers shall ensure that all employees with occupational exposure participate in a training program.

(ii) Training shall be provided at the time of initial employment or within 90 days after the effective date of this standard and at least annually thereafter.

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

(iv) The training program shall contain the following elements:

(A) A copy of this standard and an explanation of its contents;

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

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

(D) An explanation of the employer's infection control program.

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

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

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

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

(I) Information on the hepatitis B vaccine, including information on its efficacy, safety, and the benefits of being vaccinated.

(J) Information on the appropriate actions to take and persons to contact in an emergency;

(K) An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available. Also information on the medical counseling that the employer is providing for exposed individuals; and

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

(v) Additional training. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following training in addition to the above training requirements:

(A) Employees shall be trained in and 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) Employees shall be experienced in the handling of human pathogens or tissue cultures prior to working with HIV or HBV.

(C) A training program shall be provided 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 employee shall participate in work activities involving infectious agents only after proficiency has been demonstrated.

(h) *Recordkeeping*—(1) *Medical records.* (i) The employer shall establish and maintain an accurate record for each employee subject to paragraph (f) of this section, in accordance with 29 CFR 1910.20.

(ii) This record shall include:

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

(B) A copy of the employee's hepatitis B vaccination records and medical records relative to the employee's ability to receive vaccination or the circumstances of an exposure incident;

(C) A copy of all results of physical examinations, medical testing, and follow-up procedures as they relate to the employee's ability to receive vaccination or to post exposure evaluation following an exposure incident;

(D) The employer's copy of the physician's written opinion; and

(E) A copy of the information provided to the physician as required by paragraphs (f)(4).

(iii) Confidentiality. The employer shall assure that employee medical records required by paragraph (f) are:

(A) Kept confidential; and

(B) Are not disclosed or reported to any person within or outside the workplace except as required by this section or as may be required by law.

(iv) The employer shall maintain this record for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.20.

(2) *Training Records.* (i) Training records shall include the following information:

(A) The dates of the training sessions;

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

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

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

(ii) These records shall be maintained for 5 years.

(3) *Availability.* (i) The employer shall assure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

(ii) Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, employee representatives, and the Assistant Secretary in accordance with 29 CFR 1910.20.

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

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

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

(i) *Dates*—(1) Effective Date. The standard shall become effective on [insert date 30 days after publication in the Federal Register].

(2) Exposure Determination. The exposure determination required by paragraph (c)(1) of this section shall be completed within 90 days of the effective date of this standard.

(3) Infection Control Plan. The Infection Control Plan required by paragraph (c)(2) of this section shall be completed within 120 days of the effective date of this standard.

(4) Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Follow-up, (g) Communication of Hazards to Employees, and (h) Recordkeeping shall take effect 150 days after the effective date of this standard. OSHA expects that the employer will have initiated, but perhaps not completed, the HBV vaccination series within this time period.

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APPENDIX B

BIOLOGICAL SAFETY AUDIT CHECKLIST

Department: _____ Div: _____ Building: _____ Room: _____

Lab manager: _____ Phone/ext. _____

Type of facility: clinical/diagnostic laboratory (CDL); research laboratory (RL); production facility (PF) _____

	YES	NO
I. ENTRY (For RL and PF only; for CDL, go to II)		
1. Are Biohazard warning signs present on all access doors to area?	___	___
2. Is name of infectious agent(s), name/phone numbers (work & home) of personnel to contact in case of emergency and special requirements for entering the area present?	___	___

Contacts Ext. Phone

_____

_____

Agents: _____

_____

3. Are doors closed when work is ongoing?	___	___
4. If PF, is facility separated from areas which are open to unrestricted traffic flow within the bldg.?	___	___
a. Is entry into facility made by passage through two sets of doors?	___	___
b. Do access doors to area self close?	___	___
c. Is airflow directed into the work area when the door is opened?	___	___
d. If access to facility is by means of an airlock, is it functioning properly?	___	___
II. WORK AREA		
1. LABORATORY EQUIPMENT/ITEMS		
a. Are refrigerators/freezers where biohazards are stored marked with appropriate labels?	___	___
b. Are incubators/baths for biohazards marked with appropriate labels?	___	___
c. Is sink/soap/towels available for washing hands and are hand washing facilities accessible?	___	___

d. If PF, are sinks automatically operated and near door? ____ ____

e. Is disinfectant available on the counters for surface decontamination and spill cleanup? ____ ____

f. Are vacuum lines used with biohazards protected with a disinfectant trap and filter? (.2um or HEPA) ____ ____

g. If RL or PF, is centrifuge containment proper?
- sealed heads or safety cups minimum or HEPA vented containment device ____ ____

h. Proper syringe usage? (only needle-locking or complete syringe-needle units to be used) ____ ____

2. PERSONAL PROTECTION

a. Are laboratory coats, gowns, smocks present &/or made readily available? ____ ____

i. are they worn and appropriate for procedure observed? (wrap around disposable smocks are mandatory for PF) ____ ____

ii. are they buttoned or fully fastened? ____ ____

iii. are they removed before going to non-lab areas? ____ ____

b. Is eye/face protection (including safety glasses, masks and chin length face shields) present &/or made readily available? ____ ____

i. is it worn and appropriate for procedure observed? (eye protection mandatory for PF) ____ ____

c. Are gloves present &/or made readily available? ____ ____

i. are they worn and appropriate for procedure observed? (mandatory for PF) ____ ____

ii. are surgical/examination gloves replaced and disposed of (not washed/disinfected & re-used) as soon as visibly soiled, torn, or their ability to function as a effective barrier is compromised? ____ ____

d. For PF, in addition to above, are disposable shoe coverings, face mask or respirator and hair net worn? ____ ____

3. HAZARDOUS WASTE: CONTAINMENT, REMOVAL, TRANSPORT

a. Container for needles/sharps present? ____ ____

i. proper type? (no needle-clipping types) ____ ____

ii. properly labeled or color-coded red? ____ ____

b. Container present for liquid disposal? ____ ____

i. properly labeled? (red containers may be substituted for labels) ____ ____

ii. is container unbreakable? ____ ____

iii. note kind and concentration of disinfectant used; is it appropriate? ____ ____

iv. is container left to sit overnight and changed daily? ____ ____

c. Container(s) present for biohazardous solid waste disposal? ____ ____

i. are they clean and disinfected regularly? ____ ____

ii. are they properly labeled? (red containers may be substituted for labels) ____ ____

iii. are proper autoclave bags used? ____ ____

iv. are bags reasonably filled? (approx. 2/3 full) ____ ____

v. are bags appropriately labeled or color-coded red? ____ ____

vi. are bags appropriately sealed for transport? ____ ____

vii. are liquids present with solid wastes? (if yes, comment) ____ ____

d. Are bags of waste placed in a second leakproof container or bag which is appropriately labeled or color-coded red during storage/ transport for decontamination? ____ ____

e. Is an autoclave close/present in building? ____ ____

4. ENGINEERING CONTROLS

a. General Ventilation (for PF only; CDL & RL go to 4.c.)

i. Is a ducted, exhaust air ventilation system provided? ____ ____

ii.. Is exhaust air from the work area directly discharged to the outside (non recirculated) away from intakes and occupied areas? ____ ____

b. Facility Design (applies only to PF)

i. Are walls, floors and ceiling of facility water resistant? ____ ____

ii. Are all cracks, crevices, joints and penetrations sealed to facilitate decon. ____ ____

c. Biosafety Cabinets/Clean Air Stations/Fume Hoods

i. What type(s) of cabinets are present?	____	____	____	____
ii. Asset #	____	____	____	____
iii. Date last certified?	____	____	____	____
iv. Is this date current?	____	____	____	____
v. Does hood indicate normal operative conditions?	____	____	____	____
vi. Is hood cluttered or objects intake portals/vents?	____	____	____	____
vii. Is hood proper for type/ manipulation of agent?	____	____	____	____
viii. Is unit left "on" at all times?	____	____	____	____
ix. Is alarm kept in the "on" position?	____	____	____	____
x. Are work surfaces disinfected after every use?	____	____	____	____
xi. Is sash kept at required levels?	____	____	____	____

III. LABORATORY TECHNIQUE / WORK PRACTICE CONTROLS

1. If RL or PF, are all potentially infectious and known biohazardous materials used in a biological safety cabinet?	____	____
2. If CDL, are personnel using techniques to minimize aerosolization (splashing, spraying, spattering) of potentially infectious materials?	____	____
a. If risk for aerosilization persists, is proper eye and mouth protection used &/or proper physical containment devices?	____	____
3. Are food/drinks/cigarettes/cosmetics/contact lenses used/stored in work environment? (food & drinks must be stored in refrigerators designated only for consumables)	____	____
4. Is laboratory clean/unclutterd?	____	____
5. Are surfaces cleaned and disinfected upon completion of a procedure, at end of work shift, and immediately after a spill of potentially infectious materials?	____	____

6. Are paper toweling or "protective covering material" (eg. plastic, aluminum foil, etc.) used on bench top removed and discarded daily? ___ ___

7. Are mechanical pipetting devices present? No mouth pipetting allowed! ___ ___

8. Is laundry that is overtly contaminated with potentially infectious materials treated as contaminated, bagged at location and not sorted or rinsed in patient care areas? ___ ___

   a. Is it placed and transported in bags that are biohazard labeled or color-coded red? ___ ___

      i. are these bags leakproof? ___ ___

9. Do laundry workers wear a minimum of protective gloves when handling or sorting such laundry? ___ ___

10. Are specimens of blood or other potentially infectious materials placed in a closable, leakproof container and labeled or color-coded appropriately prior to being stored or transported? ___ ___

    a. If outside contamination of primary container is likely to occur during storage/handling/transport, is it placed in a durable, watertight secondary container, that is puncture proof if necessary and labeled or color-coded appropriately.? ___ ___

11. Are reusable items decontaminated prior to washing and/or reprocessing? ___ ___

12. Are spills & accidents resulting in overt exposure to employees reported to the lab. director/mananger? ___ ___

IV. <u>EVALUATION OF PERSONNEL PROGRAMS, POLICIES AND TRAINING</u>

1. If RL or PF, do personnel have written Biosafety policies, procedures, or manual to reference? ___ ___

2. Have personnel at risk to an occupational exposure to blood or other infectious materials been through the appropriate Biosafety training? ___ ___

   a. Is it proper and in accordance with paragraphs (g)(2) of standard? ___ ___

   b. Are training records kept and in accordance with paragraphs (h)(2)(3) of standard? ___ ___

3. Have personnel been offered or actively participate in a Hepatitis B vaccination program if exposed to blood or other potentially infectious materials one or more times a month? ___ ___

   a. Is it proper and in accordance with paragraphs (f)(1)(2)(4)(5) of standard? ___ ___

b. Are medical records kept of all employees that qualify for program in accordance with paragraphs (h)(1)(3) of standard? ___ ___

4. Have personnel been offered or at one time have participated in a post exposure evaluation and follow-up program? ___ ___

   a. Is it proper and in accordance with paragraph (f)(3) of standard? ___ ___

   b. Are medical records kept for exposed individuals in accordance with paragraphs (h)(1)(3) of standard? ___ ___

5. Has an infection control plan been established to minimize or eliminate employee exposure in accordance with paragraphs (c)(1)(2) of standard? ___ ___

6. Is there any training that the personnel would like to receive that has not been offered? ___ ___

7. Were there any comments made by personnel regarding safety? (if yes, comment) ___ ___

V. REMARKS:

Audit Performed By: _____ Date: _____

Audit Reviewed By: _____ Date: _____

APPENDIX C

Eddie Schwartz
Dept. 9ZTR
Bldg. AP-20
Room #1000

June 28, 1990

Eddie Schwartz,

A biological safety audit of your laboratory was performed on 06/10/90. In accordance with Corporate Safety and Loss Prevention Policy No. 30.0, we noted some areas where biological safety is potentially compromised. The purpose of this letter is to bring such areas to your attention and provide you with suggestions as to how they may be corrected. After reviewing the attached report, please send us a letter by 08/02/90 stating the steps that were taken to remedy the conditions noted as well as the dates they were implemented. Also for your review is a copy of the audit form used to assess your laboratory. Letters and questions regarding the audit should be directed to Dr. David Mulligan, Corporate Biological Safety, Dept. 585, AP-6D, ext. 77043.

Sincerely,

David Mulligan
Manager Corporate
Biological Safety

Rick Mattick
auditor

Attachment

- Improper use or no biohazard warning signs present on entry to area. Your laboratory requires a biosafety level "2" sign on all doors entering your laboratory and any preparation rooms, production rooms, or inner laboratories where your biohazardous agents are used/manipulated/stored. These can be obtained through the sign shop in North Chicago and are square 6"x 6" permanent plastic signs with color designations of yellow, orange and red for Potential, BSL-2, and BSL-3 level hazards respectively. They may be ordered using an interior signage request form. Contact the sign shop at ext. 76827. Temporary paper biohazard signs to be used until the permanent signs arrive can be obtained through Mary Cipriano, Manager of ADD Biological Safety, D917, AP6C, ext. 72225 or Dave Mulligan, Corporate Biological Safety, D585, AP6D, ext. 77043.

- For BSL-2 and 3 laboratories, included on the sign shall be the name of the infectious agent(s) and name/phone numbers (work and home) including area code, of at least two personnel to contact in case of an emergency. This list should appear in the form of a 3"x 9" sticker which can attach directly to the plastic, permanent signs. The stickers can be obtained through Mary Cipriano, Manager of ADD Biosafety, D917, AP6C, ext. 72225.

- All refrigerators/freezers where biohazardous material is stored should be appropriately marked with a label containing the universal biohazard symbol. The contents of the refrigerator/freezer should also appear on the label. Recommended are the red, 1" x 3" biohazard/hazard identity stickers, stock #5560, or the orange, 1" x 3" Human Blood or Tissues: Potential Biohazard stickers, stock #8910, if only blood or tissues of unknown pathogenicity are stored. Both can be obtained in rolls of 1000 through the Scientific Stockrooms located in buildings AP8B (70664), AP9 (75274) and R1B (76020).

- All incubators/baths for biohazardous materials should be marked with a label containing the universal biohazard symbol. Recommended are the red biohazard/hazard identity stickers attainable as above.

- Disinfectant should be readily available. Recommended for surface decontamination is a 2% bleach solution (1000 ppm available chlorine). Bleach is very effective in the decontamination of a wide spectrum of microorganisms. For spill cleanup, a 20% bleach solution is recommended (10,000 ppm available chlorine) for biohazardous materials or a 2% gluteraldehyde solution when the biohazardous materials also contain radioactivity. A bleach solution up to 20% (10,000 ppm available chlorine) can be used on stainless steel surfaces, such as those found in biosafety cabinets, as long as it is followed by a water rinse.

- If house vacumn lines are used to filter, draw, transfer biohazardous liquids, the line must be protected with a disinfectant trap composed of a flask containig a 20% bleach solution (10,000 ppm available chlorine) as well as a vacuum line filter. "Vac-U-Shield" filters (Stock #8320) are available through the PPD

Scientific Stockrooms located in buildings AP8B (70664), AP9 (75274) and R1B (76020).

- It is required that latex or vinyl gloves be worn during any laboratory procedure or technique where potential or known biohazardous agents may come in contact with the skin due to the fact that the skin of most individuals is not completely intact.

- A puncture resistant container for disposal of the entire syringe/needle unit, or other contaminated sharp waste (eg. scalpels, pasteur pipettes) should be present and labeled with a biohazard sticker. Recommended containers are obtained through the PPD Scientific Stockrooms in buildings AP8B, AP9, and R1B and through ADD Manufacturing Supplies (Dept. 49K), located in buildings AP-8B and AP-32. There are three types available: an all purpose, 8 quart sharps disposal container (stock #9865), a 8 quart syringe disposal container which stacks complete syringe units to maximize capacity (stock #9864), and a 14 quart pipette disposal container, for large sharps disposal (stock #9866).

- Needle clipping disposal containers shall not be used. Recommended are puncture resistant containers for disposal of complete syringe/needle unit.

- All syringe/sharps containers should be labeled with a sticker containing the universal biohazard symbol.

- A container must be present so that liquid biohazardous waste can be decontaminated prior to disposal. The final disinfectant concentration, (i.e. disinfectant and liquid waste mixture) should contain:

  - 10% bleach (5,000 ppm available chlorine) if mixture is allowed to sit 12 hours before disposal down the drain.
  - 20% bleach (10,000 ppm) if the mixture is allowed to sit for at least 2 hours prior to disposal down the drain.
  - 2% gluteraldehyde if radioactive biohazardous wastes are used. This mixture does not go down the drain.

Rad/Bio waste containers can be purchased through the ADD warehouse, on the AP8B dock or at AP32 when open. These containers are black steel drums with small screw off caps and come in 5 gallon (Stock # 76-0039) and 30 gallon (stock #76-0067) capacities. You must order with a finishing request form (FSR). When full, contact housekeeping for removal of container. If generating relatively small amounts of bio wastes, like those generated from an IMX, TDX, excess clinical samples, etc.. storage for decontamination is easiest in a carboy, plastic bottle, or a similar, non-breakable container. All liquid biohazard containers must be labeled with an appropriate biohazard sticker.

- All biohazardous solid waste must be 2x bagged.
Autoclave bags for biowaste are available through the PPD Scientific Stockrooms located in buildings AP8B, AP9, and R1B (stock #5544). They are semi-opaque bags and when used with biohazard stickers for proper identity are less expensive than the biowaste bags typically available from most lab supply vendors.

- All waste containers, bins and cans housing biohazardous waste should remain clean at all times and be disinfected regularly.

- Laundry contaminated with biohazardous materials, blood or other

potentially infectious materials shall be treated as contaminated, bagged at the location where it was used, and decontaminated prior to laundering.

- All laboratory personnel, including temporaries, must attend the biohazard training course. See attached "Biosafety Training Schedule" for dates and times.

APPENDIX D

OUTLINE FOR BLOOD-BORNE PATHOGEN AUDIT SYSTEM

I. Goal:

a. To develop a computer based biological safety audit system that can be used by safety professionals to evaluate research, clinical and production laboratories for compliance to the proposed Occupational Safety and Health Administration (OSHA) blood-borne pathogen standard plus existing HIV/HBV guidelines.

b. To be able to use information collected on audit as a means of classifying research, clinical, and production laboratories as high, medium, or low risk with respect to occupational exposure to bloodborne pathogens and subsequent infection.

II. System Structure:

The entire audit system will be comprised of three main elements, the computer data base, the paper checklist, and the fault tree analysis.

a. The database system selected will display the following characteristics:

1. flexibility; to be used on IBM and IBM compatible systems.

2. user friendly for easy incorporation by safety professionals/industrial hygienists with minimal computer skills.

3. low cost; allowing system to be attainable by both small and large companies and institutions.

4. data management capabilities featuring the ability to:

   A. store audit data.
   B. generate audit response reports noting deficiencies and providing remedial information.
   C. manipulate audit data into informative graphs and reports.
   D. supply emergency response capabilities.

b. A portable, paper audit form will be used to review laboratory on-site. The audit will assess the following elements of biological safety:

1. Entry and Facility Design

   A. Is the facility design adequate to contain the agent and provide protection to human health

both in the internal and external laboratory environment?

B. Do external signs adequately identify and warn of agents used in the laboratory and provide emergency response information?

2. Laboratory Work Area

A. Laboratory Equipment/Items

i. Is lab equipment/accessories proper for use with blood-borne pathogens and identified as such?

B. Personal Protection

i. Is proper personal protection worn?

C. Biohazard Waste Management

i. Is solid and liquid biological waste properly identified, stored, transferred, and disposed of?

D. Engineering Controls

i. Is general ventilation proper for type of facility?

ii. Are biosafety cabinets, clean air stations and fume hoods appropriate for type of work, used correctly, and certified?

3. Facility Practices and Habits

A. Are appropriate biological safety and laboratory practice procedures followed?

4. Evaluation of Programs, Policy and Training

A. Are employees adequately trained for work in a biological laboratory?

B. Are they informed on the present federal regulations and guidelines as well as any internal policies?

C. Are medical surveillance and hepatitis B vaccination programs offered and do the employees actively participate?

D. Do employees have any comments or concerns regarding safety in their laboratory?

c. The fault tree will be constructed and used in conjunction with the on-site paper audit checklist to classify facilities as either high, medium, or low risk based on their potential ability to cause a bloodborne pathogen exposure and subsequent infection. The fault tree will:

1. identify the potential pathways of exposure to blood and other potentially infectious materials

2. classify these various exposure routes as high, medium, or low risk with respect to their ability or to cause infection

3. list the elements contained in the audit that contribute to the risk of the specific exposures noted in the exposure scheme.

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