H370 EX315

federal register

Friday
December 6, 1991

Part II

Department of Labor

Occupational Safety and Health Administration

29 CFR Part 1910.1030
Occupational Exposure to Bloodborne Pathogens; Final Rule

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910.1030

[Docket No. H-370]

Occupational Exposure to Bloodborne Pathogens

AGENCY: Occupational Safety and Health Administration (OSHA), Labor

ACTION: Final rule.

SUMMARY: The Occupational Safety and Health Administration hereby promulgates a standard under section 6(b) of the Occupational Safety and Health Act of 1970 (the Act), 29 U.S.C. 655 to eliminate or minimize occupational exposure to Hepatitis B Virus (HBV), Human Immunodeficiency Virus (HIV) and other bloodborne pathogens. Based on a review of the information in the rulemaking record, OSHA has made a determination that 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 hepatitis B virus which causes Hepatitis B, a serious liver disease, and human immunodeficiency virus, which causes Acquired Immunodeficiency Syndrome (AIDS). The Agency further concludes that this exposure can be minimized or eliminated using a combination of engineering and work practice controls, personal protective clothing and equipment, training, medical surveillance, Hepatitis B vaccination, signs and labels, and other provisions.

DATES: This standard shall become effective on March 6, 1992.

Any petitions for review must be filed not later than the 59th day following the promulgation of the standard. See Section 6(f) of the OSH Act; 29 CFR 1911.18(d) and *United Mine Workers of America v. Mine Safety and Health Administration*, 900 F.2d 384 (D.C. Cir. 1990).

ADDRESSES: For additional copies of this standard, contact OSHA Office of Publications, U.S. Department of Labor, room N3101, 200 Constitution Ave., NW., Washington, DC 20210, Telephone (202) 523-9667.

For copies of materials in the docket, contact: OSHA Docket Office, Docket No. H-370, room N2625, U.S. Department of Labor, 200 Constitution Ave, NW., Washington, DC 20210, Telephone (202) 523-7894. The hours of operation of the Docket Office are 10 a.m. until 4 p.m.

In compliance with 28 U.S.C. 2112(a), the Agency designates for receipt of petitions for review of the standard, the Associate Solicitor for Occupational Safety and Health, Office of the Solicitor, room S-4004, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Mr. James F. Foster, OSHA, U.S. Department of Labor, Office of Public Affairs, Room N3647, 200 Constitution Avenue, NW., Washington, DC 20210, telephone (202) 523-8151.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Pertinent Legal Authority
III. Events Leading to the Standard
IV. Health Effects
V. Quantitative Risk Assessment
VI. Significance of Risk
VII. Regulatory Impact Analysis and Regulatory Flexibility Analysis
VIII. Environmental Impact
IX. Summary and Explanation of the Standard
X. Authority and Signature
XI. The Standard

References to the rulemaking record are in the text of the preamble. References are given as "Ex." followed by a number to designate the reference in the docket. For example, "Ex. 1" means exhibit 1 in the Docket H-370. This document is a copy of the Advance Notice of Proposed Rulemaking for Bloodborne Pathogens that was published in the Federal Register on November 27, 1987 (52 FR 45438). References to the transcripts of the public hearings are given as "Tr." followed by the date and page. For example, "Mr. Clyde R. Bragdon, Jr. Tr. 9/14/89, p. 100" refers to the first page of the testimony of Mr. Clyde A. Bragdon, Jr., Administrator of the U.S. Fire Administration, given at the public hearing on September 14, 1989. A list of the exhibits, copies of the exhibits, and copies of the transcripts are available in the OSHA Docket Office.

I. Introduction

The preamble to the Final Standard for Occupational Exposure to Bloodborne Pathogens discusses the events leading to the promulgation of final standard, health effects of exposure, degree and significance of the risk, an analysis of the technological and economic feasibility of the standard's implementation, regulatory impact and regulatory flexibility analysis, and the rationale behind the specific provisions of the standard.

The public was invited to comment on these matters following publication of the Advance Notice of Proposed Rulemaking on November 27, 1987 (52 FR 45436) and following publication of the Proposed Standard on May 30, 1989 (54 FR 23042).

The Agency recognizes the unique nature of both the healthcare industry and other operations covered by this standard. The Agency concludes the employee protection can be provided in a manner consistent with a high standard of patient care.

Hazardous Waste Operations and Emergency Response Standard

The Hazardous Waste Operations and Emergency Response (HAZWOPER) Standard (29 CFR 1910.120) covers three groups of employees: workers at uncontrolled hazardous waste remediation sites; workers at Resource Conservation Recovery Act (RCRA) permitted hazardous waste treatment, storage, and disposal facilities; and those workers expected to respond to emergencies caused by the uncontrolled release of hazardous substances.

The definition of hazardous substance includes any biological agent or infectious material which may cause disease or death. There are three potential scenarios where the bloodborne and hazardous waste operations and emergency response standard may interface. These scenarios include: workers involved in cleanup operations at hazardous waste sites involving regulated waste; workers at RCRA permitted incinerators that burn infectious waste; and workers responding to an emergency caused by the uncontrolled release of regulated waste (e.g., a transportation accident).

Employers of employees engaged in these three activities must comply with the requirements in 29 CFR 1910.120 as well as the Bloodborne Pathogens Standard. If there is a conflict or overlap, the provision that is more protective of employee health and safety applies.

Information Collection Requirements

5 CFR part 1320 sets forth procedures for agencies to follow in obtaining OMB clearance for information collection requirements under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq. The final bloodborne pathogen standard requires the employer to allow OSHA access to the exposure control plan, medical and training records. In accordance with the provisions of the Paperwork Reduction Act and the regulations issued pursuant thereto, OSHA certifies that it has submitted the information collection to OMB for review under section 3504(h) of that Act.

Public reporting burden for this collection of information is estimated to average five minutes per response to

allow OSHA compliance officers access to the employer's records. Send comments regarding this burden estimate, or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Information Management, Department of Labor, room N-1301, 200 Constitution Avenue, NW., Washington, DC 20210; and to the Office of Management and Budget, Paperwork Reduction Project (Bloodborne Pathogens), Washington, DC 20503.

Federalism

This standard has been reviewed in accordance with Executive Order 12612, 52 FR 41685 (October 30, 1987), regarding Federalism. This Order requires that agencies, to the extent possible, refrain from limiting State policy options, consult with States prior to taking any actions that would restrict State policy options, and take such actions only when there is clear constitutional authority and the presence of a problem of national scope. The Order provides for preemption of State law only if there is a clear Congressional intent for the Agency to do so. Any such preemption is to be limited to the extent possible.

Section 18 of the Occupational Safety and Health Act (OSH Act), expresses Congress' clear intent to preempt State laws with respect to which Federal OSHA has promulgated occupational safety or health standards. Under the OSH Act a State can avoid preemption only if it submits, and obtains Federal approval of, a plan for the development of such standards and their enforcement. Occupational safety and health standards developed by such Plan-States must, among other things, be at least as effective in providing safe and healthful employment and places of employment as the Federal standards.

The bloodborne pathogens standard is drafted so that employees in every State will be protected by general, performance-oriented standards. To the extent that there are State or regional peculiarities, States with occupational safety and health plans approved under Section 18 of the OSH Act would be able to develop their own State standards to deal with any special problems. Moreover, the performance nature of this standard, of and by itself, allows for flexibility by States and employers to provide as much safety as possible using varying methods consonant with conditions in each State.

In short, there is a clear national problem related to occupational safety and health for employees exposed to bloodborne pathogens. Those States which have elected to participate under Section 18 of the OSH Act would not be preempted by this regulation and would be able to deal with special, local conditions within the framework provided by this performance-oriented standard while ensuring that their standards are at least as effective as the Federal standard.

State Plans

The 23 States and 2 territories with their own OSHA-approved occupational safety and health plans must adopt a comparable standard within 6 months after the publication of a final standard for occupational exposure to bloodborne pathogens or amend their existing standard if it is not "at least as effective" as the final Federal standard. OSHA anticipates that this standard will have a substantial impact on State and local employees. The States and territories with occupational safety and health state plans are: Alaska, Arizona, California, Connecticut, Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York, North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, the Virgin Islands, Washington, and Wyoming. (In Connecticut and New York, the plan covers only State and local government employees). Until such time as a State standard is promulgated, Federal OSHA will provide interim enforcement assistance, as appropriate.

II. Pertinent Legal Authority

The primary purpose of the Occupational Safety and Health Act (29 U.S.C. 651 *et seq.*) (the Act) is to assure, so far as possible, safe and healthful working conditions for every American worker over the period of his or her working lifetime. One means prescribed by the Congress to achieve this goal is the mandate given to, and concomitant authority vested in, the Secretary of Labor to set mandatory safety and health standards. The Congress specifically directed that:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. Development of standards under this subsection shall be based upon research, demonstrations, experiments, and such other information as may be appropriate. In addition to the attainment of the highest degree of health and safety protection for the employee, other considerations shall be the latest available scientific data in the field, the feasibility of the standards, and experience gained under this and other health and safety laws. Whenever practical, the standard promulgated shall be expressed in terms of objective criteria and of the performance desired. [Section 6(b)(5)].

Where appropriate, standards are required to include provisions for labels or other appropriate forms of warning to apprise employees of hazards, suitable protective equipment, exposure control procedures, monitoring and measuring of employee exposure, employee access to the results of monitoring, and training and education. Standards may also prescribe recordkeeping requirements where necessary or appropriate for enforcement of the Act or for the development of information regarding occupational accidents and illnesses [section 8(c)].

In vacating OSHA's 1978 revision to its benzene standard, the Supreme Court required in *Industrial Union Department, AFL-CIO* v. *American Petroleum Institute*, 448 U.S. 601, 64 L. Ed. 2d 1010, 100 S. Ct. 2844 (1980), that before the issuance of a new or revised standard pursuant to section 6(b)(5) of the Act, OSHA must make two threshold findings: that a place of employment is unsafe in that significant risks are present; and that the risks can be reduced or eliminated by a change in practices (448 U.S. at 642).

The Court also stated "that the Act does limit the Secretary's power to requiring the elimination of significant risks" (448 U.S. at 644, n. 49). The Court indicated, however, that the significant risk determination is "not a mathematical straitjacket," and that "OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty." The Court ruled that "a reviewing court [is] to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge [and that] the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection" (448 U.S. at 655, 656). The Court also stated that "while the Agency must support its finding that a certain level of risk exists with substantial evidence, we recognize that its determination that a particular level of risk is 'significant' will be based largely on policy considerations." (448 U.S. at 655, 656, n. 62).

OSHA has used these guidelines provided by the Supreme Court in setting health standards for known carcinogens such as benzene and ethylene oxide as well as other substances such as cotton dust whose

adverse health effect is not carcinogenic but is very serious. Exposure to cotton dust, for example, causes byssinosis.

After OSHA has determined that a significant risk exists and that such risk can be reduced or eliminated by the regulatory action, it must set the standard "which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employees will suffer material impairment of health" [Section 6(b)(5) of the Act]. The Supreme Court has interpreted this section to mean that OSHA must enact the most protective standard possible to eliminate a significant risk of material health impairment, subject to the constraints of technological and economic feasibility. *American Textile Manufacture's Institute, Inc.* v. *Donovan*, 452 U.S. 490 (1981). The Court held that "cost-benefit analysis is not required by the statute because feasibility analysis is." (452 U.S. at 509). The Court stated that the Agency could use cost-effectiveness analysis and choose the least costly of two equally effective standards. (452 U.S. 531, n. 32).

Authority for this action is also found in section 8(c)(3) of the Act. In general, this section empowers the Secretary to require employers to make, keep, and preserve records regarding activities related to the Act. In particular, section 8(c)(3) gives the Secretary authority to require employers to "maintain accurate records of employee exposures to potentially toxic materials or harmful physical agents which are required to be monitored or measured under Section 6."

The Secretary's authority to issue this standard is further supported by the general rulemaking authority granted in section 8(g)(2) of the Act. This section empowers the Secretary "to prescribe such rules and regulations as [she] may deem necessary to carry out [her] responsibilities under the Act"—in this case as part of a Section 6(b) standard. The Secretary's responsibilities under the Act are defined largely by its enumerated purposes, which include:

Encouraging employers and employees in their efforts to reduce the number of occupational safety and health hazards at their places of employment, and to stimulate employers and employees to institute new and to perfect existing programs for providing safe and healthful working conditions [29 U.S.C. 651(b)(1)];

Authorizing the Secretary of Labor to set mandatory occupational safety and health standards applicable to businesses affecting interstate commerce [29 U.S.C. 651(b)(3)];

Building upon advances already made thro igh employer and employee initiative for providing safe and healthful working conditions [29 U.S.C. 651(b)(4)];

Providing for appropriate reporting procedures with respect to occupational safety and health which procedures will help achieve the objectives of this Act and accurately describe the nature of the occupational safety and health program [29 U.S.C. 651(b)(12)];

Exploring ways to discover latent diseases, establishing causal connections between diseases and work in environmental conditions [29 U.S.C. 651(b)(6)];

Encouraging joint labor-management efforts to reduce injuries and disease arising out of employment [29 U.S.C. 651(b)(13)]; and

Developing innovative methods, techniques, and approaches for dealing with occupational safety and health problems [29 U.S.C. 651(b)(5)].

The Agency's judgement is that the bloodborne pathogens standard is reasonably related to these statutory goals, that the evidence satisfies the statutory requirements, and that the standard will reduce a significant risk of hepatitis B and other adverse health effects, including but not limited to AIDS and hepatitis C. Thus, the Secretary finds that this standard is necessary and appropriate to carry out her responsibilities under the Act.

III. Events Leading to the Final Standard

Hepatitis B virus (HBV) has long been recognized as a pathogen capable of causing serious illness and death. Because the virus is transmitted through blood and certain body fluids, persons who come in contact with blood and other potentially infectious materials as the result of carrying out their duties have been at increased risk of contracting HBV. The human immunodeficiency virus (HIV), the virus that causes AIDS, has only been recognized in the last decade. Because the transmission of HIV is considerably less efficient than HBV, the risk of HIV infection to employees who must handle blood and other potentially infectious materials is less than for HBV infection (i.e., HIV results in fewer seroconversions following exposure incidents). The consequences of HIV infection are grave, however, because HIV causes the fatal disease AIDS.

Although OSHA has no standard that was designed specifically to reduce occupational exposure to these viruses, the Agency has a number of existing regulations that apply to this hazard. For example, 29 CFR 1910.132 requires employers to provide personal protective equipment and 29 CFR 1910.145(f) requires accident prevention tags to warn of biological hazards. In addition, section 5(a)(1) the General Duty Clause of the Act requires that each employer:

furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees.

In 1983, OSHA issued a set of voluntary guidelines designed to reduce the risk of occupational exposure to hepatitis B virus (Ex. 4–25). The voluntary guidelines, which were sent to employers in the healthcare industry, included a description of the disease, recommended work practices, and recommendations for use of immune globulins and the hepatitis B vaccine.

On September 19, 1986, the American Federation of State, County and Municipal Employees (AFSCME) petitioned OSHA to take action to reduce the risk to employees from exposure to certain infectious agents (Ex. 2A). They requested that OSHA issue an emergency temporary standard (ETS) under section 6(c) of the Act. The petitioners also requested that OSHA immediately initiate a section 6(b) rulemaking that would require employers to provide the HBV vaccine at no cost to employees at risk for HBV infection and would require employers to follow work practice guidelines such as those issued by the Centers for Disease Control. AFSCME also requested that OSHA amend the Hazard Communication Standard (48 FR 53280) to require a training program for employees exposed to infectious diseases, require counseling for pregnant employees about diseases that have reproductive effects, and mandate posting of isolation precautions in patient areas and in contaminated areas.

On September 22, 1986, the Service Employees International Union, the National Union of Hospital and Healthcare Employees, and RWDSU Local 1199—Drug, Hospital and Healthcare Union petitioned the Agency to promulgate a standard to protect healthcare employees from the hazard posed by occupational exposure to hepatitis B virus (Ex. 3). They requested that, as a minimum, the standard should contain all of the provisions in OSHA's 1983 guidelines with special emphasis on making workers aware of the benefits of vaccination. In addition, they asked OSHA to immediately issue a directive stating that employers must provide the HBV vaccine free of charge to all high risk healthcare workers.

Having determined that the available data did not meet the criteria for an ETS as set forth in section 6(c) of the Act, Assistant Secretary John A. Pendergrass denied the petitions by letter dated October 22, 1987. OSHA further determined that the appropriate course of action was to publish an Advance

Notice of Proposed Rulemaking (ANPR) to initiate rulemaking under section 6(b) of the Act and to collect further information. Concurrently with the collection of this information, the Agency committed to enforcing existing regulations and section 5(a)(1) of the Act in healthcare settings and to undertaking an educational program in cooperation with the Department of Health and Human Services.

The enforcement program has resulted in reduction of risks for certain workers but, in general, is not a sufficient long-term response to the hazards presented by bloodborne pathogens. The General Duty Clause of the Act requires that each employer shall:

> furnish to each of his employees employment and a place of employment which are free from recognized hazards causing or likely to cause death or serious physical harm.

To prove a violation of section 5(a)(1) OSHA must prove, among other things, that a serious hazard is recognized by the employer's industry or the employer. *Kelly Springfield Tire Co., Inc.* v. *Donovan*, 729 F.2d 317, 321 (5th Cir. 1984). OSHA must also prove there is a feasible and useful method for abating the hazard. *National Realty & Const. Co.* v. *OSHRC and Secretary*, 489 F.2d 1252 (D.C. Cir. 1973).

Among the abatement methods listed in the section 5(a)(1) part of the OSHA instruction are Hepatitis B vaccination, training on the hazards of bloodborne pathogens and universal precautions, and follow-up procedures after an HIV or HBV exposure incident. The standards discussed in the OSHA instruction include 29 CFR 1910.132(a), requiring personal protective equipment where there is exposure to hazards, under which OSHA has required the use of gloves and gowns, among other things, where there is exposure to blood and potentially infectious body fluids; 29 CFR 1910.22(a), requiring places of employment to be kept clean and in a sanitary condition, under which OSHA requires the use of certain disinfectants following initial clean up of blood or potentially infectious body fluids; 29 CFR 1910.141(a)(4) (i) and (ii), which requires the use of non-leaking waste containers and the removal of wastes in such a manner to avoid creating a menace to health, under which OSHA prohibits the recapping of needles by hand and requires the use of puncture-resistant sharp containers, among other things; and 29 CFR 1910.145(f), which requires tags or other means of identification where employees are exposed to potentially hazardous conditions, under which OSHA mandates biological hazard tags or red bagging for bags or other receptacles containing articles contaminated with potentially infectious material. Because most of these standards are broadly worded, and apply only where there is a "hazard", OSHA must generally prove that a reasonable person familiar with the circumstances surrounding an allegedly hazardous condition, including any facts unique to a particular industry, would recognize a hazard warranting the use of personal protective equipment. *General Dynamics Corp.* v. *OSHRC*, 599 F.2d 453, 464 (1st Cir. 1979).

To flesh out the requirements of the General Duty Clause and the General Industry Standards, OSHA has relied on guidelines adopted by the Center for Disease Control. (Exs. 6–153; 6–316).

Although the current OSHA enforcement program has reduced the risks of occupational exposure to bloodborne pathogens to some extent, significant risks remain and the Agency has concluded that an occupational health standard promulgated under section 6(b) of the Act will much more efficiently reduce these risks. First, the OSH Act intends that OSHA issue occupational health standards to make clear what is necessary to protect employees, to inform employers of their specific obligations. Standards developed through the rulemaking process with its opportunity for public comment lead to increased protection for employees and easier enforcement as the standards reflect expert opinions, comments from affected parties and scientific findings, all of which are part of the rulemaking record. Second, a standard is more protective of employee health than an enforcement program that is based upon a general provision; consequently, greater reduction of significant risks are achieved. The standard requires more abatement methods than those required by the General Duty Clause and the General Industry Standards. Third, because the standard is much more specific than the current requirements, employers and employees are given more guidance in carrying out the goal of reducing the risks of occupational exposure to bloodborne pathogens. Fourth, the general duty clause and the cited general industry standards impose heavy litigation burdens on OSHA. In each contested case under the current enforcement program OSHA must generally prove that a recognized hazard exists at a particular workplace. In enforcing this standard, which specifies both the conditions which trigger the application of the standard and the abatement obligations, the standard presumes the existence of the hazard and no independent proof of the hazard, i.e. the potential infectivity of blood and certain other body fluids, in the particular workplace need be presented. Furthermore, OSHA need not prove the feasibility of abatement methods where a standard, such as this one, specifies the abatement methods. The reduction in litigation burdens will mean that the Labor Department, as well as the employer, will save time and money in litigation cases. Finally, since states with OSHA-approved state-plans are not required to adopt general duty clauses (29 U.S.C. 667(e)) and thus are not mandated to require the bloodborne pathogen abatement methods which Federal OSHA now requires under section 5(a)(1) (although they are strongly encouraged to do so), employees in state-plan states which do not require these abatement methods are denied protection because, generally, Federal OSHA does not conduct enforcement in these states. Since state-plan states are required to adopt standards at least as effective as Federal OSHA standards (29 U.S.C. 667(c)), the promulgation of this standard will result in increased protection for these employees.

On October 30, 1987, the Departments of Labor and Health and Human Services published a Joint Advisory Notice entitled, "Protection Against Occupational Exposure to Hepatitis B Virus [HBV] and Human Immunodeficiency Virus [HIV]" (52 FR 4161). In the cover letter to employers, Secretaries Brock and Bowen urged the "widest possible adherence to the appropriate precautions as exemplified by the CDC guidelines and the Joint Advisory Notice." The letter, notice and a pamphlet written by OSHA for healthcare workers were mailed to more than 600,000 employers, employee representatives and trade and professional associations.

On November 27, 1987, OSHA published in the **Federal Register** an ANPR announcing the initiation of the rulemaking process (52 FR 45438). The Agency requested information relevant to reducing occupational exposure to HBV and HIV under section 6(b) of the OSH Act. The public was asked to comment on the scope, the modes of controlling exposure, personal protective equipment, vaccination programs, management of exposure incidents, medical surveillance, training and education, generic standards, advances in hazard control, effectiveness of alternative approaches and the environmental effects. A sixty day period was set for comments, and these comments were to be submitted to the OSHA docket by January 26, 1988,

as noted in a correction published in the Federal Register December 11, 1987 (52 FR 47097).

OSHA received an overwhelming response to the ANPR. Interested parties included employers, unions, health professionals, trade representatives, professional associations, manufacturers, and government agencies. The comments were analyzed and the data along with other information in the record were used in preparing a Notice of Proposed Rulemaking (NPRM).

On May 30, 1989, OSHA published the NPRM in the Federal Register (54 FR 23042). In it, the Agency made a preliminary 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 hepatitis B virus which causes Hepatitis B, a serious liver disease, and human immunodeficiency virus, which causes AIDS. The Agency also preliminarily concluded that this significant health risk can be minimized or eliminated using a combination of engineering and work practice controls, personal protective clothing and equipment, training, medical follow-up of exposure incidents, vaccination, and other provisions.

Public hearings on the proposed standard were held in Washington, DC, September 12-27, 1989; Chicago, Illinois, October 17-20, 1989; New York City, November 13-16, 1989; Miami, Florida, December 19-22, 1989; and San Francisco, California, January 9-17, 1990. OSHA presented 10 expert witnesses in the areas of Hepatitis B vaccination programs, infection control, clinical laboratories, hazardous waste, training, engineering controls including equipment design and needlesticks, HBV and HIV research and production facilities, and public safety officers' risks. Over 400 persons, representing the wide range of interested parties including healthcare providers, labor unions, trade and professional organizations, and other affected parties participated in the hearings. At the close of the last public hearing on the proposed standard in San Francisco, January 17, 1990, Administrative Law Judge James Guill set the following deadlines for participants to send material to OSHA: March 20, 1990, for the submission of additional information and April 19, 1990, for submission of comments, summations and briefs. These dates were extended to April 19, 1990, for additional information and May 21, 1990, comments, summations and briefs. In addition, comments from any interested persons or organizations on OSHA's surveys relating to the technological and economic feasibility of implementing the proposed standard in hospital and non-hospital facilities were solicited and required to be postmarked on or before May 21, 1990 (54 FR 10250).

The record of the public hearing includes the following: the original transcript of the hearing, which incorporated the record as a whole; exhibits number 24 to 220, which were received into the record during the hearing; exhibits number 221 to 313, which were received as post-hearing comments; Federal Register notice, 55 FR 10250, extending the comment period and notifying the public of information in the record; and Judge Guill's order of July 23, 1991, receiving the post-hearing submissions and closing and certifying the record of the public hearing in accordance with 29 CFR 1911.17. Copies of materials contained in the record may be obtained from the OSHA Docket Office, room N-2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. The Docket Office is open to the public from 10 a.m. until 4 p.m., Monday through Friday except Federal holidays.

The final standard on occupational exposure to Bloodborne Pathogens is based on full consideration of the entire record of this proceeding, including materials discussed or relied upon in the proposal, the record of the informal hearing, and all written comments and exhibits received.

IV. Health Effects

A. Introduction

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

A discussion of two of the most significant bloodborne pathogens, hepatitis B virus, and human immunodeficiency virus, follows. This includes a discussion of each of the viruses, the disease each causes, modes of transmission, and documented risk of infection resulting from occupational exposure. In addition, a discussion of other bloodborne diseases, hepatitis C, delta hepatitis, syphilis, and malaria, is included.

B. Hepatitis Viruses

Hepatitis means "inflammation of the liver," and can be caused by a number of agents or conditions including drugs, toxins, autoimmune disease, and infectious agents including viruses. The most common causes of hepatitis are viruses. There are four types of viral hepatitis which are important in the U.S. (Exs. 6-449; 6-430; 6-199). Hepatitis A, formerly called "infectious" hepatitis, is spread by fecal contamination and is not generally considered to be a significant risk to healthcare workers, although episodes of transmission to healthcare workers in hospitals have been reported (Exs. 6-449; 6-456; 6-449; 6-456). Hepatitis B, formerly called "serum" hepatitis, is a major risk to healthcare workers and is extensively discussed in this document. Delta hepatitis may coinfect with hepatitis B or may infect persons already infected with HBV and can increase the severity of acute and chronic liver disease in these individuals (Ex. 6-470). Nosocomial infection with this virus has been reported (Ex. 234 Lettau, et al., 1986). Non-A, non-B hepatitis is caused by viral agents other than hepatitis A and hepatitis B. Two that have been identified are hepatitis E, previously known as enterically transmitted (ET) non-A, non-B hepatitis and hepatitis C, previously known as parenterally transmitted (PT) non-A, non-B hepatitis. Hepatitis E is transmitted by the fecal-oral route and has occurred both in epidemic and sporadic forms in parts of Asia, North and West Africa and Mexico. It is not known whether the virus is present in the United States or Western Europe. Parenterally transmitted non-A, non-B hepatitis is caused by at least one bloodborne virus, designated hepatitis C virus (HCV). This virus is efficiently transmitted by blood transfusion and by needle sharing among IV drug users (Exs. 6-430; 6-449; 6-286G). As there are reports of occasional transmission of HCV to healthcare workers, this virus is discussed further in this document (Exs. 6-39; 6-455; 286G).

(1) Hepatitis B

Hepatitis B virus (HBV) infection is the major infectious bloodborne occupational hazard to healthcare workers. The Hepatitis Branch of the Centers for Disease Control (CDC) estimates that there are approximately 8,700 infections in healthcare workers with occupational exposure to blood and other potentially infectious materials in the United States each year (Ex. 298). These infections cause over 2,100 cases of clinical acute hepatitis, 400–440 hospitalizations and approximately 200 deaths each year in healthcare workers. Death may result from both acute and chronic hepatitis. Infected healthcare workers can spread the infection to family members or rarely, to their patients. [For detailed discussion, see section V, Quantitative Risk Assessment.] The use of hepatitis B vaccine, engineering and work practice controls, and personal protective equipment will prevent almost all of these occupational hepatitis B infections. Efforts to reduce blood exposure and minimize puncture injuries in the workplace setting will reduce the risk of transmission of all bloodborne hepatitis viruses.

HBV: Biology

Hepatitis B is caused by the hepatitis B virus (HBV) that attacks and replicates in liver cells (Exs. 6–430; 6–449). The virus has an inner core and an outer shell structure. The inner core contains DNA, enzymes, and various proteins, including the hepatitis B core antigen (HBcAg) and hepatitis B e antigen (HBeAg). The outer shell is composed of a lipoprotein called hepatitis B surface antigen (HbsAg), formerly called the Australia Antigen. The HbsAg is produced in great excess by liver cells replicating the virus, and is found in the form of small spheres and larger tubular particles in the blood of infected persons. The plasma derived hepatitis B vaccines are composed of a highly purified preparation of these excess HBsAg particles which are immunogenic but not infectious. There is a readily available laboratory test for HBsAg, and its presence in blood indicates that an individual is currently infected with the HBV, and is potentially infectious to others. Highly infectious HBV carriers and persons with acute Hepatitis B are also HBeAg-positive.

TABLE IV–1.—HEPATITIS NOMENCLATURE (EX. 286G P. 6, 7)

Abbreviation	Term	Definition/Comments
HBV	Hepatitis B virus	Etiologic agent of "serum" hepatitis also known as Dane particle.
HBsAg	Hepatitis B surface antigen	Surface antigen(s) of HBV detectable in a large quantity in serum; several subtypes identified.
HBeAg	Hepatitis B e antigen	Soluble antigen of HBV; correlates with HBV replication, high titer HBV in serum, and infectivity of serum.
HBcAg	Hepatitis B Core antigen	No commercial test available.
Anti-HBs	Antibody to HBsAg	Indicates past infection with and immunity to HBV, passive antibody from HBIG, or immune response from HB vaccine.
Anti-HBe	Antibody to HBeAg	Presence in serum of HBsAg carrier indicates lower titer of HBV.
Anti-HBc	Antibody to HBcAg	Indicates prior infection with HBV at some undefined time.
IgM anti-HBc	IgM class antibody to HBcAg	Indicates recent infection with HBV; detectable for 4–6 months after infection.
IG	Immune globulin (previously ISG, immune serum globulin, or gamma globulin).	Contains antibodies to HBV lower-titer antibodies to HBV.
HBIG	Hepatitis B immune globulin	Contains high-titer antibodies to HBV.

HBV: Disease Outcomes

Infection with the hepatitis B virus in a susceptible person can produce two types of outcomes: self-limited acute hepatitis B and chronic HBV infection (Exs. 6–430; 6–449). Similarly, the human body can mount two types of response to HBV infection. The most frequent response seen in healthy adults is development of self-limited acute hepatitis and the production of an antibody against HBeAg, called anti-HBs. The production of this antibody coincides with the destruction of liver cells containing the virus, elimination of the virus from the body, and signifies lifetime immunity against reinfection. Persons having this response also develop an antibody against the core protein, called anti-HBc, and usually maintain both anti-HBc and anti-HBs in their blood for life.

Unfortunately, the destruction of liver cells in an attempt to rid the body of this infection often leads to clinically apparent acute hepatitis B. About one third of infected individuals have no symptoms when infected with the virus, one third have a relatively mild clinical course of a flu-like illness which is usually not diagnosed as hepatitis, and one third have a much more severe clinical course with jaundice (yellowing of the eyes and skin), dark urine, extreme fatigue, anorexia, nausea, abdominal pain, and sometimes joint pain, rash, and fever. These symptoms require hospitalization in about 20% of jaundiced cases, and often cause several weeks to months of work loss even in those cases that do not require hospitalization. Fulminant hepatitis, which is about 85% fatal with even the most advanced medical care, develops in about 1–2% of reported acute hepatitis B cases, and an estimated 1 per 1000 HBV infections (Ex. 6–217).

The second type of response—development of chronic HBV infection—has more severe long term consequences (Exs. 6–430; 6–449). About 6% to 10% of newly-infected adults cannot clear the virus from their liver cells and become chronic HBV carriers. These individuals continue to produce HBsAg for many years, usually for life. They do not develop anti-HBs, but do produce anti-HBc antibody. HBV carriers are at high risk of developing chronic persistent hepatitis, chronic active hepatitis, cirrhosis of the liver, and primary liver cancer. About 25% of carriers develop chronic persistent hepatitis, a relatively mild, non-progressive form of chronic liver disease, and 25% develop chronic active hepatitis. The latter is a progressive, debilitating disease that often leads to cirrhosis of the liver after 5–10 years (Exs. 5–5; 6–448). Patients with end-stage cirrhosis may develop ascites (fluid accumulation in the abdomen), esophageal bleeding from distended veins (causing patients to vomit large volumes of blood), coma, and death. Chronic HBV infection has been estimated to cause 10% of the 25,000–30,000 deaths that occur due to cirrhosis in the U.S. each year (Ex. 6–199).

The DNA of HBV in chronic carriers can integrate into the DNA of the host

liver cell. This integration may lead to malignant transformation of the liver cell, and development of primary hepatocellular carcinoma (PHC) (Exs. 6–419; 6–443). PHC is almost uniformly fatal if diagnosed after symptoms appear. Patients with PHC usually die within four to six months after diagnosis. PHC usually develops in HBV carriers after a latency period of 20 to 60 years. In parts of the world where HBV infection is a common childhood infection, PHC is one of the leading causes of cancer death. In Taiwan, for example, Beasley and colleagues have found that 5 per 1000 adult male HBV carriers develop PHC each year, and estimate that approximately 25% of all HBV carriers, and 40% of male HBV carriers, will die from either PHC or cirrhosis (Ex. 6–419). The relative risk of developing PHC in an HBV carrier compared to a non-carrier in his studies is 100. Studies in the United States and in Great Britain, where HBV infection usually occurs in adulthood, have shown 13 to 40 fold increased risk of developing PHC among HBV carriers (Exs. 6–640; 6–444). This may be compared to the relative risk of lung cancer in smokers vs. non-smokers of 10–20. Studies in many other populations worldwide have confirmed this extremely high relative risk.

The causal link between HBV carriage and PHC is not only based on epidemiologic studies, but is confirmed by both animal and molecular biological studies (Exs. 6–449; 6–443). Other animal species can become infected with HBV-like viruses (which belong to the same virus family—Hepadna viruses), and woodchucks, Pekin ducks, ground squirrels, and other species that become infected may develop a carrier state. These carrier animals develop primary liver cancers at very high rates. Molecular biological studies have shown that PHC tumor cells contain integrated HBV DNA in virtually all humans and animals cases of PHC (Ex. 6–443).

There is likely a higher risk of developing PHC if infection occurs from perinatal (mother to child) transmission, or from infection during childhood than from infection in adulthood. Although persons who develop HBV carriage during adulthood are at increased risk of developing PHC, the exact risk of developing PHC following adult infection has not been established. The risk observed in blood donors in the United States is probably an underestimate, as PHC is most likely in persons with chronic liver disease or cirrhosis and who are excluded from such studies because they cannot be blood donors. In addition, many carriers will die of other causes before they develop PHC because of the long latency of this cancer. Nevertheless, it has been estimated that, in the U.S., about 25%–33% of all PHC cases, or 750–1000 PHC cases annually, result from HBV infection.

HBV: Modes of Transmission

Workplace: HBV is spread via several routes: parenteral (by direct inoculation through the skin), mucous membranes (blood contamination of the eye or mouth), sexual, and perinatal (from infected mother to newborn infant) (Exs. 6–430; 6–449). The most efficient mode of transmission is direct inoculation of infectious blood, such as might occur during blood transfusion, needle sharing by IV drug users, or needlestick or other sharp instrument injury in health care workers. One milliliter of HBsAg positive blood may contain 100 million infectious doses of virus; thus, exposure to extremely small inocula of HBV-positive blood may transmit infection. In different studies, 7% to 30% of susceptible healthcare workers sustaining needlestick puncture injuries from HBsAg positive patients became infected if they did not receive post-exposure prophylaxis (Exs. 4–27; 4–28). Since 1972, all units of blood collected for transfusion in the U.S. have been screened for HBsAg, greatly decreasing the incidence of transfusion related HBV infection.

Blood and blood-derived body fluids (serous exudates and fluids from internal body cavities) contain the highest quantities of virus and are the most likely vehicles for HBV transmission (Exs. 6–430; 6–449). Certain other body fluids such as saliva and semen contain infectious virus but at 1000-fold lower concentration (Ex. 6–445). Other body fluids such as urine or feces contain only small quantities of virus unless they are visibly contaminated with blood.

Direct inoculation of infectious blood may occur in less apparent ways. Preexisting lesions on hands from injuries incurred at the workplace or at home or from dermatitis may provide a route of entry for the virus (Ex. 6–427). In addition, transfer of contaminated blood via inanimate objects or environmental surfaces has been shown to cause infection in the healthcare workplace (Exs. 6–464; 6–433; 4–461). In general, fewer than 20% of infected healthcare workers report discrete needlestick injuries from a known infected patient. The importance of this finding should not be underestimated. Although gloving will not stop direct puncture injuries, it can provide a barrier between blood and an open lesion.

Infectious sera placed in both the eye and mouth of experimental animals has induced HBV infection (Exs. 6–430; 6–449). Splashes of blood or serum into the individual's eye or mouth in clinical settings or in the laboratory must be regarded as potentially serious exposures. While there has been concern about the potential infectivity of aerosols generated by dental, medical, and laboratory equipment, and although HBsAg may be found in large particles of "spatter" that travel short distances, OSHA is not aware of any data that link HBV transmission with aerosols through inhalation.

Transmission in Other Settings

Sexual transmission of HBV infection is an efficient mode or viral spread as HBsAg has been found in both semen and vaginal secretions (Exs. 6–430; 6–445). Deposition of virus onto mucous membranes and trauma to tissue causing small lesions may both play roles in transmission. Approximately 30% of spouses or regular sexual partners of acutely infected HB patients become infected. Spouses of chronic carriers, who have a much longer duration of infectivity, escape infection less frequently. Preventing transmission of HBV infection to the spouse/sexual partners of infected healthcare workers is an additional benefit derived from and reason for controlling this disease (Ex. 6–425).

Non-sexual family contacts of HBV carriers are also at risk of infection. Although the relative importance of various transmission modes has not been determined in families, in various studies about 40–60% of household contacts of carriers identified by blood donation had markers of HBV infection (Exs. 6–420; 6–430). Daily exposure to the carrier for many years presents occasions for sharing razors or toothbrushes, exposure to blood and other events that could result in infection. Family contacts of adopted carrier children have been shown to have a higher prevalence of infection than families who do not live with a carrier.

Perinatal infection with the HBV is an efficient mode of transmission with particularly severe consequences. Mothers positive for both HBeAg and HBsAg will infect 70% to 90% of their newborns, most of whom will become chronic HBV carriers (Exs. 6–419; 6–199). These carriers have a 25% chance of dying from cirrhosis or PHC. They also remain infectious to others and can perpetuate the cycle of perinatal transmission. Fortunately, treatment of newborns at birth with hepatitis B immune globulin (HBIG) and hepatitis B

vaccine is 85% to 95% effective in preventing these infants from becoming carriers (Exs. 6–419; 6–199). To be able to treat these infants at birth, their mothers must be recognized as carriers before delivery. The Immunization Practices Advisory Committee (ACIP) of the U.S. Public Health Service has recommended that all pregnant women in the U.S. be screened for HBsAg during an early prenatal visit (Ex. 6–424). Because pregnant healthcare workers may, if infected, transmit HBV to their newborn infants, prevention of HBV infection is critical in women of child bearing years who work in occupations where they are at risk for exposure.

HBV: Epidemiology

HBV infection does not occur uniformly in the U.S. population. There is a substantial difference in the reported numbers of hepatitis B cases by geographical region. The presence of certain populations with a high percentage of individuals who are carriers may result in higher prevalence rates for certain defined areas, such as parts of Alaska and the U.S. Trust Territories. HBV infection is more prevalent in certain ethnic and racial groups, and is especially prevalent in certain "high risk" groups defined by occupation and lifestyle (Exs. 6–430; 6–449; 6–199). The prevalence of HBV antibodies in the general population, reflecting the percentage of the population ever infected, is 3% to 4% for whites and 13% to 14% for blacks (Ex. 6–390). Foreign born Asians have a prevalence of antibody of greater than 50%. The HBsAg prevalence, reflecting the percentage of the population who are HBV carriers, is 0.2% for whites, 0.7% for blacks, and up to 13% for foreign born Asians. The high prevalence in the last group is a reflection of the fact the most HBV infections in Asia occur in childhood.

The ACIP has listed a number of groups who are at substantial risk for HBV infection and should receive the hepatitis B vaccine (Ex. 286G). Healthcare workers and public safety workers, who have contact with blood or certain body fluids, and staff of institutions for the developmentally disabled are included on this list.

Transmission to Healthcare Workers: Although outbreaks of clinical hepatitis have been reported for many years (Exs. 6–438; 6–459), it was not until the 1970's that the risk to healthcare workers from HBV infection was well defined. The first studies noted that dentists were more likely than attorneys to have had clinical hepatitis (Ex. 6–441). When HBsAg and antibody testing became available, it was possible to show that the type of hepatitis that occurred more commonly in healthcare workers was hepatitis B. Dentists and physicians were 4 to 10 times more likely to have serologic markers indicating previous HBV infection than first time blood donors, and the prevalence of markers increased significantly with years in practice (Exs. 6–440; 6–65; 4–13; 4–16; 4–12; 4–15; 6–68).

During the next decade, dozens of studies were published measuring the prevalence of HBV markers in various healthcare occupational groups, and in various healthcare settings (Exs. 6–427; 6–88; 6–72; 6–54; 6–53; 6–44; 640; 4–14). The prevalence of markers was studied in hospitals of all sizes and types, in various sized communities, serving all types of populations. Studies were also done on a wide variety of individual occupational groups at meetings and through special studies. Most of the studies relied upon the voluntary cooperation of the study population, so there is some chance for bias to be introduced into any estimate of HBV prevalence. Healthcare workers who know they are infected with HBV at the time of study or who know they are HBV carriers may decline to participate in a study which they may feel could jeopardize their careers. This would lead to an underestimate of the prevalence of HBV infection among health care workers. The most useful studies showed that risk of HBV infection in hospital personnel was increased several-fold over that in blood donors, that risk was closely related to frequency of contact with blood and not related to contact with patients per se, and that risk was directly related to duration in the occupation (Exs. 6–440; 6–65; 4–12; 4–13; 4–15; 4–16). Certain studies attempted to quantify the frequency of blood and needle exposure in various categories of healthcare workers, and relate this to risk of infection (Ex. 4–16). The following general observations can be made from these studies:

(1) These studies revealed that workers exposed to blood on the job had a prevalence of HBV markers several times that of non-exposed workers and the general population. The prevalence of markers increased with years on the job.

(2) The prevalence of HBV markers was related to the degree of blood exposure or frequency of needle exposure, and not to patient contact per se. Persons working in operating rooms, emergency rooms, labs, and dialysis units had a higher marker prevalence than persons working on medical or pediatric wards, who in turn had a higher prevalence than clerical workers, social workers, and administrators.

(3) Groups at high risk include (but are not limited to): medical technologists, operating room staff, phlebotomists and intravenous therapy nurses, surgeons and pathologists, oncology and dialysis unit staff, emergency room staff, nursing personnel, staff physicians, dental professionals, laboratory and blood bank technicians, emergency medical technicians, and morticians (Ex. 6–199).

Most infected healthcare workers are unaware that they have been exposed to or infected with HBV. Approximately 1% (or more) of hospitalized patients are HBV carriers; most HBV carrier patients seen in the healthcare setting are not symptomatic, are unaware that they are carriers, and their medical charts do not contain this information (Ex. 6–427). Health care workers may take extraordinary precautions when dealing with a known carrier, but are often unaware that they may treat five carriers for each one they recognize. This is a key point in understanding the rationale for the concept on "universal precautions," and for use of the hepatitis B vaccine in workers with exposure to blood. Although the risk of encountering HBV carriers may vary in the hospital setting, being highest in inner city referral hospitals dealing with high risk groups such as drug abusers and homosexual men, risk will be present in any work setting where human blood is encountered. The risk of HBV carriage in the general population is uniform (i.e. does not markedly vary within each region of this country), and high risk groups such as Southeast Asian refugees, the developmentally disabled individuals, and occult drug abusers may be found in rural as well as urban settings (Ex. 6–390).

Percutaneous exposure to blood through needlesticks and cuts with other sharp instruments are visible and efficient modes of transmission, but reported injuries do not account for the majority of infections in healthcare workers (Exs. 6–65; 6–427). This fact often goes unrecognized by worker's compensation boards, which sometimes deny coverage to infected workers unless they had reported a discrete needlestick or similar injury from a HBsAg positive patient. Some workers doing traumatic procedures get cuts, needlesticks or large blood exposures so frequently that they do not bother to report them; other workers become infected when the blood of an unsuspected HBV carrier gets into a small preexisting skin lesion or is rubbed into the eye. Prevention of these occupational infections is the goal of this standard.

Transmission from HCWs to Patients: Transmission of HBV from healthcare workers to patients is an uncommon but extremely serious consequence of healthcare worker infection. More than twenty clusters of patients infected in this way have been reported, although instances involving only one or a few patients may go unrecognized or unreported (Exs. 6–103; 6–446; 6–476; 4–471; 6–144). Most clusters of these cases have involved oral surgeons, dentists, gynecologists, or surgeons, occupations where significant blood exposure, trauma, and use of sharp instruments occur routinely. Some episodes have involved transmission to between 20 and 55 patients, with deaths and secondary transmission to family members of patients occurring (Exs. 6–103; 6–144).

Most healthcare workers who have transmitted to patients have several factors in common (Exs. 6–476; 6–471):

(1) The dentists and surgeons were chronic HBV carriers, had high titers of virus in their blood (HBeAg positive), and were unaware that they were infected.

(2) Transmission occurred most frequently during the most traumatic procedures.

(3) The dental personnel who transmitted did not routinely wear gloves. However, some infected HCWs continued to transmit HBV to patients in spite of the use of gloves and additional precautions.

(4) The dentists and surgeons often had a personal medical problem (such as exudative dermatitis on the hands), or used techniques that made transmission more likely. Several of the gynecologists used their index fingers to feel for the tip of the suture needle when they were performing deep abdominal surgery.

The most recent guidelines for HIV and HBV infected healthcare workers were published after the record for this rulemaking closed and are not contained in the record. These guidelines, "Recommendations for Preventing Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Patients During Exposure-Prone Invasive Procedures," were published in Morbidity and Mortality Weekly Report, Vol. 40, on July 12, 1991.

Transmission Via the Environment: Transmission of HBV infection from exposure to contaminated environmental surfaces has been documented to be a mode of HBV spread in certain settings, particularly hemodialysis units (Exs. 6–56; 6–446; 6–480; 6–461). The virus can survive for at least one week dried at room temperature on environmental surfaces, and medical procedures as well as disinfection and sterilization techniques must be adequate to prevent the spread of this virus (Exs. 6–422; 6–458). HBV contaminated blood from the surface of dialysis machines and carried on the hands of medical personnel to patients has been postulated as one mechanism of transmission in dialysis units. Unsterilized or improperly sterilized acupuncture needles have been implicated as the cause of two outbreaks of HBV infection in patients (Ex. 6–439). Potential problems of environmental contamination in the dental operatory have been discussed in the CDC guidelines for dentistry (Ex. 6–490).

HBV is thought to be far less resistant to sterilization and disinfection procedures than microbial endospores or mycobacteria used as reference criteria (Ex. 6–421). Any sterilization or disinfection procedure or sterilizing agent or high level disinfectant will kill the virus if used as directed. Diluted solutions (1:10–1:100) of sodium hypochlorite (household bleach) are particularly effective, if used properly, and inexpensive, although they may be corrosive or damaging to certain materials. Certain low-level "germicides" such as quaternary ammonium compounds are not considered to be effective against the virus (Ex. 6–422). Unfortunately, soaking medical and dental instruments in these solutions is a common and potentially dangerous procedure, since health workers may handle the sharp instruments soaked in these solutions with a false sense of security.

Hepatitis B Vaccine

In 1982 a safe, immunogenic and effective hepatitis B vaccine derived from human plasma was licensed in the U.S. and was recommended for use in healthcare workers with blood or needle exposure in the workplace (Ex. 6–199). A second vaccine, produced in yeast by recombinant technology was first licensed in 1987 (CDC, Ex. 6–200). Since the introduction of these vaccines, OSHA estimates a minimum of 2,568,974 persons in the United States have been vaccinated, 2,029,189 of whom are healthcare workers. HB vaccination is the most important part of any HBV control program, because gloving and other protective devices cannot completely prevent puncture injuries from needles and other sharp instruments.

Early efforts to immunize healthcare workers were hindered by fear that the plasma derived vaccine might be unsafe. The AIDS epidemic was just being recognized, and there was concern that the plasma derived hepatitis B vaccine might contain the infectious agent causing AIDS. Concerns about the safety of the plasma derived vaccine have been adequately studied and addressed (CDC, Ex. 6–199). The procedures used to manufacture the vaccine were shown to inactivate HIV virus and representatives of all known viral groups. The vaccine was shown not to contain HIV DNA, and those receiving vaccine do not develop anti-HIV antibodies. This vaccine is no longer available in the U.S. The yeast-derived vaccines contain no human plasma and there is no possibility that they could be infectious for HIV (6–200).

The currently licensed hepatitis B vaccines are given intramuscularly in the deltoid, in three doses over a six month period. These vaccines, when given according to manufacturers directions, induce protective antibody levels in 85% to 97% of healthy adults. Protection against both the illness and the development of the carrier state lasts at least nine years (the duration of follow-up studies) and perhaps considerably longer. Although antibody in many individuals will decay below detectable levels within seven years after immunization, if these individuals are exposed to HBV, they develop a rapid (anamnestic) antibody response and do not become ill or develop the HBV carrier state (Exs. 6–200; 6–435). For persons with normal immune status, the ACIP has not recommended that a booster dose of hepatitis B vaccine be given after the initial series but may do so in the future if it appears that immunity conferred by the vaccine wanes after some period of time. However, vaccine-induced protection is less complete for hemodialysis patients and may last only as long as antibody levels remain above 10 mIU/ml. For these individuals, the need for booster doses should be assessed by annual antibody testing. Booster doses should be given when antibody levels fall below 10 mIU/ml (Ex. 286G).

Persons planning hepatitis B vaccine programs may consider the need for pre-vaccination and post-vaccination testing for antibody (Exs. 6–200; 6–199). Prescreening may be cost-effective, depending on the likelihood of prior HBV infection. An algorithm to help assist with this determination has been published by the ACIP (Ex. 6–199). Discussions on the issues surrounding the option of post-vaccination testing have also been published. At this time post-vaccination testing is not considered necessary unless poor response to vaccine is anticipated (such as for those who have received vaccine in the buttock, persons $\geq$ 50 years of age and persons known to have HIV infection), subsequent patient management depends on knowing the immune status (such as with dialysis

patients and staff) or there may be a need to know whether the person ever responded to vaccine for management of post-exposure prophylaxis (Ex. 286G).

Post-exposure prophylaxis

Percutaneous and mucous membrane exposures to blood occur and will continue to occur in the healthcare setting (Exs. 6–431; 6–468). HBV infection is the major infectious risk that occurs from these exposures, and needlesticks from HBsAg positive individuals will infect 7% to 30% of susceptible healthcare workers (Exs. 6–27; 4–28). Pre-exposure vaccination is the most effective method for preventing such infection. However, it can be expected that some individuals, who initially decline vaccination, will experience an exposure incident. Fortunately, effective post-exposure prophylaxis exists for HBV exposures if appropriate protocols are followed. The February 9, 1990 recommendations of the Immunization Practices Advisory Committee specify that if the source individual is known to be HBsAg-positive then the exposed individual should be given hepatitis B immunoglobulin (HBIG) and the hepatitis B vaccine series be initiated (286G). Hepatitis B vaccine is recommended for any previously unvaccinated healthcare worker who has a needlestick or other percutaneous accident with a sharp instrument or permucosal (ocular or mucous membrane) exposure to blood (Ex. 286G, p. 19).

(2) Non-A, non-B hepatitis

Non-A, non-B hepatitis in the United States is caused by more than one viral agent (Exs. 6–437; 6–429; 6–449). Studies have shown that parenterally transmitted (PT) non-A, non-B hepatitis accounts for 20–40% of acute viral hepatitis in the U.S. and has epidemiologic characteristics similar to those of hepatitis B (Ex. 6–39). Recently, a virus designated as Hepatitis C virus (HCV) was cloned and has been shown to account for a large proportion of parenterally transmitted non-A, non-B hepatitis in this country (CDC/NIOSH, Ex. 298). An immunoassay that detects antibody to HCV has been developed and was licensed in May 1990 for use in screening blood donors. Because the test is so new, there is not enough data to define how important this pathogen is in the occupational setting. Further research will help in clearly defining the importance of bloodborne transmission of this virus in the workplace.

The principal mode of transmission in the United States is bloodborne; therefore, persons at greatest risk for infection include IV drug users, dialysis patients and transfusion recipients. Over 90% of all post-transfusion hepatitis is due to the non-A, non-B virus(es). These hepatitis viruses cause not only acute hepatitis, but may also lead to chronic hepatitis; an average of 50% of patients who have acute PT non-A, non-B hepatitis infection later develop chronic hepatitis with potential for progression to cirrhosis and for infectivity to others for the duration of life (Exs. 6–429; 6–449, 286G). The amount of virus present in the blood of acutely or chronically infected persons is modest, usually less than 1,000 infectious doses per milliliter, although occasionally up to 1,000 times higher (Ex. 6–423). Thus, relative infectivity of blood is 100 to 100,000 fold lower than with hepatitis B virus. Relative infectivity of other body fluids is not known.

Some evidence indicates that non-A, non-B hepatitis also presents an occupational risk to healthcare workers. At least one episode of transmission of non-A, non-B hepatitis from an acutely infected patient to a nurse by needlestick has been reported (Ex. 6–455). One case-control study has shown an increased risk of non-A, non-B hepatitis for patient care and lab workers (Ex. 6–39). Furthermore, non-A, non-B hepatitis transmission from infected patients to other patients and to staff has been reported in hemodialysis units; several outbreaks have been observed in this setting, and an incidence of 1.8% of non-A, non-B hepatitis among hemodialysis patients nationwide was observed in 1983 (Exs. 6–462; 6–386). While pathways of transmission in this setting have not been rigorously documented, nor has survival of HCV been defined, bloodborne transmission by environmental contamination, similar to that of HBV, may occur.

In their May 1990 post-hearing comment, CDC/NIOSH supplied some additional information about non-A, non-B hepatitis and hepatitis C virus (HCV).

Non-A, non-B hepatitis is poorly reported at a national level and the best estimates of U.S. disease burden and risk groups come from the CDC Sentinel Counties Study of Viral Hepatitis. Extrapolating from this surveillance study, it is estimated that there were 170,000 non-A, non-B hepatitis infections in the U.S. 1988. Of these 3,400 (2%) were among health care workers. The estimates of non-A, non-B hepatitis attributable to occupational exposure come from the Sentinel Counties Study. In 1988, 2% of cases of non-A, non-B hepatitis were related to occupational exposure.

Recently, a virus has been cloned that appears to account for a large proportion of cases of non-A, non-B hepatitis in the U.S. and has been designated hepatitis C virus (HCV). In May 1990, an immunoassay that detects antibody to HCV (anti-HCV) was licensed for use in screening blood donors. Preliminary studies indicate that approximately 70% of patients with non-A, non-B hepatitis in the U.S. are anti-HCV positive when tested at the appropriate time in the course of their illness. At this time no data are available on the rate of HCV infection among health care workers or the risk of infection from various exposures. However, it is known that the risk of chronic liver disease following acute non-A, non-B hepatitis is approximately 50% (CDC/NIOSH Ex. 298).

Because the primary mode of transmission is blood to blood contact, and a large asymptomatic carrier reservoir exists, precautions to prevent non-A, non-B hepatitis transmission in the workplace are identical for those of other bloodborne viruses such as HBV (Exs. 6–461; 6–74; 6–426). Several studies have evaluated the efficacy of immunoglobulin (IG) prophylaxis following parenteral exposure, but results have been equivocal (Exs. 6–447; 6–436). Nevertheless, the CDC considers it reasonable to give IG as treatment to a healthcare worker after percutaneous exposure to blood from a known non-A, non-B infected patient (Ex. 6–199).

C. Human Immunodeficiency Virus

In June of 1981, the first cases were reported in the United States of what was to become known as Acquired Immunodeficiency Syndrome (AIDS) (Ex. 6–382). Investigators described an unusual illness characterized by *Pneumocystis carinii* pneumonia (PCP) and Kaposi's sarcoma (KS) that developed in young, homosexual men without a known underlying disease or cause for immunosuppression (Exs. 6–359; 6–380).

By early 1982, 159 AIDS cases had been identified in 15 states, the District of Columbia and 2 foreign countries. All but one of them were men and over 92% of them were homosexual or bisexual (Ex. 6–359). By the end of 1982, cases of AIDS were reported among children, intravenous (IV) drug users, blood transfusion recipients, hemophilia patients treated with clotting factor concentrates, and Haitians (Exs.6–380; 6–349). In 1983 the disease was also documented among female sexual partners of male IV drug users in the U.S. and among Africans (Ex. 6–349). By the end of 1985, all 50 states, the District of Columbia and three U.S. territories had reported AIDS cases (Ex. 6–359).

During 1983 and 1984, French and American scientists independently isolated a human virus associated with

AIDS. Dr. Luc Montagnier and co-workers, of the Institute Pasteur in Paris, called it lymphadenopathy associated virus (LAV). Dr. Robert Gallo and co-workers at the National Cancer Institute identified this virus as human T-cell lymphotropic virus type III (HTLV-1) (Ex. 6-380). Eventually human immunodeficiency virus type 1 (HIV-1) became the universally accepted term for the virus (Ex. 6-383). (In this document, unless specifically noted, HIV refers to HIV-1.)

The Centers for Disease Control estimates that in the United States, between 1 million and 1.5 million persons are infected with HIV-1 (Ex. 6-356). In addition, CDC reports in the August 1991 issue of HIV/AIDS Surveillance that as of July 1991, 186,895 cases of AIDS had been reported to the CDC, 3,199 of whom are children less than 13 years old. At least 116,734 (63.5%) of the adult/adolescent cases had died as well as 1,677 (52.4%) of the pediatric cases. Although the rate of spread of HIV-1 in the future is unknown, scientists with the U.S. Public Health Service have estimated that in the United States alone, a cumulative total of more than 365,000 cases of AIDS will have been reported by the end of 1992 with 80,000 new cases diagnosed during that year (Ex. 6-356). It is projected that there will be 66,000 deaths that year and 263,000 cumulative deaths. It is expected that a total of 172,000 AIDS patients will require medical care in 1992.

Of perhaps greater importance for healthcare workers is the 1.0 to 1.5 million persons who are infected with HIV, often unknowingly so, and who require medical treatment for related or unrelated conditions. For example, in 1987, Baker and colleagues examined 203 anonymous serum samples from a group of critically ill or severely injured patients with no history of HIV infection treated at the Johns Hopkins University Hospital Department of Emergency Medicine (Ex. 6-111). They found that six patients (3% of the sample) were seropositive for HIV antibody. In particular, all seropositives were trauma victims between the ages of 25 and 34 who were bleeding and their treatment involved multiple invasive procedures. In a more recent study in 1988 at an inner city emergency department, Kelen and co-workers tested blood samples from 2,302 consecutive adult patients for the presence of HIV antibodies. One hundred nineteen patients (5.2%) were seropositive for HIV. Of this group 92 (77%) had "unrecognized HIV infection" (Ex. 6-370).

There are reports of at least 30 healthcare workers who apparently were infected with HIV through occupational exposure to blood or other potentially infectious materials (Ex. 286U). Of the cases of HIV infection associated with occupational exposure discussed in this section, five occurred outside the United States. The number of known work related HIV seroconversions among healthcare workers is approximately 24 at present. However, many infections are likely to go unrecognized for several years until the HIV-infected individual develops AIDS. If effective preventive procedures are not instituted, the number of occupational HIV infections is likely to increase as the number of infected individuals requiring healthcare increases.

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

HIV: Biology

HIV is a member of a group of viruses known as human retroviruses. Its genetic material is ribonucleic acid (RNA) rather than deoxyribonucleic acid (DNA), the genetic material found in most living organisms. The virus particle is comprised of a core containing the RNA and viral enzymes surrounded by an envelope consisting of lipids and proteins (Ex. 6-380, p.131-154).

Because they lack the cellular machinery necessary to reproduce, all viruses must reproduce intracellularly, that is, within the host cell. HIV replicates in human macrophages and T4 lymphocytes, two types of human cells that are vital components of the immune system. T4 lymphocytes and a few other cell types have protein molecules on their surfaces called CD4 antigens or receptors. HIV particles bind with the CD4 receptor sites of the hosts' cells and then release their viral RNA. The RNA is then transcribed by viral enzymes into double-stranded DNA that is incorporated into the DNA of the host cell. The viral DNA then serves as a template to produce more virus particles. The transcription of RNA to DNA is the reverse of what occurs in most organisms and thus HIV is called a retrovirus. The process occurs with the aid of the viral enzyme reverse transcriptase, which is considered to be a marker for retrovirus production (Exs. 6-384; 6-175; 6-380, pp. 186-249). HIV gradually depletes the number of cells which are essential for host immune function, rendering the infected individual increasingly susceptible to opportunistic infections (Exs. 6-360; 6-380, pp. 131-154).

Circulating macrophages are also considered a reservoir as well as another target for HIV infection. Since some macrophages can circulate freely throughout the body, they may actually transport HIV to the brain which may lead to neurologic complications (Ex. 6-384).

HIV: Serological Testing

Infection with HIV may be identified through testing the blood for the presence of HIV antibodies. Tests were first licensed for use in the United States in 1985 and have been used routinely to screen donated blood, blood components and blood products, and by physicians and clinics to diagnose HIV infection in patients (Ex. 6-380, pp. 1-17). The military also uses the antibody tests to screen recruit applicants and active duty personnel for HIV infection (Ex. 6-380, pp. 1-17). Although the antibodies do not appear to defend or protect the host against HIV, they serve as markers of viral infection. Most people infected with HIV have detectable antibodies within 6 months of infection, with the majority generating detectable antibodies between 6 and 12 weeks after exposure (Ex. 6-204).

The enzyme-linked immunosorbent assay (ELISA or EIA) technique used to detect HIV antibodies is sensitive, economical and easy to perform. However, as with all laboratory determinations, this test can produce a false positive result, that is, the test gives a positive result when HIV antibody is not present. Therefore, current recommendations include repeating the ELISA test if the first test is positive. If the second test is also positive, another test, usually employing the Western blot technique, is used to validate the ELISA results. A positive ELISA test and a positive Western blot result indicate the presence of HIV antibodies and HIV infection (Ex. 6-345).

Although many new tests are still in the experimental stages, one that is being developed uses the polymerase chain reaction (PCR) technique. This test detects integrated viral DNA rather than antibody and it may have the potential to detect HIV infection earlier than currently available antibody tests (Ex. 6-329).

HIV: Transmission

HIV has been isolated from human blood, semen, breast milk, vaginal secretions, saliva, tears, urine,

cerebrospinal fluid, and amniotic fluid; however, epidemiologic evidence implicates only blood, semen, vaginal secretions and breast milk in the transmission of the virus (Ex. 6–317). Documented modes of HIV transmission include: Engaging in sexual intercourse with an HIV-infected person; using needles contaminated with the virus; having parenteral, mucous membrane or non-intact skin contact with HIV-infected blood, blood components or blood products; receiving transplants of HIV-infected organs and tissues including bone, or transfusions of HIV-infected blood; through semen used for artificial insemination and perinatal transmission (from mother to child around the time of birth) (Exs. 6–349; 6–327; 6–310; 286U).

HIV is not transmitted by casual contact. Studies evaluating nearly 500 household contacts of individuals diagnosed with AIDS reveal no cases of HIV infection of household members who had no other risk factors for the virus (including no sexual contact with or exposure to blood from the infected person) (Ex. 6–349). Friedland and Klein examined household members who lived with a person with AIDS for at least 3 months and within an 18-month period prior to the onset of symptoms in the infected person (during which time infection was presumably present). Other household members had been unaware of the infected individual's HIV status, and had not taken precautions during this time period (Ex. 6–349). This study produced no evidence that HIV was transmitted by shaking hands or talking, by sharing food, eating utensils, plates, drinking glasses or towels, by sharing the same house or household facilities or by "personal interactions expected of family members" including hugging and kissing on the cheek or lips. Other studies have shown that HIV is not transmitted by mosquitoes or other animals (Ex. 6–328).

The vast majority of people with AIDS in the United States can be placed in known transmission categories and the proportion of infected persons associated with each group has remained relatively stable since reporting began in this country in 1981. For adults and adolescents, the transmission categories are shown in Table IV–2. Table IV–3 displays the transmission categories for children less than 13 years old.

TABLE IV–2[1].—AIDS TRANSMISSION CATEGORIES

Transmission group	Percent of cumulative total of AIDS cases for adults/ adolescents
Homosexual/bisexual men	59
Intravenous drug users (female and heterosexual male)	22
Homosexual/bisexual contact and IV drug users	7
Hemophilia/coagulation disorder	1
Heterosexual contact	5
Sex with IV drug user; Sex with person with hemophilia; Sex with bisexual male; Sex with transfusion recipient with HIV infection; Sex with HIV-infected person risk not specified; Born in Pattern II country.[2]; Sex with person born in Pattern II country.	
Receipt of blood transfusion, blood components or tissue [3]	2
Other/Undetermined [4]	4

[1] HIV/AIDS Surveillance, August, 1991, p. 8.
[2] Pattern II transmission is observed in areas of central, eastern and southern Africa and in some Caribbean countries. In these countries, most of the reported cases occur in heterosexuals and the male-to-female ratio is approximately 1:1. Intravenous drug use and homosexual transmission either do not occur or occur at a low level.
[3] Includes 14 transfusion recipients who received blood screened for HIV antibody and 1 tissue recipient.
[4] "Other" refers to 3 healthcare workers who seroconverted to HIV and developed AIDS after occupational exposure to HIV-infected blood. "Undetermined" refers to patients whose mode of exposure to HIV is unknown. This includes patients under investigation; patients who died, were lost to follow-up, or refused interview; and patients whose mode of exposure to HIV remained undetermined after investigation.

TABLE IV–3.[1]—AIDS TRANSMISSION CATEGORIES

Pediatric (<13 years old) exposure category. Transmission group cases	Percent of cumulative total of pediatric AIDS cases
Hemophilia/coagulation disorder	5
Mother with/at risk for HIV infection:	84
IV drug use	
Sex with IV drug user	
Sex with bisexual male	
Sex with person with hemophilia	
Born in Pattern-11 country	
Sex with person born in Pattern-11 country	
Sex with transfusion recipient with HIV infection	
Sex with HIV-infected person, risk not specified	
Receipt of blood transfusion, blood components, or tissue	
Has HIV infection, risk not specified	
Receipt of blood transfusion, blood components, or tissue	9
Undetermined	2

[1] HIV/AIDS Surveillance, August 1991, p. 9.

Some types of exposures are clearly more efficient at transmission than others. The risk of infection following receipt of transfused blood from an HIV-infected donor is approximately 90 percent (Ex. 6–371). The risk of perinatal transmission from an HIV infected mother is estimated to be 30–50 percent or higher (Exs. 6–384; 6–349). Besides the particular type of exposure, other variables contributing to the likelihood of transmission may include susceptibility of the host, the virulence of the particular strain, the stage of infection of the source, and the size of inoculum the individual is exposed to (Exs. 6–348; 6–349). This last factor, the actual amount of virus, may be very important in the likelihood of transmission since, it appears, there is a greater probability of infection from HIV contaminated blood transfusions (890 infections per 1,000 persons transfused with contaminated blood) than from accidental needlesticks with needles that have been contaminated with HIV (3–5 infections per 1,000 persons injured with contaminated needles) (Exs. 6–384; 6–349; 6–371).

HIV: Clinical Manifestations of Disease

HIV adversely affects the immune system, rendering the infected individual vulnerable to a wide range of clinical disorders. These conditions, some of which tend to recur, can be aggressive, rapidly progressive, difficult to treat, and less responsive to traditional modes of treatment. They usually lead to the death of the HIV infected patient (Ex. 6–361). The CDC has divided disease progression into several stages according to types of infections or symptoms reported.

Group I: Within a month after exposure, an individual may experience acute retroviral syndrome, the first clinical evidence of HIV infection. This is a mononucleosis-like syndrome with signs and symptoms that can include fever, lymphadenopathy, myalgia, arthralgia, diarrhea, fatigue, and rash. Acute retroviral syndrome is usually self-limiting and followed or accompanied by the development of antibodies (Ex. 6–270).

Group II: Although most persons infected with HIV develop antibodies to the virus within 6–12 weeks after exposure, most of these individuals are asymptomatic for months to years following infection. However, they can transmit the virus to others throughout this time (Ex. 6–270).

Group III: Although no other signs or symptoms are experienced, some HIV-infected patients will develop a persistent, generalized lymphadenopathy (PGL) that lasts more than 3 months (Ex. 6–270).

Group IV: Epidemiologic data indicates that most persons who are infected with HIV will eventually develop AIDS (Ex. 6–384). AIDS can result in severe opportunistic infections that an individual with a normal immune system would only rarely experience, as well as a wide range of neurologic and oncogenic or neoplastic processes (Ex. 6–270). The clinical manifestations of patients in this group may vary extensively. Some of these patients may experience "constitutional disease," also known as HIV "wasting syndrome," which may be characterized by severe, involuntary weight loss, chronic diarrhea, constant or intermittent weakness, and fever for 30 days or longer (Ex. 6–270). This syndrome in and of itself may result in death. Individuals with AIDS may also develop HIV encephalopathy, dementia, myelopathy or peripheral neuropathy. This may occur when HIV infects mononuclear cells present in the cerebrospinal fluid surrounding the brain and spinal cord or infects these cells within the brain or spinal cord. Persons with dementia experience varying degrees of cognitive disability or impairment of intellectual function and motor disability or dysfunction. Effects ranging from apathy and depression to memory loss and severe dementia may interfere with a person's occupation as well as activities of daily living and can ultimately be fatal (Exs. 6–270; 6–380, pp 548–578). In addition, the virus is capable of affecting the peripheral nervous system causing severe pain and weakness or numbness in the limbs (peripheral neuropathy) (Ex. 6–270).

According to CDC's case definition, there are specific diseases that are considered indicators of AIDS if laboratory tests for HIV were not performed or gave inconclusive results and no other known causes of immunodeficiency are present (Ex. 6–157). Among these are parasitic diseases such as *Pneumocystis carinii* pneumonia, the most common opportunistic infection and cause of death in AIDS patients; fungal diseases such as candidiasis of the esophagus, trachea, bronchi or lungs; viral diseases such as cytomegalovirus disease of an organ other than the liver, spleen or lymph nodes; cancer/neoplastic diseases such as Kaposi's sarcoma affecting persons under 60 years of age; and bacterial infections such as *Mycobacterium avium* complex (Exs. 6–157; 6–361). In addition to the diseases listed above there are diseases caused by organisms such as disseminated or extra-pulmonary *Mycobacterium tuberculosis* (TB) which may be considered indicative of AIDS if substantiated by reactive HIV-antibody tests (Ex. 6–157). Unlike adults, children under 13 years of age can be classified as having AIDS if they experience lymphoid interstitial pneumonia or pulmonary lymphoid hyperplasia (LIP–PLH complex). Children who are seropositive for HIV can be classified as having AIDS if they experience recurring serious bacterial infections such as septicemia, pneumonia, meningitis, *Hemophilus, Streptococcus* or other pyogenic bacteria (Ex. 6–157).

AIDS is primarily managed by treating clinical disease symptoms, but conventional therapy cannot reverse the immunodeficiency (Ex. 6–361). Currently, researchers are testing experimental drugs and conducting a number of treatment protocols on patients at various stages of infection or disease. At this time, only one antiviral drug, Zidovudine or Retrovir TM, (formerly known as azidothymidine or AZT) has been approved by the FDA for some patients, specifically those who have experienced *Pneumocystis carinii* pneumonia (PCP), or are symptomatic for AIDS related illness and have less than 200 T4 cells/ml (Ex. 6–479). Although some patients have had to discontinue the drug due to severe side effects, clinical trials have shown the drug to prolong the life of AIDS patients (Ex. 6–383, pp. 153–165). There is no vaccine to prevent HIV infection (Ex. 6–384).

HIV: Workplace Transmission

Occupational transmission of HIV has been documented in healthcare workers. The information submitted to the public record indicates that as of May 1990, there are at least 65 case reports of healthcare workers whose HIV infections are associated with occupational exposure. Among these are 30 case reports that have been individually published in the scientific literature or are in press (CDC/NIOSH, Ex. 298). Eighteen of these cases seroconverted following a documented exposure incident. Thirteen of the seroconversions were caused by parenteral exposure to blood or blood-containing body fluids (11 by needlesticks and 2 by cuts with a sharp object). Five seroconversions involved blood contamination of mucous membranes or non-intact skin and one was due to parenteral exposure to concentrated HIV-I (Ex. 286U). The dates of seroconversion could not be documented for the remaining 12 individually published cases because no baseline serologic data had been obtained.

Documented cases of seroconversions in healthcare workers as of May 1990 are presented in Table IV–4. Additional cases of possible occupational transmission in healthcare workers as of May 1990 are presented in Table IV–5.

TABLE IV–4.[1]—DOCUMENTED SEROCONVERSIONS IN HEALTH WORKERS

Author and reference	Country	Type of exposure	ARS[2]
1 Editorial	United Kingdom	Needlestick	Yes.
2 Sinicof	USA	Needlestick	Yes.
3 Olsenmandier	France	Needlestick	Yes.
4 Nesson-Venant	Martinique	Needlestick	Yes.
5 CDC[3]	USA	Non-intact skin	Yes.
6 CDC	USA	Mucous membrane	No.
7 CDC	USA	Non-intact skin	Yes.
8 Gioannini	Italy	Mucous membrane	Yes.
9 Michelet	France	Needlestick	Yes.
10 Wallace	USA	Needlestick	Yes.
11 Barnes	USA	Sharp object	Yes.
12 Ramsey	USA	Needlestick	No.
13 CDC	USA	Needlestick	Yes/AIDS.
14 Marcus	USA	Needlestick	Yes.
15 Marcus	USA	Two needlesticks	Yes.
16 Gerberding	USA	Needlestick	Yes.
17 Weiss, CDC	USA	Sharp object	NR.[4]
18 CDC	USA	Cutaneous	NR.[4]

[1] From Marcus, R. et al., Transmission of Human Immunodeficiency Virus (HIV) in Health-care Setting Worldwide. *Bulletin of the World Health Organization*, 67(5): 577-582 (Ex. 6-286U).
[2] ARS: acute retroviral syndrome.
[3] CDC: Centers for Disease Control, USA.
[4] NR: not reported.

TABLE IV-5.—POSSIBLE CASES OF OCCUPATIONAL TRANSMISSION OF HIV*

Author and reference	Country	Type of exposure
1. Bygbjerg	Denmark	Surgical practice in Zaire.
2. Belani	USA	Palm prick from hospital waste.
3. Anonymous	France	Worked in intensive care unit.
4. Grint	United Kingdom.	Home-health provider, non-intact skin.
5. Weiss, McCray.	USA	Colonic Biopsy. Needlestick.
6. Weiss, CDC	USA	Two needlesticks.
7. Weiss, CDC	USA	Two exposure/ unknown source.
8 Weiss, CDC	USA	Concentrated virus on skin.
9 Klein	USA	Multiple needlesticks.
10 Ponce de Leon	Mexico	Needlestick puncture wound.
11 Schmidt	Federal Republic of Germany.	Needlestick.
12 Lima	Italy	Needlestick.

* From Marcus, R. et al., Transmission of Human Immunodeficiency Virus (HIV) in healthcare settings worldwide. Bulletin of the World Health Organization, 67(5), 577-582 (1989).

Twenty-five published cases of HIV infection associated with occupational exposure are summarized below. These cases represent a spectrum of healthcare personnel including, among others, nurses, laboratory workers and a dentist. For the 25 cases, HIV status was determined by HIV-antibody testing. Baseline blood samples analyzed for HIV-antubody revealed that at least 18 of these individuals were not infected with HIV at the time of the exposure incident. However, subsequent blood tests determined that eventually all of the 18 seroconverted to an HIV-positive-antibody status, indicating the presence of HIV infection. All 25 denied other known risk factors for HIV infection, but in cases where the baseline serologic data were unknown, other modes of transmission cannot be ruled out. Nevertheless, all cases were investigated for risk factors and none were identified.

Case Reports

Case 1: A hospital healthcare worker sustained an accidental self-inflicted injection of "several milliliters of blood while obtaining blood in a vacuum collection tube from an AIDS patient" (Ex. 6-365). The healthcare worker subsequently seroconverted to an HIV-antibody-positive status and has since developed AIDS. Having determined there were no other HIV risk factors for this individual, investigators concluded the worker acquired the infection occupationally.

Case 2: In November 1985, a previously healthy, 33 year old United States Navy hospital corpsman punctured his fingertip while disposing of a phlebotomy needle used to draw blood from a patient who was later diagnosed with *Pneumocystis Carinii* pneumonia and serologically tested HIV-positive (Ex. 6-337). Upon learning of this diagnosis two weeks after the incident, the corpsman submitted to HIV serology testing on a monthly basis and was HIV-negative for 3 months. Five months after the incident, he experienced a characteristic acute retroviral syndrome, which was self-limiting. Six months after the incident he tested HIV-positive. He reported a negative history of other risk factors for HIV, and his wife was seronegative.

Case 3: Weiss and co-workers reported that a laboratory worker, who worked with concentrated HIV-1, tested seropositive for the virus (Ex. 6-187). Clinical evaluation revealed no signs or symptoms of HIV-related illness. As part of routine laboratory duties, this individual was involved in several possible exposure circumstances such as decontaminating equipment, cleaning up spills or touching potentially contaminated surfaces with gloved hands. Virus-positive culture fluid had occasionally leaked from equipment and contaminated centrifuge rotors. Although reportedly using Biosafety level 3 precautions, the subject was not fully knowledgeable with and did not strictly follow these practices all of the time.

The subject did not recall any direct skin exposure but did report having had a nonspecific dermatitis on the arm, although the "affected area was always covered by a cloth laboratory gown." The individual also reported incidents where he had pinholes or tears in his gloves and had to change them immediately.

Strains of HIV-1 isolated from different individuals generally differ significantly, but the HIV-1 isolated from this subject was indistinguishable from 1 of the 2 predominant HIV genotypes this individual worked with in the laboratory.

Although no specific exposure incident had been identified, the investigators concluded that the subject acquired the HIV infection in the laboratory, most likely through undetected skin contact with the concentrated virus.

Case 4: A female phlebotomist reported that blood splattered on her face and in her mouth when the top of a 10-ml vacuum blood collection tube flew off while she was collecting a patient's blood (which subsequently tested HIV-positive) (Ex. 6-109). The HCW was wearing gloves and glasses and reported that no blood got in her eyes. She reported no open wounds but did have facial acne. She washed off the blood immediately after exposure. Her blood tested HIV-negative one day post-exposure and 8 weeks later. However, when donating blood 9 months after exposure, she was HIV-antibody positive. She denied having other known risk factors for HIV.

Case 5: A female medical technologist was exposed to a blood spill that covered most of her hands and forearms while she was manipulating an apheresis machine; a machine that separates blood components, retains some, and returns the remainder to the donor (Ex. 6-109). Although she was not wearing gloves, she did not report any open wounds on her hands or any mucous membrane exposure. However, she did have dermatitis on her ear and may have touched that ear. Eight weeks after the incident she experienced symptoms of acute retroviral syndrome. She was HIV-negative 5 days post exposure; however, 3 months after exposure she was HIV-antibody positive. She denied having other known risk factors for AIDS. Her husband also denied any risk factors for AIDS and tested HIV seronegative.

Case 6: Neisson-Vernant and co-workers reported that a "24-year-old female student nurse pricked the fleshy part of her index finger with a needle used to draw blood from an AIDS patient." She did not recall injecting blood. Two months later signs and symptoms of acute retroviral illness appeared, including fever and a macular eruption lasting 3 days. Although she tested HIV-negative 1 month after the incident, she tested positive 6 months after exposure. She denied all other risk

factors for HIV and her husband tested HIV negative 6 and 9 months after her exposure (Ex. 6–93).

Case 7: Michelet and co-workers reported a case of occupationally acquired HIV infection in a female nurse in France (Ex. 6–369). Having drawn a blood sample in a vacuum tube from an individual with AIDS, she stuck her finger with the large-bore needle of the adapter, but reportedly did not inject any blood. Immediately after the incident, she placed her finger in 0.5% sodium hypochlorite solution in accordance with the hospital's guidelines. Twenty-three days after exposure, she developed signs and symptoms of acute retroviral syndrome, including abdominal cramps, nausea, vomiting, and diarrhea. She later experienced anorexia, fatigue and facial palsy. Clinical evaluation found generalized lymphadenopathy. Although she tested HIV-antibody negative 13 days after the incident she was HIV-antibody positive 71 days post-exposure. Investigators failed to identify any risk factor for HIV for the nurse or her husband, who tested HIV-antibody negative 62 days after his wife's exposure incident.

Case 8: An NIH clinical laboratory worker sustained a cut that penetrated through a glove and the skin when a vial of HIV-infected blood broke in the worker's hand (Ex. 6–348). Although initially testing negative, the individual subsequently tested positive and investigators have linked the infection with the accident.

Case 9: Oksenhendler and co-workers reported that a female nurse in France stuck her finger superficially while recapping a needle contaminated by bloody pleural fluid from a patient positive for both HBsAg and HIV. Immediately post-exposure she received the hepatitis B vaccine and specific immunoglobulin. She experienced acute retroviral syndrome including fever, fatigue and vomiting 25 days after the incident. Fifty-three days after exposure, she developed an acute "anicteric" hepatitis (possibly related to the primary HIV infection). Although she tested HIV-negative after the exposure (days 1 and 13), she tested HIV-positive on day 68. She and her husband denied other known risk factors for HIV and her husband tested seronegative for HIV 110 days after the incident (Ex. 6–18).

Case 10: A nurse from England received a needlestick injury to a finger while resheathing a hypodermic needle on a syringe containing an AIDS patient's blood from an arterial line (Ex. 4–41). A small amount of blood may have been injected as well. Signs and symptoms of acute retroviral syndrome presented 13 days after exposure with a rash developing 17 days after the incident. Although she tested HIV-negative 27 days post injury, she was determined to be HIV-positive on day 49. She denied other known risk factors for HIV.

Cases 11, 12 and 13: Marcus and co-workers reported 3 cases of healthcare workers who seroconverted to an HIV antibody-positive status (Ex. 6–372). One healthcare worker sustained a deep needlestick injury inflicted by a co-worker with a 21-gauge needle while attempting to resuscitate an AIDS patient. The healthcare worker was HIV-antibody and antigen negative the day after the exposure. Four weeks after the incident the worker experienced fever, "shaking chills," night sweats, lymphadenopathy, and malaise which lasted about 4 days. One hundred twenty-one days after the exposure the worker tested HIV-seropositive. The healthcare worker denied other known risk factors for HIV and a recent sex partner tested HIV-seronegative.

A second healthcare worker accidentally stuck herself on two occasions with needles that had been used on HIV-infected patients. The first exposure occurred while recapping a needle that had been used on a patient with AIDS. Ten days later the worker stuck herself with a needle that had been used to draw blood from a symptomatic HIV-infected individual. "After removing the tube of blood from the plastic needle holder, the healthcare worker placed the needle holder upright on its base, such that the needle was pointed vertically into the air. The healthcare worker then turned away and subsequently injured herself on the exposed needle." The worker tested positive for HIV-antibody and antigen 21 days after the first exposure (11 days after the second). She developed an acute viral illness four weeks after the first incident, characterized by shaking chills, dehydration, nausea, malaise, bilateral lymphadenopathy and a weight loss of more than 10 pounds. During this illness she was HIV-antibody negative; however, lymphocyte cultures were positive for HIV-antigen and reverse transcriptase, an enzyme which serves as a marker for HIV. The healthcare worker tested HIV-antibody positive on day 121 after the first exposure (111 days after the second exposure). Four months after the exposure incidents, the worker's spouse tested HIV-antibody negative.

A third case, a healthcare worker, received a deep intramuscular needlestick injury with a large bore needle and syringe unit visibly contaminated with blood from an AIDS patient (Exs. 4–39; 6–367). Fourteen days after the incident, acute retroviral syndrome developed. Although HIV-antibody negative 9 days post-exposure, the healthcare worker was determined HIV-antibody positive on day 184. The worker and the worker's spouse denied any other risk factors for AIDS and the spouse tested HIV-antibody negative 239 days after the incident.

Case 14: Marcus and co-workers and McCray and co-workers reported a case where a female nurse received a puncture wound from a colonic biopsy needle (visibly contaminated with blood and feces) used in an AIDS patient (Exs. 6–372; 4–39). She tested HIV-positive approximately 10 months after exposure although there were no serologic baseline data before or immediately after the incident. She denied other risk factors for AIDS; however, her sexual partner also tested HIV-positive and heterosexual transmission therefore cannot be ruled out.

Case 15: Gerberding and co-workers reported a case of a healthcare worker who acquired HIV infection after sustaining a deep needlestick injury with an HIV-contaminated needle (Ex. 6–375).

Case 16: Ramsey and co-workers, conducted a prospective evaluation of 44 healthcare workers exposed to HIV and reported that one healthcare worker seroconverted to an HIV-antibody positive status after sustaining a needlestick from an HIV-contaminated needle (Ex. 6–373). The worker had been followed for at least 90 days after the exposure incident and had not reported any signs or symptoms of acute-retroviral illness.

Case 17: Gioannini and co-workers reported that a 37–year-old intensive care nurse in Italy "had her hands, eyes and mouth heavily splashed" with blood from an HIV-infected hemophiliac. Beginning 11 days post-exposure, the nurse developed signs and symptoms of acute retroviral illness including fever, fatigue, chills, arthralgia, cervical and axillary lymphadenopathy and arthritis. She was hospitalized 18 days after the incident due to the severity of her symptoms plus progressive increases of aminotransferase levels. During her 55 day hospital stay the worker developed an acute, anicteric non-A non-B hepatitis, which may have been associated with HIV infection. HIV antigen was detected in her blood on day 21 and by day 43 she had seroconverted to an HIV-antibody-positive status (Ex. 6–334).

Case 18: A 32-year-old mother tested HIV-positive subsequent to providing extensive healthcare to her male child

with a "congenital intestinal abnormality" (Ex. 4–37). Having received multiple blood transfusions (one of which was from an HIV-positive source) the child was tested and determined HIV-positive at 24 months of age. Although the mother did not report any needlestick or other parenteral exposure to the child's blood, she recalled having had frequent hand contact with the child's blood and body fluids. She did not wear gloves and did not wash her hands immediately after exposure. She did not report having open wounds or exudative dermatitis on her hands. One month after the child tested HIV-positive, the mother was determined to be seronegative for HIV. However, 4 months later she was determined to be HIV-antibody-positive. She reported a negative history for other risk factors for HIV for herself and the child. The child's father was seronegative for HIV. Investigators concluded the mother most probably acquired the infection by providing her infected child healthcare that involved extensive exposure to blood and body fluids without using infection control practices.

Case 19: A laboratory worker apparently became infected in a laboratory accident (Exs. 6–187; 6–368; 6–312). He handled large volumes of HIV in a high containment laboratory under contract with NIH, performed techniques to concentrate the virus as part of a commercial process and reportedly followed biosafety guidelines. He was tested and found to be HIV-seropositive. The lab worker was not informed of his HIV status until 16 weeks after he tested HIV-positive. At that time, he recalled having cut his finger with a blunt stainless steel needle while cleaning a piece of contaminated equipment. He had tested HIV-negative 4 to 6 months prior to the laboratory incident but tested HIV-positive 6 to 9 months post exposure. Biosafety officials were of the opinion that the accident probably caused the infection. The laboratory worker has not participated in any studies that could determine whether he is infected with a laboratory strain of HIV.

Case 20: Klein and co-workers reported a male dentist who had tested HIV-seropositive (Ex. 6–386). He denied having other risk factors for the virus. Although he did not recall treating a patient with AIDS, he had treated patients at high risk for HIV infection. He reported having frequent open lesions or "obvious breaks in the skin" on his hands; however, he only intermittently used personal protective equipment. His wife, although refusing to be tested for HIV, denied other HIV-risk factors. There was no report of baseline or convalescent serology and exposure to HIV-positive blood cannot be documented.

Case 21: A healthcare worker applied pressure to an HIV-infected patient's arterial catheter insertion site to stop bleeding (Ex. 6–109). During the procedure, she may have had a small amount of blood on her index finger for 20 minutes before washing her hand. She did not wear gloves during this procedure and although she reported no open wounds, her hands were chapped. Twenty days after exposure, she developed symptoms of acute retroviral syndrome lasting 3 weeks. Blood she had donated 8 months prior to the exposure was HIV-negative. However, blood donated 16 weeks after the incident was HIV-positive. She denied having other known risk factors for HIV. No baseline data or serologic testing results were obtained immediately following exposure for this case.

Case 22: A female healthcare worker received accidental needlestick injuries when drawing blood from AIDS patients in two incidents separated in time by 4 months (Ex. 6–258). She had her first blood test for HIV 6 months after the second exposure and was found HIV-positive. Although previously healthy, she developed a persistent mild lymphadenopathy 3 months after the second incident and intermittent diarrhea which started 5 months after that incident. She denied other HIV risk factors. Her long-term sex partner also denied any HIV risk factors, and he repeatedly tested HIV-antibody-negative over an 8-month period following the healthcare worker's positive test result. HIV was obtained from the male partner's peripheral lymphocytes within 13 months after the second incident but could not be obtained several months later. Heterosexual transmission could not be ruled out for the healthcare worker but seems less likely than parenteral transmission in this case.

Case 23: A male laboratory worker, was found to be HIV-positive when first tested (Ex. 6–258). The worker recalled having received 2 parenteral exposures to blood from persons of unknown HIV status. He sustained an accidental needlestick and a cut on the hand while processing blood 8 and 16 months respectively prior to being tested. Although asymptomatic when tested, he has experienced transient cervical lymphadenopathy. He denied all known risk factors for HIV, but non-occupational transmission could not be ruled out in this case as no serologic data were available immediately after the exposures.

Case 24: Grint and co-workers reported that a 44-year-old woman from England, although not a healthcare worker, developed AIDS after providing healthcare services for a Ghanaian man with a postmortem diagnosis of AIDS (Ex. 6–333). She recalled having small cuts on her hands, an exacerbation of chronic eczema, and frequent skin contact with his body secretions and excretions. There was no report of baseline or convalescent serology.

Case 25: Ponce de Leon and co-workers reported that a 39-year-old male laboratory technician in Mexico acquired AIDS occupationally and died as a consequence of this disease (Ex. 6–326). From 1971 to 1986 he worked as a laboratory technician in a company that processed blood and blood products and where infection control procedures were not "customary." He reported experiencing many accidental punctures and blood contact with his "teguments and mucosa". The worker also recalled a laboratory accident "in late 1985 in which a deep cut in his right hand was grossly contaminated with plasma." Early in 1986 he experienced an acute illness characterized by fever and lymphadenopathy lasting several days. In 1987 the worker experienced a seven-month illness characterized by persistent diarrhea, weight loss, persistent oral thrush, intermittent fever, generalized lymphadenopathy, anisocoria and signs of meningitis. He eventually was hospitalized on December 11, 1987 two weeks after dizziness, mental confusion and vomiting ensued. Tests revealed the presence of the opportunistic infection cryptococcoses. The worker tested HIV-antibody-positive and was diagnosed as having AIDS. The patient died on December 18, 1987. He had denied other risk factors for HIV and his wife was seronegative for HIV-antibody.

HIV: Epidemiology

A number of prospective studies and surveys have been conducted to determine occupational risks for HIV infection. Marcus and co-workers reported that the Centers for Disease Control has been conducting a national prospective study which began in 1983, to assess initially the risk of Acquired Immunodeficiency Syndrome and later, with the advent of HIV-antibody testing, the risk of HIV among healthcare workers exposed to the blood or body fluids of persons with HIV infection (Ex. 6–372). In 1986, data were reported on the first 451 healthcare workers who had entered the study and had been tested

for HIV antibody (Ex. 4–39). Initially, individuals were considered eligible for the study if they had been exposed to the *blood* or *body fluids* of a patient with *AIDS* or *AIDS-Related illness* by a needlestick, a cut with a sharp object or contamination of an open wound or mucous membrane. Thereafter, subjects were enrolled only if they had parenteral, mucous membrane or non-intact skin exposure to the *blood* of an *HIV-infected* individual.

As of July 31, 1988, a cohort of 1201 healthcare workers with exposure to HIV-contaminated blood has been followed. Of these, 751 (63%) were nurses, 164 (14%) were physicians or medical students, 134 (11%) were technicians or laboratory workers, 90 (7%) were phlebotomists, 36 (3%) were respiratory therapists and 26 (2%) were housekeeping or maintenance staff. Upon enrollment the subjects provided investigators with epidemiologic data including demographic information, medical history, details of the exposure circumstances, infection control precautions used and post-exposure treatment. Nine hundred sixty-two (80%) of the subjects had sustained needlestick injuries, 103 (8%) had been cut with a sharp object, 79 (7%) had contaminated an open wound and 57 (5%) have had a mucous membrane exposure. Seven hundred seventy-nine (65%) of the exposed healthcare workers were exposed in a patient room, on a ward or in an outpatient clinic; 161 (14%) in an intensive care unit; 87 (7%) in an operating room; 84 (7%) in a laboratory; 62 (5%) in an emergency room; and 28 (2%) in a morgue.

The 1,201 subjects had blood samples drawn and tested for the presence of HIV-antibodies. Acute blood specimens collected within 30 days after exposure were obtained and tested from 622 subjects. Exposed healthcare workers were retested at 6 weeks, 3 months, 6 months and 12 months after the exposure incident to determine if seroconversion had occurred. Seroconversions were defined as healthcare workers who were seronegative for HIV antibody within 30 days after occupational exposure and seropositive 90 days or more after the exposure incident.

Nine hundred sixty-three subjects had been followed for at least 6 months, 860 (89%) of whom had sustained either a needlestick injury or a cut with a sharp instrument. Of these, four were seropositive yielding a seroprevalence rate of 4/860=0.47%. One of the four was first tested for HIV-antibody 10 months after sustaining a needlestick exposure to blood of an HIV-infected patient (see Case 14). As there was no available acute blood specimen collected within 30 days after exposure this case cannot by definition be considered a seroconversion. The remaining 3 HIV-seropositive subjects (see Cases 11, 12, and 13) had HIV-seronegative acute blood specimens and were thus considered seroconversions, yielding a seroconversion rate of 3/860=0.35%.

Weiss and co-workers, conducted a prospective study to assess the risk of HIV in laboratory workers (Ex. 6–187). Invitations to participate in the study were issued to workers with possible exposure risk in 15 laboratory facilities from 6 states. Of the 285 subjects studied, 225 had laboratory exposure (including 99 who worked with concentrated HIV and 126 who worked with blood containing HIV, non-infectious viral proteins, or cloned viral DNA), 30 worked with AIDS patients in support of the laboratory and 10 were clerical staff working in the laboratory environment. Of the 225 laboratory workers, 10 reported one or more episodes of parenteral exposure to HIV, including needlesticks or cuts, and 35 reported one or more episodes of skin contact with HIV. Participants completed a questionnaire focusing on workplace exposure to human retroviruses, biosafety precautions used at the facility and by the subject, accidents occurring in the laboratory or other areas and the non-occupational factors such as drug use, sexual activity and transfusion history. Eight (3%) of the 285 reported non-occupational risk factors for the virus. Of the 225 workers with laboratory exposure, ten reported parenteral virus exposure, and 35 reported 1 or more skin contacts. Thirteen workers reported that they did not wear gloves at all times when working with HIV-infective material. Blood samples from all subjects were analyzed for HIV antibodies by enzyme-linked immunosorbent assay and confirmed by tests such as immunoblots and radioimmune assays. One individual who worked with concentrated HIV–1 was seropositive for the virus upon entering the study (See Case 3). The HIV isolated from the subject's blood was shown to be genetically identical to a strain of HIV used in the laboratory, thus strongly implicating occupational exposure as the source of infection. The authors concluded that the most plausible source of exposure was contact of the worker's gloved hand with culture supernatant fluid containing concentrated virus, followed by inapparent exposure to skin. No HIV seroconversions were identified in the other study participants during the period of prospective follow-up. The authors calculated that the rate of HIV infection was 0.48 per 100 person-years for laboratory personnel in this study.

Gerberding and co-workers are conducting a prospective cohort study to assess the risk of transmitting HIV to healthcare workers intensively and frequently exposed to the more than 1600 patients with AIDS and AIDS-related conditions at San Francisco General Hospital (Exs. 6–375; 6–353). After inviting the hospital healthcare workers to participate in the study, investigators recruited a cohort of 623 subjects between 1984 and 1988. At the time of enrollment blood samples from each subject were tested for HIV antibody. Upon entering the study, each subject was asked to complete a confidential, self-administered questionnaire designed to elicit information regarding demographic characteristics; employment history; medical history; type, frequency, duration and intensity of exposures to HIV-infected patients or laboratory specimens from such patients; a description of infection-control procedures; and non-occupational risk factors for HIV infection. Subjects who described non-occupational risk factors for AIDS on the questionnaire were excluded from this study, leaving 468 for prospective follow up. Forty-four percent were physicians (57 of whom were surgeons), 30% were nurses and 11% were laboratory technicians. Of these, 11% worked solely on AIDS units or research laboratories and 26% worked in the operating room, emergency room or intensive care unit. Two hundred twelve of the subjects reported having had accidental exposure (with some having had multiple exposures) to HIV-infected blood by needlestick or by splashes to mucous membranes or nonintact skin. Of the one hundred eighty subjects who received follow-up HIV-antibody testing at least 6 months after exposure, Gerberding and co-workers reported that only one, a healthcare worker who had sustained a deep needlestick injury with an HIV-contaminated needle seroconverted to HIV antibody positive (Case 15), yielding a seroconversion rate of 1/212 = 0.47%.

Klein and co-workers, conducted a study to assess the occupational risk of HIV among individuals working in the dental profession (Ex. 6–366). Dental professionals in the boroughs of Manhattan and the Bronx in New York City received a mailing requesting their participation in the study. Others were

also recruited during dental meetings in the New York City metropolitan area (between October 1985 and May 1987), and during the annual meeting of the American Dental Association in Miami Beach (October 1986). Written consent was given and questionnaires were completed by a cohort of 1,360 dental professionals. The questionnaires addressed the issues of demographics (including type, duration and location of practice), behavior or other risk factors related to AIDS, "precautions used when treating patients, type and estimated numbers of patients treated, estimated number of accidental parenteral inoculations," and HBV vaccination status. Blood samples were then obtained and analyzed for HIV antibodies by EIA and, if reactive, confirmed by Western blot assay. The blood samples of those subjects who had not received the hepatitis B vaccine were analyzed for HBV antibodies as well. Twenty-five participants who reported no or "uncertain" contact with patients and 13 subjects for whom blood samples were not obtained were excluded from the study. For 13 participants who reported non-occupational risk factors for HIV, including 10 homosexual or bisexual men, 2 heterosexual intravenous drug users and 1 homosexual or bisexual IV drug user, blood samples were analyzed separately. Among those who reported non-occupational risk factors, 4 were found to be HIV-antibody positive. The remaining cohort of 1,309 subjects consisted of 1,132 dentists, 131 dental hygienists and 46 dental assistants. Most of the dentists were male and 5% were oral surgeons. Nearly all of the dental hygienists and assistants were female. About half of the participants practiced in cities where large numbers of AIDS cases have been reported. Although the vast majority of subjects reportedly worked either with AIDS patients (15%) or with patients at high risk for AIDS (72%), only 31% of the dentists and 8% of dental assistants reported always wearing gloves when performing dental treatment; most of them did report using gloves intermittently. Seventy three percent of the hygienists reported always wearing gloves while working with patients. Most of the dentists and dental hygienists used masks, eye protection and disposable gowns intermittently, although the majority of dental assistants never used these infection control procedures. Nearly all subjects who used precautions reported they had increased their use of precautions since 1983 due to concern about AIDS. Approximately 94% of the subjects reported sustaining accidental "parenteral inoculations with sharp instruments," ranging from one to as many as 7,500 within a 5-year period. Serologic test results revealed that at least 21% of the subjects who had not receive the hepatitis B vaccine had been infected with HBV; however, only 1 subject, a male dentist, was seropositive for HIV (see Case 20).

Klein and co-workers concluded that there is a risk of dental professionals acquiring HIV occupationally. Because the study represents a point prevalence survey, the HIV seroconversion rate among dental personnel cannot be estimated from it.

Henderson and co-workers are conducting a prospective study that began September, 1983, to assess the risk of nosocomial transmission of HIV to healthcare workers (Exs. 6–377; 6–352). Investigators invited healthcare workers with varying degrees of occupational exposure to more than 1000 HIV-infected patients seen at the Clinical Center at the National Institutes of Health (NIH) to participate in the study. As of October 1988, the cohort being followed consisted of healthcare workers, including clinical and research laboratory personnel as well as healthcare workers providing direct patient care. Blood was obtained from each subject at the time of enrollment and every 6 months thereafter. The samples were tested for the presence of HIV antibody by ELISA and if reactive, were then confirmed by Western blot. Upon enrollment and every six months thereafter, questionnaires were completed to obtain demographic information, job description, type and frequency of procedures performed on HIV-infected patients, type and frequency of patient blood or body fluid exposure, and type and frequency of exposure to patient specimens. Questions regarding non-occupational risk factors were not included. Two categories of exposure were defined: "physical contact with either a patient or specimen container in routine work"; and "adverse" exposure, either parenterally (by a needle, scalpel or other sharp object contaminated with blood or body fluids from HIV-infected patients) or by splash to the mouth, nasal or conjunctival membranes (by blood, urine, saliva, sputum or feces from an HIV-infected patient). Three hundred fifty-nine of the subjects in the cohort reported collectively 482 percutaneous or mucous membrane exposures to blood or body fluids from HIV-infected patients (Ex. 286U). These individuals were evaluated separately, given more comprehensive initial and follow-up questionnaires, and were requested to provide serologic baseline samples as close as possible to the time of exposure as well as yearly samples thereafter. All adverse exposures were followed for at least 6 months (ranging from 6 to 63 months.) One subject who had been cut with a sharp object subsequently experienced an acute retroviral syndrome and developed antibodies to HIV (Ex. 6–348). For 6 subjects, blood samples were positive for HIV antibody at the time of entry into the study. None of the 6 had reported an adverse exposure to blood or body fluids. However, upon reevaluation, all 6 described having at least one non-occupational risk factor for HIV infection.

Healthcare Workers with AIDS

Further evidence of occupational transmission is provided by reports of healthcare workers who have AIDS, but have no identifiable risk for infection (Ex. 6–378). As of September 30, 1990, there were at least 69 healthcare workers with AIDS for whom no risk factors have been identified after thorough investigation. This group was comprised of 13 physicians, 1 of whom was a surgeon; 2 dental workers; 8 nurses; 14 aides/attendants; 12 housekeeping or maintenance workers; 7 technicians; 2 therapists; 3 embalmers; 1 paramedic and 7 others. Of these, 35 reported needlestick and/or mucous membrane exposures to the blood or body fluids of patients during the 10 years proceeding their diagnosis of AIDS. However, none of the source patients was known to be HIV-infected at the time of exposure, and none of the workers was evaluated at the time of exposure to determine HIV-infection status or to document seroconversion (Ex. L6–666). While data on these cases are less complete compared to the case reports mentioned earlier, it is reasonable to assume that at least some of them resulted from occupational exposure (CDC/NIOSH, Ex. 286).

Human Immunodeficiency Virus Type 2

A case of AIDS in a person from Africa, caused by another human retrovirus, human immunodeficiency virus type 2 (HIV–2), was diagnosed and reported for the first time in the United States in December, 1987 (Ex. 6–308). Since then the CDC has received reports of additional cases of HIV–2 occurring in the West Africans that were diagnosed in the United States. HIV–2 appears to be similar to HIV–1 in modes of transmission and natural history but has not yet been studied in as much detail. Although HIV–2 is

unquestionably pathogenic, there is still much to be learned regarding its epidemiology, pathogenesis and efficiency of transmission. Although only a few cases of HIV-2 has been reported in the United States, the infection is endemic in West Africa, where it was first linked with AIDS in 1986. There have also been cases of HIV-2 infection reported among West Africans living in Europe. HIV-2 surveillance is being conducted in the United States to monitor the frequency of occurrence using specific tests not yet available commercially (Ex. 6-308). The National Institute for Occupational Safety and Health reports that it is likely that additional human retroviruses will be discovered in the future (Ex. 22-634).

D. Other Bloodborne Pathogens

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

Syphilis: Syphilis is caused by infection with *Treponema pallidum*, a spirochete. Syphilis, a sexually transmitted infectious disease, is increasingly prevalent in the United States: 35,147 cases were reported in civilians in 1987 (Ex. 6-465). Marked increases occurred in 1987. The 25% increase over the 1986 rate was the largest single-year increase since 1960. Moreover the incidence of 14.6 cases per 100,000 persons in 1987, equal to that of 1982, is the highest rate since 1950. The natural history of syphilis is characterized by an incubation period of 10 to 90 days during which the patient is seronegative and asymptomatic (Ex. 6-495). Subsequent to this incubation period, a primary stage occurs, usually characterized by the appearance of a single lesion, or chancre, and normally accompanied by reactivity in serologic tests. Untreated, the primary lesion heals in weeks. Within weeks to months, a variable systemic illness, the secondary stage, characterized by rash, fever and widespread hematogenous and lymphatic dissemination of spirochetes occurs. All infected persons have reactive serologic tests in this stage (Ex. 6-495). Furthermore, the highest levels of spirochetemia (spirochetes present in blood) are reached during this period. Over two-thirds of patients then go into a latent phase when they are asymptomatic. After a variable period of latency, the rest progress to a tertiary stage with high morbidity and mortality including involvement of skin, bones, central nervous and cardiovascular system (Ex. 6-495). During latency and tertiary syphilis, spirochetemia is markedly reduced, as is infectivity. However during the course of untreated syphilis, spirochetes may be intermittently found in the bloodstream, and syphilis can probably be transmitted through the course of the illness, though not as readily as during the primary and secondary stages (Ex. 6-495). Although syphilis is primarily transmitted sexually and *in utero*, a few cases of transmission by needlestick, by tattooing instruments, and by blood transfusion have been documented (Exs. 6-453; 6-496). A reported transmission has occurred by needlestick exposure to the blood of a patient with secondary syphilis, resulting in a chancre on the hand (Ex. 6-453). Preventive treatment of an exposed healthcare worker with an antibiotic during the incubation period would be expected to prevent serological test positivity and the potential for permanent reactivity on treponemal testing, as well as preventing the manifestations of infection.

Malaria: Malaria is a potentially fatal mosquito-borne parasitic infection of the blood cells characterized by paroxysms of fever, chills, and anemia; 944 cases were reported in the United States in 1987 (Ex. 6-465). Malaria is an important health risk to immigrants from numerous malaria-endemic areas of the world and to Americans who travel to such areas. Moreover, transmission by mosquito vector has been documented in some areas of the United States. Malaria is characterized by a prolonged erythrocytic phase during which the causative agent, one of several species of the *Plasmodium* genus, is present in the blood. In many nations, malaria is among the most common transfusion-related infectious diseases. In temperate countries, it is only occasionally reported (Ex. 498). Malaria has also been transmitted by needlestick injury; in one incident, malaria was transmitted to a child who received a unit of blood and to the recipient's physician, who stuck himself with a needle (Ex. 467).

Babesiosis: Babesiosis is a tick-borne, parasitic disease similar to malaria which is caused by the intraerythrocytic parasite *Babesia microti*. It is endemic in certain islands off the northeastern coast of the United States. Transmission by transfusion of fresh blood from asymptomatic donors has been reported (Ex. 454).

Brucellosis: Brucellosis is a febrile illness caused by members of the genus *Brucella*. It is typically associated with occupational exposure to livestock or with ingestion of unpasteurized dairy products; 129 cases were reported in 1987 (Ex. 6-465). It is characterized by fever and weakness, sweats and arthralgia. Transmission by blood transfusion has been reported; in one incident, brucellosis and syphilis were transmitted in the same unit of blood to one recipient (Ex. 6-496).

Leptospirosis: Leptospirosis, a prolonged illness characterized by fever, rash, and occasionally jaundice, is caused by strains of *Leptospira interrogans*, a spirochete. The septicemic phase, during which leptospira are present in the bloodstream of patients, usually resolves within 1-2 weeks. It is typically acquired by contact with urine of infected animals, including cattle, swine, dogs, and rats; 43 cases were reported in 1987 (Ex. 6-465). No cases of nosocomial transmission by blood have been reported.

Arboviral infections: Arboviral infections generally do not lead to high or sustained levels of viremia in humans, therefore, there is little potential for person-to-person transmission of these infections through blood products or needlestick exposure.

The exception is Colorado tick fever (CTF) caused by a tick-borne virus which infects red blood cells. Within 3-14 days following tick exposures, the patient experiences fever, chills, headache, muscle and back aches. Several hundred cases are reported annually and transmission by blood transfusion has been documented (Ex. 6-416).

Relapsing fever: Relapsing fever is a rare disease, caused by pathogenic *Borreliae*, transmitted by lice or ticks and characterized by recurring febrile episodes separated by periods of relative well-being. In the United States, a few cases of tick-borne relapsing fever are reported in localized geographic areas (Western United States). Though very rare, occupational transmission as a result of patient care practices has been reported. Infections have been attributed to blood from the vein of a patient squirting into the nose of a technician and, in another incident, splashing into another HCW's eye from a placental specimen (Ex. 6-488).

Creutzfeldt-Jakob disease: Creutzfeldt-Jakob disease, a rare disease with worldwide distribution, is a degenerative disease of the brain caused by a virus. It is believed to be transmitted by ingestion of or inoculation with infectious material, primarily neural tissue. No cases of nosocomial transmission by blood have been reported, although rare instances of transmission have occurred

secondary to homologous dura mater implants, receipt of human growth hormone, and insertion of unsterilized stereotactic electrodes which had been inserted into the brains of Creutzfeldt-Jakob disease patients and then used on others (Ex. 6–492). There is a report of a case of Creutzfeldt-Jakob Disease, confirmed by autopsy, in a neuropathology histopathology technician. She had been employed in the neuropathology facility for 22 years and her duties included rinsing formalin-fixed brains and processing, cutting and staining sections of brain. Log records indicated that during her tenure two individuals with CJD were autopsied, 16 and 11 years prior to the technicians illness. It is not known how this individual became infected (Ex. 6–546). The record contains a number of articles discussing suggested precautions for handling materials from patients with CJD (Exs. 6–541; 6–542; 6–543; 6–544; 6–545 6–548).

Human T-lymphotropic Virus Type I: Human T-lymphotropic virus type I (HTLV–I), the first human retrovirus to be identified, is endemic in southern Japan, the Caribbean, and in some parts of Africa, but it is also found in the United States, mainly in intravenous drug users (Ex. 6–493). The virus can be transmitted by transfusion of cellular components of blood (whole blood, red blood cells, platelets) (Ex. 6–499). HTLV–I has been associated with a hematologic malignancy known as adult T-cell leukemia/lymphoma and with a degenerative neurologic disease known as tropical spastic paraparesis or HTLV–I-associated myelopathy. There is some evidence that the neurologic disease may be associated in some cases with blood transfusion (Ex. 6–494). No cases of occupy-tonal acquisition of HTLV–I infection have been reported.

Viral hemorrhagic fever: The term viral hemorrhagic fever refers to a severe, often fatal illness caused by several viruses not indigenous to the United States, but very rarely introduced by travelers coming from abroad. These illnesses are characterized by fever, sore throat, cough, chest pain, vomiting, and in severe cases, hemorrhage, encephalopathy and death. Although a number of febrile viral infections may produce hemorrhage, only the agents of Laesa, Marburg, Ebola, and Crimean-Congo hemorrhagic fevers are known to have caused significant outbreaks of disease with person-to-person transmission, including nosocomial transmission (Ex. 6–417). Blood and other body fluids of patients with these illnesses are considered infectious. Any patient suspected of illness due to one of these agents should be reported immediately to the local and state health departments and to the Centers for Disease Control. The bacterial and parasitic diseases listed above are treatable with antibacterial or antimalarial drugs. No specific therapy is available for the viral diseases, with the exception of Laesa fever. Precautions designed to minimize transmission of the more important bloodborne viral diseases, namely HIV, hepatitis B, and non-A, non-B hepatitis, would be effective in minimizing occupational transmission of all the above agents in the clinical setting.

V. Quantitative Risk Assessment

(A) Introduction

The United States Supreme Court, in the "benzene" decision (*Industrial Union Department, AFL–CIO* v. *American Petroleum Institute*, 448 U.S. 607 (1980)), has ruled that the OSH Act requires that, prior to the issuance of a new standard, a determination must be made, based on substantial evidence in the record considered as a whole, that there is a significant risk of health impairment under existing exposure conditions and that issuance of a new standard will significantly reduce or eliminate that risk. The Court stated that "before he can promulgate any permanent health or safety standard, the Secretary is required to make a threshold finding that a place of employment is unsafe in the sense that significant risks are present and can be eliminated or lessened by a change in practices" (448 U.S. 642). The Court also stated "that the Act does limit the Secretary's power to require the elimination of significant risks" (448 U.S. 644).

The Court in the Cotton Dust case, (*American Textile Manufacturers Institute* v. *Donovan*, 452 U.S. 490 (1981)), rejected the use of cost-benefit analysis in setting OSHA standards, it reaffirmed its previous position in "benzene" that a risk assessment is not only appropriate, but also required to identify significant health risk in workers and to determine if a proposed standard will achieve a reduction in that risk. Although the court did not require OSHA to perform a quantitative risk assessment in every case, the Court implied, and OSHA as a matter of policy agrees, that risk assessments should be put into quantitative terms to the extent possible.

OSHA has presented its views on risk assessment in detail in several proceedings such as the Supplemental Statement of Reasons for Final Rule for occupational exposure to Inorganic Arsenic (48 FR 1867), the Notice of Proposed Rulemaking for occupational exposure to Ethylene Dibromide (48 FR 45956), as well as in the rulemaking record for exposure to Bloodborne Pathogens, including the preamble to the proposed standard, the preliminary quantitative risk assessment for HBV infection, and the qualitative risk assessment for HIV infection in an occupational setting.

Quantifying the risk associated with exposure to bloodborne diseases such as HBV or HIV is different than quantifying the risk associated with exposure to toxic chemicals, the risks that OSHA has typically quantified. For most of these chemicals, response, in the form of adverse health effects, is associated with cumulative dose, and workers risk chronic health effects from long term exposure to airborne concentrations of the chemical. The response associated with exposure to bloodborne pathogens does not depend on cumulative dose acquired through years of exposure. With each exposure, either infection occurs or it does not occur. While repeated exposure increases the cumulative risk of infection within a specified time period, each exposure is associated with a unique risk which is the same for anyone exposed to the virus and depends upon the virulence of the pathogen, the size of the delivered dose, the route of exposure, among other factors, and not upon any prior exposure. Thus, in the case of bloodborne diseases, the best way to reduce the risk of trasmission is by reducing exposure.

HBV is a bloodborne pathogen for which there are sufficient data to quantify the risk of infection from occupational exposure to blood or other potentially infectious material (hereafter referred to as occupational exposure) for an entire population of workers. Further, healthcare workers are the only occupational group for which data on the risk of HBV infection in an occupational setting are available to OSHA. A healthcare worker is defined as anyone employed in the healthcare industry. It includes persons working in medical and dental labs, nursing homes, dialysis centers, housekeeping staff as well as doctors and nurses (for a more extensive listing of occupations see TABLE VII–4.) OSHA will use the available data to estimate the annual and lifetime occupational HBV infection risk to healthcare workers with occupational exposure (approximately 4.9 million employees). From this OSHA will extrapolate the HBV risk estimate

to non-healthcare employees with occupational exposure to blood or other potentially infectious material such as law enforcement officers and fire fighters (approximately 1.2 million.) OSHA believes and the record supports it, that it is the exposure to blood or other potentially infectious materials that places the employees at risk for hepatitis B and not some other factor unique to healthcare employment. This conclusion is supported by the epidemiological studies reviewed for this rulemaking as well (Exs. 4–13; 4–14; 4–16; 6–65). Therefore, OSHA will assume that the risk to non-healthcare workers with occupational exposure is similar to the risk of healthcare workers with equivalent occupational exposure. However, the record does not contain any usable quantitative data on non-healthcare workers and therefore, OSHA's extrapolated estimate may be higher or lower than the true occupational risk to non-healthcare workers.

A number of epidemiological studies demonstrate an increased prevalence of hepatitis B markers in the blood of healthcare workers with blood exposure, and a brief review of some of these studies is presented below, followed by OSHA's final assessment of HBV risk posed by occupational exposure to bloodborne pathogens including a summary and evaluation of comments submitted to the record. Finally, OSHA presents a qualitative risk assessment for infection from occupational exposure to HIV.

(B) Review of the Epidemiology of HBV Infection in Healthcare Workers

Numerous epidemiological studies have measured the prevalence of HBV infection among healthcare workers. These studies determined what proportion of healthcare workers had ever been infected with HBV and measured prevalence as the proportion of workers with any serological marker of past or present HBV infection. Most of the studies relied upon the voluntary cooperation of the study population, so there is some chance for bias to be introduced into any estimate of HBV prevalence. Healthcare workers who know they are infected with HBV at the time of study or who know they are HBV carriers may decline to participate in a study which they may feel could jeopardize their careers. This would lead to an underestimate of the prevalence of HBV infection among healthcare workers. However, the inclusion of healthcare workers who engage in non-occupational high risk behaviors could potentially lead to an overestimate of the annual HBV infection risk.

Jovanovich et al. did not rely upon voluntary participation in their study of HBV prevalence among workers at a 1000-bed community hospital in Detroit (Ex. 4–14). The authors reported a high prevalence of HBV among employees in worksites where blood and other potentially infectious materials are present (Ex. 4–14). All new employees were screened for HBV markers at the time of hire, and the blood tests were repeated every six months thereafter for all employees designated as being at high risk for HBV infection. In the hemodialysis unit, these tests were repeated monthly. This design allowed investigators to determine not only the HBV prevalence but also the conversion rate to HBV seropositivity per 100 employee-years. Jovanovich et al. reported the highest prevalence of HBV among the emergency room staff (27.9%), followed by the operating room staff (25.2%), the hemodialysis unit staff (17.2%), the dental staff and oral surgery (15.4%), and the staff of the intensive care unit (12.7%) (Ex. 4–14). The authors did not state what proportions of the study subjects were in specific occupations (e.g., physicians, nurses, etc.). The emergency room staff experienced the highest rate of conversion to HBV seropositivity with a conversion rate of 11.7 per 100 employee-years (Ex. 4–14).

Like Jovanovich et al., Dienstag and Ryan found the highest prevalence of serological markers for HBV among the emergency room staff, (specifically nurses), in a study of workers at an 1100 bed urban teaching hospital in Boston (Ex. 4–13). This study relied upon voluntary participation, and of 830 staff at the hospital, 624 or 75% agreed to participate. Among workers with frequent blood contact, the prevalence of HBV serological markers was 21.2% versus 8.6% for workers with occasional, rare, or no blood contact ($p < .001$). The highest rates of sero positivity were found among emergency room nurses, pathology staff, blood bank staff, laboratory technicians, intravenous teams, and surgical house officers. The prevalence of HBV serological markers was 30% among emergency room nurses and was in excess of 15% in each of the other groups. Workers with less contact had HBV serological markers at rates between 5% and 10%. Four of thirty-two administrators, (16%), were found to have serological markers of HBV infection, but the authors stated that the high observed prevalence among this group may have been related to the inclusion of two persons known to be members of a high risk group. All of these groups were compared to a population of 462 volunteer blood donors, which had a 5% prevalence of HBV markers. Neither frequency of patient contact nor socioeconomic status (SES), as measured by years of education, were found to be associated with the prevalence of HBV serological markers. SES is often associated with prevalence of HBV infection but not among this cohort. Indeed, as demonstrated in Table V–1, among workers with a comparable level of education, frequency of blood contact was statistically significantly associated with HBV prevalence. Prevalence increased with age for all employees regardless of degree of blood contact, but prevalence was observed to increase with years in occupation only for workers with frequent blood contact.

TABLE V-1.—CORRELATION BETWEEN FREQUENCY OF BLOOD CONTACT AND HBV PREVALENCE IN HOSPITAL WORKERS WITH UNIFORM SOCIOECONOMIC STATUS MEASURED BY YEARS OF EDUCATION [a]

Personnel	Exposure to blood	N	No. with HBV markers (%)	Odds ratio	Chi-square (p-value)
Physicians [b]	Frequent	81	17 (21)	3.11	6.02
	Infrequent	89	7 (8)		($p < .02$)
Nurses [c]	Frequent	104	22 (21)	2.80	7.16
	Infrequent	126	11 (9)		($p < .01$)

[a] Data from Table 2 of Dienstag and Ryan (Ex. 4–13)
[b] Median level of education for the physicians was 20 years.
[c] Median level of education for the nurses was 17 years.

Pattison et al. reported similar findings of the relationship between frequency of blood contact and the prevalence of HBV in an earlier study conducted between 1972 and 1974 at a 495 bed urban hospital in Arizona (Ex. 6–65). The study population was selected from consecutive employees undergoing yearly physical examination on the anniversary of their initial employment examination. Except for physicians, study participants had been affiliated with the hospital for at least two years. Over 99% of the eligible employees, excluding physicians, representing 40% of all hospital personnel participated in the study (Ex. 6–65). The overall prevalence of HBV serological markers was 14.4% (Ex. 6–65). No association was observed between frequency of patient contact and prevalence of HBV, but the association between frequency of blood contact and prevalence of HBV was statistically significant ($p<.05$) (Ex. 6–65). Among workers with frequent blood contact, the seroprevalence of HBV markers was 18.9%; for workers with occasional blood contact, it was 13.4%; and for workers with no blood contact, it was 11.4%. Socioeconomic status, as measured by the Hollingshead Index derived from educational level attained and category of employment (highest socioeconomic level corresponding to Hollingshead Index 1; lowest socioeconomic level corresponding to Hollingshead Index 5), was statistically significantly associated with HBV prevalence but only when categories 1 through 4 were combined and compared to category 5. Among workers with similar Hollingshead indices (i.e. controlling for socioeconomic status), workers with frequent or occasional blood contact were twice as likely to have serological markers for HBV as were workers with no blood contact (Ex. 6–65). This is demonstrated in Table V–2.

TABLE V-2.—CORRELATION BETWEEN FREQUENCY OF BLOOD CONTACT AND HBV PREVALENCE IN HOSPITAL WORKERS WITH SIMILAR SOCIOECONOMIC STATUS MEASURED BY THE HOLLINGSHEAD INDEX [a]

Hollingshead index [b]	Exposure to blood [c]	N	No. with HBV markers (%)	Odds ratio	Chi-square (p-value)
1 and 2	Freq/Occ	136	18 (13.2%)	2.21	1.09
	Never	31	2 (6.5%)		(p<.25)
3 and 4	Freq/Occ	125	20 (16.0%)	1.97	2.56
	Never	102	9 (8.8%)		(p<.10)
5	Freq/Occ	41	13 (31.7%)	2.55	4.34
	Never	78	12 (15.4%)		(p<.05)
Total	Freq/Occ	302	51 (16.9%)	1.66	3.57
	Never	211	23 (10.9%)		(p<.10)

(*) Data from Table 3 of Pattison et al. (Ex. 6–65).
(*) The Hollingshead Index is a measure of socioeconomic status derived from educational level attained and category of employment. The highest socioeconomic level corresponds to Hollingshead Index 1; the lowest socioeconomic level corresponds to Hollingshead Index 5.
(*) Pattison categorized blood exposure as frequent or occasional (Freq/Occ) versus never.

In a more recent study by Hadler et al., frequency of blood contact but not frequency of patient contact was again shown to be strongly related to HBV prevalence (Ex. 4–16). Of all employees at three urban teaching hospitals and two midwest community hospitals, 5,697 (36%) participated in this study. Serological markers of past or present HBV infection were found in 14.2% of the study population (Ex. 4–16). For workers with frequent blood contact, the prevalence of HBV markers increased with duration in occupation at a rate of 1.05 infection per 100 person-years ($R=.95$; $p<.01$), and for workers with occasional blood contact, the prevalence increased at a rate of .71 infections per 100 person-years ($R=.85$; $p=.05$) (Ex. 4–16). Among workers with no blood contact, HBV prevalence was constant over the duration of employment. Hadler et al. also found that frequency of needle accidents was related to HBV prevalence. Among workers with frequent or occasional needle accidents, HBV prevalence increased with duration in occupation at a rate of .80 infections per 100 person-years, and among workers with rare needle accidents, prevalence increased at a rate of .72 infections per 100 person-years (Ex. 4–16). Among workers who reported no needle accidents, the increase in HBV prevalence with duration in occupation was much lower (.24 infections per 100 person-years). When subjects were stratified into groups by degree of blood contact, frequency of needle contact was positively associated with HBV infection rates only in persons with frequent blood contact and not in persons having occasional or no blood contact (Ex. 4–16).

Needlesticks and cuts with sharp objects are by no means the only way workers with exposure to blood or other potentially infectious material can be exposed to the hepatitis B virus. In a study of the transmission of HBV in clinical laboratory areas, Lauer et al. found that 28 of 76 (34%) environmental surfaces sampled were positive for hepatitis B surface antigen (HBsAg) (Ex. 6–56). Samples were taken in a dialysis room specifically used for patients who had HBV infections at the time of dialysis. In addition, samples were collected in the clinical laboratory where tests were done on blood samples drawn from HBV-infected dialysis patients. The HBsAg was found on the outside of 6 of 11 (55%) of the sampled blood-specimen containers and 4 of 9 (44%) of the sampled serum-specimen containers (Ex. 6–60). The gloves and bare hands of personnel who had contact with the blood- and serum-specimen containers were also sampled, and two of the three samples taken, including one from a bare hand, were positive for HBsAg (Ex. 6–50). Other contaminated surfaces included the handle portion of pipetting aids, marking devices, and an assay instrument for complete determination of blood cell counts. The authors stated that their "data indicate that transmission of HBV in the clinical laboratory is subtle and mainly via hand contact with contaminated items during the various steps of blood processing. These data support the concept that the portal of entry of HBV is through inapparent breaks in skin and mucous membranes." (Ex. 6–56, p. 513).

(C) Quantitative Assessment of HBV Risk

OSHA's quantitative risk assessment focuses on HBV infection in healthcare workers because healthcare workers with occupational exposure to blood or

other potentially infectious material constitute the only occupational group with such exposure for which OSHA has sufficient data to quantitatively estimate the occupational risk of HBV infection (for a listing of occupations included see section VII, Table VII–4). OSHA believes, and the record supports it, that it is the exposure to blood or other potentially infectious material that places these workers at risk for HBV and not some other factor unique to healthcare workers. This conclusion is borne out by the epidemiological studies reviewed in the previous section. Further, OSHA believes that the risk to non-healthcare workers with occupational exposure is similar to the risk of healthcare workers. Therefore, OSHA will use the data available for healthcare workers with occupational exposure to predict the HBV infection risk to any worker with occupational exposure to blood or other potentially infectious material.

Estimates of the incidence of HBV infection in the U.S. population in general and among healthcare workers in particular come from the Hepatitis Branch of the Center for Infectious Disease, U.S. Public Health Service's Centers for Disease Control (CDC). There are two systems for collecting information on hepatitis: The CDC National Morbidity Reporting System and the Viral Hepatitis Surveillance Program (VHSP). The National Morbidity Reporting System collects data on the number and type of hepatitis infections as well as the patients' ages in reported cases. The VHSP collects serological and epidemiological data pertaining to risk factors for the disease (Ex. 6–217). Based on the 1988 national hepatitis surveillance data, the CDC estimates that there were 280,000 HBV infections in 1988 in the U.S. Of these, it is estimated that 8,700 were in persons whose only source of infection was related to healthcare employment (Ex. 298). "This estimate is derived from cases of hepatitis B reported to the Viral Hepatitis B Surveillance Program (VHSP) in which employment as a health care worker was the only source of infection and from surveillance data in the Sentinel Counties Study of Viral Hepatitis." (Ex. 298). Only a fraction of the 280,000 estimated infections are actually reported to the CDC because most infections produce no symptoms and people are unaware that they have contracted hepatitis B. Furthermore, even when people become ill enough to seek medical help, the disease is not always correctly diagnosed or faithfully reported. CDC estimates that approximately 1 in 12 cases of hepatitis B is actually reported (Stephen C. Hadler, M.D., Tr. 9/18/89, p. 12). For its risk assessment, OSHA will use the latest available data, as reported by CDC, and assume that exactly 280,000 HBV infections occur each year.

OSHA estimates that there are approximately 4.9 (4,897,595) million healthcare workers with occupational exposure putting them at risk for bloodborne diseases including HBV (see Benefits in section VII). A portion of the 4.9 million workers are not at risk for HBV infection because of immunity. OSHA estimates that approximately 2.6 million (2,568,974) adults have received either the plasma-derived or the yeast hepatitis B vaccine of which approximately 2.0 million (2,029,189) are estimated to be healthcare workers (See section VII). Further, 96% of the vaccinated workers are considered to have achieved immunity to further infection (Ex. 292). In addition, CDC estimates that between 15% and 30% of healthcare workers with occupational exposure (734,700 to 1,469,400) have already been infected with HBV and are now immune to further infection (Ex. 6–199).

The number of people vaccinated, as estimated by OSHA, differ slightly from those reported by Merck Sharp and Dohme (Merck) (Ex. 292). In their post-hearing comment Merck reported sales of approximately 5.6 million doses of the three-dose series of HEPTAVAX–B and 3.0 million doses of the three-dose series of RECOMBIVAX–B (Ex. 292). The company then extrapolated from the sales figures that, at a minimum, 2.9 million people have received the three-dose series of the hepatitis B vaccine (Ex. 292). Further, Merck estimated 85% of 2.9 million, or 2.5 million are currently in the work force covered by the proposed standard (Ronald W. Ellis, M.D., Tr. 9/18/89, p. 77). The discrepancy between Merck's and OSHA's numbers may be explained by the fact that Merck's estimate reflects company sales and not necessarily amount of vaccine actually used, where OSHA's estimate reflects the minimum number of vaccinated people who have received the three-dose regimen as derived from the Agency's survey (Exs. 284; 286). For the risk assessment, the Agency will use the results from OSHA's survey as being more reflective of the actual number of healthcare employees who are fully protected against HBV infection. However, the survey most likely underestimates the number of vaccinated individuals because not everyone will receive the three-dose regimen.

There is abundant testimony and other evidence in the record demonstrating the effectiveness of the vaccine. Protective HB antibody levels were present in over 96% of healthy adults who have received the series (Ronald W. Ellis, M.D., Tr. 9/18/89, p. 86; Ex. 292). Therefore, OSHA estimates that (2,029,189 x .96) = 1,948,021 workers, are immune to HBV as the result of vaccination. Prior infection and vaccination, remove between 2,833,000 and 3,390,500 from the pool of 4.9 million healthcare workers with occupational exposure, leaving between 2,065,000 and 2,507,500 workers at risk for HBV infection. To estimate the number of healthcare workers at risk OSHA did the following: The number of healthcare workers immune from vaccination (1,948,000) was first subtracted from the total number at risk (4,898,000). The remaining pool was further reduced by either 15% or 30% to account for the range of people who are immune to hepatitis B because of previous infections.

Of the 280,000 HBV infections each year (based on 1988 Hepatitis Surveillance data), CDC estimates that 8,700 cases occur in health care workers with occupational exposure (Ex. 298). If between 2,065,000 and 2,507,500 healthcare workers are at risk, then the annual HBV infection rate for these workers is between 3.47 and 4.21 per 1,000 exposed workers (See Table V–3). OSHA's estimate of the annual HBV infection rate is an empirical estimate of the probability of HBV infection for healthcare workers exposed to blood or other potentially infectious materials who lack immunity either because of prior infection or vaccination. This estimate of the annual HBV infection risk applies to the population of healthcare workers with occupational exposure and not to a specific healthcare worker picked at random. The estimate of the annual HBV infection risk for a healthcare worker who has been vaccinated or has been previously infected (i.e. is immune to HBV) is zero. The annual HBV infection risk for any healthcare worker with occupational exposure randomly selected will depend entirely upon the immune status of that worker.

Clearly it is possible for workers with exposure to blood to become infected with HBV by means other than occupational exposure. The virus can be transmitted sexually and by non-occupational exposure to blood. In addition, over 50% of all cases of HBV reported to the Centers for Disease Control in 1985 had no known risk factors (Ex. 6–217).

Several commenters viewed OSHA's estimates as being overestimates of the true risk by stating that OSHA did not appropriately consider the fact that most healthcare workers who are infected with hepatitis B probably contracted their infection due to factors outside the workplace (Ex. 20–2879C). In fact, OSHA took measures to exclude the effect of high risk behaviors in healthcare workers by estimating the risk attributable to occupational exposure. The risk attributable to occupational exposure is the difference between the risk faced by exposed workers and the background risk faced by the general population. In order to remove that portion of HBV cases in healthcare workers that might be due to IV drug use or other known risk factors, the Agency subtracted from the healthcare worker risk the background (population) risk of HBV infection. Dr. Stephen Hadler, an expert on viral hepatitis from the Hepatitis Branch of the CDC, supported this methodology of calculating the risk of HBV infection attributable to occupational exposure in his testimony (Stephen C. Hadler, M.D., Tr. 9/18/89, p. 36).

There were 193,220,000 residents, over the age of 15, in the U.S. in 1988 (Ex. L6–665) (note: Exhibit L6–665 is an updated version of Exhibit 6–389. Reliance on the old data would not have changed the results of the annual HBV infection rate). Of these, it is estimated that 4.8% (approximately 9.3 million) have been infected with hepatitis B and, therefore, are immune (Ex. 6–390). In addition, we will assume that all of the 2,569,000 persons who have received the hepatitis B vaccine are adults and that 96% of them (2,466,000) are immune. Therefore, of the 193 million adults in the U.S., approximately 182 million are at risk of HBV infection. The number of adults at risk in the U.S. was estimated by first removing the number of adults immune from vaccination (2,466,000) from the total population and subsequently reducing the remaining pool by 4.8%. Given that there are 280,000 cases of infection each year, the annual infection rate is 1.54 infections per 1000 adults. This estimated infection rate for the entire adult population constitutes the background risk for HBV. In other words, OSHA estimates that the probability that an adult in the U.S. will be infected with HBV this year is .00154. Estimates of the populations at risk and their HBV infection rates are given in Table V–3.

TABLE V–3.—ESTIMATE OF POPULATIONS AT RISK FOR HBV INFECTION [a]

	U.S. adults	Healthcare workers with occupational exposure
Number in population	193,220,000	4,898,000
Percent immune [c]	4.80	15–30
Number immune	9,275,000	734,700–1,469,400
Number vaccinated	2,569,000	2,029,000
Percent vaccinated	1.33	41.43
Number immune from vaccination [b]	2,466,000	1,948,000
Number at risk	181,598,000	2,065,000–2,507,500
Annual HBV infection rate per 1,000 exposed healthcare workers who lack immunity	1.542	3.470–4.213

[a] Most numbers have been rounded to the nearest thousand.
[b] This assumes vaccination efficacy to be 96%.
[c] Percent immune is the proportion of the population which has already been infected with the HB virus. Previous infection confers life-long immunity

OSHA's estimate of the background risk of HBV infection is probably much higher than the actual risk faced by most adults. Certain behaviors are known to substantially increase the risk of HBV infection, but not all adults engage in these behaviors with equal probability. For example, a recent General Social Survey conducted in early 1988 recorded homosexual activity among 3.2% of 504 sexually active men in the previous 12 months, yet the proportion of HBV cases associated with homosexual activity in 1987 in the CDC's Sentinel County study was 9%, nearly three times as large as the percentage of homosexual activity reported (Exs. 6–342; 6–321). Intravenous drug users, who accounted for 28% of the HBV cases in 1987 in the same CDC study, are another group which are disproportionately represented in the number of HBV cases as compared to their number in the adult population. Removing the HBV cases associated with homosexual activity and IV drug use from the annual number of cases and removing adult men who engage in homosexual activity and IV drug users from the population at risk would substantially reduce OSHA's estimate of the background risk of infection because a greater proportion of cases would be removed from the number of HBV cases (i.e. the numerator) than the proportion of people removed from the population at risk (i.e. the denominator). Unfortunately, there are no reliable estimates of the number of people engaging in high risk behaviors such as homosexual activity or IV drug use. Therefore, OSHA must rely on its estimate of 1.54 HBV infections per 1000 adults as its estimate of the background risk, but the Agency is aware that the true risk for most adults in the U.S., and therefore the background risk for healthcare workers, is probably much lower.

As outlined in the discussion of the health effects of HBV, there are a number of possible outcomes following infection. Between two thirds and three fourths of all infections result in either no symptoms of infection or a relatively mild flu-like illness. Between 25% and 33% of the infections, however, take a much more severe clinical course. As noted above, the symptoms include jaundice, dark urine, extreme fatigue, anorexia, nausea, abdominal pain, and sometimes joint pain, rash, and fever. For its risk assessment, OSHA will use the lower estimate of 25% as the proportion of HBV infections which take a more severe clinical course. Hospitalization is required in about 20% of the more severe clinical cases.

CDC estimates that 2.225% of HBV infections lead to death (Ex. 6–392). Death from fulminant hepatitis occurs in 0.125% of cases (Ex. 6–392). Death from cirrhosis of the liver is estimated to occur in 1.7% of cases, and death from primary hepatocellular carcinoma is estimated to occur in 0.4% of cases (Ex. 6–392). Between 5% and 10% of individuals infected with HBV become chronic carriers of the virus (Ex. 6–392). These individuals represent a pool from which the disease may spread. About 25% of the chronic carriers suffer from chronic active hepatitis (Ex. 6–392). The estimated numbers of infections that result in any of these outcomes each year in both the adult population and in the population of healthcare workers is presented in Table V–4. Among the

adult population, approximately 182 million persons are estimated to be at risk for HBV. As shown in Table V–3, there are between 2,065,000 and 2,507,500 healthcare workers annually at risk for HBV infection. Using the estimates of annual HBV infections from Table V–4 and the population estimates from Table V–4, the annual risk of HBV infection for the adult population and for any healthcare worker with occupational exposure have been calculated and are presented as rates per 1,000 exposed workers in Table V–5. A healthcare worker is defined as anyone employed in the healthcare industry. It includes persons working in medical and dental labs, nursing homes, dialysis centers, housekeeping staff as well as doctors and nurses. OSHA assumes that the annual risk of HBV infection for workers with occupational exposure to blood and other potentially infectious materials is similar to that of healthcare workers with equivalent exposures.

TABLE V–4.—ESTIMATES OF THE NUMBER OF ANNUAL HBV INFECTIONS AND OUTCOMES IN THE U.S. POPULATION AND AMONG HEALTHCARE WORKERS EXPOSED TO BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIAL [a]

	U.S. adults	Healthcare workers with occupational exposure
HBV Infections	280,000	8,700
Clinical Illness (25%)	70,000	2,175
Hospitalized (5%)	14,000	435
HBV Carrier (5%–10%)	14,000–28,000	435–870
Chronic HBV (25% Carriers)	3,500–7,000	109–218
Fulminant Death (.125%)	350	11
Death—Cirrhosis (1.7%)	4,760	148
Death—PHC [b] (0.4%)	1,120	35
All Deaths (2.225%)	6,230	194

[a] Data from Ex. 298 and Ex. 6–392.
[b] Primary Hepatocellular carcinoma.

Table V–6 presents the risk attributable to occupational exposure for HBV infection and its outcomes per 1000 exposed workers. The annual risk attributable to occupational exposure is simply the difference between the annual risk faced by exposed workers and the annual risk faced by the adult population, both given in Table V–5. Because Section (6)(b)(5) of the OSH Act states that no employee shall suffer "material impairment of health or functional capacity even if such an employee has regular exposure to the hazard dealt with * * * for the period of his working life", OSHA has converted the attributable annual risk into an attributable lifetime risk on the assumption that a worker is employed in his or her occupation for 45 years. Table V–6 shows that for every 1000 workers with occupational exposure to blood or other potentially infectious material, between 83 and 113 will become infected with HBV over the course of their working lifetime because of occupational exposure to the virus. Of these, 21 to 30 will suffer clinical illness and 4 to 6 will need hospitalization. Between 4 and 12 of the cases with clinical illness will become chronic carriers, and 1 to 3 of them will suffer from chronic hepatitis. HBV infection from occupational exposure will lead to the death of 2 to 3 of these 1000 exposed workers.

TABLE V–5.—ESTIMATES OF THE ANNUAL RISK FOR HBV INFECTION AND ITS OUTCOMES IN THE U.S. ADULT POPULATION AND AMONG HEALTHCARE WORKERS EXPOSED TO BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIAL [a]

	U.S. adults	Healthcare workers with occupational exposure [b]
HBV Infections	1.542	3.470–4.213
Clinical Illness (25%)	0.386	0.868–1.053
Hospitalized (5%)	0.077	0.174–0.211
HBV Carrier (5%–10%)	0.077–0.154	0.174–0.421
Chronic HBV (25% Carriers)	0.019–0.039	0.043–0.105
Fulminant Death (.125%)	0.002	0.004–0.005
Death—Cirrhosis (1.7%)	0.026	0.059–0.072
Death—PHC [c] (0.4%)	0.006	0.014–0.017
All Deaths (2.225%)	0.034	0.077–0.094

[a] Risks are expressed as the number of events per 1,000 exposed healthcare workers who lack immunity.
[b] Risks for exposed workers are estimated assuming 15% and 30% of the workers had a previous infection and are thus immune.
[c] Primary Hepatocellular carcinoma.

TABLE V–6.—HBV RISK ATTRIBUTABLE TO OCCUPATIONAL EXPOSURE FOR HEALTHCARE WORKERS EXPOSED TO BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIAL [a, b]

	Annual risk [c]	Lifetime occupational risk [d]
HBV Infections	1.928–2.671	83.18–113.40
Clinical Illness (25%)	0.482–0.668	21.46–29.61
Hospitalized (5%)	0.096–0.134	4.33–5.99
HBV Carrier (5%–10%)	0.096–0.267	4.33–11.95
Chronic HBV (25% Carriers)	0.024–0.067	1.06–3.00
Fulminant Death (.125%)	0.002–0.003	0.11–0.15
Death—Cirrhosis (1.7%)	0.033–0.045	1.47–2.04

TABLE V–6.—HBV RISK ATTRIBUTABLE TO OCCUPATIONAL EXPOSURE FOR HEALTHCARE WORKERS EXPOSED TO BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIAL [a, b]—*Continued*

	Annual risk [c]	Lifetime occupational risk [d]
Death—PHC (0.4%)	0.008–0.011	0.35–0.48
All Deaths (2.225%)	0.043–0.059	1.93–2.67

[a] Risks are expressed as the number of events per 1,000 exposed healthcare workers who lack immunity.
[b] The risk attributable to occupational exposure is the difference between the annual risk faced by exposed workers and the annual risk faced by the adult population, both given in Table V–5.
[c] Risks for exposed workers are estimated assuming 15% and 30% of the workers had a previous infection and are thus immune.
[d] Assumes 45 years of occupational exposure and is calculated as $[\ 1 - (\ 1 - p\ )^{45}\ ]$, where p is the annual risk divided by 1,000. Assumes p is constant through time.

OSHA's estimate of the risk of HBV infection attributable to occupational exposure to blood or other potentially infectious material is most likely an underestimate of the true risk. As noted above, the true risk of HBV infection among the majority of U.S. adults is probably much lower than OSHA's estimate of the background risk since the majority of adults do not engage in the high risk behaviors associated with a large proportion of HBV infections. By overestimating the background risk, OSHA has probably underestimated the risk attributable to occupational exposure. In addition, OSHA's estimate of the number of people with immunity to hepatitis B because they have been vaccinated reflects the minimum number of vaccinated people who have received the three-dose regimen. However, OSHA's survey most likely underestimates the number of vaccinated individuals because not everyone receives the three-dose regimen. In doing so, OSHA's estimate of HBV risk attributable to occupational exposure may be slightly underestimated.

Nonetheless, OSHA's calculations show that workers with occupational exposure are at a substantially increased risk of infection, clinical illness, hospitalization, chronic hepatitis, and death over the course of their working lifetimes. These workers are at an increased risk of becoming HBV carriers which is frequently associated with serious chronic illness and of transmitting the infection sexually and perinatally.

Since 1982, a plasma-derived hepatitis B vaccine, HEPTAVAX B, has been available. In July of 1986, a genetically engineered hepatitis B vaccine, RECOMBIVAX HB, manufactured by Merck Sharp & Dohme, was licensed by the U.S. Food and Drug Administration. In August of 1989, a second recombinant DNA hepatitis B vaccine, ENGERIX B, manufactured by SmithKline and Beecham, was approved for marketing in the United States by the U.S. Food and Drug Administration (Jerome A. Boscia, M.D., Tr. 12/19/89, p.985): "Due to the increasing popularity of Merck's alternative recombinant vaccine, as well as the increasing difficulty of obtaining plasma suitable for the manufacturing process, HEPTAVAX B is no longer in production" (Ronald W. Ellis, M.D., Tr. 9/18/89, p. 74). All vaccines have proven to be highly effective in preventing hepatitis B infection in high risk populations. When given in the recommended three dose series, Merck Sharp & Dohme reports that RECOMBIVAX HB has been found to induce protective antibodies in over 95% of healthy adults 20–39 years of age, but like the plasma-derived vaccine, the new vaccine induced a somewhat lower antibody response in older adults (Ex. 6–176). Although it was stated during testimony that large-scale studies directly measuring the efficacy of the recombinant hepatitis B vaccine in adults have not been done, Merck has sponsored numerous clinical studies of vaccine immunogenicity. The vaccine's immunogenicity is impacted by the age of the recipient with response rates lower in older adults than in younger adults. When a weighted average was taken to account for the age distribution of the recipients, it was determined that 96.4% of the healthy adults who receive the recombinant vaccine developed protective levels of antibody. However, when the data were adjusted to account for the difference between the age distribution of employees covered by this standard and the age distribution of recipients of the vaccine in the Merck study the immunogenicity rate was adjusted down to 92.7 percent (Ronald W. Ellis, M.D., Tr. 9/18/89, pp.85–86). Based on Merck's latest data, the .. seroconversion rate using RECOMBIVAX HB is expected to reach 99% when given in the recommended three-dose series to healthy adults between 20 and 29 years old (Ex. 292). To estimate the remaining occupational risk after vaccination, OSHA will assume a 96% vaccine efficacy rate instead of 92.7%, which is Merck's estimate of vaccine efficacy adjusted for the age distribution of those covered by this standard. Although the final estimate of 92.7% was provided to OSHA, Merck did not provide the basic data and underlying methodology based upon which this estimate was derived. Therefore, the Agency is unable to duplicate these results and determine the accuracy of these figures. By assuming 96%, OSHA may be underestimating the remaining risk to workers with occupational exposure. OSHA believes that administration of the hepatitis B vaccine will lead to a significant reduction in the HBV infection risk faced by workers with occupational exposure to blood or other potentially infectious material.

OSHA estimates that there are between 2,517,649 and 3,057,145 healthcare and other workers with occupational exposure who are both at risk for HBV and covered by this standard (see Table VII–4.) If all of these workers were vaccinated with a 96% effective hepatitis B vaccine, then over 45 years (a working lifetime under the Act), OSHA estimates that between 244,000 and 274,000 HBV infections would be prevented, between 61,000 and 68,500 cases of clinical illness would be prevented, and between 5,400 and 6,100 deaths would be prevented. The estimated number of HBV infections prevented is calculated as follows: the number of workers (at risk and covered by the standard) is multiplied by the lifetime occupational exposure risk (given in Table V–6) and by 0.96 to account for the vaccine efficacy. The estimated number of HBV infections and their outcomes which would be prevented by this provision are presented in Table V–7.

TABLE V-7.—INFECTIONS AND OUTCOMES PREVENTED IN HEALTHCARE WORKERS WITH 45-YEAR WORKING LIFETIME OF OCCUPATIONAL EXPOSURE TO BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS AFTER ADMINISTRATION OF HEPATITIS B VACCINE WITH 96% EFFICACY [a]

	Number prevented [b]
HBV Infections	244,122-274,081
Clinical Illness (25%)	61,031-68,520
Hospitalized (5%)	12,206-13,704
HBV Carrier (5%-10%)	12,206-27,408 [c]
Chronic HBV (25% Carriers)	3,052-6,852
Fulminant Death (.125%)	305-343
Death—Cirrhosis (1.7%)	4,150-4,659
Death—PHC (0.4%)	976-1,096
All Deaths (2.225%)	5,432-6,098

[a] Numbers are calculated assuming that vaccine is given to all workers with occupational exposure who are covered by this standard and who have not been vaccinated or had a prior HBV infection. The estimate of healthcare workers at risk and covered by the standard is between 2,517,649 and 3,057,145 (see TABLE VII-4). Benefits are estimated by applying 96% of the lifetime HBV risk attributable to occupational exposure given in TABLE V-6 to the estimates of healthcare workers at risk and covered by the standard.

[b] Risks for all exposed workers are estimated assuming 15% and 30% had a previous infection and are thus immune.

[c] Smaller number assumes that 30% of the workers are immune due to prior infection and 5% of the workers infected will become HBV carriers. Larger number assumes that 15% of the workers are immune and 10% of the workers infected will become HBV carriers.

Table V-8 presents the lifetime risk of HBV infection and its outcomes attributable to occupational exposure after administration of a 96% efficacious hepatitis B vaccine to employees at risk. Table V-8 shows that even if all employees are vaccinated and assuming the vaccine is 96% effective, the remaining risk of HBV infection to workers with occupational exposure is greater than 3 per thousand. After vaccination, the lifetime risk of HBV infection is between 3 and 5 per 1000, and the risk of clinical illness is approximately 1 per 1000. In constructing Table V-8, OSHA assumed that all workers at risk will agree to be vaccinated. However the record indicates that this has not been the case in the past and, although education of employees on the benefit of vaccination should increase acceptance, it is unlikely all workers will be willing to be vaccinated. OSHA witnesses testified that "* * * This [vaccination] program yielded about a 65 percent vaccination rate * * *" (Kathleen F. Gordon, M.S., Tr. 9/19/89, p. 9). "* * * The vaccination rates from 1982-1985 were 36-55 percent in the dental school and 23-47 percent in the medical school. The vaccination rate for the nursing school has always been below 10 percent which is attributed to lack of mandatory education, advocacy, and follow-up procedures * * *" (James A. Cottone, M.S., Tr. 9/19/89, p. 56). Dr. Joseph H. Coggin reported that the acceptance rate ranged from 20-25 percent primarily in blood laboratories, to 50 percent in the hospital because of a fairly active program, to 90 percent in laboratories where they work with hepatitis B or with HIV, to 100 percent where employees are required to be vaccinated if they want to work there (Joseph H. Coggin, Ph.D., Tr. 9/12/89, pp. 56-58). Dr. Campbell from The Baptist Medical Center testified that "* * * Eighty percent have accepted the offer and have been vaccinated. * * *" (Dr. L.L. Campbell, Tr. 9/19/89, p. 72). Angelica Corporation Health Services group reported approximately 40 percent of the employees at one plant accepted the vaccine (Jill Witter, Esq., Tr. 9/18/89, p. 163). Baylor University Medical Center reported that their latest data, January through June of 1989, indicated an average acceptance rate of 92 percent, while the overall rate for the years since the vaccine has been offered was in the 70 percent range. (Dr. W.L. Sutker, Tr. 9/27/89, p. 14). The National Funeral Directors Association reported a 40 percent acceptance rate of their vaccination program among members, (T. Ryan, Tr. 9/27/89, p. 293). The Methodist Hospital of Dallas reported a 90 percent rate amongst those offered the vaccine, (Dr. J.A. Barnett, Tr. 9/27/89, p. 221).

TABLE V-8.—ESTIMATE OF HBV INFECTION AND ITS OUTCOMES AMONG HEALTHCARE WORKERS EXPOSED TO BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIAL AFTER ADMINISTRATION OF HEPATITIS B VACCINE WITH 96% EFFICACY [a]

	Lifetime occupational risk [b,c]
HBV Infections	3.3272-4.5360
Clinical Illness (25%)	0.8318-1.1340
Hospitalized (5%)	0.1664-0.2268
HBV Carrier (5%-10%)	0.1664-0.4536
Chronic HBV (25% Carriers)	0.0416-0.1134
Fulminant Death (.125%)	0.0042-0.0057
Death—Cirrhosis (1.7%)	0.0566-0.0771
Death—PHC [d] (0.4%)	0.0133-0.0181
All Deaths (2.225%)	0.0740-0.1009

[a] Risks are expressed as the number of events per 1,000 exposed healthcare workers who lack immunity.

[b] Risks for exposed workers are estimated assuming 15% and 30% of the workers had a previous infection and are thus immune.

[c] Assumes 45 years of occupational exposure and is calculated by multiplying the lifetime occupational risk from Table V-6 by 0.04.

[d] Primary Hepatocellular carcinoma.

In general, acceptance rates of various hepatitis B vaccination programs implemented throughout the country ranged from over 95 percent to below 10 percent. This clearly demonstrates that, even in the presence of a well organized and supported vaccination program, not everyone is willing to accept the vaccine. A descriptive analysis of the reported compliance rates revealed a distribution with a mean of 55.9, a median of 56.5, a first quartile of 40, and a third quartile of 73 percent. This indicates that, based on evidence in the record, three fourths of the vaccination programs in existence reported compliance rates less than 75 percent. In addition, OSHA estimated an average compliance rate of 50 percent (see section VII). OSHA's average compliance rate was derived as a weighted average of data obtained from two surveys conducted by the Agency. Data from the surveys were collected for nineteen industry groupings (e.g., dentists' offices, dialysis centers, and home health care) and four occupational categories of employees. The four occupational categories represented were doctors, dentists and nurses (Category A); laboratory workers, emergency responders and fire fighters (Category B); housekeepers (Category C); and service workers (Category D). Vaccination acceptance rates were calculated for each occupational category found in a particular industry group. These acceptance rates were then weighted by the number of affected workers and yielded a 50 percent average acceptance rate. OSHA constructed a scenario where 50 percent of those offered the vaccine would actually agree to be vaccinated and estimated the remaining lifetime occupational risk assuming a 96% vaccine efficacy. These numbers are found in Table V-9. Under an assumption of 50 percent compliance to a vaccination program and 96 percent efficacy rate the remaining lifetime occupational risk is highly significant. A range of 43 to 60 HBV infections are expected to occur per one thousand exposed workers per working lifetime. This will result in 11 to 15 clinical illnesses and approximately one death per thousand exposed workers.

TABLE V-9.—ESTIMATE OF LIFETIME OCCUPATIONAL RISK AMONG HEALTHCARE WORKERS EXPOSED TO BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIAL [a]

	Lifetime occupational risk [b]		
	100% vaccination rate	50% vaccination rate [c]	0% vaccination rate
HBV Infections	3.485–4.797	43.25–58.97	83.18–113.40
Clinical Illness (25%)	0.867–1.201	10.81–14.74	21.46–29.61
Hospitalized (5%)	0.174–0.240	2.16–2.95	4.33–5.99
HBV Carrier (5%–10%)	0.174–0.481	2.16–5.90	4.33–11.95
Chronic HBV (25% Carriers)	0.043–0.120	0.54–1.47	1.08–3.00
Fulminant Death (.125%)	0.004–0.006	0.05–0.07	0.11–0.15
Death—Cirrhosis (1.7%)	0.059–0.082	0.74–1.00	1.47–2.04
Death—PHC (0.4%)	0.014–0.019	0.17–0.24	0.35–0.48
All Deaths (2.225%)	0.077–0.107	0.96–1.31	1.93–2.67

[a] Risks are expressed as the number of events per 1,000 exposed healthcare workers who lack immunity.
[b] Risks for exposed workers are estimated assuming 15% and 30% of the workers had a previous infection and are thus immune.
[c] Assumes 45 years of occupational exposure and is caclulated by multiplying the lifetime occupational risk from Table V-6 by 0.52 (0.50*0.04 + .50 = 0.52)

In reviewing the record, a number of commenters expressed concern over certain aspects of the OSHA risk assessment. Specifically, two chapters of the Association for Practitioners in Infection Control (APIC), Dade County and Greater Omaha, the Joint Committee on Health Care Laundry Guidelines and the Presbyterian-University Hospital of Pittsburgh, among others, argued that without disease incidence data specific to particular occupations it is impossible for OSHA to make an accurate determination of the risk of HBV infection in an occupational setting (Exs. 20–371; 20–943; 20–1113; 20–1101). Further, they assert that the use of sero-prevalence data significantly overestimates current incidence of HBV infections in hospital personnel in most settings. Presbyterian-University Hospital stated that "* * * More appropriate data would be provided by real incidence data that control for non-occupational etiologies which can significantly confound data like that used [by OSHA] to arrive at this occupational risk assessment" (Ex. 20–1101). Further, Dr. W.L. Sutker of Baylor University Medical Center, in his testimony, disputed the validity of using an estimate of the number of healthcare workers infected with HBV as opposed to actual incidence data, even though he admitted he did not have a way to prove or disprove the accuracy of CDC's estimates which were used by OSHA (W.L. Sutker, M.D., Tr. 9/27/89, pp. 103–105). OSHA agrees that the use of incidence data adjusted for non-occupational etiologies would be ideal to use in determining the actual risk of HBV infection attributable to occupational exposure. However, actual incidence data simply do not exist at a national level. A limited amount of incidence data was submitted to the record, specific to certain hospitals or certain regions (Exs. 272; 20–1366). Regional data such as those cited above as well as those data presented in testimony by Baylor University Medical Center and the Presbyterian Health Care system can not be used for OSHA's risk assessment (W.L. Sutker, M.D., Tr. 9/27/89, pp. 102–122). While they are appropriate to show incidence of infection for an institution or a region, they are not appropriate for OSHA's risk assessment. OSHA's goal is to estimate the nationwide risk of HBV infection to workers with occupational exposure from national incidence rates of hepatitis B in healthcare workers. To do so, OSHA needs to rely on data that are not affected by regional differences and are adjusted for non-occupational etiologies. It would be inaccurate to use data from a low-incidence region to determine an overall occupational risk just as it would be inaccurate to use data from a high-incidence region. In our attempt to estimate the risk of infection OSHA needs data from a representative sample of the nation as a whole. The Centers for Disease Control is the only source of reliable national estimates of the numbers needed for OSHA's risk assessments. When faced with a choice of using regional data that are not adjusted for regional differences or data derived from non-representative samples (these are samples selected subjectively) as opposed to data estimated from national surveys, such as CDC's estimates, OSHA believes the only reasonable approach is to use the estimates provided by CDC. These estimates have been adjusted for factors such as under-reporting and are less affected by regional factors.

Another issue of concern to several commenters was OSHA's use of 45 years to estimate lifetime occupational risk. Dr. Sutker of Baylor University Medical Center believes that OSHA has overestimated the risk by a factor of 11 based on Baylor's historical data demonstrating that the average occupational tenure of a healthcare worker at Baylor is approximately 4 years (W.L. Sutker, M.D., Tr, 9/27/89, p. 21). Likewise, Dr. Goodman of the Presbyterian Hospital of Dallas argued in his testimony that OSHA's extrapolated figures of a lifetime occupational risk are probably inaccurate by a factor of at least 13, which he asserted vastly overestimated the true medical risk based on Presbyterian Hospital's historical figures indicating that the average tenure of a healthcare worker at Presbyterian is approximately 3.3 years (E.L. Goodman, M.D., Tr. 9/27/89, pp. 142–143). Turnover at an individual hospital is not the same as turnover in a particular occupation whether it be at the support staff level, among paraprofessionals or among professionals. A phycisian, for example, may leave a particular hospital, but would likely not leave the healthcare field. In any case, section 6(b)(5) of the OSH Act mandates that the Secretary "* * * set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by standard for the period of his working life." For the purposes of OSHA health standards, this working lifetime is 45 years (Asbestos, 51 FR 22612), (Benzene, 52 FR 34460), (Ethylene Oxide, 53 FR 11414). The record contains no evidence that would indicate that another time period for a working lifetime for healthcare employees would be more appropriate.

Another point of concern to several commenters was OSHA's methodology for estimating the risk of HBV infection. Dr. Sutker, representing Baylor University Medical Center and the Presbyterian Health Care system, suggested that "* * * [a] better method of accurately assessing healthcare

worker risk to hepatitis B virus, is by utilizing officially reported probability figures * * * [to estimate the risk of infection due to a single needlestick exposure in a hospital setting] * * *" (W.L. Sutker, M.D., Tr. 9/27/89, pp. 11–14). The same argument was repeated by Dr. Goodman of the Presbyterian Hospital of Dallas in his testimony and in a post-hearing comment (E.L. Goodman, M.D., Tr. 9/27/89, pp. 139–140; Ex. 272). OSHA has considered Dr. Goodman's recommendation, but has concluded that his approach does not provide an accurate estimate of the risk of HBV infection because it completely disregards non-percutaneous exposures and exposures in non-hospital settings. Given the fact that healthcare workers may also be infected by coming in contact through breaks in the skin, and contact with mucous membranes as with needlesticks, measuring the HBV infection risk purely by percutaneous exposures will result in an underestimate of the true risk. OSHA's estimate of risk applies to employees with occupational exposure to blood or other potentially infectious materials regardless of occupational environment, whether it is a hospital, a dental office, or a funeral home and the estimate of HBV risk from a single incident does not vary with frequency or route of exposure or infectivity of the source individual. What the Agency has attempted to do is estimate an overall risk to HBV infection from occupational exposure regardless of the environment and not restrict its estimate to the risk from a percutaneous exposure from any single needlestick in a hospital setting.

In the preamble to the proposed standard, OSHA outlined its approach to the quantitative estimate of risk from exposure to HBV, including the selection of data sources and methodology used. On the basis of the preliminary quantitative risk assessment, OSHA concluded that the lifetime occupational risk from exposure to HBV was 75 to 119 HBV infections and 2 to 3 deaths per 1000 exposed healthcare workers who lack immunity. This figure was used to support OSHA's finding that exposure to bloodborne pathogens, and specifically HBV, represented a significant risk to workers exposed to blood or other potentially infectious materials. In this final risk assessment OSHA estimates that the lifetime occupational risk from exposure to HBV is 83 to 113 HBV infections and 2 to 3 deaths per 1000 exposed healthcare workers who are not immune. Even though the Agency used the same methodology to estimate the lifetime occupational risk as in the preamble, the number of expected infections changed in the final risk assessment for reasons outlined below. For its final risk assessment OSHA used the latest available data in the record. Based on CDC's 1988 reported data, the number of HBV infections in persons whose only source of infection was related to healthcare employment was reduced from 12,000 to 8,700. In addition, the number of healthcare workers with occupational exposure was reduced from 5.3 million to approximately 4.9 million. The reduction in the number of HBV infections in the later years is primarily due to the introduction of the hepatitis B vaccine. OSHA used 1988 Census population values instead of the 1985 Census figures used in the proposal (this changed the number of U.S. adults from 180 million to 193 million). In addition, the Agency used estimates of the number of HBV infections in U.S. adults and healthcare workers with occupational exposure based on the 1988 national hepatitis surveillance data instead of 1987 data used in the proposal (this changed the number of infections from 300,000 to 280,000). The above changes affected the estimates of the annual HBV infection rate and the lifetime occupational risk per 1000 healthcare workers; the numbers changed from 3.59–4.56 to 3.47–4.21 and from 75.38–118.54 to 83.18–113.40, respectively. Finally, in the proposal, 90 percent was used as an estimate of the vaccine's efficacy rate, whereas in the final, based on the latest data submitted to the record, the vaccine efficacy rate was estimated to be 96 percent.

(D) Qualitative Assessment of HIV Risk

The CDC estimates that there are between 1 million and 1.5 million HIV-infected persons in the U.S. (Ex. 6–356). As of September 30, 1990 occupational information was available for 122,159 of the AIDS cases reported to CDC. Of these, 5,815 or 4.8% were identified as healthcare workers (Ex. L6–666) (note: Exhibit L6–666 is an updated version of Exhibit 6–378). This proportion is similar to the proportion of the labor force employed in the healthcare field.

Most healthcare workers with AIDS also belong to some other group which places them at high risk for HIV infection (e.g. homosexual men, intravenous drug users, etc.). There is, however, a statistically significantly larger proportion of healthcare workers with no known risk factors (6%), than the proportion of other AIDS cases (i.e. individuals with AIDS not in the healthcare field) with no known risk factors (3%). As of September 30, 1990, there were 337 reported cases of healthcare workers with AIDS with no known risk factors. These cases are being studied further. CDC reports that 69 could not be assigned to a risk group after follow-up, 65 had either died or refused to be interviewed, and 203 were still under investigation (Ex. L6–666).

Because the prevalence of HIV infection among healthcare and other workers with occupational exposure to blood or other potentially infectious material is unknown, it is not possible to estimate an "observed" infection rate. Therefore, it is not possible to quantify the risk as was done for occupational exposure to HBV. Certain deductions, however, can be made. It is known that the virus is present only in blood or certain body fluids and that exposure to these fluids from an HIV-infected person puts one at risk for HIV-infection. Therefore, workers who have occupational exposure to blood or certain body fluids are at risk.

No case of infection due to casual contact with these fluids has been documented. Rather, infection can occur only if infectious fluids enter the body either through a percutaneous or mucosal route, although exposure by either of these routes does not mean that infection will occur. In several prospective studies of healthcare workers with HIV exposures, seroconversions have been observed. Although the rate of infection is low, it is not insignificant.

The most recent report from the CDC Cooperative Needlestick Surveillance Group authored by Marcus and colleagues shows that of 860 healthcare workers with an exposure to HIV-infected blood through needlestick or cut from sharp instruments, 4 workers became infected with the virus yielding a seroprevalence rate of 4/860 = 0.47 (Ex. 6–372). One of the four was first tested for HIV antibody 10 months after sustaining a needlestick exposure to blood of an HIV-infected patient. As there was no available acute blood specimen collected within 30 days after exposure this case cannot by definition be considered a seroconversion. The remaining 3 HIV-seropositive subjects had HIV-seronegative acute blood specimens and were thus considered seroconversions, yielding a seroconversion rate of 3/860 = 3.5 per 1000 exposures to infected blood through needlestick or cut. Gerberding et al. recently reported that of 180 workers with 215 exposures to HIV-infected blood through needlesticks, 1 worker became infected with the virus (Ex. 6–375). This leads to a seroconversion rate of 4.7 per 1000 exposures to infected blood through needlestick. The HIV infection rates

reported by both of these studies are very close.

Both the CDC and the Gerberding et al. studies provide estimates of the risk of infection given parenteral exposure to HIV-infected blood. Neither study, however, provides estimates of the risk of all occupational exposure. One approach to this problem has been suggested by Wormser et al. who estimated the probability of HIV infection in terms of HIV-infected patient-days for hospital staff caring for HIV-infected patients (Ex. 6–388). For the 18 month period from January of 1986 to June of 1987, the authors observed a needlestick rate of 1.9 per 1000 HIV-infected patient-days among staff caring for HIV-infected patients (Ex. 6–388). This rate was substantially lower than the needlestick rates of 4.3 and 4.6 per 1000 HIV-infected patient-days reported at the hospital for 1985 and 1984, respectively (Ex. 6–388).

Using the observed rate of 1.9 needlesticks per 1000 HIV-infected patient-days, Wormser et al. estimated the expected number of needlesticks for different numbers of HIV-infected patient-days. For example, for 45,000 HIV-infected patient-days, (750 HIV-infected patients hospitalized for 60 days, 1500 HIV-infected patients hospitalized for 30 days, etc.), the expected number of needlesticks is 86 (1.9/1000 x 45,000) (Ex. 6–388). Wormser et al. then estimated the probability of at least one exposed worker becoming infected with HIV as $1-[(1-p)^n]$, where n is the number of needlesticks and p is the probability of becoming infected with HIV given needlestick exposure to HIV-infected blood, which the authors assumed to be 0.0035 (Ex. 6–388). The estimated probabilities, which are expressed per expected number of needlesticks or per HIV-infected patient-days, are presented in Table 1 (Ex. 6–388). In addition, OSHA has calculated these probabilities using Gerberding et al.'s estimate of 4.7 infections per 1000 needlestick exposures to HIV-infected blood and has included them in Table V–10.

In reviewing Table V–10, it is important to remember that the probabilities presented there do not represent an estimate of the number of exposed workers who will become infected with HIV. "Number of workers exposed" is not used in any of the calculations, and therefore an expected number of infections per some number of workers caring for HIV-infected patients can not be calculated. One worker may experience more than one needlestick. The probabilities in Table V–10 depend only upon the number of needlesticks which, in turn, depends only upon the number of HIV-infected patient-days and the assumption that needlesticks occur at a rate of 1.9 per 1000 HIV-infected patient-days.

TABLE V–10.—PROBABILITY OF AT LEAST ONE INFECTION DUE TO NEEDLESTICK EXPOSURE TO HIV-INFECTED BLOOD [a]

HIV-infected patient-days	Estimated number of needlesticks [b]	Probability of at least 1 infection	
		Wormser [c]	Gerberding [d]
5,000	10	.03	.05
20,000	38	.12	.16
45,000	86	.26	.33
105,000	200	.50	.61
200,000	380	.74	.83
440,000	836	.95	.98

[a] Probabilities are binomial (n,p) and calculated as one minus the probability of no infections.
[b] Number of needlesticks is calculated based on the estimated rate of 1.9 needlesticks per 1000 HIV-infected patient-days.
[c] From Wormser et al. (Ex. 6–388). Assumes that the probability of infection give needlestick exposure to HIV-infected blood is 3.5 per 1000 exposures.
[d] Probabilities calculated by OSHA using Gerberding et al.'s estimate of 4.7 infections per 1000 needlestick exposures to HIV-infected blood (Ex. 6–375).

Table V–10 shows that the probability of HIV infection for at least one healthcare worker caring for HIV-infected patients does not increase linearly as the number of HIV-infected patient-days increases. A ten-fold increase in HIV-infected patient-days from 20,000 to 200,000 leads only to a six-fold increase in the probability of at least one infection. If one were to assume that the needlestick rate were two times higher than the rate used in Table V–10 (i.e. 3.8 needlesticks per 1000 HIV-infected patient-days instead of 1.9 needlesticks per 1000 HIV-infected patient-days), the probability of at least one infection doubles at 5000 HIV-infected patient-days but increases only 6% at 440,000 HIV-infected patient-days. If one were to assume that the needlestick rate were half as high as the rate used in Table V–10 (i.e. .95 needlesticks per 1000 HIV-infected patient-days instead of 1.9 needlesticks per 1000 HIV-infected patient-days), the probability of at least one infection is one-third smaller at 5000 HIV-infected patient-days but only one-fifth smaller at 440,000 HIV-infected patient-days. This approach to estimating the risk of HIV infection would apply only to staff caring for HIV-infected patients because Wormser et al. used a needlestick rate per HIV-infected patient-days which was estimated from this population.

Clearly, reducing the risk of needlestick will reduce the probability of HIV infection. CDC reported that of 1,201 exposures to HIV-infected blood through needlesticks, cuts with sharp objects, contamination of open wounds, or contamination of mucous membrane, 37% of the exposures might have been prevented if recommended infection control precautions had been followed (Ex. 6–372). Recapping of needles by hand accounted for 17% of the 1,201 exposures, improper disposal of used needles or sharp objects accounted for 14%, and contamination of open wounds accounted for 6% (Ex. 6–372).

A study of needlestick injuries among hospital personnel by Jagger et al. found that the risk of injury depended upon the type of device used and that devices requiring disassembly had the highest risks (Ex. 6–350). Jagger investigated 326 needlestick injuries over a 10 month period and found that 17% occurred during use of the device, and 13% occurred during or after disposal of the devices. The majority (70%), however, occurred after use but before disposal of the devices (Ex. 6–350). The single largest cause of injury was due to recapping. Workers missed the cap and stabbed themselves when attempting to cover a used needle in 17.8% of the injuries (Ex. 6–350). Other major causes of injury were needles piercing caps when recapped after use (12.3%), contacting needles on exposed surfaces after use (10.7%), and needles protruding from trash (8.9%) (Ex. 6–380). The largest number of injuries was associated with disposable syringes, but when the injury

rate for various devices was adjusted for the number of each type of device purchased, disposable syringes had the lowest accident rate at 6.9 per 100,000 purchased (Ex. 6–350). All of the devices requiring disassembly had higher accident rates ranging from 8.3 per 100,000 purchased for prefilled cartridge injection syringes to 36.7 per 100,000 purchased for intravenous tubing and needle assemblies (Ex. 6–380).

While most of the epidemiological investigations have concentrated on assessing the risk of HIV infection to healthcare workers exposed to HIV-infected blood through needlesticks or cuts with sharp objects, there is evidence that workers in research and production laboratories routinely exposed to high concentrations of the virus are also at risk of infection. Weiss et al. prospectively studied 265 laboratory and affiliated workers and found one worker infected with the same strain of HIV as was used in the laboratory (Ex. 6–187). The infected worker reported occurrences of HIV contamination in the work area but could not recall any episode of direct skin exposure with the virus and denied any parenteral exposures. The worker reported that double gloves were worn whenever there were bandaged cuts on fingers or hands. An episode of nonspecific dermatitis on the arm was recalled, but the affected area was always covered by a cloth laboratory gown. There was no contact of potentially infectious material with these areas as has been reported for healthcare workers infected after clinical exposure to HIV-infected fluids (see Case Reports in the discussion of HIV health effects). For 99 workers who shared a work environment involving exposure to concentrated virus, the authors estimated the HIV infection rate to be .48 per 100 person-years with a 95% upper confidence limit of 2.30 infections per 100 person-years of exposure (Ex. 6–187). OSHA estimates tha over a 45 year working lifetime, the HIV infection risk would be 195 per 1000 exposed workers in research and production laboratories. The lifetime risk is estimated by using $(1-(1-p)45)$ where p is .0048.

Weiss et al. also reported a second incident of HIV infection in a research laboratory worker who was employed in the production of concentrated virus and who was cut on the hand with a potentially contaminated stainless steel needle used for cleaning an apparatus. The worker was not part of the Weiss et al. cohort, and it is not yet known whether the virus which infected this worker is the same (i.e. genetically identical) as was found in the laboratory. Weiss et al. noted that although the infected workers were careful, neither was fully conversant with or strictly adhered to biosafety guidelines in day to day procedures at all times. Weiss et al. concluded that "infection in the laboratory workers took place under prescribed Biosafety Level 3 containment suggests the need to review carefully all operations involving highly concentrated infectious material and to ensure proficiency in the conduct of recommended safeguards." (Ex. 6–187).

Although it is not possible to quantify the risk of HIV infection in healthcare or other workers with occupational exposure to blood or other potentially infectious material or with direct exposure to the virus itself, the data show that a risk does exist. As the number of people with HIV-associated illnesses increases, the probability that workers exposed to blood or other potentially infectious material will also be exposed to HIV also increases. Given needlestick exposure to HIV-infected blood, the risk of seroconversion is estimated to be between 3.5 and 4.7 per 1000 exposures. For research and production laboratory workers with occupational exposure to high concentrations of the virus, the risk of seroconversion is estimated to be 4.8 per 1000 person-years. Over a 45 year working lifetime, the risk would be 195 per 1000 exposed workers. By reducing the risk of exposure to blood and other potentially infectious material and by strictly adhering to biosafety procedures in handling the virus in laboratories, the risk of HIV infection can be reduced.

As described in the health effects discussions, there are other bloodborne pathogens, such as syphilis and malaria, which are present in blood during certain phases of infection. During these phases, the blood of infected individuals poses a risk to exposed workers. Although the risk of these infections has not been quantified, it does exist and will be minimized or eliminated by preventing occupational exposure to blood.

VI. Significance of Risk

Section 6(b)(5) of the OSH Act vests authority in the Secretary of Labor to issue health standards. This section provides, in part, that:

> The Secretary, in promulgating standards dealing with toxic materials or harmful physical agents under this subsection, shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life.

OSHA's overall analytical approach to making a determination that workplace exposure to certain hazardous conditions presents a significant risk of material impairment of health is a four-step process consistent with recent court interpretations of the OSH Act and rational, objective policy formulation. In the first step, a quantitative risk assessment is performed where possible and considered with other relevant information to determine whether the substance to be regulated poses a significant risk to workers. In the second step, OSHA considers which, if any, of the regulatory alternatives being considered will substantially reduce the risk. In the third step, OSHA examines the body of "best available evidence" on the effects of the substance to be regulated to set the most protective requirements that are both technologically and economically feasible. In the fourth and final step, OSHA considers the most cost-effective way to achieve the objective.

In the Benzene decision, the Supreme Court indicated when a reasonable person might consider the risk significant and take steps to decrease it. The Court stated:

> It is the Agency's responsibility to determine in the first instance what it considers to be a "significant" risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, the odds are one in a billion that a person will die from cancer by taking a drink of chlorinated water, the risk clearly could not be considered significant. On the other hand, if the odds are one in a thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant and take the appropriate steps to decrease or eliminate it. (*I.U.D. v. A.P.J.*), 448 U.S. at 655).

The Supreme Court's language indicates that the examples given were of excess risk over a lifetime. It speaks of "regular inhalation" which implies that it takes place over a substantial period of time and refers to the "odds * * * that a person will die," obviously a once in a lifetime occurrence.

The Court indicated that "while the Agency must support its findings that a certain level of risk exists with substantial evidence, we recognize that its determination that a particular level of risk is 'significant' will be based largely on policy considerations." The Court added that the significant risk determination required by the OSH act is "not a mathematical straitjacket" and

that "OSHA is not required to support its findings with anything approaching scientific certainty." The Court ruled that "a reviewing court (is) to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge and that the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection" (448 U.S. at 655, 656).

OSHA has used these guidelines provided by the Supreme Court in setting health standards for known carcinogens such as benzene and ethylene oxide as well as other substances such as cotton dust whose adverse health effects is not carcinogenic but is, none the less, very serious. For example, exposure to cotton dust can cause byssinosis.

As part of the overall significant risk determination, OSHA considers a number of factors. These include the type of risk presented, the quality of the underlying data, the reasonableness of the risk assessments, and the statistical significance of the findings.

The hazards presented by the transmission of bloodborne pathogens such as infection, illness and death, are very serious, as detailed above in the section on health effects. Hepatitis B infections cause acute and chronic disease. When an individual is infectious, either because of acute infection or because the individual has become a carrier, his or her blood and certain body fluids can transmit the virus to others. The hepatitis B infection places other members of the infectious individual's family at risk. If the patient has an acute infection, there is a 30% chance that a sexual partner will become infected. If the patient is a carrier the probability of transmission is much higher. Blood and certain other body fluids from the infected individual pose a risk to workers who may have contact as the result of occupational exposure. Perinatal transmission from an infected employee to her infant is an efficient mode of transmission with a particularly serious outcome. Symptoms of the disease can range from a flu-like illness to a more severe clinical illness characterized by jaundice, dark urine, nausea, vomiting, extreme fatigue, anorexia, abdominal pain, diarrhea, and sometimes joint pain, rash and fever. About 20% of jaundiced cases require hospitalization. Cases that do not require hospitalization often cause several weeks to months of work loss due to the disease symptoms reviewed above. Chronic HBV infection may result in frequent periods of illness, and continual, usually life-long, infectious status. In the most extreme cases of infection, death can result from fulminent hapatitis, viral cirrhosis of the liver or liver cancer (See Section IV.)

HIV, the other major bloodborne pathogen, attacks the immune system, causing disease and death. Within a month following infection, the individual may experience an acute retroviral syndrome characterized by a mononucleosis-like syndrome. Later signs and symptoms can include persistent, generalized lymphadenopathy, myalgias, arthralgias, diarrhea, fatigue, rash, fever, and constitutional illness characterized by wasting syndrome which may lead to death. HIV infected individuals who have developed AIDS may develop neurologic, oncogenic or neoplastic problems as well as opportunistic infections. Common conditions include encephalopathy, dementia, myelopathy or peripheral neuropathy, *Pneumocystis carinii* pneumonia; Kaposi's sarcoma; Candidiasis of the esophagus, trachea, bronchi or lungs; cytomegalovirus disease of an organ other than the liver, spleen or lymph nodes; as well as bacterial infections. The blood and certain body fluids from an infected individual present a risk of infection to others.

In this standard, OSHA has presented quantitative estimates of the lifetime risk of infection, clinical illness, and death from occupational exposure to HBV infected blood or other potentially infectious materials. Qualitative evidence of occupational transmission of HIV is also included in OSHA's risk assessment.

In preparing its quantitative risk assessment, the Agency began by considering whether some of the approximately five million occupationally exposed healthcare workers would be immune to hepatitis B because they had received the vaccine or because they had previously been infected with the virus. OSHA estimated that approximately two million of these individuals had received the hepatitis B vaccine. OSHA assumed a vaccination efficacy rate of 96% and calculated the number of employees who would develop immunity as the result of the vaccination. Based on information from the CDC, OSHA assumed that between 15 and 30 percent of healthcare workers had already been infected with hepatitis B virus, the vast majority of whom had been infected on the job, since only 3 to 6 percent of the general population has evidence of a previous infection. OSHA then added 96% of the vaccinated workers to the 15 to 30 per cent immune because of prior infection and subtracted that total from the population of healthcare workers. It is appropriate to subtract these workers because they will not be infected or reinfected with hepatitis B virus; their risk of acquiring a HBV infection approaches zero. This left a population of between 2.0 and 2.5 million. It is this group that constitutes the population at risk for hepatitis B infection.

OSHA estimates the risk of material impairment of health or functional capacity, that is, the lifetime occupational risk of infection from HBV to be from 83 to 113 cases per thousand with 21 to 30 cases of clinical hepatitis per thousand exposed workers who lack immunity. The estimated lifetime risk of death from HBV is 2 to 3 per one thousand exposed workers who are not previously immune. These estimates are based on the assumption of occupational exposure to HBV present in blood or other potentially infectious materials for the period of a working lifetime of 45 years. Moreover, OSHA's risk assessment shows that even if every exposed worker at risk were to receive the hepatitis B vaccine there would still be a remaining lifetime risk of material impairment of health of 3 to 5 per one thousand exposed workers based on the 96% efficacy of the vaccine. OSHA believes these estimates understate the risk; the actual risks attributable to occupational exposure to bloodborne diseases may be much higher for the following reasons: First, the true risk of HBV infection among the majority of the general population of U.S. adults is probably much lower than OSHA's estimate of the background risk since the majority of adults do not engage in the high risk behaviors associated with a large proportion of HBV infections. Thus, by overestimating the background risk, OSHA has probably underestimated the risk attributable to occupational exposure. Second, OSHA has assumed a 96% vaccine efficacy rate instead of 92.7% which is Merck, Sharp & Dohme's (Merck) estimate of vaccine efficacy adjusted for the age distribution of those covered by this standard. The Agency was unable to duplicate Merck's results and determine the accuracy of these figures since Merck did not provide the basic data and underlying methodology upon which the 92.7% estimate was based. By assuming 96% efficacy rate, OSHA may be underestimating the remaining risk to workers with occupational exposure.

However, factors such as changing prevalence of hepatitis B in the U.S.

population, lack of data on non-healthcare workers, lack of data on differential risk by occupation and geographic location and assuming a 45-year working lifetime could cause the annual and lifetime HBV risk estimates to vary. OSHA estimated a lifetime occupational risk based on current information on U.S. population prevalence rates. Those prevalence rates may increase or decrease and will affect the lifetime risk estimates accordingly. Having specific quantitative data for non-healthcare workers and for particular occupations and locations would add more precision to the quantitative risk assessment, but that level of detail is not possible, given the data available in the record, nor necessary to a finding of significant risk, especially when the risk of infection is based upon occupational exposure to blood or other potentially infectious materials. The fact that not everyone would be exposed for exactly 45 years may mean less or more exposure incidents for a given individual over his or her lifetime, but would not affect a pooled risk estimate based on full time equivalents.

In the "benzene" decision, the Court wrote of deaths from carcinogens, but the Act requires the Agency to assure that no employee will suffer "material impairment of health or functional capacity." Obviously, material impairment includes not only death from HBV infection, but also serious illnesses or the development of permanent infectious status (HBV carrier). Moreover, OSHA has concluded that due to the number of possible outcomes following infection, the material impairment occurs when infection takes place regardless of the ultimate course of the disease. As noted above, in the case of severe infection, death can result from fulminant hepatitis, viral cirrhosis of the liver or liver cancer. In the case of chronic infection, the individual may experience frequent periods of illness, and continual, usually life-long, infectious status. An individual may remain infectious either because of acute infection or because he or she has become a carrier. This individual represents a pool from which the disease may spread to other family members or to the patient's sexual partner. Perinatal transmission from an infected employee to her infant is an efficient mode of transmission with a particularly serious outcome. Individuals who are infected as newborns have a 25% chance of dying from cirrhosis or PHC. They also remain infectious to others and can perpetuate the cycle of perinatal transmission.

HBV infection can result in very serious and debilitating illnesses. In most cases of clinical illness, symptoms of the disease will prevent the employee, for a period of time, from carrying out his or her routine daily activities often resulting in missed work days. In cases where the infected employee is hospitalized, the employee would be unable to work during the time he or she is hospitalized, and undoubtedly the out-of-work time would be longer as additional recovery time is invariably required following hospital discharge. Since symptoms typically last from several weeks to several months and, in the case of chronic hepatitis, several years, there can be considerable lost work time. Becoming a carrier is a material impairment of health even though the carrier may have no symptoms. This is because the carrier will remain infectious, probably for the rest of his or her life, and any person who is not immune to HBV who comes in contact with the carrier's blood or certain other body fluids will be at risk of becoming infected. Given the health hazards associated with HBV infection, it is OSHA's opinion that the material impairment of health occurs when an individual becomes infected with HBV Moreover, OSHA's interpretation of material impairment of health is consistent with NIOSH/CDC's pre-hearing and post-hearing comments on the standard. (Exs. 298, p. 4; 20–634).

OSHA's risk estimates for HBV infection are comparable to other risks which OSHA has concluded are significant, and are substantially higher than the example presented by the Supreme Court.

Public response to the bloodborne pathogen rulemaking hearings indicated general agreement that the risk of contracting hepatitis B to workers with occupational exposure to blood or other potentially infectious materials is unacceptably high. Indeed, it was the testimony of many employers that they had already instituted or upgraded their infection control programs and were vaccinating their employees, indicating an acceptance by employers that employees who are not provided the protections that would be mandated by this standard are at risk of contracting HBV.

After thoroughly considering the magnitude of the risk as shown by the quantitative and qualitative data, OSHA concludes that the risk of death and material impairment of health resulting from acute and chronic HBV infection is significant, that HBV presents a significant risk to both unvaccinated employees and employees who have been vaccinated but have not developed immunity. Moreover, because HBV is not the only bloodborne pathogen capable of causing disease, all employees who are exposed to blood and other potentially infectious materials, whether they are HB-vaccinated or not, may be at risk of infection.

At this time, OSHA believes that there are not sufficient data on HIV to quantify the occupational risk of infection. Nevertheless, the epidemiological data on HIV provide strong qualitative evidence that HIV can be transmitted in the workplace and serve to further illustrate risk remaining after the major protection measure of HBV vaccination is implemented. Individuals who have a needlestick exposure to blood from an HIV infected individual have a 3 to 4 per 1,000 risk of developing an HIV infection.

OSHA's determination that employees who work in virus research and production facilities are at risk is supported by the report of one employee out of a population of less than 100 who were working with concentrated HIV who seroconverted. These employees are at risk because the virus is concentrated and is present in much higher titers than in blood, thus increasing the likelihood of the employee becoming infected following an exposure incident.

OSHA also concludes that the final bloodborne pathogen standard will result in a substantial reduction of significant risk. The risk of HBV infection is most efficiently and dramatically reduced by vaccinating all workers exposed to blood and other potentially infectious materials. Based on OSHA's estimate of lifetime occupational risk, vaccination of all workers would result in 2 to 3 fewer deaths per 1,000 workers exposed over a working lifetime. Further, vaccination would result in 80 to 108 fewer cases of material impairment of health due to HBV infection, and 20 to 28 fewer cases of clinical illnesses per 1,000 workers exposed over a working lifetime. Assuming 15% of the population at risk is immune to HBV because of prior infection, OSHA estimates that vaccinating the remainder and all of their replacement in the labor force will prevent approximately 270,000 infections, over 68,000 of which will result in clinical illness, including, in addition to cases of acute and chronic symptomatic illness, 27,000 HBV carriers and 6,000 deaths over 45 years. If 30% of the population at risk is immune, the number of infections prevented following vaccination of all employees

is estimate to be approximately 244.000 including 61.000 cases of clinical illness, over 12,000 HBV carriers and more than 5.400 deaths over 45 years.

Despite these dramatic decreases in infections, OSHA estimates that 3 to 5 HBV infections would occur with one case of clinical hepatitis per 1,000 exposed workers who lack immunity over 45 years even if all exposed employees were to receive the hepatitis B vaccine. This is because the vaccine is effective for only 96% of the people to whom it is given. Moreover, in constructing Table V-8 in Section V: Quantitative Risk Assessment, OSHA assumed that all workers at risk will agree to be vaccinated. However, the record indicates that this has not been the case in the past and, although education of employees on the benefit of vaccination should increase acceptance, it is unlikely all workers will be willing to be vaccinated. For example, OSHA witnesses testified that some vaccination programs yielded between 90–100 percent acceptance rate when the employee was required to be vaccinated to work at the facility (Joseph H. Coggin, Ph.D., Tr., 9/12/89, pp. 56–58; James A. Cottone, M.S., Tr., 9/19/89, p. 56; Dr. L. L. Campbell, Tr., 9/19/89, p. 72; Dr. W. L. Sutker, Tr., 9/27/89, p. 14; Dr. J. A. Barnett, Tr., 9/27/89, p. 221). Other witnesses from OSHA and the public noted that their vaccination programs ranged between 25–55 percent compliance rates (Kathleen F. Gordon, M.S., Tr., 9/19/89, p. 9; James A. Cottone, M.S., Tr., 9/19/89, p. 56; Jill Witter, Esq., Tr., 9/18/89, p. 163; T. Ryan, Tr., 9/27/89, p. 293). According to two OSHA witnesses still other programs yielded between 10–25 percent participation in the vaccination program in part due to the lack of mandatory education, advocacy and follow-up procedures (James A. Cottone, M.S., Tr., 9/19/89, p. 56; Joseph H. Coggin, Ph.D., Tr., 9/12/89, pp. 56–58).

In general, compliance rates of various Hepatitis B vaccination programs implemented throughout the country varied from over 95 percent to below 10 percent. This clearly demonstrates that even in the presence of a well organized and supported vaccination program, not everyone is willing to accept the vaccine. A descriptive analysis of the reported compliance rates based on evidence in the record indicated that three fourths of the vaccination programs in existance reported compliance rates less than 75 percent. In addition, based on survey results, OSHA estimated the average acceptance rate of a vaccination program to be approximately 50 percent. Using this information, OSHA constructed a scenario where 50 percent of those offered the hepatitis B vaccine would actually agree to be vaccinated, and estimated the remaining lifetime occupational risk assuming a 96% vaccine efficacy. These numbers are found in Table V-9 in Section V: Quantitative Risk Assessment. Under the assumption of 50 percent compliance to a vaccination program and 96 percent efficacy rate, the remaining lifetime occupational risk is significant. A range of 44 to 59 HBV infections are expected to occur per one thousand exposed workers per working lifetime. This will result in 11 to 15 clinical illnesses and approximately one death per thousand exposed workers. In addition, OSHA's estimate of remaining risk is probably an underestimate of the number of HBV infections that are likely to occur because of the overestimation of the background risk and the assumption of a 96% efficacy rate instead of Merck's estimate of 92.7%. Moreover, the hepatitis B vaccine will not protect employees from other bloodborne pathogens such as HIV. Based on these data, OSHA has concluded that widespread administration of the hepatitis B vaccine will not eliminate significant risks.

Congress passed the Occupational Safety and Health Act of 1970 because of a determination that occupational safety and health risks were too high. Based on this, Congress gave OSHA authority to reduce risks of average or above average magnitude when feasible. It is clear that the risks associated with HBV infection are not insignificant. Without the implementation of the present standard, OSHA estimates the lifetime risk of infection from HBV to be from 83 to 113 cases per thousand with 21 to 30 cases of clinical hepatitis per thousand exposed workers. The lifetime risk of death from HBV is 2 to 3 per one thousand workers who lack prior immunity. OSHA estimates that the standard for bloodborne pathogens will reduce the risk of death and material impairment of health from 83 to 113 cases per thousand to 3 to 5 per 1000. The risk of death from HBV will be reduced to one death per ten thousand. Even when a more realistic scenario is considered, where the compliance rate to a vaccination program is 50 percent and the efficacy of the vaccine is still 96 percent, the remaining lifetime occupational risk remains significant. This scenario will result in an estimate of 43 to 59 HBV infections per thousand employees with 11 to 15 cases of clinical hepatitis and approximately one death per one thousand exposed workers.

The above estimated figures are comparable to other risk estimates judged significant by OSHA in previous health and safety rulemakings. Typical occupational risk of death (from all causes including accidents and illness) in occupations of average risk are 2.7 per 1,000 for all manufacturing and 1.62 per 1,000 for all service employment derived from 1979 and 1980 Bureau of Labor Statistics data for employers with 11 or more employees adjusted to 45 years of employment for 48 weeks per year. The lifetime risk of death associated with HBV, 2 to 3 per one thousand non-immune exposed worker is comparable to those stated above; even the risk of material impairment of health due to HBV infection is sufficiently high to prompt OSHA to protect the health of healthcare workers by implementing this standard.

In summary, OSHA estimates this standard for bloodborne pathogens will result in 2 fewer deaths, 80 to 108 fewer cases of HBV infection, and 20 to 28 fewer cases of clinical illnesses per 1,000 workers exposed over a working lifetime. As OSHA believes the standard for bloodborne pathogens will reduce risk of HBV infection and material impairment of health from 83 to 113 per thousand to 3 to 5 per 1000, the Agency is carrying out the Congressional intent and is not attempting to reduce insignificant risks.

OSHA estimates that vaccination of exposed workers alone would leave a remaining significant risk of HBV infection (3 to 5 or 43 to 59 per thousand exposed workers, depending on acceptance rates of the hepatitis B vaccine), OSHA has concluded that compliance with the standard as a whole, that is, compliance with all of the final provisions, including vaccination, engineering controls, work practices, protective equipment, housekeeping, and training, would reduce that significant risk substantially. After adjusting for background risk, OSHA has estimated between 5,814 and 6,645 cases of occupational exposure to Hepatitis B virus. Compliance with the standard is estimated to prevent between 5,058 and 5,781 cases of occupationally induced HBV infection per year, of which 1,265 to 1,445 would have resulted in acute symptoms, and 113 to 129 in death. In addition, between 3,077 and 3,325 estimated non-occupational induced cases of hepatitis B infection will be prevented due to the substantial elimination of background risk (non-occupational risk) for vaccinated workers and due to the reduced transmission of infection to sex partners of employees. In total, the final

standard is expected to prevent between 8,383 and 8,858 infections and between 187 and 197 deaths annually. As previously stated, there are no sufficient data on HIV to quantify the occupational risk of infection; however, the above listed protective provisions of the standard will also reduce exposure to HIV infected body fluids and other materials thus reducing the risk of infection to HIV. In light of all of the above, OSHA concludes the entire standard is needed. This is consistent with the congressional intent and the Supreme Court rationale that OSHA is to reduce significant risks, which, in this case, would include risks remaining after administration of the hepatitis B vaccine. OSHA has considered various regulatory alternatives in addressing the risks of occupational exposure to bloodborne pathogens. These include informing employers and employees of the risk through the Joint Advisory Notice published in the **Federal Register** by the Department of Labor and the Department of Health and Human Services (52 FR 4181) and the institution of an enforcement program. The enforcement program has consisted of citing employers for violating Section 5(a)(1) of the OSH Act, the general duty clause (29 U.S.C. 654(a)(1)), and certain general industry standards. (For a brief explanation of OSHA's enforcement program, see OSHA Instruction LPL 2-2.44B and Section III: Events Leading to the Standard, below).

Although the current OSHA enforcement program has reduced the risks of occupational exposure to bloodborne pathogens to some extent, significant risks remain and it is the Agency's opinion that an occupational health standard promulgated under section 6(b) of the Act will much more effectively reduce these risks for the following reasons. First of all, because of the standard's specificity employers and employees are given more guidance in reducing exposure to bloodborne pathogens. Second, it is well known that a standard is more protective of employee health than an enforcement program that is based upon a general provision because the standard requires more abatement methods than those required by the general duty clause and the general industry standards. Third, the general duty clause and the cited general industry standards impose heavy litigation burdens on OSHA because OSHA must prove that a recognized hazard exists at a particular workplace. Since this standard specifies both the conditions which trigger the application of the standard and the abatement obligations, thereby assuming the existance of the hazard, no independent proof of the hazard in the particular workplace need be presented. The reduction in litigation burdens will mean that the Labor Department, as well as the employer, will save time and money in litigation cases. Finally, the promulgation of this standard will result in increased protection for employees in state-plans states because these states, although not required to adopt general duty clauses, must adopt standards at least as effective as Federal OSHA standards.

In summary, the Joint Advisory Notice and the institution of the enforcement program have been fruitful, but they have not eliminated the significant risks. Therefore OSHA has concluded that a standard specifically addressing the risks of bloodborne pathogens is necessary to further substantially reduce significant risks. OSHA's current data indicate the alternative selected is both technological and economically feasible. OSHA's analysis of technological and economic feasibility of the standard is discussed in the following section of the preamble.

VII. Regulatory Impact and Regulatory Flexibility Analysis

Executive Summary

The Occupational Safety and Health Administration (OSHA) has prepared a Regulatory Impact and Regulatory Flexibility Analysis for the Bloodborne Pathogens standard. The analysis is presented in seven sections: Introduction; Industry Profile; Benefits; Technological Feasibility; Costs of Compliance; Economic Impacts and Regulatory Flexibility Analysis; and Nonregulatory Environment and Regulatory Alternatives. Also, a technical appendix has been included, in which details of the two OSHA surveys and compliance rate computations are presented.

Industry Profile

Industries where workers are in contact with or handle blood and other potentially infectious materials will be affected by the standard. Twenty-four such industry sectors were identified for this analysis: offices of physicians (including ambulatory medical services) (SIC 801, 803); dental offices (SIC 802); hospitals (SIC 806); medical and dental laboratories (SIC 807); nursing homes (SIC 805); residential care facilities (SIC 836); dialysis centers (8092); drug treatment centers (8093); home health care (8082); hospices (various SIC codes); government outpatient facilities (SIC 9431); blood collections and processing (SIC 8099); health clinics in industrial facilities (various SIC codes); personnel services (SIC 7363); funeral homes and crematories (SIC 7261); research laboratories (SIC 8221; 8731; 8733; 283); linen services (SIC 721); medical and dental equipment repair (SIC 384; 7699) law enforcement (SIC 9221); fire and rescue (SIC 9224); correctional institutions (SIC 9223); schools for the mentally retarded (SIC 9411); lifesaving (9229); and handlers of regulated waste (SIC 4953; 9511).

Table E.S.-1 provides a summary of the number of affected establishments and employees by SIC classification. Over 500,000 establishments are estimated to be affected by the rule. Any employee who may come in contact with human blood and other potentially infectious materials and who comes under OSHA's purview is affected by this standard. On this basis, it is estimated that approximately 5.6 million workers will be affected by the standard. Approximately 78 percent of these workers are employed in health care occupations.

Benefits

OSHA has estimated that occupational exposures are responsible for between 5,814 and 6,645 cases of hepatitis B virus (HBV) infection per year. In total, considering the full combination of the standard's provisions, including vaccination, engineering controls, work practices, protective clothing, housekeeping, and training, OSHA believes that the great majority of these HBV cases can be avoided.

TABLE E.S.-1.—INDUSTRY PROFILE OF AFFECTED ESTABLISHMENTS AND POPULATION AT RISK [1990]

SIC code	Type of establishment	Number of affected establishments	Population at risk
801; 803	Offices of Physicians.	122,104	640,681
802	Offices of Dentists.	100,174	316,237
805	Nursing Homes	12,200	485,303
806	Hospitals	6,197	2,386,165
807	Medical and Dental Labs.	4,425	62,854
808	Home Health	6,437	212,246
*	Hospices	651	10,856
8092	Hemodialysis	782	12,688
8093	Drug Rehabilitation.	744	6,722
9431	Government Clinics.	10,883	56,345
8099	Blood/Plasma/ Tissue Centers.	730	18,788
836	Residential Care.	2,425	49,102

TABLE E.S.-1.—INDUSTRY PROFILE OF AFFECTED ESTABLISHMENTS AND POPULATION AT RISK [1990]—Continued

SIC code	Type of establishment	Number of affected establishments	Population at risk
7362	Personnel Services.	1,348	163,477
726	Funeral Services.	19,890	57,013
*	Health Units in Industry.	202,540	178,732
8221; 873; 283.	Research Labs	1,453	89,151
7218	Linen Services	1,250	50,000
384	Medical Equipment Repair.	1,076	6,185
9221	Law Enforcement**.	4,946	341,546
9224	Fire and Rescue***.	3,174	252,048
9223	Correctional Facilities.	1,895	120,224
9229	Lifesaving	100	5,000
9411	Schools	6,321	41,362
4953; 9511.	Waste Removal		13,300
Totals		511,755	5,576,026

* Includes various SIC codes.
** Includes state and local departments only.
*** Includes fire departments and private ambulance services
Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

In sum, compliance with the standard is estimated to prevent between 8,383 and 8,858 occupational and non-occupational cases of HBV infection per year, of which 2,096 to 2,215 would have resulted in acute symptoms, and 187 to 197 in death. Moreover, OSHA estimates that the standard will prevent between 253 and 578 employees from becoming HBV carriers, thereby halting the spread of this disease to others.

In addition to hepatitis B, the provisions of the standard will greatly reduce workers' risk of contracting non-A, non-B hepatitis, acquired immune deficiency syndrome (AIDS), and other bloodborne diseases. The Centers for Disease Control (CDC) reports 24 documented cases of human immunodeficiency virus (HIV) infection in the U.S. which have resulted from occupational exposure. Four of these workers have developed AIDS.

Technological Feasibility

Limiting worker exposure to bloodborne diseases is achieved through the implementation of the following categories of controls:

- Engineering Controls
- Immunization Programs
- Work practices, such as careful hand-washing after each patient contact and procedures for handling sharps
- Disposal and handling of contaminated waste
- Use of personal protective equipment, especially gloves, gowns and goggles
- Use of mouth pieces, resuscitation bags or other ventilation devices
- Use of disinfectants
- Labeling and signs
- Training and education programs
- Post-exposure follow-up

OSHA finds with respect to the technological feasibility of the standard that its provisions permit practical means to reduce the risk now faced by those employees working with blood and other infectious materials and that there do not appear to be any major obstacles to implementing the rule.

These conclusions were supported by OSHA's findings with respect to the current infection control practices in the workplace. Since the requirements of the standard closely follow the guidelines issued by the Centers for Disease Control (CDC) on universal precautions (UP), efforts by many organizations to adhere to the guidelines have created a solid base of practices and technology for the supplemental implementation of the standard. Based on recent surveys conducted by the Agency and other information available in the rulemaking docket, OSHA produced quantitative estimates of the compliance baseline, or extent of current compliance. OSHA found that most establishments have already implemented measures to protect workers from occupational exposure to blood and other potentially infectious materials, and that many are very close to full compliance with this standard.

Costs of Compliance

Net compliance costs were estimated for each provision of the standard by each type of facility affected. These costs represent the additional costs of fully complying with the requirements of the standard, after deducting from total cost the current baseline activities that already voluntarily occur at affected facilities. One-time costs were annualized to reflect the opportunity cost of capital. Table E.S.-2 summarizes annual net compliance costs by type of facility and by provision. The total annual costs amount to about $813 million.

Personal protective equipment accounts for the largest amount of net compliance costs ($327 million per year). Training ($134 million), vaccine and post-exposure follow-up ($107 million), and housekeeping ($102 million) were also found to be significant cost components.

OSHA found that costs varied among the various affected sectors, depending on the characteristics of exposure and extent of current compliance. Owing to these factors, certain establishments may find the impact of the standard to be somewhat greater than others.

TABLE E.S.-2.—SUMMARY OF COMPLIANCE COSTS—GRAND TOTALS

Industry	Engineering/ work practices *	Vaccination/ post exposure follow-up	Exposure control plan	Housekeeping	PPE	Training	Recordkeeping	Totals
Offices of Physicians	$8,985,997	$14,770,091	$6,834,476	$7,169,447	$68,611,270	$34,826,736	$2,792,511	$143,990,528
Offices of Dentists	5,443,408	21,566,118	5,592,113	6,843,189	30,422,020	14,117,012	4,446,195	87,429,055
Nursing Homes	935,780	8,195,138	1,021,579	21,037,030	31,917,227	5,706,284	966,616	69,779,663
Medical and Dental Labs	1,242,593	792,155	298,191	3,534,660	4,559,722	1,780,771	123,287	12,321,399
Residensal Care	81,202	1,128,257	157,835	539,902	905,583	1,401,437	146,073	4,360,390
Hospitals	66,761,203	26,745,404	1,614,393	56,414,706	138,972,636	25,773,835	3,611,521	321,913,697
Home Health	386,799	3,087,128	418,229	226,335	2,360,670	4,689,431	277,980	11,449,573
Hospices	9,978	196,713	42,398	22,163	104,442	196,925	20,948	593,588
Hemodialysis	271,929	241,868	50,930	42,356	1,320,193	302,054	77,834	2,306,964
Drug Rehabilitation	10,409	71,810	48,455	9,760	68,171	196,751	8,157	413,514
Government Clinics	790,219	1,451,787	709,439	516,634	3,893,082	3,047,676	248,574	*0,657,412

TABLE E.S.-2.—SUMMARY OF COMPLIANCE COSTS—GRAND TOTALS—Continued

Industry	Engineering/ work practices *	Vaccination/ post exposure follow-up	Exposure control plan	Housekeeping	PPE	Training	Recordkeeping	Totals
Blood Plasma/ Tissue Center	1,193,678	299,277	47,543	80,434	1,949,073	331,395	100,778	4,012,178
Personnel Services	11,926	1,614,021	112,876	0	8,068,434	3,365,324	176,165	13,348,746
Funeral Services	50,206	1,503,382	1,110,339	579,318	2,423,908	2,981,395	194,599	8,843,149
Health Units in Industry	3,719,231	15,039,779	13,226,259	4,803,681	5,265,303	23,276,485	2,573,588	67,904,326
Research Labs	150,111	1,290,801	94,631	102,497	2,751,244	1,860,448	73,178	6,322,908
Linen Services	924	394,322	81,410	33,150	1,088,947	268,162	75,024	1,941,939
Medical Equipment Repair	213,104	276,128	70,078	618,485	4,543,377	253,503	38,581	6,013,256
Law Enforcement	195,410	2,237,428	322,123	52,344	3,311,809	4,189,199	545,597	10,853,911
Fire and Rescue	216,141	2,708,562	206,716	73,862	9,573,585	1,909,586	325,485	15,013,937
Correctional Facilities	93,437	1,322,391	114,886	153,978	1,581,115	1,438,951	211,278	4,916,036
Lifesaving	503	157,623	6,513	73,300	84,375	139,333	12,225	473,872
Schools	146,412	1,398,763	411,674	0	1,717,971	2,103,241	196,277	5,974,338
Waste Removal	0	222,960	3,256	0	1,383,200	249,063	10,681	1,869,160
Totals	97,523,109	106,710,705	32,587,446	101,937,270	326,877,357	134,405,018	17,253,151	812,703,560

* Includes $5,416,815 in recurring costs for leakproof containers.
Source. Occupational Safety and Health Administration, Office of Regulatory Analysis.

Economic Feasibility and Regulatory Flexibility Analysis

Table E.S.-3 provides a summary of economic impacts for the types of facilities affected by the standard.

TABLE E.S.-3.—SUMMARY OF ECONOMIC IMPACTS

Industry	Revenue, budget * ($ million)	Profits * ($ million)	Annual costs ($ million)	Costs/revenue (percent)	Costs/profits * (percent)
Offices of Physicians	90,000	*5,533	143.99	0.160	2.602
Offices of Dentists	31,678	*2,014	87.43	0.276	3.590
Nursing Homes	45,872	1,159	69.78	0.152	4.577
Hospitals	230,000	1,012	321.91	0.140	6.998
Medical/Dental Labs	4,446	325	12.32	0.277	3.797
Home Health Care *	8,900	503	11.45	0.119	2.108
Hospice Care	325.5	19	0.59	0.182	3.100
Hemodialysis Centers	1,200	87	2.31	0.192	2.637
Drug Rehabilitation	744	45	0.41	0.056	0.926
Government Clinics *	2,400	N/A	10.66	0.444	N/A
Blood/Plasma/Tissue Centers	1,500	N/A	4.01	0.267	N/A
Residential Care	3,168	*75	4.36	0.138	4.674
Personnel Services	5,400	210	13.35	0.247	6.342
Funeral Services	6,782	608	8.84	0.130	1.454
Health Units in Industry	(*)	(*)	67.90	N/A	N/A
Research Labs	3,500	*54	6.32	0.181	3.991
Linen Services	4,800	99	1.94	0.040	1.962
Medical Equipment Repair	1,000	72	6.01	0.601	8.383
Police *	17,300	N/A	10.85	0.063	N/A
Fire & Rescue *	4,000	N/A	15.01	0.375	N/A
Corrections *	8,500	N/A	4.92	0.058	N/A
Lifesaving *	140	N/A	0.47	0.338	N/A
Schools *	2,774	N/A	5.97	0.215	N/A
Waste Removal	595	22	1.87	0.314	4.245

N/A Not Applicable
* Revenue totals represent affected facilities only; profit totals reflect estimated pre-tax 1989 totals for proprietary establishments, unless noted otherwise.
* Revenue data represent non-public agencies only.
* Revenue data represent public agencies only.
* Based on profit margin of nursing home sector.
* Health care budgets not estimated.
* Represents commercial, noncommercial, and pharmaceutical labs.
* Ratio reflects proprietary firms, unless noted otherwise.
Source Occupational Safety and Health Administration, Office of Regulatory Analysis.

As shown, OSHA estimated compliance costs to represent less than 1 percent of revenues for all sectors, and less than one-half of 1 percent for most others.

The cost of the standard relative to profit was estimated to be largest for the medical equipment repair sector, where

costs may represent over 8 percent of profits. OSHA estimated profit impacts to be less than 7 percent for all other sectors.

These estimates and the inelastic demand for health care services led the Agency to conclude that it is probable a large part of the compliance costs for establishments in SIC 80 (health care) will be passed on to consumers and third party payers. In addition, OSHA estimated most affected establishments will be able to finance the balance of compliance costs from profits. OSHA concludes that impacts will not impose a significant burden on industry. Impacts were not estimated to exert significant pressure toward increased industry concentration.

OSHA also found that a large number of small businesses will be affected by the rule. In general, OSHA did not find that smaller establishments lagged appreciably behind their larger counterparts with respect to current practices. This indicates that the differential impact related to the implementation of similar, supplemental employee protection measures as required under the standard, will be minimal between small and large firms. Thus, the impact on small business should not differ significantly from the impact on the affected universe as a whole.

A. Introduction

Executive Order 12291 (46 FR 13197, February 19, 1981) requires that a regulatory impact analysis be conducted for any rule having major economic consequences on the national economy, individual industries, geographical regions, or levels of government. Similarly, the Regulatory Flexibility Act (5 U.S.C. Subsection 601 et seq.) requires the Occupational Safety and Health Administration (OSHA) to consider the impact of the regulation on small entities.

Consistent with these requirements, OSHA has prepared a Regulatory Impact and Regulatory Flexibility Analysis for the Bloodborne Pathogens standard. This analysis describes the industries affected by the standard, the potential benefits that will be realized by health care and other workers currently at risk, the current infection control practices in the workplace, the costs of compliance, and OSHA's assessment of the technological and economic feasibility of the standard.

B. Industry Profile

1. Profile Overview

Of interest in this rulemaking are those workplaces in which employees are exposed to blood or other potentially infectious materials during the performance of their duties. OSHA has included twenty-four such industry sectors in this analysis: offices of physicians (including ambulatory medical services) (SIC 801, 803); dental offices (SIC 802); hospitals (SIC 806); medical and dental laboratories (SIC 807); nursing homes (SIC 805); residential care facilities (SIC 836); dialysis centers (8092); drug treatment centers (8093); home health care (8082); hospices (various SIC codes); government outpatient facilities (SIC 9431); blood collections and processing (SIC 8099); health clinics in industrial facilities (various SIC codes); personnel services (SIC 7363); funeral homes and crematories (SIC 7261); research laboratories (SIC 8221; 8731; 8733; 283); linen services (SIC 721); medical and dental equipment repair (SIC 382; 384; 7699) law enforcement (SIC 9221); fire and rescue (SIC 9224); correctional institutions (SIC 9223); schools (SIC 9411); lifesaving (9229); and regulated waste removal (SIC 4953).

Four sectors, linen services, schools, lifesaving, and regulated waste removal, were not included in OSHA's Preliminary Regulatory Impact Analysis (PRIA) [54 FR 23073]. New information received during the post-proposal comment period and during OSHA's informal hearings indicated, however, that occupational exposure to blood and other potentially infectious materials also occurred in these service sectors.

OSHA's final estimates of the number of affected establishments were based on information obtained from various sources, including government statistical publications, public comments and testimony, and two surveys conducted by the Agency. A multi-sector survey conducted during 1989 encompassed eighteen industry sectors. A separate survey of hospitals was also conducted. Health care and non-health care workers employed by state and local governments in non-state-plan states and self- employed facilities were not included in the scope of the survey. The objectives of the surveys were to estimate the number of potentially exposed workers, the extent of current compliance, the number of employee blood exposure incidents occurring in the workplace, and the number of affected establishments. Only facilities with exposure to blood or other potentially infectious materials were considered to be affected by the standard.

Each question in the survey was carefully reviewed, and interviewers were highly trained to ensure the accuracy of data collected. Pre-notification letters were sent to all establishments in the sample to prepare respondents for the telephone interview. The interviewers collected data using a Computer Assisted Telephone Interviewing (CATI) system, which allowed the computer to immediately identify answers that were out of range or inconsistent with previous answers. In these cases, the interviewers resolved the problems by asking the respondent for clarification. This method virtually eliminated the problem of invalid and inconsistent responses arising during the data collection process.

Although only 2,545 responses were required to achieve statistical accuracy, OSHA received over 3,500 responses. For further details on the survey, see appendix A and appendix B. References made to OSHA survey data will refer to either Ex. 264 (multi-sector survey) or Ex. 266 (hospital survey) and will list the relevant table number(s) where the estimates appear, or from which OSHA derived figures used in its calculations. (See Technological Feasibility below and Technical appendices A and B for details on survey methodology and results.) For example, calculations incorporating the estimated number of health care workers exposed to blood or other potentially infectious materials would be referenced as [Ex. 264, Q38] for non-hospital sectors, with tabulated data from question 38 noted.

Table VII-1 enumerates affected establishments and occupationally exposed workers by SIC code. As shown in the table, an estimated 511,755 establishments will be affected by the standard.

TABLE VII-1.—INDUSTRY PROFILE OF AFFECTED ESTABLISHMENTS AND POPULATION AT RISK [1990]

SIC code	Type of establishment	Number of affected estab.	Population at risk
801; 803	Offices of Physicians.	122,104	640,681
802	Offices of Dentists.	100,174	316,237
805	Nursing Homes	12,200	485,303
806	Hospitals	6,197	2,386,165
807	Medical and Dental Labs.	4,425	62,854
808	Home Health	6,437	212,246
*	Hospices	651	10,856
8092	Hemodialysis	782	12,688
8093	Drug Rehabilitation.	744	6,722
9431	Government Clinics.	10,893	56,345
8099	Blood/Plasma/ Tissue Centers.	730	18,788
836	Residential Care.	2,425	49,102

TABLE VII-1.—INDUSTRY PROFILE OF AFFECTED ESTABLISHMENTS AND POPULATION AT RISK [1990]—Continued

SIC code	Type of establishment	Number of affected estab.	Population at risk
7362	Personnel Services	1,348	163,477
726	Funeral Services	19,890	57,013
*	Health Units in Industry	202,540	178,732
8221, 873, 283	Research Labs	1,453	89,151
721	Linen Services	1,250	50,000
39, 7699	Medical Equipment Repair	1,076	6,185
9221	Law Enforcement**	4,946	341,546
9224	Fire and Rescue***	3,174	252,048
9223	Correctional Facilities	1,895	120,224
9229	Lifesaving	100	5,000
9411	Schools	6,321	41,362
4953; 9511	Waste Removal		13,300
Totals		511,755	5,576,026

* Includes various SIC codes.
** Includes state and local departments only.
*** Includes fire departments and private ambulance services.
Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

OSHA's final estimates of the affected worker population were also based on the OSHA surveys, as well as various other sources (see General Overview of Methodology and individual sector profiles below). Table VII-2 provides a tabular summary of the populations at risk, by occupational category. (Unless noted otherwise, estimates of the population at risk and the number of affected establishments include state and local government representation only for states with occupational safety and health plans in place. A total of about 1.2 million workers employed by state and local governments in non-state-plan states were estimated to be at risk, but are not covered by the rule. Moreover, these data do not include an estimated 190,000 self-employed physicians and dentists who do not fall under OSHA's purview.)

TABLE VII-2.—OCCUPATIONAL EMPLOYMENT DISTRIBUTION OF THE POPULATION AT RISK

[1990]

Occupation	Number of affected workers							
	Hospitals	Dental offices	Physicians offices	Med./dent. labs	Nursing homes	Residential care	Home health	Hospice care
Healthcare Workers	1,960,639	313,219	593,992		450,567	41,211	202,946	10,665
Morticians								
Paramedics								
Emergency Personnel								
Laboratory Workers	164,604			57,421				
Educators								
Corrections Officers								
Firefighters								
Line of Duty Officers								
Unpackers								
Equipment Cleaners								
Equipment Technicians								
Housekeepers/Janitorial	157,520	3,018	4,283	445	27,221	1,138	3,000	164
Drivers/Couriers				4,988				
Service Personnel	103,402				7,515			
Additional Workers			42,406			6,753	6,300	27
Total at-Risk	2,386,165	316,237	640,681	62,854	485,303	49,102	212,246	10,856

Occupation	Number of affected workers							
	Hemodialysis clinics	Drug rehabilitation	Government outpatient	Personnel services	Blood/tissue collection	Industrial clinics	Funeral homes	Linen services
Healthcare Workers	11,926	6,067	52,156	61,387	7,869	34,184		
Morticians							51,054	
Paramedics								
Emergency Personnel						141,051		
Laboratory Workers					10,329			
Educators								
Corrections Officers								
Firefighters								
Line of Duty Officers								
Unpackers								
Equipment Cleaners								
Equipment Technicians	553							
Housekeepers/Janitorial	209	149	381		200	3,497	2,721	
Drivers/Couriers							(*)	
Service Personnel				102,090			(*)	50,000
Additional Workers		506	3,808		390		3,238	
Total at-Risk	12,688	6,722	56,345	163,477	18,788	178,732	57,013	50,000

Occupation	Number of affected workers								
	Equipment repair	Research labs	Police depts.	Correctional institutions	Fire & rescue	Lifesaving	Schools	Waste removal	Total
Healthcare Workers				8,381	(*)				3,755,210
Morticians									51,054
Paramedics					113,866				113,866
Emergency Personnel						5,000			146,051
Laboratory Workers		87,484	1,137						320,975
Educators				(*)			23,514		23,514
Corrections Officers				82,883					82,883
Firefighters					136,412				136,412
Law Enforcement Officers			306,769						306,769
Unpackers	473								473
Equipment Cleaners	200								200
Equipment Technicians	5,152				(*)				5,705
Housekeepers/Janitorial		1,315	2,617	7,273					215,152
Drivers/Couriers									4,988
Service Personnel (1)				(*)	(*)		(*)	13,300	276,307
Additional Workers	360	352	31,022	21,687	1,770		17,848		136,467
Total at-Risk	6,185	89,151	341,546	120,224	252,048	5,000	41,362	13,300	5,576,026

* Workers in these occupational categories are included as "Additional Workers," due to disaggregation limitations of survey data.
Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

The most common routes of exposure are by needlestick or entry through mucosal membranes or non-intact skin. These types of exposure occur across all of the affected industry sectors and throughout the various occupational categories. Exposure also takes place via cuts with sharp instruments or broken glass. Other routes of exposure are more or less confined to certain types of procedures. For example, laboratory employees may be exposed to contaminated equipment such as centrifuges or pipefitting devices.

The remainder of this section is presented in the form of a general overview describing OSHA's reasoning and estimation methodology with respect to its estimates of the number of affected facilities and population at risk, followed by an examination of each industry.

2. General Overview of Methodology

In developing the estimates of the number of affected facilities and the population at risk, OSHA relied heavily on the data produced by its 1989 nationwide statistical sample surveys of health care and other service sector establishments. In some sectors, OSHA surveyed only a portion of the overall universe; in such cases, additional data from the record were used to supplement survey generated statistics.

Secondary sources relied upon included:

- U.S. Department of Labor:

—Bureau of Labor Statistics—*Industry Occupation Matrix*, 1988 (IOM)

—Bureau of Labor Statistics—*Employment and Earnings*, September, 1990 (E&E)

- U.S. Department of Commerce:

—Bureau of the Census—*County Business Patterns*, 1987 (CBP)

—Bureau of the Census—*Census of Service Industries*, 1987 (CSI)

- U.S. Department of Justice:

—Bureau of Justice Statistics—*Census of Local Jails*, 1988 (CLJ)

—Bureau of Justice Statistics—*Profile of State and Local Law Enforcement Agencies*, 1987 (PLEA)

—Bureau of Justice Statistics—*Sourcebook of Criminal Justice Statistics*, 1988 (SCJS)

The statistical survey conducted by the Agency provided a sound framework for developing estimates of the costs and economic impacts of the bloodborne pathogens rule. (In addition to estimates of the affected universe and the population at risk, estimates of the extent of current compliance with the provisions of the standard were generated via the statistical sample survey. These estimates are discussed in the Technological Feasibility section of this preamble, and in Technical Appendix B.)

To facilitate the incorporation of survey data into the analysis, and to enable the development of more accurate estimation models, survey data were collected and tabulated with respect to four major occupational groups. OSHA labeled these groups simply A, B, C, and D. The major occupational groups represented in Category A are workers directly involved in providing health care; laboratory workers, emergency responders and firefighters in Category B; housekeepers and janitorial workers in Category C; and additional workers in Category D. Table VII–3 presents survey data showing occupations cross tabulated by industry sector.

TABLE VII–3.—EMPLOYMENT CLASSIFICATION SCHEME

Category	Offices of physicians	Offices of dentists	Nursing homes
A	Health Care Workers (Physicians and Surgeons; Registered Nurses; Therapists; Lab Technicians, Emergency Medical Technicians; Surgical Technicians; Other Health Professionals; Licensed Practical Nurses; Therapy Assistants; Other Health Service; Physician Assistants; Medical Assistants; Nursing Aides.)	Health Care Workers (Physicians and Surgeons; Dentists; Registered Nurses; Therapists; Dental Hygienists; Lab Technicians; Surgical Technicians; Other Health Professionals; Licensed Practical Nurses; Dental Assistants; Other Health Service; Medical Assistants.)	Health Care Workers. (Physicians and Surgeons; Dentists; Registered Nurses; Therapists; Dental Hygienists; Lab Technicians; Other Health Professionals; Licensed Practical Nurses; Dental Assistants; Nursing Aides and Orderlies; Psychiatric Aides; Other Health Service; Physician Assistants; Medical Assistants.)
	Affected Population: 593,992	Affected Population: 313,219	Affected Population: 450,567.
	Exposed to splash/splatter: 348,822	Exposed to splash/splatter: 281,897	Exposed to splash/splatter: 197,617.
B	None	None	None.
C	Housekeepers/Janitorial	Housekeepers/Janitorial	Housekeepers/Janitorial.
	Affected Population: 4,283	Affected Population: 3,018	Affected Population: 27,221.

TABLE VII-3.—EMPLOYMENT CLASSIFICATION SCHEME—Continued

Category	Offices of physicians	Offices of dentists	Nursing homes
D	Exposed to splash/splatter: 0 Additional Workers (Health Aides) Affected Population: 42,406 Exposed to splash/splatter: 0	Exposed to splash/splatter: 425 Additional Workers (None)	Exposed to splash/splatter: 6,645. Additional Workers (Service). Affected Population: 7,515. Exposed to splash/splatter: 1,958.

Category	Hospitals	Medical and Dental Labs	Home Health
A	Direct Patient Care (Diagnosing Occupations; Health Assessment, Treating, and Technical Occupations; Health Service Occupations.) Affected Population: 1,960,639 Exposed to splash/splatter: 1,649,937	Laboratory Workers (Physicians; Dentists; Scientists; Nurses; Therapists; Technicians; Dental and Medical Assistants.). Affected Population: 57,421 Exposed to splash/splatter: 29,349	Health Care Workers. Affected Population: 202,946. Exposed to splash/splatter: 56,967
B	Laboratory Workers Affected Population: 164,604 Exposed to splash/splatter: 141,559	None	None.
C	Service Workers (Housekeepers/Janitors; , Laundry; Central Supply; Other Service.). Affected Population: 260,922 Exposed to splash/splatter: 143,507	Housekeepers Affected Population: 445 Exposed to splash/splatter: 272	Housekeepers. Affected Population: 3,000. Exposed to splash/splatter: 143.
D	Additional Workers (None)	Additional Workers (Couriers/Drivers) Affected Population: 4,988 Exposed to splash/splatter: 1,477	Additional Workers (Service). Affected Population: 6,300. Exposed to splash/splatter: 0.

Category	Hospice care	Hemodialysis centers	Drug rehabilitation centers
A	Health Care Workers Affected Population: 10,665 Exposed to splash/splatter: 7,126	Health Care Workers Affected Population: 11,926 Exposed to splash/splatter: 11,105	Health Care Workers. Affected Population: 6,067. Exposed to splash/splatter: 2,094.
B	None	None	None.
C	Housekeepers Affected Population: 164 Exposed to splash/splatter: 164	Housekeepers Affected Population: 209 Exposed to splash/splatter: 199	Housekeepers. Affected Population:149. Exposed to splash/splatter: 0.
D	Additional Workers (Social Work/Support) Affected Population: 27 Exposed to splash/splatter: 27	Additional Workers (Equipment Technicians) Affected Population: 553 Exposed to splash/splatter: 428	Additional Workers. (Counselors). Affected Population: 506. Exposed to splash/splatter: 32.

Category	Government outpatient clinics	Personnel services	Linen services
A	Health Care Workers Affected Population: 52,156 Exposed to splash/splatter: 31,045	Health Care Workers Affected Population: 61,387 Exposed to splash/splatter: 51,565	None.
B	None	None	None.
C	Housekeepers Affected Population: 381 Exposed to splash/splatter: 0	None	None.
D	Additional Workers (Health Aides) Affected Population: 3,808 Exposed to splash/splatter: 0	Additional Workers (Service Workers) Affected Population: 102,090 Exposed to splash/splatter: 56,150	Additional Workers. (Laundry Workers). Affected Population: 50,000. Exposed to splash/splatter: 7,500.

Category	Blood plasma/tissue centers	Residential care	Funeral services
A	Health Care Workers (Nurses Laboratory workers) Affected Population: 18,198 Exposed to splash/splatter: 14,311	Health Care Workers (Physicians; Nurses; Therapists; Aides.) Affected Population: 41,211 Exposed to splash/splatter: 8,181	Morticians. Affected Population: 51,054. Exposed to splash/splatter: 37,330.
B	None	None	None.
C	Housekeepers Affected Population: 200 Exposed to splash/splatter: 89	Housekeepers Affected Population: 1,138 Exposed to splash/splatter: 180	Housekeepers. Affected Population: 2,721. Exposed to splash/splatter: 430.
D	Additional Workers (Drivers, Technicians, Maintenance) Affected Population: 390 Exposed to splash/splatter: 255	Additional Workers (Aides, Social Work, Service Workers) Affected Population: 6,753 Exposed to splash/splatter: 1,386	Additional Workers. (Service Workers). Affected Population: 3,238. Exposed to splash/splatter: 1,766.

Category	Research laboratories	Industrial health	Medical equipment repair
A	Laboratory Workers (Academic Scientists; Technicians; Research Assistants) Affected Population: 87,484 Exposed to splash/splatter: 17,222	Health Care Workers (Physicians; Nurses.) Affected Population: 34,184 Exposed to splash/splatter: 17,367	Unpackers. Affected Population: 473. Exposed to splash/splatter: 0.

Category	Research laboratories	Industrial health	Medical equipment repair
B	None	Emergency Responders Affected Population: 141,051 Exposed to splash/splatter: 37,119	Cleaners. Affected Population: 200. Exposed to splash/splatter: 27.
C	Housekeepers Affected Population: 1,315 Exposed to splash/splatter: 658	Housekeepers Affected Population: 3,497 Exposed to splash/splatter: 350	Technicians. Affected Population: 5,152. Exposed to splash/splatter: 2,318.
D	Additional Workers Affected Population: 352 Exposed to splash/splatter: 0	Additional Workers (None)	Additional Workers (Sales). Affected Population: 360. Exposed to splash/splatter: 330.

Category	Fire and rescue	Corrections	Law enforcement
A	Paramedics Affected Population: 113,866 Exposed to splash/splatter: 97,600	Health Care Workers (Physicians; Nurses.) Affected Population: 8,361 Exposed to splash/splatter: 3,461	Law Enforcement Officers. Affected Population: 306,769. Exposed to splash/splatter: 219,442.
B	Firefighters Affected Population: 136,412 Exposed to splash/splatter: 92,078	Corrections Officers Affected Population: 82,883 Exposed to splash/splatter: 34,384	Laboratory Workers. Affected Population: 1,137. Exposed to splash/splatter: 922.
C	None	Housekeepers Affected Population: 7,273 Exposed to splash/splatter: 3,158	Housekeepers. Affected Population: 2,617. Exposed to splash/splatter: 1,891.
D	Additional Workers (Other Health Care Staff; Vehicle Maintenance.) Affected Population: 1,770 Exposed to splash/splatter: 1,475	Additional Workers (Educators, Service Workers, paid Prisoners.) Affected Population: 21,987 Exposed to splash/splatter: 11,072	Additional Workers. (Jailors; Investigators). Affected Population: 31,022. Exposed to splash/splatter: 9,457.

Category	Lifesaving	Schools	Waste removal
A	Lifeguards Affected Population: 5,000	Educators (Teachers of the Mentally Retarded) Affected Population: 23,514	None.
B	None	None	None.
C	None	None	None.
D	None	Additional Workers Affected Population: 17,848	Additional Workers. (Service Workers). Affected Population: 13,300.

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis and Bureau of Labor Statistics.

Based on its survey, OSHA estimated 163,000 establishments in the physicians' offices sector. Many physicians operate multiple satellite offices which they may visit and staff only when office hours are held at that location. To count these offices as establishments would have overstated the count. OSHA believes that its final survey count of 163,000 establishments represents the best estimate of the number of practices in this sector: out of business, out of scope, and temporary offices were excluded from the total. (Also included in this estimate of establishments are ambulatory care centers and health maintenance organizations (HMO), since these centers are now included under SIC 801.)

To estimate the number of affected establishments, OSHA relied on answers to questions in the multi-sector survey which indicated that occupational exposure to blood and other potentially infectious materials occurred in about 75 percent of the esumated 163,000 physicians' offices [Ex. 264, Q11]. Thus, about 122,104 establishments were estimated to be affected by the standard. Although 75 percent seems rather low, this percentage reflects a developing trend for physicians' offices to contract blood and serum work out to medical laboratories. Furthermore, psychiatry and some opthalmology practices did not have routine blood exposure. The number of occupationally exposed workers was estimated directly from survey-generated statistics, which were tabulated separately for each of the four occupational categories introduced above. Thus, for category "A" workers, OSHA estimated the occupationally exposed worker population to be 593,992, as presented in Table 38 of OSHA's multi-sector survey [Ex. 264]. Tables 46 and 50 provided estimates of the number of occupationally exposed category "C" and "D" workers, respectively (no category "B" workers were employed in physicians' offices).

Thus, in total, OSHA estimated 640,661 workers to be occupationally exposed in this sector.

OSHA developed the industry profiles for the balance of the affected sectors following the methodology outlined above for physicians' offices. In sectors where additional data were deemed necessary to supplement survey data, alternative methods and reasoning are presented.

Estimates of financial indicators (revenue/receipt, profit levels) are also presented in the Sector Profiles. In general, OSHA estimated pre-tax profits based on Dun and Bradstreet financial reports (Industry Norms and Key Business Ratios, 1990) and corporate tax schedules.

3. Sector Profiles

Offices of Physicians. Frequency and type of exposure in a physician's office depends on the type of practice and the distribution of tasks. It is likely that phlebotomy is performed in a large number of offices, especially those with laboratory facilities. Injections are also commonly administered. Physicians performing gynecological examinations or examining patients for sexually transmitted diseases are most certainly at risk. Routine physical exams can also put the examining physician at risk. Other types of procedures commonly encountered which place physicians and physicians' assistants at risk are treatment of lacerations, abrasions, and compound fractures.

While some physicians' offices have contracted out blood analysis work, others have established office laboratories (POLs). These office-based

laboratory facilities have recently grown in number by about 15 percent annually, though the total number of such facilities is unknown [Ex. 13, p. I–38].

Another possible activity which could involve occupational exposure to blood in the physicians' office is housekeeping. However, it does not appear that, in general, housekeepers perform tasks involving exposure in physicians' offices, as only about 3 percent of offices reporting blood exposure on the OSHA survey indicated that housekeepers were occupationally exposed [Ex. 264, Qs. 45, 11].

OSHA estimated the number of affected establishments in this sector to be 122,104 [Ex. 264, Q11], while the population at risk was estimated to be 640,681 [Ex. 264, Qs. 38, 46, 50]. These estimates were generated from data collected as part of OSHA's multi-sector survey.

Commerce Department estimates indicate a level of $120 billion dollars in expenditures for physicians' services in 1989 [1990 U.S. Industrial Outlook, U.S. Department of Commerce, p. 49–1].

Considering only establishments affected by the standard, total revenue was estimated to be $90 billion, while profits were estimated to be $5.5 billion.

Offices of Dentists. A common route of exposure in the dental office is allowing chapped or abraded skin to come into contact with saliva and/or blood. Needle punctures are a potential hazard and instances where the face or eyes are splashed or spattered with saliva, blood, or tissue fluids represent risk. Dental workers are also exposed if improper procedures are employed when disinfecting dental instruments. Frequency of exposure varies by specialty, with oral surgery presenting a greater potential for exposure and orthodontics presenting a lesser potential for exposure. Housekeepers may also be exposed, though this does not often appear to be the case [Ex. 264, Qs. 45, 46].

OSHA estimated that 100,174 dental facilities will be affected by the rule [Ex. 264, Q11]. [This includes only those offices where salaried employees are exposed to blood.] This estimate is based on the results of the multi-sector survey, and was found to be consistent with other sources. The occupationally exposed workforce was estimated to be 316,237 employees. This estimate was derived by adjusting OSHA survey results [Ex. 264, Qs. 38, 46] to account for non-incorporated owner (self employed) dentists.

Data on expenditures for dental care were submitted by the American Dental Association (ADA) [Ex. 20–665, p. 7]. Expenditures for dental care in 1987 were reported to be $32.8 billion. Commerce Department estimates indicated 1989 expenditures would reach $33.7 billion [1990 U.S. Industrial Outlook, U.S. Department of Commerce].

Receipts for affected establishments in 1989 were estimated to be $31.7 billion. By applying the pre-tax profit rate for the dental sector to the revenues of proprietary firms, pre-tax profits for 1989 were estimated to be $2 billion.

Hospitals. Most hospitals perform a great variety of services, and there are many different exposure scenarios. One frequently reported was needlestick, with the greatest potential for exposure occurring during needle recapping [Ex. 13, pp. II–16, II–19]. Other hospital procedures that are associated with frequent exposure include phlebotomy, IV line placement, bronchoscopy, intubation, airway suction, endoscopy, colonoscopy, and proctosigmoidoscopy [Ex. 13, p. II–19]. Areas with the greatest potential for exposure include the emergency room, surgical suite, hemodialysis center, and intensive care unit. Laundry workers and janitors may also be exposed, particularly when handling soiled linen or refuse.

It is estimated that 6,197 hospitals will be affected by the standard [Ex. 266]. This estimate is based on the 1989 OSHA survey of hospitals. (Hospitals in states without state occupational safety and health plans were excluded.)

OSHA estimated that 2,386,165 workers are at risk in hospitals [Ex. 266, Qs. 7–12]. Based on responses given during the hospital survey, approximately 86 percent of all direct patient care employees, 88 percent of all laboratory employees, and 47 percent of all service employees were estimated to be occupationally exposed. Nurses and nursing aides comprise over 80 percent of the population at risk.

Expenditures on hospital care were estimated to be $230 billion in 1989 [1990 U.S. Industrial Outlook, U.S. Department of Commerce].

The total margin for hospitals (the difference between revenue from all sources and total expenses expressed as a percentage of total revenue) was preliminarily estimated to be about 4.5 to 5 percent [Ex. 13, p. I–10]. However, rural hospitals indicated margins ranging from negative to about 2 percent [Exs. 20–713; 20–891; 20–946]. These hospitals did not specify whether these data represented total margin or patient margin (the percentage of patient revenue retained after expenses). The Connecticut Hospital Association reported statewide average total margin to be 2.2 percent [Ex. 20–275].

Medical and Dental Laboratories. Procedures that most often result in exposure in the laboratory are specimen collection and specimen processing. Workers are exposed through needlesticks (phlebotomists), spills, or the improper use of laboratory equipment, such as the centrifuge. Phlebotomists appear to have the highest rate of exposure incidents [Ex. 13, p. II–68].

OSHA estimated the number of affected establishments in this sector to be 4,425 [Ex. 264, Q11], while the population at risk was estimated to be 62,854 [Ex. 264, Qs. 38, 46, 50]. These estimates were generated from data collected as part of OSHA's multi-sector survey.

Based on Department of Commerce data, revenue for medical and dental labs was estimated to be $5.2 billion and $1.9 billion, respectively, in 1988 (Ex. 13, p. I–39). Pre-tax profits were estimated at $348 million and $127 million for the two subsectors for that year (Ex. 13, p. I–39). Commerce Department data also indicated an increase in expenditures, however, of 10 percent for health services and supplies between 1988 and 1989 (1990 U.S. Industrial Outlook, U.S. Department of Commerce, p. 49–1); thus, OSHA estimated 1989 revenue for medical and dental labs to be $5.7 billion and $2.1 billion, respectively. Associated pre-tax profits were estimated to total $570 million for the two subsectors for 1989, respectively.

Considering only establishments affected by the standard, total revenue was estimated to be $4.4 billion, while profits were estimated to be $325 million.

Nursing Homes. Sandra Fitzler, corporate safety director and an occupational health nurse for the nation's second largest nursing home chain, testified at OSHA's informal hearing in Washington, D.C. that the majority of nursing home residents require assistance in performing routine activities, such as bathing, dressing, grooming, toileting, mobility, and eating [Tr. 9/21/89, p. 44]. These tasks are not associated with excessive exposure to potentially infectious materials. According to Ms. Fitzler, who represented the American Health Care Association (AHCA), "very few injections and almost no intravenous infusions are administered" [Tr. 9/21/89, p. 44].

Situations where exposure would be expected were described by the Service Employees' International Union (SEIU) in their post-hearing brief:

> It is SEIU's experience that nursing home workers come in contact daily with blood

and body fluids. Nursing home workers frequently are exposed to drainage from decubitus ulcers, and to blood contaminated urine and feces from incontinent patients. (Ex. 299, p. 35)

It is the nursing aide who most often comes into contact with body fluids of patients (Tr. 10/18/89, p. 387).

OSHA's field survey identified almost 13,000 establishments in this sector. The number of affected establishments was estimated to be 12,200 (Ex. 264, Q11). The number of occupationally exposed workers in this sector was estimated to be 485,303 (Ex. 264, Qs. 38, 46, 50).

Based on Commerce Department data, gross revenues for all nursing homes were about $43.9 billion in 1988, increasing to $48.8 billion in 1989 (1990 U.S. Industrial Outlook, Department of Commerce, p. 49–1).

Considering only establishments affected by the standard, total revenue was estimated to be $45.9 billion, while profits were estimated to be $1.6 billion in 1989.

Residential Care. Nursing aides and orderlies make up the largest percentage of workers involved in residential care followed by nurses. Blood exposures in residential care occur less often than in nursing homes. According to Vera Rublinger of AHCA, residential care patients are generally more independent and have less need for staff to assist with bodily functions, etc. (Tr. 9/21/89, p. 68). The number of residential care providers affected by the standard is 2,425 (Ex. 264, Q11), while the number of occupationally exposed workers in this sector is estimated to be 49,102 (Ex. 264, Qs. 38, 46, 50).

Revenues for 1988 were estimated to be $8.7 billion (Ex. 13, p. I–66). Allowing for a 10 percent increase in expenditures between 1988 and 1989 (1990 U.S. Industrial Outlook, U.S. Department of Commerce, p. 49–1), 1989 revenues were estimated to be $9.6 billion.

Considering only establishments affected by the standard, total revenue was estimated to be $3.2 billion, while pre-tax profits were estimated to be $75 million (the pre-tax profit margin for nursing homes was applied to the residential care sector).

Hospice Care Though critically ill clients of hospice services often do not require the intensive care received by hospital patients; occupational exposure to blood or other potentially infectious materials may occur in hospices, although exposure generally would not involve large quantities of fluids or other material.

OSHA's best estimate of the number of hospices is 944 (Ex. 264, Q3). To estimate the prevalence of blood exposure in hospices, OSHA relied on its survey. Respondents reported no occupational exposure in 31 percent of hospices surveyed; thus, OSHA estimated the number of hospices affected by the standard to be 651 (Ex. 264, Q11), with 10,856 employees occupationally exposed (Ex. 264, Qs. 38, 46, 50).

Total annual revenue for affected establishments in this sector was estimated to be $325.5 million in 1989. Pre-tax profits were estimated to be $19 million.

Home Health Care. Circumstances of exposure to blood or other potentially infectious materials in home health care are similar to those of nursing homes or residential care, and may range from situations with a very low potential for exposure to activities providing regular exposure. Clients may require non-medical services, such as those provided by Kelly Assisted Living: "although a company may indeed provide home health services, this does not necessarily mean that the company provides the types of services that expose its employees to blood or other body fluids." (Ex. 20–1298). However, services may also be provided which require the use of sharps; SEIU noted that in some locations "over one in twenty homecare workers regularly give their clients injections" (Ex. 299, p. 38).

The number of home health care facilities was estimated to be 7,573, based on 1987 data on Medicare-certified establishments and on 1987 data from the National Association of Home Health Care (Ex. 13, p. I–73). (This estimate excludes 50 percent of all government administered agencies, OSHA's estimate of agencies operating in non-state plan states.) To estimate the number of agencies affected by the standard, OSHA applied the exposure prevalence factor obtained through its survey. Respondents indicated that employees were occupationally exposed in 85 percent of home health agencies surveyed (Ex. 264, Q11); the number of agencies affected by the standard was estimated to be 6,437, with 487 believed to be government administered.

To develop its estimate of the exposed workforce, OSHA relied on comments received from the public, as well as the multi-sector survey. For example, the Home Care Association of New York State reported that an estimated 70,860 home health workers in 652 entities in the state are potentially affected by the regulation (Ex. 20–929). Similar information was received from SEIU, who reported in their post-hearing brief that 50,000 home health aides are employed in Los Angeles County alone, and that more than 600,000 home health workers could be at risk nationally (Ex. 299, p. 52).

OSHA's survey of private home health agencies indicated an average of 51 health care workers per agency (Ex. 264, Q22). Thus, all affected non-government agencies employed 303,450 health care workers (5,950×51). As noted above, some government administered agencies appear to employ greater numbers of care givers. If the national average is similar to that of New York State at 108 workers per agency (70,860/652), the estimated number of care givers for government entities in state plan states was estimated to be 52,596. Thus, 356,046 health care providers are estimated to be employed in home health agencies affected by the standard.

To estimate the number of occupationally exposed health care workers, OSHA used factors derived from data obtained from its multi-sector survey. Using data from responses to questions 38 and 22, it was estimated that 57 percent of all health care workers employed by agencies where blood exposure was reported were actually occupationally exposed (Ex. 264, Qs. 22, 38).[1] Thus, OSHA estimated that 202,946 health care workers are occupationally exposed in this sector.

OSHA also derived estimates of the number of exposed housekeepers in this sector. Based on multi-sector survey data, OSHA estimated 3 housekeepers to be occupationally exposed in approximately 15 percent of all affected agencies (Ex. 264, Qs. 45, 46). Thus, OSHA estimated approximately 3,000 housekeepers to be exposed in this sector (6,437×0.15×3). Survey respondents also indicated "other" workers were exposed in approximately 14 percent of all affected facilities (Ex. 264, Q49). OSHA estimated an average of 7 workers to be exposed in such facilities (Ex. 264, Q50); thus, 6,300 additional workers were identified as being affected by the rule.

In sum, OSHA identified 212,246 workers affected by the rule in this sector.

Annual revenue for non-public agencies was estimated based on data obtained from the OSHA survey. Total revenue for affected establishments was estimated to be $8.9 billion in 1989 ($1.5 million×5,950). Associated pre-tax

[1] To derive the estimated percentage of health care workers (category "A" workers) occupationally exposed, the number of occupationally exposed health care workers (obtained from participants' weighted responses to Q38), 41,191, was divided by the total number of health care workers employed (obtained from participants' weighted responses to Q22), 71,964.

profits were estimated to be $500 million.

Personnel Services. The number of temporary help agencies affected by the standard is estimated to be 1,348. This includes an estimated 530 agencies which supply health care workers (Ex. 264, Q37) and an estimated 818 agencies which supply laborers or service workers, who may come into contact with blood or other potentially infectious materials in the form of regulated waste (Ex. 264, Q49).

The population at risk for this sector was estimated to be 163,477. This estimate includes 61,387 health care workers and 102,090 service workers.

Information supplied at the hearing in Washington, D.C. by the Home Health Services and Staffing Association (HHSSA) indicated a population of over 200,000 temporary nurses and aides were provided by personnel services [Tr. 9/21/89, p. 87]. However, no data were submitted regarding the prevalence of occupational exposure; thus, OSHA relied upon its multi-sector survey estimates in performing its calculations, as these were the best data available in the record.

While revenues for all personnel supply companies were reported to be $10.4 billion in 1986 [Ex. 13, p. I–88], OSHA estimated that average revenue was about $4.0 million (66 percent of affected facilities reported annual revenue in excess of $3.5 million on the multi-sector survey [Ex. 264, Q196]). Thus, annual revenue of personnel service companies affected by the rule was estimated to be $5.4 billion. Associated pre-tax profits were estimated by OSHA to be $210 million.

Drug Treatment Centers. Opportunities for occupational exposure in drug rehabilitation centers, though infrequent, would be expected to arise during use of sharps or through contact with open wounds.

The best source of data on which to base an estimate of the number of potentially affected drug treatment centers is the OSHA multi-sector survey. The estimate generated from the survey, 3,916 independent centers, is based on the 1987 National Drug and Alcoholism Treatment Unit Survey, from which OSHA drew its sample. (The survey excluded centers based in hospitals or correctional institutions.) Only 19 percent of these establishments reported that employees were occupationally exposed [Ex. 264, Q11]. Thus, OSHA estimated the number of establishments affected by the standard to be 744.

The number of affected employees was also based on the OSHA survey. Estimates from the responses to question 38, for health care workers (6,067), question 46, for housekeepers (149), and question 50, for "other" workers (506) were summed totalling 6,722 workers at risk.

To estimate annual revenues for this sector, OSHA relied on the financial profile of respondents to its multi-sector survey [Ex. 264, Q196]. Based on these data, OSHA estimated average revenue to be about $1 million in 1989. Total annual revenues for establishments affected by the standard were thus estimated to be $744 million for this sector. Associated pre-tax profits were estimated to be $45 million.

Hemodialysis Centers. Principal occupational hazards to workers in hemodialysis centers include contaminated sharps and contaminated dialysis equipment.

Medicare-certified hemodialysis centers numbered 1,578 in 1986, but only 861 were freestanding (not affiliated with hospitals or other health care facilities) [Ex. 13, p. I–75]. Based on a 1987 listing obtained from the Health Care Financing Administration, OSHA surveyed the sector as part of its multi-sector survey; using these survey data, OSHA estimated 782 freestanding facilities [Ex. 264, Q3]. Based on responses to the OSHA survey, all of these facilities will be affected by the standard [Ex. 264, Q11].

The population at risk was also estimated from responses to the OSHA multi-sector survey. Approximately 12,000 health care workers were estimated to be occupationally exposed in hemodialysis centers [Ex. 264, Q38]. In addition, 209 housekeepers and 553 maintenance workers and equipment technicians were estimated to be exposed [Ex. 264, Qs. 46, 50]. In sum, 12,688 workers are occupationally exposed in hemodialysis centers.

To estimate the annual revenues of this sector, OSHA used the financial profile of respondents to its multi-sector survey. Based on this data, OSHA estimated average revenue to be about $1.5 million in 1989. Total annual revenues for establishments affected by the standard were estimated to be $1.2 billion for this sector. Associated pre-tax profits were estimated to be $87 million.

Government Outpatient Care Facilities. Public clinicians perform procedures typical of physicians' offices, and thus exposure risks are similar to those outlined for that sector.

Public clinics for general medical care were not surveyed. However, OSHA estimates that 10,893 government outpatient care facilities are in operation. This estimate assumes that each of 10,483 local administrations operate at least one public outpatient clinic in states with state occupational safety and health plans [Ex. 13, p. I–75]. OSHA also assumed that each of 82 metropolitan statistical areas (MSA) located in states with state occupational safety and health plans operate 5 public clinics, on average. OSHA estimated that all clinics would be affected by the standard.

The affected worker population was estimated to be 56,345. This estimate was derived by assuming that staffing levels and potential for occupational exposure in public clinics resemble staffing levels and potential for occupational exposure in physicians' offices and ambulatory clinics. For example, based on survey data collected from physicians' offices affected by the standard, OSHA estimated that average employment for health care, or category "A," workers was 5.7 employees per affected establishment [Ex. 264, Q22]. It was also estimated that 84 percent of these workers were occupationally exposed [Ex. 264, Qs. 22, 38].[2] Applying these figures to the 10,893 affected public clinics yields an estimated 52,156 occupationally exposed health care workers in this sector. Summing estimates for occupationally exposed housekeepers and "other" workers identified in the OSHA survey, OSHA estimated that 56,345 workers were occupationally exposed in this sector.

Revenues were estimated to be 50 percent of private physicians' offices. Private physicians' offices average about $450,000 in revenue annually; OSHA estimated annual funding for government clinics to be $2.4 billion.

Blood Collections and Processing. Workers in this sector are exposed most often during blood collection and blood processing. As in medical and dental labs, workers in this sector are exposed through needlesticks (phlebotomists), mucous membrane contacts, spills, or the improper use of laboratory equipment, such as the centrifuge [Ex. 13, p. II–125].

Recent data (1989 Food and Drug Administration (FDA) listing of blood collection and processing facilities) indicate 293 blood centers (excluding blood centers in hospitals and military facilities) and 425 plasma centers. Accepting these data, OSHA estimates that 718 blood and plasma centers will be affected by the standard. Additionally, 12 tissue banks were estimated to be affected [Ex. 13, p. I–95].

OSHA's best estimate of the population at risk for all establishments

[2] These calculations were performed in a manner similar to that described for the home health sector. See footnote 1.

in this sector was estimated to be 18,788 workers [Ex. 264, Qs. 38, 46, 50]. This total included 18,198 health care workers (phlebotomists, nurses, and laboratory workers), 200 housekeepers, and 390 "other" workers at risk (including maintenance workers, drivers, and technicians).

Revenue for blood centers was estimated at $1.3 billion in 1987, based on data obtained from 106 members of the American Association of Blood Banks (AABB) [Ex. 13, p. I–96]. More recent information indicated a unit of blood represented about $50 in revenue, on average [Ex. 6–627]. Since blood banks draw an estimated 12 million units annually [Trs. 9/21/89, p. 11; 10/20/89, p. 758], annual revenue of at lease $600 million was indicated. Since there is a great deal of uncertainty on revenue for this sector, OSHA estimated total revenue for this SIC to be the average of these data (approximately $1 billion). No data were available which would allow OSHA to estimate profit/operating margins for these establishments.

Health Care Personnel in Industrial Facilities. Traumatic injuries occur in industrial facilities, giving rise to the potential for blood exposure. Invasive procedures or the administration of injections may also occur.

This group of establishments includes industrial facilities with health care or designated emergency response personnel. These facilities are found throughout manufacturing sectors and are not unique to any SIC code or industry.

OSHA's best estimate of the universe is 203,622, based on NIOSH's 1981–1982 National Occupational Exposure Survey [Ex. 13, p. I–101]. This total includes 36,056 plants with health units and 185,594 plants with emergency health care personnel [Ex. 13, p. I–101]. Since responses to the OSHA survey of large industrial facilities (establishments with a total workforce of 500 employees or more) indicated that approximately one-half of the plants with health units also employed emergency personnel, OSHA estimates that about 18,028 plants employ both types of health care workers.

Estimates generated from OSHA's multi-sector survey indicated that workers were occupationally exposed to blood or other potentially infectious materials in 97 percent of all health units surveyed [Ex. 264, Q11]. Thus, 34,974 health units were estimated to be affected by the standard (36,056 × 0.97). OSHA assumed that all establishments where designated emergency personnel are employed will be affected. Therefore, the estimate of the affected universe includes 16,946 plants with health units only, 18,028 plants employing health unit workers and emergency personnel, and 167,566 plants employing emergency personnel only (185,594 – 18,028 health units employing emergency personnel). Thus, OSHA's best estimate of the affected universe of establishments is 202,540.

An estimate of the number of emergency personnel and health care workers employed in health units was derived from the NIOSH survey [Ex. 13, p. I–101]. It was assumed that 185,594 facilities employing emergency response personnel, employed one such worker. In the survey of health care workers in health units, a physician and one additional employee, on average, were reported in 2,251 units. Assuming that 97 percent of these have potential exposures to blood or other potentially infectious materials, 2,183 units have potentially exposed workers. In 32,791 (34,974 – 2,183) health units, one health care worker was employed [Ex. 13, p. I–101]. Thus, OSHA estimated 37,157 health care workers were employed in health units.

Based on the survey, OSHA estimated that 76 percent, or 141,051 (185,594 × 0.76), of all emergency personnel were occupationally exposed [Ex. 264, Qs. 24, 42]. OSHA survey data also indicated that approximately 92 percent, or 34,184 (37,157 × 0.92), of all health care workers were occupationally exposed [Ex. 264, Qs. 22, 38]. Housekeepers were identified as being exposed about 10 percent of the time [Ex. 264, Q46]. It was assumed that there would be one housekeeper for each of the 3,497 (34,974 × 0.10) affected health units with occupationally exposed housekeepers, yielding an estimated 3,497 housekeepers affected by the standard. Thus, OSHA estimated the occupationally exposed workforce in this sector to number 178,732.

Health care budgets were not estimated for health units in manufacturing facilities. OSHA assumed the incremental costs of the rule to represent a small portion of the overall cost of manufacturing operations and will have no significant impact on the firms' ability to operate.

Research and Production Laboratories. Exposure incidents in this sector, as in all others, tend to be linked to procedures. Spills, which may cause infectious material to come into contact with non-intact skin, mucous membrane contamination, and cuts with sharp instruments are the most frequent routes of exposure in these facilities [Ex. 13, p. II–125].

OSHA's best estimate of the number of affected establishments in this sector was 1,453. This figure was based on three sources. First, OSHA surveyed commercial research establishments, noncommercial research establishments, and pharmaceutical establishments. From these data, it was estimated that occupational exposure occurs in 496 of 1,873 labs (all 496 would be affected by the standard) [Ex. 264, Q11].

Second, based on U.S. Department of Education (USDE) statistics [1989 Digest of Education Statistics, National Center for Education Statistics, USDE, Table 5]. OSHA identified an additional 782 academic institutions doing medical research, which would be affected by the standard. This estimate excludes medical schools and public institutions in states without state administered occupational safety and health programs (judged to be 50 percent of all public institutions).

Finally, based on a survey performed by Booz, Allen, and Hamilton (BAH), and excluding public institutions in non-state plan states, OSHA estimated that about 75 public and private medical schools would also be affected [Ex. 13, p. I–42] (for the purposes of this analysis, these programs were judged to have more extensive medical practice activities than other academic programs).

Also, 1000 faculty and on-site supporting staff per affected medical school were estimated to be occupationally exposed (75,000 workers, total) [Tr. 1/10/90, p. 230]. OSHA identified 100 federal government laboratory complexes would be included in the affected universe [Ex. 13, p. I–42]. Based on the results from the survey, OSHA estimated that 4,636 workers in commercial, noncommercial, and pharmaceutical research labs were occupationally exposed [Ex. 264, Qs. 38, 46, 50, revised]. These workers are scientists, research assistants, laboratory technicians (4,546), housekeeper/janitorial personnel (70), and certain "other" workers (doctors, service workers) (20).

Assuming that the average number of occupationally exposed laboratory workers in non-professional (other than medical and dental) academic and federal labs is similar to that in labs included in the OSHA survey, 7,938 laboratory workers would be at risk in these institutions.

OSHA estimated the population of exposed housekeepers and "other" workers in academic and federal labs by computing the ratio of exposed housekeepers and "other" workers to exposed laboratory personnel in commercial, noncommercial, and pharmaceutical research labs (0.015 for

housekeepers and 0.004 for "other" workers) and applying these ratios to the population of housekeepers and "other" workers in academic and federal labs. The number of exposed housekeepers in non-professional (other than medical and dental) academic and federal labs was thus estimated to be to 120, and the number of exposed housekeepers in medical school labs was estimated to be 1,125 (75,000×0.015). The number of "other" workers exposed in non-professional academic and federal labs was likewise estimated to be to 32, and the number of "other" workers exposed in medical school labs was estimated to be 300.

In sum, the population at risk in this sector was estimated to be 89,151.

Total revenues for commercial, noncommercial, and pharmaceutical establishments were estimated to be $744 million, and assuming average revenue of about $1.5 million [Ex. 264, Q196] for this sector. Additionally, it was estimated that $2.6 billion was spent on the medical sciences in academia and that budgets for federal labs (incorporated here as a proxy for revenues) were about $220 million in 1986 [Ex. 13, p. I–44]. OSHA's best estimate of total revenues for affected establishments in this sector was approximately $3.5 billion.

Pre-tax profits for commercial, noncommercial, and pharmaceutical establishments were estimated at $54 million.

Funeral Homes. Procedures placing funeral home workers at risk of exposure are embalming, cleaning, disinfecting, and transporting cadavers. Embalmers are at risk due to the presence of uncontained blood, and the need to handle various body parts and tissues and to suture incisions [Ex. 11–111, p. 2].

The total number of funeral homes and crematories was estimated to be 20,936. This is based on testimony given in Washington, D.C. by Howard C. Raether, former director of and consultant to the National Funeral Director's Association [Tr. 9/27/89, p. 291]. The OSHA survey indicated that occupational exposure did not occur in all establishments, however. Based on survey results, OSHA estimated 95 percent of the universe, or 19,890 establishments, to be affected by the standard.

OSHA used survey data to estimate the population at risk. Estimates were derived by first multiplying the estimated average number of workers per establishment for each of three categories (morticians, housekeepers, and "other" workers, which included maintenance workers and drivers) by the number of affected establishments. Next, ratios computed from the OSHA multi-sector survey were used to estimate the proportion of workers occupationally exposed. For example, survey data indicated that funeral homes employ, on average, 2.76 morticians [Ex. 246, Q22], and that 93 percent were occupationally exposed [Ex. 264, Qs. 22, 38]. Thus, for all 19,890 affected facilities, OSHA estimated that 51,054 morticians were occupationally exposed. OSHA also estimated 19 percent of 14,321 (2,721) housekeepers were occupationally exposed and 11 percent of 29,437 (3,238) "other" workers were occupationally exposed. In sum, the population at risk for this sector was estimated to be 57,013.

According to census data, revenues for all funeral services and crematories were $5.3 billion in 1987. Thus, average revenue per facility (for the 15,544 facilities enumerated by the census) was $341,000. Multiplying this figure by the number of affected facilities yields an estimated revenue of $6.8 billion industry wide. Associated 1989 pre-tax profit levels for the industry were estimated by OSHA to be about $610 million.

Linen Services. Laundry workers providing services to health care institutions may be occupationally exposed through contact with soiled laundry or concealed sharps.

Based on information in the record, OSHA estimated the number of affected establishments providing linen services to the health care sectors. The Textile Rental Services Association of America (TRSA) reported more than 100,000 workers were employed in over 2,500 establishments in the linen supply and industrial laundry sectors [Tr. 9/25/89, p. 74]. They also indicated that about 50 percent of these establishments handled laundry from health care facilities [Tr. 9/25/89, p. 91]. Based on this information, OSHA estimated that there are approximately 1,250 affected establishments in this sector. The population at risk was estimated to be 50,000.

Total revenue was estimated based on 1987 Census of Service Industries (CSI) data, which indicated average receipts of $1.6 million per linen supply establishment. Total revenue for affected facilities was thus estimated to be $4.8 billion. OSHA estimated pre-tax profits for affected facilities to be $99 million.

Medical Equipment Repair. Exposure to potentially infectious bodily fluids can occur in this sector when "sales, service and repair, quality assurance, and teaching personnel must come in contact with a patient in the hospital, clinic, or the home environment or with contaminated devices" or when "used products are returned to the manufacturer for a variety of reasons," such as replacement or investigation [Tr. 9/25/89, p. 141–2].

OSHA received comments and testimony in which commenters indicated that the Agency underestimated the number of affected establishments in this sector in its preliminary analysis. John A. Matta, senior counsel for PPG industries, explained that no evidence existed in OSHA's preliminary analysis which indicated that manufacturers of clinical laboratory equipment were included, though these companies often provide calibration, maintenance, and repair services to customers [Ex. 20–369, p. 2]. Mr. Matta indicated that over 16,000 medical device manufacturing facilities are registered with FDA. Similarly, David Hopps, representing Ohmeda (a manufacturer of critical care medical equipment) and the Health Industry Manufacturers Association (HIMA), testified in New York that OSHA underestimated the number of affected employees [Tr. 11/14/89, p. 484]. Unfortunately, neither commenter provided estimates of the affected universe or the population at risk. In written comments, however, HIMA indicated that their membership of 320 manufacturers represented "90–95 percent of the commerce in this sector of the health care delivery market [Ex. 20–795]." Additional testimony was received which indicated that about 10 percent of the 200,000 workers employed in the medical device manufacturing industry were occupationally exposed [Tr. 9/25/89, p. 141].

OSHA surveyed establishments in the surgical, medical, and dental instruments and supplies sectors (SIC 384), as well as independent medical equipment repair firms. Additional potentially affected establishments not surveyed included establishments which manufacture laboratory apparatus (SIC 382), or facilities which repair dental/hospital equipment (SIC 7699). Based on Dun and Bradstreet counts, OSHA estimated that there are 1,200 potentially affected firms in these sectors, in addition to the 2,060 firms estimated from data obtained during the OSHA multi-sector survey [Ex. 264, Q11]. Thus, 3,260 establishments were identified.

To estimate the number of firms affected by the standard, OSHA used data from the multi-sector survey. Respondents indicated that occupational exposure occurred in approximately one-third of all medical device establishments surveyed [Ex. 264,

Q11]. Thus, OSHA estimated the affected universe to be 1,076 establishments.

To estimate the population at risk, OSHA again relied on its multi-sector survey. The average number of occupationally exposed employees per affected establishment was derived from survey data and extrapolated over the entire universe of affected establishments. For example, survey data indicated occupationally exposed unpackers per affected establishment. About 44 percent of establishments surveyed averaged one occupationally exposed unpacker [Ex. 264, Qs. 38, 11]. Extrapolating over the entire affected universe yielded an estimated 473 occupationally exposed unpackers. Performing similar computations for cleaners (200 occupationally exposed [Ex. 264, Qs. 42, 11]), technicians (5,152 occupationally exposed [Ex. 264, Qs. 46, 11]), and sales professionals (360 occupationally exposed [Ex. 264, Qs. 50, 11]), OSHA estimated that 6,185 workers are at risk in this sector.

The total revenues for this sector were estimated from survey data and indicated average revenue for repair establishments to be about $1 million [Ex. 264, Q196]. OSHA thus estimated revenues to be approximately $1 billion for affected establishments. Pre-tax profits for 1989 were estimated to be approximately $72 million.

Law Enforcement. Law enforcement personnel are at risk because they may come into contact with blood or body fluids during the course of duty. In testimony presented in Washington, DC, Ms. Jolanda N. Janczewski stated that she had personally observed numerous situations during which opportunities were present for exposure to contaminated fluids [Tr. 9/12/89]. Examples given included searches of scenes of violent crime and collection and transportation of evidence.

The multi-sector survey's estimate of 4,241 state and local police departments was generated from a sampled universe of 4,273 departments in OSHA state plan states only. The sampling frame used, the National Police Chiefs and Sheriffs Information Bureau, had 12,980 departments listed. The "1987 Profile of State and Local Law Enforcement Agencies" [U.S. Department of Justice, Bureau of Justice Statistics Bulletin] enumerated some 15,118 police departments in the U.S., with the difference resulting from unlisted and uncounted township police departments on the sampling frame. To account for departments not appearing on the sampling frame, OSHA estimated that, in addition to the 4,241 affected departments identified by the survey, 705 departments were affected.[3] Thus, OSHA estimated the affected universe to be 4,946 departments.

OSHA's estimate of employment was based upon survey data, adjusted to include federal law enforcement personnel at risk. OSHA derived its estimate of the population at risk as follows.

Based on OSHA's survey, 237,162 state and local police officers were estimated to be at risk [Ex. 264, Q38]. However, this estimate was adjusted to account for township departments not surveyed. Thus, OSHA estimated 275,769 state and local police officers to be at risk.[4] Additionally, based on Bureau of Justice Statistics (BJS) and Census Bureau data, Federal law enforcement personnel at risk were estimated to number approximately 31,000 [Ex. 13, p. I–49].

Laboratory workers are also at risk of exposure to blood and other body fluids in police department labs, as was indicated by information on laboratory procedures submitted by the New York State Police [Ex. 234]. Survey results indicated that 72 percent of lab workers were occupationally exposed, 60 percent of housekeepers were occupationally exposed, and 51 percent of "other" workers were occupationally exposed (including jailers and investigations personnel) [Ex. 264, Qs. 24, 42, 26, 46, 30, 50]. After adjusting survey estimates to account for township departments, 34,777 additional workers were estimated to be at risk in police departments.

In sum, the occupationally exposed workforce for this sector was estimated to be 341,546.

According to BJS, expenditures for state and local law enforcement totalled $28 billion in 1987, with 47.5 percent [Ex. 13, p. I–47], or 13.3 billion, occurring in states with state occupational safety and health plans. OSHA estimated that federal spending was about 14 percent of state and local expenditure levels [Ex. 13, p. I–47]; thus, OSHA estimated federal expenditures on law enforcement to be about $4 billion ($28 billion x 14%) in 1988.

Fire Protection. Emergency responders' potential for exposure to blood was described by Mr. Clyde Bragdon of the USFA during testimony in Washington, D.C.:

> [f]ire and rescue personnel often come into contact with infectious diseases through routine channels. . . . In addition to the routine medical emergencies, automobile accidents, and rescues that fire fighters, EMTs, and paramedics respond to, there are numerous other situations unique to these professions where there is a strong potential for occupational exposure to bloodborne diseases. [Tr. 9/14/89, pp. 105–106]

Mr. Bragdon added during questioning that "all firefighters, because of the nature of being first responders, have the potential to be exposed to emergency medical situations" [Tr. 9/14/89, p. 137].

It was estimated, based on information obtained from the National Fire Protection Association's (NFPA) 1987 U.S. profile, that 3,174 fire/emergency medical service (EMS) departments, public and private, will be affected by the standard [Ex. 13, p. I–51]. Although testimony presented in Washington, DC by the United States Fire Administration (USFA) indicated that approximately 34,000 departments exist across the country [Tr. 9/14/89, p. 103], the bloodborne pathogens standard applies only to departments with paid employees, in states with occupational safety and health plans. The American Ambulance Association (AAA), with a membership of 500, also testified, reporting their estimate that close to 5,000 private organizations provide EMS services [Tr. 1/17/90, p. 881]. OSHA relied on NFPA data for this analysis.

The population at risk for fire and rescue departments consists principally of fire fighters and emergency medical technicians (EMTs), or paramedics. OSHA's best estimate of the number of paid fire fighters is 170,515 [Ex. 13, p. I–53], and is based on NFPA data. Information was also received into the record regarding the population of emergency medical technicians (EMTs). Mr. Paul Maniscalco, representing the National Association of Emergency Medical Technicians (NAEMT) testified that, "based on the 1988 Survey of Emergency Medical Technician Population * * * the aggregate of EMTs in the OSHA states is 282,408" [Tr. 9/14/89, p. 126]. No indication was given as to how many of these EMTs were volunteers. Also, it is likely that a large number of these EMTs are fire fighters [Tr. 9/14/89, p. 183; Seattle Fire Fighters Union and San Antonio Professional Firefighters Association, Ex. 22–122].

To estimate the number of EMTs affected by the standard, OSHA first deducted from the estimated 282,408 EMTs in state-plan states all EMTs believed to be paid fire fighters. Incorporating its assumption that 50

---

[3] This estimate was derived by multiplying the number of departments omitted from the sampling frame, 2,138, by the percentage estimated to be affected, 0.33 (4,241/12,980).

[4] Since the township departments were estimated to represent 14 percent of all affected departments (705/4,946), OSHA estimated the percentage of total employment attributable to township departments to be 14 percent. Thus, 237,162/(1–0.14) = 275,769.

percent of all cities with fire departments also had separate EMS units, OSHA assumed 50 percent of municipalities in state plan states have no separate EMS unit; thus, OSHA estimated that approximately 85,258 EMTs are also paid fire fighters (170,515 x 0.50). Next, it was assumed that public EMS departments separate from fire departments in state plan states require about the same number of paid paramedics (85,258). Finally, using OSHA's best estimate of the number of EMS workers who are employed by private ambulance companies in state plan states, 15,466 (30,932/2) [Ex. 13, p. I-53]. OSHA estimated that 96,426 EMTs in state plan states are volunteer (282,408 – (85,258 + 85,258 + 15,466)). The total number of EMTs affected by the standard in state plan states was thus estimated to be 100,724 (85,258 + 15,466).

In total, employment among firefighters and EMTs in state plan states was estimated to be 271,240 (85,258 fire fighters, 85,258 fire fighters/EMTs, 100,724 EMTs, public and private). An additional 15,466 private EMTs were also estimated to be employed in states without state plans.

OSHA based its estimate of the population at risk on survey responses which indicated essentially all EMTs to be exposed (98 percent [Ex. 264, Q38]) and 80 percent of all firefighters to be exposed [Ex. 264, Qs. 24, 42].[8] OSHA also estimated 885 public health care professionals, vehicle maintenance, and equipment technicians to be at risk in state plan states [Ex. 264, Q50]. An additional 885 health care professionals, vehicle maintenance, and equipment technicians were estimated to be at risk in states without state plans. Thus, in sum, OSHA estimated the population at risk for this sector to be 252,048.

Expenditures on fire protection in state plan states was estimated to be approximately $4.0 billion [Ex. 13, p. I-52]. No data were received regarding revenues for private ambulance companies.

Correctional Institutions. Situations putting correctional employees at risk of exposure include violence and emergency medical treatment, and sharps (syringes).

OSHA identified an estimated 1,158 local jails, 762 state prison establishments, and 71 federally administered prison establishments, exclusive of state and locally administered facilities in states without occupational safety and health plans. These estimates were based on the Bureau of Justice Statistics' (BJS) 1988 Census of Local Jails [U.S. Department of Justice, Bureau of Justice Statistics] and the OSHA multi-sector survey (OSHA surveyed state and federal facilities).

Results from the OSHA survey indicated that employees were occupationally exposed in about 95 percent of state prisons and 100 percent of federal prisons [Ex. 264, Q11, revised]. OSHA had no data regarding prevalence of occupational exposure at local jails; thus, OSHA assumed that employees were occupationally exposed in 95 percent of local jails, as well. Thus, 1,895 correctional facilities are estimated to be affected by the rule.

OSHA estimated that 120,224 workers were at risk in correctional facilities. In state and federal institutions, 57,883 custodial and security employees, 8,381 health care workers, 7,273 housekeepers, and 21,687 "other" workers (maintenance workers and paid prisoners) were estimated to be occupationally exposed, based on OSHA's survey [Ex. 264, Qs. 38, 42, 46, 50, revised]. To develop estimates of the number of occupationally exposed correctional staff in local jails, OSHA relied on 1988 BJS data, adjusted to exclude workers not occupationally exposed. Based on OSHA survey data, it was estimated that 67 percent of correctional staff in state and federal institutions were occupationally exposed [Ex. 264, Qs. 24, 42, revised]. Thus, it was estimated that of 73,280 correctional officers in local jails, 49,098 were occupationally exposed, of which approximately 25,000 were estimated to be employed in state plan states. (BJS data did not allow OSHA to develop estimates for other categories of employees.)

Expenditures for local correctional facilities in state plan states was estimated to have reached $2.5 billion in fiscal year 1988 [1988 Census of Local Jails, U.S. Department of Justice, Bureau of Justice Statistics]. OSHA estimated that expenditures made by state administrations were about double that of local governments [Ex. 13, p. I-92]; thus, OSHA estimated expenditures on state correctional facilities to be approximately $5.0 billion in 1988. Federal government spending on corrections was reported to be $779 million in 1985. OSHA estimated 1988 federal expenditures to be approximately $1 billion. Total expenditures for this sector are estimated to be $8.5 billion.

Schools. Teachers and instructional aides in facilities where instruction is provided for the developmentally disabled are at increased risk due to childrens' vulnerability to injury, special medical needs, and dependence on adults for personal care [Tr. 1/12/90, pp. 487-501].

U.S. Department of Education (USDE) data indicated that during the 1986-87 academic year, teachers of the developmentally disabled taught 601,288 students, or 14.6 percent of all children classified with specific handicaps ["Eleventh Annual Report to Congress on the Implementation of the Education of the Handicapped Act, 1989," USDE]. The numbers and percentages of students receiving their education in a variety of locations are: regular classes within public schools (33,711, or 5.68 percent); resource rooms within public schools (142,341,or 23.97 percent); separate classes within public schools (341,958, or 57.59 percent); separate public facilities (60,815, or 10.24 percent); separate private facilities (6,847, or 1.15 percent); public residential facilities (3,767, or 0.63 percent); private residential facilities (2,316, or 0.39 percent); and homebound hospital environment (2,041, or 0.34 percent). Thus, over 98 percent of developmentally disabled students were instructed in public facilities.

Based on USDE data, OSHA estimated 23,514 teachers of the developmentally disabled to be employed in school districts located in states with occupational safety and health plans. Testimony presented in San Francisco by the California School Employees Association indicated that staff other than teachers were occupationally exposed [Tr. 1/12/90, pp. 495-497]. An estimated 17,848 staff other than teachers will also be covered by the standard [derived from the "Eleventh Annual Report to Congress on the Implementation of the Education of the Handicapped Act, 1989", USDE].

OSHA estimated the number of affected school districts to be 6,321 ["Eleventh Annual Report to Congress on the Implementation of the Education of the Handicapped Act, 1989", USDE].

Data on finances for public school systems were not submitted to the record. Data were available, however, from recent publications. Based on data from the National Education Association (NEA), total school system revenues nationally for the 1985-86 school year approximated $160 billion with the federal government providing about $10 billion (6.3 percent); state governments funding $75.5 billion (47.3 percent); local governments providing $67.2 billion (42.1 percent) and nonrevenue receipts (i.e., bonds) supporting $7 billion (4.3 percent)

[8] These calculations were performed in a manner similar to that described for the home health sector. See footnote 2.

["Estimates of School Statistics", National Education Association, 1988].

Nationally, school systems spend approximately $2.8 billion educating 601,288 developmentally disabled students. This estimate is based on a $4,615 per student cost according to the U.S. Department of Education. The regulations will affect every state and probably most school districts because the data indicate that every state has one or more settings for educating its developmentally disabled citizens [Supplement to "Patterns in Special Education Service Delivery and Cost, Report for Department of Education by Decision Resources Corporation", 1988].

Lifesaving. Exposure of lifeguards to bloodborne pathogens comes from saving and performing life saving procedures on victims of swimming, boating or fishing accidents. One dangerous aspect of their work is that lifeguards usually cannot use personal protective equipment during the rescue operation; lifeguards do not have access to dry dressings and gloves in the water. They use their bare hands to apply direct pressure to stop a victim's bleeding.

The first possibility of exposure in a rescue, therefore, is due to the "prolonged and extensive direct contact * * * between the rescuer and his victim" in the presence of body fluids [Tr. 12/20/89, p. 1139]. This may include blood contact from holding the victim or saliva contact from administering "mouth-to-mouth resuscitation" [Tr. 12/20/89, p. 1139].

A second avenue of exposure is medical waste that has been thrown or washed up on beaches. One report noted that a lifeguard stepped on a hypodermic needle while walking on the beach, subsequently receiving a gamma globulin vaccination [Tr. 12/20/89, p. 1173].

Testimony indicated approximately 10,000 ocean lifeguards to be at risk [Tr. 12/20/89, p. 1258]. OSHA estimated that up to 5,000 ocean lifeguards may be subject to the final rule. This estimate includes only state and local government employees who are employed in states with occupational safety and health plans. There was no testimony or public comment on private lifeguards. Assuming average employment during the summer is approximately 50 full-time, part-time, and on-call lifeguards, OSHA assumed 100 ocean rescue departments to be affected by the rule [Tr. 12/20/89, p. 1294].

No data were available on expenditures for the lifesaving sector. OSHA's budget estimate for this sector was based on expenditures for fire and rescue services, since both sectors practice similar paramedic type activities. Based on OSHA's estimated level of spending of $4.0 billion in the fire and rescue sector, expenditure per exposed employee was estimated to be $13,925; thus, OSHA estimates that expenditures for lifesaving services were approximately $140 million.

Waste Removal. Evidence in the record indicated that waste handlers are at risk of occupational exposure. For example, Brown-Ferris Industries Corporation (BFI) reported a medical-waste related needle injury rate of over 11 injuries per 1,000 workers annually [Ex. 286D, p. 5.28].

While it is estimated that there are over 200,000 refuse collectors [Ex. 286D, p. 2.8], not all of these workers will be involved specifically in the collection of medical waste. BFI reported that 2,700 employees worked specifically with medical waste, while 24,800 worked with municipal waste [Ex. 286D, p. 5.28]. No other data were available which would allow the Agency to derive estimates of the population at risk for this sector; thus, assuming that this ratio is typical throughout the industry, OSHA estimated about 10 percent of all waste handlers, or 20,000, were occupationally exposed. However, this estimate includes public sector workers in states without occupational safety and health plans who are not covered by Federal OSHA regulations. For the purposes of this analysis, OSHA assumes that two-thirds (67 percent) of all workers specifically handling medical waste are public employees. OSHA also assumes that 50 percent of all public sanitation workers are employed in states without occupational safety and health plans. Thus, OSHA estimates that 6,700 public and 6,600 private sanitation workers will be affected by the standard.

OSHA was not able to accurately estimate the number of affected establishments for this sector, since existing data combine private waste haulers and publicly administered sanitation services.

The Agency for Toxic Substances and Disease Registry estimated that 500,000 tons of regulated medical waste is generated by 380,000 regulated generators in industry hospitals, physicians' offices, dentists offices, biomedical research facilities, clinical laboratories, manufacturing facilities, veterinary offices and clinics, funeral homes, in-home medical care, other health care and residential care facilities and illicit intravenous drug users [Ex. 286D, pp. 3.13–3.36]. Unit costs of disposal were estimated by OSHA to range from $0.44 to $0.75 per pound (see Appendix C). Thus, OSHA estimated average annual expenditures on removal of regulated medical waste to be $440 to $750 million.

Approximately one-half of total expenditures were estimated to be directed toward proprietary operations. Estimated pre-tax profits, based on an average estimated annual revenue figure of $300 million for such operations, were estimated by OSHA to be $22 million in 1989.

C. Benefits

1. Introduction

OSHA's standard to reduce occupational exposure to bloodborne pathogens, including hepatitis B virus (HBV), non-A, non-B hepatitis virus, and human immunodeficiency virus (HIV), includes provisions applicable to the wide range of occupational settings where potential exposure to such bloodborne pathogens exist. In this section, OSHA presents its estimates of the expected reduction in disease cases among the employees affected by the standard.

2. Hazard Abatement

OSHA's standard for reducing worker exposure to bloodborne pathogens is based on the adoption of universal precautions as a method of infection control. This approach, which is fundamentally different from traditional procedures that isolate known infectious individuals and materials in the health care setting, assumes that all human blood and body fluids are potentially infectious for HIV, HBV, and other bloodborne pathogens. The rationale for this approach is that carriers of these diseases are not always identifiable in the health care setting, and that contaminated materials are not always properly labeled. Thus, the exposed worker can be at great risk without warning.

The standard will apply to widely varying workplace settings, including research laboratories, funeral homes, hospitals, prisons and police and fire departments. Hazard abatement measures will be developed by the employer to best suit the work place setting and accomplish the common objective of protecting the worker from contact with potentially infectious blood and body fluids and other potentially infectious materials.

In implementing the standard, employers will first develop an exposure control program that identifies the tasks and/or positions associated with occupational exposures to blood or other potentially infectious materials

and which documents the schedule of implementation of the measures that will be used to reduce potential risk. Employers will also be required to develop procedures to evaluate the circumstances surrounding exposure incidents.

The development of procedures to evaluate the circumstances surrounding exposure incidents is critical to reducing risk associated with bloodborne pathogens. Data in the record indicated that an emphasis on education, enforcement, and monitoring was associated with an increase in reporting of exposure incidents [Tr. 12/19/89, pp. 864–868]. Thus, to the extent that the OSHA standard increases employee awareness and compliance with employers' exposure control policies, promulgation of the standard will result in an increase in such reporting. Data indicated increased reporting of incidents could result in the reduction or elimination of certain exposure hazards, once such hazards are identified [Tr. 12/19/89, p. 868; Ex. 20–655, p. 2]. One example was provided for the record by Dr. Janine Jagger, Assistant Professor of Neurosurgery at the University of Virginia's Health Sciences Center [Ex. 300]. This submission demonstrated how accurate incident reporting and recordkeeping will support risk managers in their analysis and prioritization of alternative solutions to various types of needle injuries. Documenting the circumstances of exposure will contribute to overall risk reduction by allowing risk managers to more efficiently focus resources on exposure problems and ensure that other provisions of the standard are implemented in a timely manner to reduce or eliminate risk.

Another requirement of the standard is that the employer shall offer HBV vaccine to occupationally exposed employees. HBV vaccination is a means of achieving substantial reduction in the risk of infection for non-immune employees. In testimony provided by a manufacturer of the vaccine, the immunogenicity rate for employees covered by the OSHA standard was estimated to be 96 percent [Ex. 292]. A weighted average of OSHA's survey data on vaccine acceptance rates indicated that 50 percent of employees offered the vaccine would accept. Some may argue that the acceptance rate should be higher due to the provision requiring workers to sign a declination form if they refuse the vaccine. OSHA acknowledges that although the declination form is not a waiver, and the employee reserves the right to accept the vaccine at a future date, signing such a form may cause workers to think twice about turning down the offer and thus, result in a higher acceptance rate. However, there is no available data which would allow such an effect to be quantified.

The standard also requires post exposure evaluation and treatment. This includes testing to determine whether there has been transmission of infection, and follow-up treatment and counseling.

In the case of exposure to HBV, follow-up treatment can prevent illness. Under the standard, employers must offer safe and effective post-exposure prophylaxis, and hepatitis B immune globulin (HBIG) injections will be administered to employees experiencing exposure incidents. This post-exposure treatment appears to be highly effective in preventing HBV infection when an exposed employee lacks anti-HBs [Ex. 6–45].

This is another example of the importance of reporting exposure incidents. Since promulgation of the OSHA rule is expected to increase incident reporting, OSHA estimated an increase in the proportion of potentially infected workers receiving post-exposure prophylaxis, thereby preventing illness. The requirements under this provision of the standard will also assure that workers not presently provided access to prophylaxis (results of OSHA's multi-sector survey indicated many facilities were not offering such treatment to employees) will be offered treatment under the standard.

Counseling will reduce risk, through modification of the behavior of workers acquiring infection. These workers will be less likely to infect sexual partners or neonates (newborn children).

Training will be an integral part of overall risk reduction. In a series of case studies conducted by Jack Faucett Associates, hospitals reported that one of the most important aspects of employee compliance with infection control programs was an understanding of the risk [Volume III: Hospital Case Studies, Ex. 13, pp. 20, 48, 82, 123]. The employee training that conveys this risk becomes an indispensable link in hazard abatement. This requirement of the standard assures maximum effectiveness of most other provisions of the standard.

Work practices can have a substantial impact on hazard abatement by altering the manner in which a task is performed or by ensuring that equipment designed to prevent occupational exposure, such as engineering controls or PPE, is used in a manner which maximizes its effectiveness. The importance of strict adherence to work practice controls was reflected by evidence in the record. For example, the American Association of Bioanalysts stated their position that

> [h]ealthcare workers exposed to blood, body fluids, or tissues can be protected from the risk of infection with HBV and HIV by imposing the use of * * * clothing, masks, gloves, and other protective equipment. These protective barriers must be coupled with mandated operating procedures combining education and enforcement of safe handling regimens for all specimens. [Ex. 237, p. 1]

The authors of one study concluded that the breakdown of good work practices most likely led to the contamination of environmental surfaces in an autopsy suite, and that their results "underscore the importance of establishing and consistently following good work practices and cleanup procedures to minimize the risk of exposure * * *" [Ex. 260F (Beaumont)]. Like training, this requirement contributes to overall risk reduction by assuring maximum effectiveness of other provisions of the standard.

The standard also requires that engineering controls be used. As described below (see Technological Feasibility), engineering controls are available to reduce risk of occupational exposure by confining or isolating infectious material. Evidence clearly indicated the potential for risk reduction associated with the use of equipment designed to greatly reduce or eliminate the risk of accidental exposure [Tr. 9/15/89, p. 160; "Estimated Cost of Needlestick Injuries for Six Major Needled Devices," Ex. 300, p. 11].

Personal protective equipment (PPE) is a direct line of defense for health care workers whose exposure occurs through non-intact skin or mucous membrane contact with blood or other potentially infectious materials. Evidence submitted regarding the effectiveness of PPE in reducing risk included a study of embalmers in an urban area which identified factors associated with risk of HBV infection. Specifically, embalmers not wearing gloves routinely were found to be ten times more likely to have serologic markers of HBV infection than those who did [Ex. 6–549, p. 1425]. Another study found that in clinical laboratories "the portal of entry for the HBV is subtle and most likely through inconspicuous breaks in the skin or contact with mucous membranes" [Ex. 260A (Lauer)]. Since PPE isolates such portals of entry from potentially infectious materials, its proper use was judged to be a highly effective approach in preventing infections due to this mode of transmission.

The housekeeping provisions of the standard, including the provision for disposal of regulated waste, contribute to overall risk reduction by ensuring that work areas and equipment are kept free of contamination and that potentially infectious materials destined for disposal are packaged so as to isolate them from the workforce.

Also, under the standard, laboratories producing HIV for research or laboratories concentrating these viruses will be required to establish procedures according to paragraph (e) of the standard. These procedures were based on accepted industry practice. As documented [54 FR 23057], HIV infection has occurred in the laboratory environment, thus emphasizing the importance of implementing stringent infection control practices in this facility type.

3. Population-at-Risk

Table VII–4 identifies by SIC code and facility type OSHA's estimates of the total number of workers at risk of exposure to HBV and HIV. "Health Care Workers" includes all workers, regardless of occupation, employed in health care providing establishments and health care professionals in non-health care facilities (i.e. correctional facilities, personnel services, etc.). As shown in the table, the population-at-risk to HBV infection is smaller than the population at risk to HIV infection. This is because prior exposure or vaccination may result in immunity to HBV infection.

TABLE VII–4.—POPULATION AT RISK

SIC	Facility type	Affected workforce at risk to HIV	Affected workforce at risk—HBV 15% IMM.[a]	Affected workforce at risk—HBV 30% IMM.[a]
Health Care Workers:				
806	Hospitals	2,386,165	1,163,655	958,304
802	Dental offices	316,237	97,066	79,937
801; 803	Physicians' offices	640,681	313,206	257,934
807	Medical and dental labs	62,854	33,703	27,755
805	Nursing homes	486,303	367,944	303,013
836	Residential care facilities	49,102	29,461	24,262
808	Home health	212,246	141,709	116,697
(*)	Hospice care	10,856	7,142	5,881
8092	Hemodialysis	42,868	3,977	3,275
8093	Drug treatment	6,722	3,110	2,561
9431	Public clinics	58,345	27,533	22,674
8099	Blood banks and others	18,788	9,841	8,105
(*)	Industrial facilities	34,184	20,686	17,038
9223	Correctional facilities	8,361	5,686	4,684
7362	Personnel services	61,387	46,166	38,021
		4,361,940	2,270,883	1,870,139
Other Employees at Risk				
7362	Personnel services	102,090	86,777	71,463
726	Funeral homes	57,013	32,903	27,096
(*)	Industrial facilities	144,548	103,299	85,070
8221, 873, 283	Research laboratories	89,151	42,583	35,068
721	Linen services	50,000	42,500	35,000
38, 7699	Medical equipment repair	6,185	4,843	3,988
9221	Law enforcement	341,546	241,402	198,802
9224	Fire and rescue	252,048	89,586	73,777
9223	Correctional facilities	111,843	92,678	76,323
9229	Lifesaving	5,000	3,230	2,660
9411	Schools	41,362	35,158	28,953
4953; 9511	Waste removal	13,300	11,305	9,310
		1,214,086	786,262	647,510
Totals		5,576,026	3,057,145	2,517,649

[a] Totals assume vaccination efficacy to be 0.86.
[b] Includes various SIC codes.
Source: Occupational Safety and Health Administration, Office of Regulatory Analysis, 1991.

4. Quantification of Benefits

Employees exposed to infectious materials are at risk of contracting a variety of diseases associated with bloodborne pathogens. However, OSHA has not been able to quantify all of the potential benefits expected from the standard.

With respect to AIDS, the relatively short history of the HIV epidemic has made it difficult to develop a precise projection of the number of job-related AIDS cases that will be averted. It is known that the probability of HIV transmission in most workplace settings is low, and to date, 24 cases of HIV infection associated with occupational exposure have been documented (see Health Effects). Four of these cases have developed into AIDS. Nonetheless, the prevalence of AIDS continues to climb among the general population, and in the absence of strict exposure control, the rate of occupational risk will grow accordingly.

Similarly, available information did not allow OSHA to develop a quantitative estimate of the benefits associated with a reduction in non-A, non-B hepatitis infections. However, it is clear that the standard should provide protection to workers from these illnesses since, like hepatitis B, at least one of the several viruses which cause non-A, non-B hepatitis is transmitted primarily by direct exposure to blood [Tr. 9/14/89, p. 23]. It was estimated that 3,400 non-A, non-B hepatitis infections were attributable to occupational exposure in 1988 [Ex. 298, p. 5]. It was also reported that non-A, non-B viruses cause between 15 and 35 percent of

acute hepatitis cases in the U.S., with 40 to 60 percent of the infections leading to chronic hepatitis and the potential for death [Tr. 9/14/89, p. 24].

The risk of contracting hepatitis B at the workplace has been studied for many years. For the purposes of this rulemaking, OSHA relied on a nationwide annual risk estimate of health care workers contracting hepatitis B infections. This use of a nationwide estimate is necessary because data were lacking for many sectors covered by the rule. Partial data concerning risk were introduced for some sectors, including blood banks. However, OSHA did not develop separate risk estimates for these sectors because of the large variations in the statistics provided, and in some cases, the lack of underlying data and supporting documentation. The studies did, however, emphasize the effectiveness of and need for safety measures in reducing the risk of contracting HBV infections.

Data were submitted to the record specific to the risk of workers in blood banks. The American Association of Blood Banks (AABB) submitted comments to the record suggesting that health care workers handling donor blood are at lower risk than other occupations [Ex. 10–1059]. AABB cites a study by the South Central Association of Blood Banks in which 33 blood centers were surveyed and no cases of HIV or HBV infection were reported. However, these data are of limited use due to the lack of supporting documentation. No data were provided on the number of workers covered, the number of donors or the number of donations. There was also no information on any protective measures already taken at the facilities. More importantly, the results do not establish an absence of risk for blood bank workers and may be consistant with the average estimated average risk in this sector.

AABB also cites a study of Southwest Florida Blood Bank, which indicated that 56 accidental exposures occurred over a four year period in a facility which draws over 1,000 donors per week, and none of the exposures resulted in HBV or HIV infection. These data only allow conclusions to be made about the blood involved in the 56 cases of accidental exposure and does not allow any conclusions to be drawn on the overall quality of blood collected. Furthermore, there is no information whether the facility was already taking precautions to prevent infection. This study generally supports the conclusion that blood bank workers are exposed to the risks of HBV infection.

The American Red Cross submitted comments on the risk of HBV infection in blood banks. Hanson and Polesky conducted a study of incidences of Hepatitis-B cases among workers over a 10 year period in War Memorial Blood Bank in Minneapolis [Ex. 20–784, Attachment 4]. The study determined an annual incidence rate for the facility of 1.4 percent, over 5 times higher than the risk used in OSHA's analysis. The study indicated that of the 185 people tested, 11 became HBV infected. However, no clinical cases of HBV infection occurred after 1977.

> The decrease in HBV infections noted during the study period was inversely proportional to the increase in reported accidental exposures. This suggests that a heightened awareness of the potential risks and prophylactic treatment of exposures was a factor in reducing HBV infection. [Ex. 20–784, Attachment 4, p. 20]

Furthermore, the study noted that of the 16 subjects employed in hepatitis testing, none become HBV infection. Hanson and Polesky indicated that "the lack of infection in this high risk area was due to awareness of the potential infectivity of the blood samples handled and strict enforcement of safety measures." [Ex. 20–784, Attachment 4, p. 20]

The study also concluded that

> routine surveillance may be useful in identifying procedures or work areas that present increased risk to employees. In addition, it provides a mechanism for periodically reminding personnel of the potential risks associated with handling blood and other body fluids. [Ex. 20–784, Attachment 4, p. 20]

The first part of the statement suggests the need for exposure control. OSHA's standard requires employers to make exposure determinations by identifying all job classifications and procedures in which occupational exposure may occur. The standard also requires employers to maintain, periodically update, and make available to employees an exposure control plan which includes information in the exposure determination and all the safety precautions required in the standard.

The study results suggest that workers handling donor blood may be at lower risk than workers handling patient blood samples. However, there is still a risk from first-time donors and certain high-risk populations. The need for safety precautions is stressed.

Hanson and Polesky state that workers in blood banks may not be at higher risk than the general population. However,

> [t]he introduction of high-risk patient samples may significantly alter the attack rate unless appropriate precautions are used. In this setting the establishment of safety precautions are effective means of preventing HBV infection. [Ex. 20–784, Attachment 4, p.20]

This study emphasizes the need for safe work practices such as those being required under OSHA's Bloodborne Pathogens rule, including the use of personal protective equipment; engineering and work practice controls; and training to increase awareness of the hazard and to reinforce the need for safety precautions.

The second study cited by the American Red Cross done by P.L. Page of the Northeast Region of Red Cross Blood Services states that workers in American Red Cross Blood Centers in this region are at lower risk than workers in hospital blood centers [Ex. 20–784, Attachment 5]. The incidence rate provided for the Northeast Region over a 3 year period was 5.4 percent. However, the study also provides statistics on the prevalence of HBV infection in other blood centers. A regional center in Kansas City had a 0.9 percent rate for workers with blood contact. In eight Red Cross Blood Services Regions, the rate was 8.8 percent for workers with no previous work involving blood contact, and 20.4 percent for workers with a history of work involving blood contact outside the centers. The great variation in these statistics supported the use of an average risk estimated across the affected population.

The American Red Cross states that the overall rate of infection among its donors is 0.035 percent. The American Red Cross also indicates that 15 percent of the donors are "first time" donors not previously tested for HBV [Ex. 20–784, p. 3]. This suggests that there remains an unidentifiable risk in 15 percent of the donors. Furthermore, American Red Cross deals with patients as well as donors. When workers deal with patients, they are required to wear gloves.

OSHA believes that any worker who handles blood products is at risk since there is no way of telling whether in fact a donor is infected. Furthermore, the nature of the hazard is such that a single exposure to HBV infected blood is all that is required for a worker to become infected. Study data showed a large variation in the infection rate among exposed workers in blood banks. OSHA used an average rate covering workers in all sectors based on the number of CDC documented HBV infection cases among health care workers.

The Centers for Disease Control (CDC) reported 8,700 cases of Hepatitis B infection occurred among the universe of health care workers in the U.S in 1988. (OSHA estimates that a universe of 4,897,595 health care workers are at risk.) From survey data, OSHA estimated the number of workers who have already received the hepatitis B vaccine. OSHA assumed that 15 to 30 percent of workers have acquired lifetime immunity from prior occupational exposure to Hepatitis-B (see Preliminary Risk Assessment). The population at risk was estimated by subtracting the number of people vaccinated (times the 96 percent efficacy rate of the vaccine) and the immune population. OSHA used the number of HBV infections reported by CDC to determine the annual rate of occupationally-induced HBV infection. For health care workers, annual occupational risk was estimated to range from 3.47 per thousand (assuming a 15 percent immune population) to 4.21 per thousand (assuming a 30 percent immune population). The rate of infection is higher with a 30 percent immune population, since the same number of HBV infections is spread over a smaller population at risk (hence, a greater number of infections per thousand). Furthermore, the size of the immune population is directly related to the prevalence of HBV exposure. For non-health care workers, occupational risk was estimated to be similar. (This level of risk equates with an annual rate of infection of about 4,400 total cases for non-health care workers, about one-half the total estimated to occur in health care workers.)

Next, OSHA addressed the potential benefits of the vaccine provision by estimating the annual number of cases of each hepatitis B-related condition that would be avoided by offering all affected employees the opportunity for vaccination. In performing these calculations, OSHA subtracted the background risk of HBV infection (risk for U.S. adult population) from the rates of infection for workers and applied these rates to the affected population at risk. Based on survey data, OSHA assumed that 50 percent of the workers would accept the offer of free vaccination. OSHA used this vaccine acceptance rate and the 96 percent efficacy rate of the vaccine to determine the number of HBV infections avoided. The results for occupationally-induced HBV cases are shown in Table VII–5.

The first two columns of Table VII–5 present estimates of the baseline annual incidence of work-related cases of HBV infection and the number of such cases avoided annually following the implementation of the new vaccination programs. As shown, for workers covered by the standard, OSHA estimated that the current number of occupationally-related cases is between 5,814 and 6,645 per year, depending on current rates of prior immunity, of which almost half could be prevented by offering vaccination.

TABLE VII–5.—ANNUAL BASELINE CASES AND CASES-AVOIDED OF OCCUPATIONALLY-INDUCED HEPATITIS B

	Baseline cases	Cases avoided due to vaccine	Total cases avoided
HBV infections	5,814–6,645	2,791–3,190	5,058–5,781
Acute symptoms	1,454–1,661	698–797	1,265–1,445
Hospitalized	291–332	140–159	253–289
Fulminant death	7–8	3–4	6–7
HBV carrier	291–664	140–319	253–578
Chronic HB	73–166	35–80	63–145
Death cirrhosis	99–113	47–54	86–98
Death PHC	23–27	11–13	20–23
All deaths	129–148	62–71	113–129

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Since many workers may choose to decline the employers' offer of vaccination, and since the vaccine is not 100 percent effective, workers at risk who will not be protected by vaccination must rely on the other provisions of the standard, including engineering controls, work practices, personal protective equipment, post-exposure follow-up, housekeeping and training, for protection against occupationally acquired infections.

OSHA preliminarily estimated the effectiveness of these additional provisions to protect workers not protected by vaccination to be 75 percent. Though commenters expressed concern regarding this estimate [Exs. 20–655, pp. 3–4; L20–2943], data in the rulemaking record supported OSHA's preliminary calculations.

Data clearly indicated the number of exposure incidents could be reduced by measures required under the rule. As noted above, employees in one occupational category not routinely wearing gloves were found to be ten times more likely to have serologic markers of HBV infection than those who did [Ex. 6–548, p. 1425]. This suggests a substantial reduction in risk was associated with glove use alone for this occupation. The evidence leads OSHA to conclude that a 75 percent reduction in incidents, on average, due to non-intact skin or mucous membrane exposure is likely when PPE is used in a manner consistent with the requirements of the rule [Exs. 260A (Lauer); 237, p. 1].

With regard to percutaneous incidents, such as needle-stick injuries, evidence indicated that the majority of the most common injuries were preventable. For example, based on data in the record, OSHA estimated that about 75 percent of all exposure incidents caused by disposable syringes and 90 percent of all exposure incidents caused by pre-filled cartridge syringes could be prevented by using syringes which incorporate resheathing or retracting designs ["Estimated Costs of Needlestick Injuries for Six Major Needled Devices," Ex. 300, p. 11; Ex. 6–350, p. 286]. Since these data also indicated these injuries constituted 75 percent of reported percutaneous injuries associated with exposure to potentially infectious fluids (excluding IV tubing), OSHA estimated that needle-stick incidents could be reduced by more than 50 percent by implementing these engineering controls.

Further, evidence was presented which supported OSHA's position that following implementation of the standard, incident reporting will improve. The implications of this reporting were demonstrated to be: (1) In conjunction with the documentation of circumstances surrounding incidents, increased reporting leads to a better understanding of hazards, which in turn can lead to corrective action with respect to previously unsuspected hazards (thus ensuring maximum

effectiveness of all provisions of the standard); and (2) increased reporting can lead to an increase in prophylactic treatment, thereby preventing additional cases of potential HBV infection. These benefits were estimated to be significant, as OSHA found that "reported injuries do not account for the majority of infections in health care workers" [54 FR 23050/3].

As noted in OSHA's preliminary analysis, the effectiveness of the non-vaccine provisions in reducing the incidence of HBV infections was exemplified by the experience of a large mid-western hospital, where less than 20 percent of the high-risk employees chose to receive the vaccine. Still, this facility was able to reduce its incidence of reported HBV infection from 160 cases during a two year period in the early 1970's to one case in 1985 and none in 1986 and 1987 [Ex. 13, volume III, p. 88]. This was accomplished through the establishment of a comprehensive program of infection control practices, including aggressive post-exposure protocol, and supports OSHA's belief that although HBV vaccination is a key protective measure, a very high degree of disease avoidance can be maintained through ancillary infection control practices.

In a study submitted by the American Red Cross, conducted by Hanson and Polesky of War Memorial Blood Bank in Minneapolis, the effectiveness of safety precautions is emphasized. The reduction in HBV infections seen in the study was believed to be attributable to the "strict enforcement of safety measures." The study further emphasizes that exposures to blood samples from patients who may be high risk

> may significantly increase alter the attack rate [of the hepatitis B virus] unless appropriate precautions are used * * * the establishment and enforcement of safety precautions are effective means of preventing HBV infection. [Ex. 20-784, Attachment 4, p. 20]

OSHA recognizes that the effectiveness of the non-vaccine provisions of the rule may be higher or lower. However, OSHA maintains that, with the combination of PPE, training, engineering and work practice controls, and the other non-vaccine provisions of the standard, its preliminary estimate of 75 percent is a reasonable estimate of the effectiveness of these provisions.

In total, considering the full combination of provisions, including vaccination, engineering controls, work practices, protective clothing, housekeeping, and training, OSHA estimated that 87 percent of occupationally induced HBV cases exposure could be avoided. The final columns of Table VII-5 display OSHA's estimate that compliance with the standard will prevent between 5,058 and 5,781 occupational cases of HBV infection per year, of which 1,265 to 1,445 would have resulted in acute symptoms, and 113 to 129 in death.

Moreover, a considerable amount of additional illness will be prevented since the vaccine will also prevent workers from contracting HBV while off the job; that is, the vaccine will also reduce non-occupational risk. Since about 30 percent of those with acute infections in turn infect sex partners and over 50 percent of pregnant women pass the disease on to infants, additional risks associated with non-occupational transmission will be reduced. OSHA estimates that the standard will prevent between 253 and 578 employees per year from becoming HBV carriers, thereby helping to halt the spread of this disease to the non-occupationally exposed population. Table VII-6 presents OSHA's estimates of the reductions in non-occupationally induced HBV infections due to the standard.

Table VII-7 presents the total number of HBV infections estimated to be prevented by the standard, including 187 to 197 HBV related deaths annually.

TABLE VII-6.—ANNUAL CASES-AVOIDED OF NONOCCUPATIONALLY-INDUCED HEPATITIS B

	Cases avoided due to vaccine	Cases avoided by sex partners	Total cases avoided
HBV infections	1,863-2,263	1,062-1,214	3,077-3,325
Acute symptoms	466-566	266-304	769-831
Hospitalized	93-113	53-61	154-166
Fulminant death	2-3	1-2	4-4
HBV carrier	186-226	106-121	308-332
Chronic HB	47-57	27-30	77-83
Death cirrhosis	32-38	18-21	52-57
Death PHC	7-9	4-5	12-13
All deaths	41-50	24-27	66-74

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

TABLE VII-7.—ANNUAL NUMBER OF OCCUPATIONAL AND NONOCCUPATIONAL HEPATITIS B CASES AVOIDED

	Occupational cases avoided	Nonoccupational cases avoided	Total cases avoided
HBV infections	5,058-5,781	3,325-3,077	8,383-8,858
Acute symptoms	1,265-1,445	831-769	2,096-2,215
Hospitalized	253-289	166-154	419-443
Fulminant death	6-7	4-4	10-11
HBV carrier	253-578	332-308	585-886
Chronic HB	63-145	83-77	146-221
Death cirrhosis	86-98	57-52	143-151
Death PHC	20-23	13-12	34-35
All deaths	113-129	74-68	187-197

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

D. Technological Feasibility

In this section, the provisions of the standard are examined with respect to their effectiveness in reducing the occupational risk faced by workers within the 16 industry sectors identified. Current compliance, or the level to which the requirements of the standard have already been implemented by employers, will also be discussed.

1. Effectiveness and Feasibility

The requirement in the exposure control provision of the standard that employers document circumstances surrounding exposure incidents will contribute to overall risk reduction by increasing awareness of hazards. One witness reported that since emphasizing education, enforcement, and monitoring at her facility, reporting of exposure incidents has increased [Tr. 12/19/89, pp. 864–868]. Increased reporting of incidents, in turn, will allow safety and health practitioners to devise solutions to exposure hazards, once such hazards are identified [Tr. 12/19/89, p. 868; Ex. 20–655, p. 2]. There are no technological barriers associated with this requirement.

The most effective method of preventing occupationally acquired HBV is the hepatitis B vaccine; evidence indicated that HBV vaccine will induce antibody in 85 to 98 percent of healthy young adults [Exs. 4–20; 6–45]. In testimony provided by a manufacturer of the vaccine, the immunogenicity rate for employees covered by the OSHA standard was estimated to be 96 percent [Ex. 292]. Thus, it is clear that employees can greatly reduce their risk of HBV infection by participating in a company-sponsored vaccine program.

The standard requires that all employees who are exposed to blood or other potentially infectious materials be offered the vaccine. To ensure that technological constraints would not preclude this provision of the standard from implementation, OSHA solicited comment on vaccine production capabilities [54 FR 23044]. Testimony presented by Merck, Sharp, and Dohme provided evidence that sufficient quantities of the vaccine could be produced and distributed [Tr. 9/18/89, pp. 90–104]; thus, OSHA determined the HBV vaccine provision of the standard to be technologically feasible.

The standard also provides for post-exposure prophylaxis against HBV. This prophylaxis consists of the hepatitis B immune globulin (HBIG) injection. This post-exposure treatment appears to be highly effective in preventing HBV infection when an exposed employee lacks anti-HBs [Ex. 6–45]. OSHA assumed that the production and distribution of additional quantities of HBIG would not pose a serious obstacle to the implementation of this requirement, since many facilities are already providing employees with this prophylaxis [Exs. 264, Q161; 266, Q138].

The standard also requires employers to provide personal protective equipment (PPE) to all potentially exposed workers and to ensure its proper use. PPE includes gloves, coats or gowns, masks and eye protection (such as safety glasses or goggles), and face shields. These items serve as a barrier between the infectious material and the worker. Not all workers would be expected to require all items, however. Dentists will need eye and face protection when performing oral surgery or any other procedure which may result in the splattering or spraying of blood or saliva contaminated with blood, but this level of protection would seldom be necessary for a physician in an outpatient facility. Likewise, protective foot coverings may be required to reduce risk in a surgical or autopsy suite but would rarely be necessary for a nurse in a residential care facility.

Used properly, PPE will reduce the risk of occupational exposure to bloodborne pathogens, as indicated by evidence in the record [Exs. 6–549, p. 1425; 237, p. 1; 280A (Lauer)].

Resuscitation equipment such as ambubags or pocket respirators are another type of PPE. These devices are most useful for emergency responders in reducing risk where the emergency situation requires resuscitation.

Potential limitations in implementing a PPE program include availability, interference with the performance of certain tasks, and physical variability of the workforce.

Commenters reported that certain types of gloves were in short supply [Exs. 11–73; 11–124]. However, this situation was reported to have improved [Tr. 9/19/89, p. 125]. Additionally, worker acceptance and compliance have also improved [Tr. 9/19/89, p. 120], and current rates of use are generally high (see Technical appendix B); thus, incremental use attributable to the standard was not estimated to place significant demand on supplies.

Commenters have also asserted that during certain procedures requiring manual dexterity, such as phlebotomy, glove use will not allow proper performance of tasks [Ex. 11–124]. However, data submitted into the record demonstrated that workers can be trained to perform tasks proficiently while using appropriate protective equipment [Exs. 230; 238]. The rule provides for training in and monitoring of proper work practices (this provision will be discussed more fully below) and all employers shall be expected to instruct workers in a manner that will increase their proficiency in performing all tasks using the appropriate precautions.

Some workers may be susceptible to dermatitis from frequent handwashing (handwashing is required by the standard whenever gloves are changed). Others may be allergic to certain types of gloves or the powder they contain [Ex. 13, p. II–27]. OSHA does not believe that the impact of the rule will be such that an excessive amount of additional handwashing will be required. Additionally, it is OSHA's understanding that alternatives to latex gloves are available [Exs. 20–647; 20–1320b; 20–390, p. 2]. Administrative controls, such as rotating employees, would also be useful when possible.

Communicating hazards to employees and providing training and information is paramount in the implementation of a standard such as this, since protective measures such as PPE and proper work practices will not be effective unless employees are instructed in their correct use. Training is also an important factor in risk reduction because not all employees are aware of the risks that they face in the workplace. Information programs can increase employee acceptance of HBV vaccine [Ex. 11–86, p. 15] and worker compliance with policies regarding personal protective equipment [Ex. 267C (Lynch)]. In one hospital, PPE usage increased from 50–75 percent to 95–98 percent when proper work practices were explained and enforced [Ex. 11–119]. Also, evidence indicated adherence to established work practice procedures could reduce needlestick exposures by as much as 40 percent [Ex. 6–160].

Estimates of the current level of compliance with this provision indicated that a substantial number of establishments are currently providing some level of training to their at-risk employees (see Technical appendix C, Communication of Hazards). Most facilities, then, will only need to adjust their programs incrementally rather than to construct a training program from the ground up. No technological constraints were associated with such an adjustment.

Many feasible engineering controls are available to reduce risk of occupational exposure. The most ubiquitous engineering control required by the rule is the puncture-resistant sharps container. The purpose of the container is to eliminate the need for employees to transport needles and

other sharps while looking for a place to dispose of them, and to support the prohibition against recapping, bending, breaking, or otherwise manipulating sharps by hand. Injuries also occur to housekeeping personnel when contaminated sharps are left on a bed, concealed in linen. Another device, which reportedly has the potential to eliminate needle-stick injuries associated with I.V. line junctions, is the needleless connector ["Estimated Cost of Needlestick Injuries for Six Major Needled Devices," Ex. 300, p. 11].

Other feasible engineering controls that can be used to meet requirements are mechanical pipetting devices, biosafety cabinets, and safety equipment for centrifuges. (Pipetting is a procedure by which fluid is drawn into a narrow tube by suction. The fluid may then be dispensed as needed.) These controls reduce risk by confining or isolating the infectious material from the worker. While these controls will typically be most appropriate for a laboratory environment, many types of establishments operate laboratories. For example, such controls might be necessary in a police lab or in a physician's office, as well as in a hospital.

Baseline information, where available, indicated that engineering controls were available or have already been introduced into the workplace in a number of establishments [Trs. 9/15/89, p. 160; 1/9/90, pp. 122-125; 1/11/90, p. 111; Exs. 20-961; 20-1290; 20-8; 264, Qs. 162, 187; 266, Q158].

It is clear that engineering controls, where appropriate, will reduce risk by confining or isolating infectious material. The equipment described is readily available and currently in use.

Work practice controls are extremely important in preventing occupational exposure. These types of controls will reduce risk by requiring employers to ensure that at-risk employees are performing their tasks in the safest manner possible, consistent with universal precautions. Examples of work practice controls are the forbidding of needle recapping when disposable needles are used, the forbidding of mouth-pipetting, and ensuring that hands are washed after removing personal protective equipment. The importance of strict adherence to work practice controls was reflected by evidence in the record [Exs. 237, p. 1; 260F (Beaumont)].

In any environment where engineering controls are available, workers must use such equipment properly. Thus, all training programs should provide at-risk workers with comprehensive instructions regarding the safest procedures for performing work tasks. As noted above, such training can be effective [Exs. 230; 238; 267C (Lynch)]; thus, OSHA finds that implementing safe work practices will not present significant difficulty for affected employers.

Finally, no technological obstacles exist with respect to the implementation of the housekeeping provision of the standard. Materials required, such as cleaning/disinfecting solutions and biowaste bags, are readily available.

In sum, OSHA has determined there will be no technological obstacles to implementing the standard.

2. Rates of Current Compliance

Current practices were examined to determine the extent to which measures have been implemented by affected establishments for the prevention of occupational exposure to bloodborne pathogens. Principal sources for this data were the OSHA 1989 multi-sector and hospital surveys and public comment.

Compliance rates for 19 sectors were generated from data collected during OSHA's multi-sector and hospital surveys following protocols detailed in Technical appendix B to this analysis. Rates generated represented estimates of current compliance aggregated to the industry level. These rates were tabulated by provision and, where applicable, occupational categories for each of the 19 sectors surveyed. Exhibit B-3, Technical appendix B, provides a tabulation of estimated compliance rates, by sector and provision. (Since no data were collected on the OSHA surveys with respect to current practices for PPE kits and resuscitation devices, current practice estimates for disposable glove use were used as a proxy in cost estimation formulas for kits, and resuscitation devices.)

OSHA compared its survey-generated rates to similar data existing in the record. Where data were comparable, they supported OSHA's survey-generated compliance rates.

For example, in the dental sector, information on current practices with respect to use of PPE were provided by the Academy of General Dentists (AGD) and the ADA. The AGD testified that their 1987 survey found that more than 75 percent of its members were wearing gloves with all patients, and since that time "the dental profession has greatly stepped up its efforts" with respect to infection control [Tr. 9/22/89, p. 4-5]. The ADA submitted data which indicated similar trends. According to a 1988 survey performed by the ADA, the use of gloves with all patients varied from 76 percent for general practitioner dentists and assistants to 97 percent for hygienists, with use by general practitioner dentists increasing from 23 percent to 76 percent between 1986 and 1988 [Ex. 20-665N, IV.B.4]. The American Association of Orthodontics indicated that "recent" ADA studies show that 85 percent of dentists wear gloves [Tr. 10/17/89, p. 107-114]. Rates of mask use and gown use estimated by the ADA were lower than OSHA's estimated 47-58 percent and 15-20 percent, respectively.

Though the ADA argued that its 1988 survey was a "much more representative sample of the dentists in the U.S.," and suggested that current compliance estimates based on their 1988 survey are a more accurate representation of current practice in the dental sector, OSHA incorporated current practice estimates generated from the Agency's 1989 multi-sector survey into this analysis. OSHA judged the multi-sector estimates most representative for the following reasons.

First, both the AGD and ADA data represented periods of time approximately 2 years and 1 year, respectively, prior to the OSHA survey. Since information cited above clearly indicated improvements in current practices with respect to glove use, OSHA concluded that the ADA estimates understated current compliance. OSHA's estimates were based on the most recent data available.

Second, the ADA estimate for glove use covered dentists only. OSHA's estimate for health care workers included data for all dentists, hygienists, and assistants.[6]

Third, the ADA estimated the use of mask and gown protection for all patients, whereas under the regulation, use of these items would not be required for all patients. Thus, the ADA estimate of current practice with respect to the use of these items necessarily understated current practice in association with the requirements of the OSHA standard.

Additional multi-sector survey data were submitted by the American Federation of State, County, and Municipal Employees (AFSCME) [Ex. 297]. The survey was conducted after publication of the OSHA rulemaking and gathered data on PPE usage which

[6] OSHA notes that estimated compliance rates for the occupational groups not included in the ADA estimate exceeded that of dentists. The American Board of Pediatrics indicated that compliance in the pediatric dental setting was about 90 percent [Tr. 10/19/89, p. 476], while ADA data indicated hygienists complied at a rate of 97 percent and maxillofacial surgeons complied at a greater rate than general practitioners [Ex. 20-665N, IV.B.4].

indicated most facilities surveyed provided items in sufficient quantity, though not always in sufficient quality or size variations (questions 19–28). The data also indicated that employees did not use PPE in all recommended situations (question 29).

Survey results reported by AFSCME pertaining to source individual testing and counseling in hospitals were comparable to OSHA results. For example, AFSCME results indicated that hospitals attempted to test source individuals involved in an exposure incident to determine the presence of HIV or hepatitis infection 68 percent of the time. That is, 68 percent of all hospitals responding indicated that such testing was attempted. OSHA's calculations indicated that hospitals had policies consistent with such practice about 79 percent of the time with respect to hepatitis and 61 percent of the time with respect to HIV. AFSCME also reported that counseling was provided prior to HIV blood screening by 70 percent of all hospitals surveyed; OSHA's calculations indicated that hospitals had policies consistent with such practice about 72 percent of the time.

AFSCME data on follow-up procedures reported for nursing homes/institutions for developmentally disabled indicated rates somewhat higher than those reported by OSHA. However, the AFSCME survey collected data pertaining to policies, while OSHA's multi-sector survey (which included nursing homes/institutions for developmentally disabled) collected data pertaining to actual practice. Consequently, the discrepancy between the AFSCME results and the OSHA results was most likely due to the failure of practice to equate to policy. The multi-sector survey presents the most accurate representation of actual practice in this area.

Other data examined included estimates of current practices with respect to the disposal of infectious waste in hospitals. One national study reported that over 95 percent of 441 American Hospital Association member hospitals surveyed segregated infectious waste from other waste and that over 96 percent of hospitals segregating used labels or color coded bags [Ex. 6–609]. These data supported estimates derived from OSHA's survey of hospitals. OSHA survey results indicated a 92 percent current compliance rate for infectious (regulated) waste disposal.

SEIU submitted data showing that slightly more than half of the occupations in its survey had received training [Ex. 20–979 (Table 4)]. The survey reported rates of current practice regarding training and workplace precautions: 58 percent for health professionals; 63 percent for other professionals; 49 percent for health technicians; 56 percent for nurse aides and other support personnel; 51 percent for maintenance workers and 39 percent for laundry workers. OSHA's current training estimates were generated for each of two separate requirements under the standard, turnover, or initial training (training required before a new employee begins work where occupational exposure is expected) and in-service training (training required at least annually to update previous training) and took into account both frequency and duration of training sessions. Since SEIU's estimates did not specify whether training was received prior to employment or during employment, and did not cover frequency or duration, they were of limited utility.

For sectors not surveyed, OSHA estimated levels of current practice solely from public comments and testimony. These estimated rates appear in Table VII–8, and are discussed below.

TABLE VII–8.—ESTIMATED RATES OF COMPLIANCE FOR NON-SURVEYED INDUSTRIES

Industry	PPE (percent)	Post-exposure follow-up (percent)	Training (percent)	Housekeeping (percent)
Linen services	90	90	90	90
Lifesaving	25	50	25	50
Schools	25	0	0	N/A
Waste removal	50	50	50	N/A

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

In the lifesaving sector, it was reported that training programs for lifeguards were inadequate with respect to information regarding bloodborne pathogens [Ex. 221, p. 4; Tr. 12/20/89, p. 1176]. However, some lifeguards are EMTs [Tr. 12/20/89, p. 1175], and may receive more comprehensive training. With regard to post-exposure follow-up, information provided by witnesses indicated that formal procedures were not in place, though access to follow-up was reportedly available [Tr. 12/20/89, pp. 1173, 1175, 1178]. Evidence also indicated that personal protective equipment may be provided, though this would not be considered typical [Tr. 12/20/89, p. 1181]. No information were provided regarding disposal procedures for contaminated sharps; therefore, OSHA assumed a 50 percent rate of current compliance for the housekeeping provision.

In the linen services sector, data indicated current compliance with personal protective equipment (PPE) and training requirements were high for one linen service company, Angelica Health Care Services, which reportedly followed universal precautions [Tr. 10/20/89, pp. 809–10, 817–818]. Since testimony by Mr. Steven Fellman, appearing for the Textile Rental Services Association (TRSA) and representing over 90 percent of the linen supply industry, indicated that Angelica was typical of TRSA's membership [Tr. 9/25/90, p. 74], OSHA estimated current compliance with PPE and training requirements to be high in this sector (90 percent). Also, since universal precautions were reportedly stressed, OSHA assumed that recommended housekeeping procedures are routinely followed, and that post-exposure follow-up is made available to any worker requesting treatment.

Information indicated that in schools, universal precautions are generally not practiced. For example, testimony presented by Ms. Barbara Brooks indicated the need for both training and post exposure follow-up programs at her place of employment [Tr. 1/12/90, pp. 485–487]. Similarly, testimony by Ms. Terry Nakatani also indicated the need for training, though PPE was apparently available [Tr. 1/12/90, pp. 487–492].

Finally, in the waste removal sector, data were limited regarding current practices. However, OSHA received comments from Browning-Ferris Industries (BFI), "the largest medical

waste management company in North America engaged in the collection, transportation, and off-site treatment of medical waste" [Ex. 20–138, p. 1]. BFI reported that the company

uses a variety of controls to prevent worker exposure to bloodborne pathogens and other infectious materials: training and education programs, medical surveillance programs that include pre-employment and annual physical exams, use of personal protective clothing and equipment, work practices, engineering controls, use of disinfectants, immunization programs, and post-exposure follow-up. [Ex. 20–138, p. 3]

BFI indicates that the hazards posed by blood and other potentially infectious materials have been recognized by the medical waste collection and disposal industry. This information is assumed to be representative of both public and private waste removal establishments. Based on this evidence, OSHA estimated current practice to represent approximately 50 percent of the cost of the standard's requirements for this sector.

Additional data regarding current practices were obtained from confidential surveys submitted by seven hospitals in response to question 163 [Ex. 266]. OSHA reviewed these data and produced the summary presented in Table VII–9. These data provided the Agency with information regarding worker compliance with hospital policy, and are addressed in more detail in Technical appendix C (Compliance Cost Computations). Participating hospitals noted the difference between full compliance (percentage of affected population always performing in accordance with hospital policy) and partial compliance (measure of how often hospital policy is followed).

TABLE VII–9.—CURRENT COMPLIANCE DATA FOR SEVEN HOSPITALS WHICH SUPPLIED USEABLE RESULTS FROM IN-HOUSE SURVEYS

[Hospitals #1 and #5 supplied data covering general staff and emergency room staff separately]

Bloodborne standard provisions	Hospitals #1–#7, in percentages								
	1		2	3	4	5		6	7
	ER	General				ER	General		
—Exposure Control Plan:									
—Methods of Compliance:									
—Universal Precautions					100				
—Engineering & Work Practice Controls:									
Provision of handwashing facilities				72					80
Employees wash hands									
Removal of infected garment									
Removal of PPE									
No recapping of sharps and needles	28	17–89	20–40	42			84		44
Placing of blood specimens in closable containers				95					
—Personal Protective Equipment:									
Provision for availability of PPE									[1] 80
Provision for use of PPE by employees									[2] 95
Provision for accessibility of PPE	100	33–100							
Provision for cleaning, launder, & disposal of PPE									
Provision for repair & replace	96								
Provision for gloves				78				10–70	[1] 34–80 [2] 78
Provision for masks, eye protection				90					
Provision for gowns, aprons and other PPE				50					35
—Housekeeping									
General									
All equip. & environment shall be clean									
Regulated Waste Disposal									
All regulated waste for disposal placed in closed containers				100					50
Sharps disposed in closable containers (not allowed to overfill)	91	61–100		42		92	62–94		[1] 29 [2] 75
Laundry									
—HIV & HBV Research Laboratories & Production Facilities:									
—Hepatitis B Vaccination and Post Exposure Follow-up			82						
—Communications of Hazards to Employees:									
Signs and labels									
Information and training	69	55–100			36–68			66–100	78

[1] Represents proportion of workers in full compliance.
[2] Represents partial compliance rate.
ER: Emergency Room.
Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

E. Costs of Compliance

This section presents OSHA's final estimates of total net costs of compliance. Unless otherwise indicated, cost estimates presented represent the annualized, incremental costs associated with the standard. Calculations were based on data collected in two OSHA surveys and information submitted to the rulemaking docket.

In the discussion that follows, OSHA first presents a brief overview of estimation methods, followed by cost totals for each affected sector.

1. Methods

Incremental costs were first calculated for each respective provision of the standard, then aggregated to the industry level. Since many facilities were estimated to incur no cost (blood exposure was not reported on OSHA surveys), costs are associated only with those establishments affected by the rule. Costs were estimated in association with the following requirements of the standard: development of the exposure control plan; provision of hepatitis B vaccine and post-exposure follow-up at no cost to employees; provision of personal protective equipment; communication of hazards; housekeeping procedures; engineering and work practice controls;

special precautions for research and production facilities; and recordkeeping.

For example, OSHA first estimated incremental compliance costs for the development of the exposure control plan, producing estimates for each affected sector. Other provisions were then addressed in turn, enabling total incremental costs for each affected sector to be calculated by summing the respective provisions.

To calculate estimates of incremental costs of compliance by provision, OSHA generally employed cost models developed in connection with its preliminary analysis [54 FR 23087–105]. In some cases, models were revised to reflect more recent information. Cost models used in this analysis are presented in Technical appendix C.

Model inputs allowed cost calculations to reflect size and type of establishment, as well as occupational group (where applicable). For example, incremental costs were calculated for the development of the exposure control plan by using the following formulas:

Initial Costs
(wage of infection control practitioner) x (time required)
Recurring costs
(wage of infection control practitioner) x (time required)
Total Annual Costs
(initial costs x amortization factor) + (recurring costs)

The general formulas developed and shown above for estimating costs were applicable to all establishments. Inputs such time requirements reflected variations between facility types, as well as current compliance.

In revising its preliminary models and cost estimates, OSHA relied principally on the Agency's multi-sector and hospital surveys, public comments to the record, and testimony presented at informal public hearings. These data allowed the Agency to refine preliminary estimates of unit costs, rates of use of personal protective equipment, and number of workers vaccinated against hepatitis B. (See Technical appendix C for a complete discussion of data reviewed and revisions made).

In particular, with regard to estimates of the extent of current compliance, OSHA found that its surveys provided the best source of occupation-specific data. Technical appendix B presents OSHA's methodology for calculating measures of current practice, or current compliance factors, as well as compliance profiles, from the survey data base.

As presented in Technical appendix C, costs were generally estimated by performing calculations representing the full cost of compliance with the requirements of the standard reduced by a current compliance factor. The current compliance factor accounted for worker protection activities already taking place for which no additional expenditures would be required by an employer to comply with an OSHA rule.

2. Results

Table VII–10 presents net annualized costs of compliance by major provision for each affected sector. As shown in the table, the greatest share of costs will be borne by hospitals, followed by physicians' offices, offices of dentists, and nursing homes. These four sectors represent approximately three-quarters of the total costs of compliance. These sectors include over 68 percent of the affected worker population and 47 percent of all affected establishments.

In general, incremental compliance costs for personal protective equipment and training were found to represent the greatest share of costs within each individual industry. Gloves and gowns were found to be high cost items in many sectors due to frequency of use, higher unit cost per use and low rates of current compliance. With regard to training, current practices were estimated to be inadequate for many establishments, resulting in costs which were a significant portion of overall costs.

Following is a sector by sector review of OSHA's estimated costs of compliance. Costs tabulated by provision are presented for each sector. For each sector, significant cost items are highlighted, and a brief discussion addressing factors affecting incremental compliance costs is presented. (Establishment counts and compliance rates were previously developed and/or described above in "Industry Profile" and "Technological Feasibility". Additional citations will not be presented here.)

TABLE VII–10.—SUMMARY OF COMPLIANCE COSTS—GRAND TOTALS

Industry	Engineering/ work practices *	Vaccination/ post exposure follow-up	Exposure control plan	Housekeeping	PPE	Training	Recordkeeping	Totals
Offices of Physicians	8,985,997	14,770,091	6,834,476	7,169,447	68,611,270	34,826,736	2,792,511	143,990,528
Offices of Dentists	5,443,406	21,565,118	5,592,113	5,843,189	30,422,020	14,117,012	4,446,195	87,429,055
Nursing Homes	935,790	8,195,138	1,021,579	21,037,030	31,917,227	5,706,284	986,616	69,779,663
Medical and Dental Labs	1,242,583	792,155	288,191	3,534,680	4,559,722	1,760,771	123,287	12,321,399
Residential Care	81,202	1,128,257	157,936	539,902	905,583	1,401,437	146,073	4,360,390
Hospitals	68,781,203	26,745,404	1,814,363	56,414,706	138,972,636	25,773,635	3,611,521	321,913,697
Home Health	366,799	3,087,128	419,229	226,335	2,360,670	4,689,431	277,980	11,449,573
Hospices	9,978	198,713	42,398	22,183	104,442	196,925	20,948	593,588
Hemodialysis	271,929	241,868	80,830	42,356	1,320,193	302,054	77,834	2,306,964
Drug Rehabilitation	10,409	71,810	48,455	9,760	68,171	196,751	8,157	413,514
Government Clinics	790,219	1,451,787	709,439	516,634	3,893,082	3,047,676	248,574	10,657,412
Blood/Plasma/Tissue Center	1 193,678	299,277	47,543	90,434	1,949,073	331,395	100,778	4,012,178
Personnel Services	11,928	1,814,021	112,876	0	8,068,434	3,365,324	176,165	13,348,746
Funeral Services	60,208	1,503,382	1,110,339	579,318	2,423,908	2,981,395	194,599	8,843,149
Health Units in Industry	3,718,231	15,038,779	13,226,259	4,803,681	5,265,303	23,276,485	2,573,588	67,904,326
Research Labs	150,111	1,290,801	94,631	102,497	2,751,244	1,860,446	73,178	6,322,908
Linen Services	924	394,322	91,410	33,150	1,068,947	268,162	75,024	1,941,939
Medical Equipment Repair	213,104	276,128	70,078	618,485	4,543,377	253,503	38,581	6,013,256
Law Enforcement	195,410	2,237,428	322,123	52,344	3,311,809	4,169,199	545,597	10,853,911
Fire and Rescue	216,141	2,708,562	206,716	73,862	9,573,585	1,909,586	325,485	15,013,937
Correctional Facilities	93,437	1,322,391	114,886	153,978	1,581,115	1,438,951	211,278	4,916,036
Lifesaving	603	157,623	6,513	73,300	84,375	139,333	12,225	473,872
Schools	146,412	1,398,763	411,674	0	1,717,971	2,103,241	196,277	5,974,338
Waste Removal	0	222,980	3,256	0	1,383,200	249,083	10,681	1,869,180

TABLE VII-10.—SUMMARY OF COMPLIANCE COSTS—GRAND TOTALS—Continued

Industry	Engineering/ work practices *	Vaccination/ post exposure follow-up	Exposure control plan	Housekeeping	PPE	Training	Recordkeeping	Totals
Totals	$97,523,109	$106,710,705	$32,587,446	$101,937,270	$326,877,357	$134,405,018	$17,253,151	$812,703,560

* Includes $5,416,815 in recurring costs for leakproof containers.
Source: Occupational Safety and Health Administration, Office of Regulatory Affairs.

Offices of Physicians. Total annual incremental costs for the 122,104 physicians' offices affected by the standard were estimated to be $144 million. (Based on OSHA's multi-sector survey, 40,261 offices were estimated to incur no cost, since employees were not exposed to blood or other potentially infectious materials.)

Table VII-11 presents costs for affected facilities by provision. As shown in the table, personal protective equipment represented the largest cost of any major provision of the standard, nearly 50 percent ($68.6 million) of total costs and costs for gowns comprised well over one-half this total. This cost reflects the low level of current compliance for gown use of 43 percent. Compliance estimates indicated that in over 40 percent of all physicians' offices the level of current practice for gown use was 10 percent or below, while 38 percent of all offices were estimated to be at a level exceeding 90 percent, indicating that overall incremental costs for this PPE item will not be shared equally across all establishments in the sector.

Current compliance for face protection was estimated to be lower than for gowns; however, unit costs for masks were considerably lower than unit costs for gowns and costs for face protection were estimated to be substantially less. Though compliance with glove use was significantly better, costs exceeded $17 million due to the high frequency of use of this item.

TABLE VII-11.—OFFICES OF PHYSICIANS

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Exposure Control Plan	1,154,198	5,680,278	6,834,476	55.97
Medical Provisions	2,602,896	12,167,194	14,770,091	120.96
HB Vaccination	2,602,896	1,867,862	4,470,759	36.61
Exposure Follow-up	0	10,299,332	10,299,332	84.35
Personal Protective Equipment	0	68,611,270	68,611,270	561.91
Gloves	0	17,159,437	17,159,437	140.53
Gowns	0	43,428,970	43,428,970	355.67
Masks	0	6,414,563	6,414,563	52.53
Goggles	0	1,318,547	1,318,547	10.80
Kits				
Respirators	0	289,753	289,753	2.37
Training	6,720,505	28,106,232	34,826,736	285.22
Housekeeping	372,455	6,796,992	7,169,447	58.72
Sharps Disposal	372,455	705,941	1,078,396	8.83
Biowaste bags		716,594	716,594	5.87
Waste Hauling		5,374,456	5,374,456	44.02
Engineering/Work Practice Controls		8,985,997	8,985,997	73.59
Handwashing, Glove Change		3,961,662	3,961,662	32.44
Safety Syringes		5,024,335	5,024,335	41.15
Recordkeeping	346,065	2,444,445	2,792,511	22.87
Totals	$11,196,120	$132,792,409	$143,990,528	$1,179.24

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Costs for training also represented a significant portion of total costs (about 24 percent). Once again, estimates of current practice were quite low for this provision, indicating a lack of emphasis in this area.

Offices of Dentists. Total annual incremental costs for the 100,174 dentists' offices affected by the standard were estimated to be $87.4 million. (Based on OSHA's multi-sector survey, 6,679 offices were estimated to incur no cost, since employees were not exposed to blood or other potentially infectious materials.)

Table VII-12 presents costs for affected facilities by provision. As shown in the table, personal protective equipment represented the largest cost of any major provision of the standard, representing over one-third of total costs ($30.4 million); costs for gowns comprised over one-half this total. This reflects the relatively low level of current compliance estimated for gown use (37 percent overall), coupled with this item's relatively high unit cost.

Costs for medical provisions, particularly post-exposure follow-up, represented just under 25 percent of overall compliance costs. The two factors responsible for the significant cost in this area were low current practice and the relatively high frequency of occurrence of exposure incidents.

TABLE VII-12.—OFFICES OF DENTISTS

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Exposure Control Plan	932,019	4,660,094	5,592,113	55.82
Medical Provisions	1,070,521	20,494,597	21,565,118	215.28
HB Vaccination	1,070,521	182,241	1,252,762	12.51
Exposure Follow-up	0	20,312,356	20,312,356	202.77
Personal Protective Equipment	0	30,422,020	30,422,020	303.69
Gloves	0	9,384,935	9,384,935	93.69
Gowns	0	16,176,269	16,176,269	161.48
Masks	0	4,640,724	4,640,724	46.33
Goggles	0	220,092	220,092	2.20
Kits	0	0	0	0.00
Respirators	0	0	0	0.00
Training	3,209,257	10,907,755	14,117,012	140.92
Housekeeping*	887,605	4,955,585	5,843,189	58.33
Sharps Disposal	887,605	1,682,344	2,569,948	25.65
Biowaste bags		32,146	32,146	0.32
Waste Hauling		241,095	241,095	2.41
Engineering/Work Practice Controls		5,443,408	5,443,408	54.34
Handwashing/Glove Change		1,667,650	1,667,650	16.65
Safety Syringes		3,775,758	3,775,758	37.69
Recordkeeping	154,461	4,291,734	4,446,195	44.38
Totals	$6,253,863	$81,175,193	$87,429,055	$872.77

* Includes $3 million for surface coverings.

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Nursing Homes. Total annual incremental costs for the approximately 12,200 nursing homes affected by the standard were estimated to be $69.6 million. Based on OSHA's multi-sector survey, about 770 homes were estimated to incur no cost, since employees were not exposed to blood or other potentially infectious materials.

Table VII-13 presents costs for affected facilities by provision. Incremental compliance costs associated with housekeeping and personal protective equipment contributed the greatest cost in this sector. Costs attributable to the disposal of regulated waste and gown use represented over one-half of total incremental costs. Costs for regulated waste disposal were significant due primarily to the volume of waste estimated to be generated (only 30 percent of all homes surveyed by OSHA reported an autoclave to be operated) (Ex. 264, Q193). Gowns were a significant cost item due to frequency of use and high rate of non-compliance.

Compliance distributions indicated non-compliance to be somewhat concentrated for both provisions. With respect to waste removal, 18 percent of establishments surveyed indicated current practice to be no more than 10 percent, while 74 percent reported full compliance with the standard. With respect to gown use, 36 percent of establishments surveyed were at or below 10 percent compliant, while about 30 percent were reported in excess of 90 percent.

TABLE VII-13.—NURSING HOMES

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Exposure Control Plan	454,035	567,544	1,021,579	83.74
Medical Provisions	1,713,621	6,481,516	8,195,136	671.73
HB Vaccination	1,713,621	4,049,626	5,763,247	472.40
Exposure Follow-up	0	2,431,890	2,431,890	199.34
Personal Protective Equipment	0	31,917,227	31,917,227	2,616.17
Gloves	0	5,355,432	5,355,432	438.97
Gowns	0	24,668,004	24,668,004	2,023.61
Masks	0	1,192,671	1,192,671	97.76
Goggles	0	432,972	432,972	35.49
Kits	0	0	0	0.00
Respirators	0	248,148	248,148	20.34
Training	816,920	4,889,364	5,706,284	467.73
Housekeeping	164,928	20,872,102	21,037,030	1,724.35
Sharps Disposal	164,928	312,601	477,529	39.14
Biowaste bags		3,807,315	3,807,315	312.08
Waste Hauling		16,752,186	16,752,186	1,373.13
Engineering/Work Practice Controls		935,790	935,790	76.70
Handwashing/Glove Change		460,137	460,137	37.72
Safety Syringes		475,654	475,654	38.99
Recordkeeping	248,222	718,395	966,616	79.23
Totals	$3,397,726	$86,381,937	$89,779,663	$5,719.64

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Hospitals. Total annual incremental costs for the 6,197 hospitals affected by the standard were estimated to be $322 million. OSHA estimated between 800 and 900 hospitals to incur no cost, since these facilities were publicly administered in states without state occupational safety and health plans.

Table VII–14 presents costs for affected facilities by provision. The greatest cost impact will be due to increased glove usage. Costs for the purchase of additional gloves were estimated to be over one-fifth of total incremental costs. Engineering and work practice controls, which included costs associated with glove donning and doffing, handwashing, and the purchase of safety syringes, were also significant. Incremental housekeeping costs were related to the high volume of waste items (contaminated sharps and other regulated waste items) generated.

Current compliance in all areas was generally estimated to be high, with some problems identified with follow up procedures and training. The compliance profile indicates general consistency across surveyed establishments.

TABLE VII–14.—HOSPITALS

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Exposure Control Plan	$461,255	$1,153,138	$1,614,393	$260.51
Medical Provisions	9,845,664	16,899,740	26,745,404	4,315.86
HB Vaccination	9,845,664	13,821,630	23,667,294	3,819.15
Exposure Follow-up	0	3,078,110	3,078,110	496.71
Personal Protective Equipment	0	138,972,636	138,972,636	22,425.79
Gloves	0	67,850,128	67,850,128	10,948.87
Gowns	0	52,075,076	52,075,076	8,403.27
Masks	0	12,922,799	12,922,799	2,085.33
Goggles	0	1,923,075	1,923,075	310.32
Kits	0	0	0	0.00
Respirators	0	4,201,568	4,201,568	678.00
Training	4,347,497	21,426,338	25,773,835	4,159.06
Housekeeping	1,210,408	55,204,298	56,414,706	9,103.55
Sharps Disposal	1,210,408	7,568,579	8,778,986	1,416.65
Biowaste bags		8,821,429	8,821,429	1,423.50
Waste Hauling		38,814,290	38,814,290	6,263.40
Engineering/Work Practice Controls		68,781,203	68,781,203	11,099.11
Handwashing/Glove Change		28,513,097	28,513,097	4,601.11
Safety Syringes		40,268,106	40,268,106	6,498.00
Recordkeeping	1,340,609	2,270,912	3,611,521	582.79
Totals	$17,205,433	$304,708,254	$321,913,687	$51,946.70

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Medical and Dental Laboratories. Total annual incremental costs for the 4,425 medical and dental laboratories affected by the standard were estimated to be $12.3 million. Based on OSHA's multi-sector survey, 3,346 laboratories were estimated to incur no cost, since employees were not exposed to blood or other potentially infectious materials.

Table VII–15 presents costs for affected facilities by provision. Personal protective equipment represented the largest share of total incremental compliance costs. Though OSHA's current practice estimates for this sector indicated high compliance for glove use relative to other provisions, glove use will command a significant share of overall costs due to frequent usage.

Costs for sharps disposal units were also estimated to be a significant percentage of overall costs, due to both a high rate of usage of disposable sharps and current practice levels (less than 60 percent of all labs had sharps disposal containers available at all points of sharps use).

OSHA compliance calculations also indicated training to be an area where improvement in current practice will be required to comply with the standard. Training represented a fairly high proportion of overall costs for labs.

TABLE VII–15.—MEDICAL AND DENTAL LABS

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Exposure Control Plan	82,340	205,851	288,191	65.13
Medical Provisions	311,784	480,370	792,155	179.02
HB Vaccination	311,784	394,635	706,419	159.64
Exposure Follow-up	0	85,736	85,736	19.38
Personal Protective Equipment	0	4,559,722	4,559,722	1,030.45
Gloves	0	1,696,456	1,696,456	383.38
Gowns	0	1,929,829	1,929,829	436.12
Masks	0	841,843	841,843	190.25
Goggles	0	78,844	78,844	17.82
Kits	0	0	0	0.00
Respirators	0	12,751	12,751	2.88
Training	269,269	1,511,502	1,780,771	402.43
Housekeeping	679,505	2,855,174	3,534,680	798.80
Sharps Disposal	679,505	1,287,917	1,967,422	444.62
Biowaste bags		237,463	237,463	53.66
Waste Hauling		1,329,794	1,329,794	300.52
Engineering/Work Practice Controls		1,242,593	1,242,593	280.81
Handwashing/Glove Change		270,545	270,545	61.14

TABLE VII–15.—MEDICAL AND DENTAL LABS—Continued

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Safety Syringes		972,049	972,049	219.67
Recordkeeping	39,736	83,551	123,287	27.86
Totals	$1,382,635	$10,936,764	$12,321,399	$2,784.50

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Residential Care Facilities. Total annual incremental costs for the 2,425 residential care establishments affected by the standard were estimated to be $4.4 million. Based on OSHA's multi-sector survey, 4,850 establishments were estimated to incur no cost, since employees were not exposed to blood or other potentially infectious materials. A large number of residential care facilities do not involve blood exposure, since residents in these establishments are generally more independent and self-sufficient than people in nursing homes. For this reason, employees are often involved in activities other than assisting with bodily functions. Residential care employees perform activities such as assisting the blind or deaf, running errands, etc.

Table VII–16 presents costs for affected facilities by provision. OSHA's calculations indicated most of the compliance costs in this sector to be fairly uniformly distributed among personal protective equipment, medical provisions, and training.

Estimates of current practices were consistent across most areas of worker protection, though the level of effort associated with each particular provision will vary significantly among establishments. For example, with respect to regulated waste disposal, OSHA's compliance profile indicated that 46 percent of all affected establishments currently comply less than 10 percent of the time, while 51 percent of affected establishments reported full compliance.

TABLE VII–16.—RESIDENTIAL CARE

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Exposure Control Plan	45,124	112,811	157,935	65.13
Medical Provisions	217,640	910,617	1,128,257	465.26
HB Vaccination	217,640	503,381	721,020	297.33
Exposure Follow-up	0	407,237	407,237	167.93
Personal Protective Equipment	0	905,583	905,583	373.44
Gloves	0	528,744	528,744	218.04
Gowns	0	305,832	305,832	126.12
Masks	0	15,258	15,258	6.29
Goggles	0	14,645	14,645	6.04
Kits	0	0	0	0.00
Respirators	0	41,104	41,104	16.95
Training	132,052	1,269,385	1,401,437	577.91
Housekeeping	3,551	536,351	539,902	222.64
Sharps Disposal	3,551	6,730	10,280	4.24
Biowaste bags		62,308	62,308	25.69
Waste Hauling		467,313	467,313	192.71
Engineering/Work Practice Controls		81,202	81,202	33.49
Handwashing/Glove Change		49,250	49,250	20.31
Safety Syringes		31,952	31,952	13.18
Recordkeeping	29,161	116,912	146,073	60.24
Totals	$427,528	$3,932,882	$4,360,390	$1,798.10

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Home Health Care. Total annual incremental costs for the 6,437 home health establishments affected by the standard were estimated to be $11.4 million. Based on OSHA's multi-sector survey, about 15 percent of all home health establishments were estimated to incur no cost, since employees were not exposed to blood or other potentially infectious materials. Including establishments operating in states without state occupational safety and health plans, OSHA estimated 1,623 establishments to be unaffected by the standard and to incur no compliance costs.

Table VII–17 presents costs for affected facilities by provision. Costs for training and the hepatitis B vaccination were identified as the most significant areas of cost in this sector. The relatively high costs associated with these provisions are explained by the large number of affected employees (212,246). Employees in this sector will also be required to comply with the housekeeping provisions of the standard, including procedures for sharps disposal, the use of biowaste bags, and procedures for waste hauling. The annual costs for these provisions are $100,412, $19,079 and $106,844, respectively. Costs for housekeeping, follow-up, engineering and work practice controls, and personal protective equipment are less significant for this sector because exposure to potentially infectious fluids would occur relatively less frequently than in other sectors.

OSHA's compliance profile indicated that current practices associated with training and vaccination programs varied significantly among establishments.

TABLE VII-17.—HOME HEALTH

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Exposure Control Plan	119,780	299,449	419,229	65.13
Medical Provisions	859,074	2,228,055	3,087,128	479.59
HB Vaccination	859,074	1,900,096	2,759,170	428.64
Exposure Follow-up	0	327,958	327,958	50.95
Personal Protective Equipment	0	2,360,670	2,360,670	366.73
Gloves	0	948,979	948,979	147.43
Gowns	0	559,979	559,979	86.99
Masks	0	186,547	186,547	28.98
Goggles	0	145,623	145,623	22.62
Kits	0	0	0	0.00
Respirators	0	519,542	519,542	80.71
Training	385,726	4,303,705	4,689,431	728.51
Housekeeping	34,680	191,655	226,335	35.16
Sharps Disposal	34,680	65,732	100,412	15.60
Biowaste bags		19,079	19,079	2.96
Waste Hauling		106,844	106,844	16.60
Engineering/Work Practice Controls		388,799	388,799	60.40
Handwashing/Glove Change		83,608	83,608	12.99
Safety Syringes		305,191	305,191	47.41
Recordkeeping	118,751	159,229	277,980	43.18
Totals	$1,516,010	$9,931,563	$11,449,573	$1,778.71

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Hospices. Total annual incremental costs for the 651 hospice establishments affected by the standard were estimated to be $593,588. Based on OSHA's multi-sector survey, 290 hospices were estimated to incur no cost, since employees were not exposed to blood or other potentially infectious materials.

Table VII-18 presents costs for affected facilities by provision. Similar to the situation described above for home health establishments, the most costly provisions of the standard were costs associated with employment levels, namely training and the hepatitis B vaccination.

OSHA's compliance profile indicated a broad range of activity with respect to current practice in connection with worker training; however, more than one-quarter of all establishments were estimated to be at 10 percent or lower compliance. OSHA's data also indicated most facilities were not offering the hepatitis B vaccine free of charge to all exposed employees.

TABLE VII-18.—HOSPICE CARE

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Exposure Control Plan	12,114	30,285	42,398	65.13
Medical Provisions	50,570	146,144	196,713	302.17
HB Vaccination	50,570	113,272	163,842	251.68
Exposure Follow-up	0	32,871	32,871	50.49
Personal Protective Equipment	0	104,442	104,442	160.43
Gloves	0	29,727	29,727	45.66
Gowns	0	20,719	20,719	31.83
Masks	0	7,270	7,270	11.17
Goggles	0	17,717	17,717	27.21
Kits	0	0	0	0.00
Respirators	0	29,009	29,009	44.56
Training	26,732	170,194	196,925	302.50
Housekeeping	66	22,117	22,183	34.08
Sharps Disposal	66	125	192	0.29
Biowaste bags		3,332	3,332	5.12
Waste Hauling		18,659	18,659	28.66
Engineering/Work Practice Controls		9,978	9,978	15.33
Handwashing/Glove Change		2,525	2,525	3.88
Safety Syringes		7,453	7,453	11.45
Recordkeeping	6,687	14,262	20,948	32.18
Totals	$96,168	$497,420	$593,588	$911.81

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Hemodialysis. Total annual incremental costs for the 782 freestanding dialysis establishments affected by the standard were estimated to be $2.3 million. Based on OSHA's multi-sector survey, all establishments were affected, since employees were reported to be exposed to blood or other potentially infectious materials in each establishment surveyed.

Table VII-19 presents costs for affected facilities by provision. Costs for personal protective equipment were estimated to be most significant for this sector, particularly for use of gowns, where current practice was estimated to be relatively low. Incremental training

costs were estimated to be the next largest category of compliance costs.

Compliance profiles indicated a substantial number of establishments to have achieved full compliance with regard to gown usage (40 percent of establishments surveyed) and in-service training (50 percent of establishments surveyed). At the same time, however, over one-quarter of establishments surveyed reported a baseline position of only 0–10 percent with regard to gown usage; 20 percent of establishments reported in-service training falling within this lowest range.

TABLE VII–19.—HEMODIALYSIS

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Exposure Control Plan	14,551	36,379	50,930	65.13
Medical Provisions	44,348	197,320	241,668	309.04
HB Vaccination	44,348	68,488	112,836	144.29
Exposure Follow-up	0	128,831	128,831	164.75
Personal Protective Equipment	0	1,320,193	1,320,193	1,688.23
Gloves	0	207,340	207,340	265.14
Gowns	0	910,787	910,787	1164.69
Masks	0	186,279	186,279	238.21
Goggles	0	15,389	15,389	19.68
Kits	0	0	0	0.00
Respirators	0	398	398	0.51
Training	41,447	260,607	302,054	386.26
Housekeeping	3,189	39,168	42,356	54.16
Sharps Disposal	3,189	6,044	9,233	11.81
Biowaste bags		5,019	5,019	6.42
Waste Hauling		28,105	28,105	35.94
Engineering/Work Practice Controls		271,929	271,929	347.74
Handwashing/Glove Change		31,399	31,399	40.15
Safety Syringes		240,531	240,531	307.58
Recordkeeping	6,354	71,480	77,834	99.53
Totals	$109,890	$2,197,074	$2,306,964	$2,950.06

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Drug Rehabilitation. Total annual incremental costs for the 744 drug rehabilitation centers affected by the standard were estimated to be $413,514. Based on OSHA's multi-sector survey, 3,162 centers were estimated to incur no cost, since employees were not reported to be exposed to blood or other potentially infectious materials.

Table VII–20 presents costs for affected facilities by provision. Training accounted for almost one-half of overall compliance costs. Providing employees with the hepatitis B vaccination will also require expenditures under the standard.

OSHA's compliance profile for this sector indicated the majority of facilities will incur significant to moderate costs to bring training programs into compliance. In contrast, over one-third of affected establishments were estimated to already offer the hepatitis B vaccine to all or most exposed employees at no charge.

TABLE VII–20.—DRUG REHABILITATION

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Exposure Control Plan	13,844	34,611	48,455	65.13
Medical Provisions	25,353	46,457	71,810	96.52
HB Vaccination	25,353	39,020	64,373	86.52
Exposure Follow-up	0	7,437	7,437	10.00
Personal Protective Equipment	0	68,171	68,171	91.63
Gloves	0	35,082	35,082	47.15
Gowns	0	19,671	19,671	26.44
Masks	0	4,809	4,809	6.46
Goggles	0	7,095	7,905	9.54
Kits	0	0	0	0.00
Respirators	0	1,513	1,513	2.03
Training	31,354	165,397	196,751	264.45
Housekeeping	69	9,691	9,760	13.12
Sharps Disposal	69	131	200	0.27
Biowaste bags		1,448	1,448	1.95
Waste Hauling		8,111	8,111	10.90
Engineering/Work Practice Controls		10,409	10,409	13.99
Handwashing/Glove Change		4,624	4,624	6.21
Safety Syringes		5,785	5,785	7.78
Recordkeeping	3,535	4,622	8,157	10.96
Totals	$74,156	$339,358	$413,514	$555.60

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Government Outpatient Clinics. Total annual incremental costs for the 10,893 public clinics affected by the standard were estimated to be $10.7 million. OSHA estimated an equal number of establishments to be administered in states without state occupational safety and health plans. Such establishments would not be affected by the standard, and will incur no costs in association with the rule.

Table VII–21 presents costs for affected facilities by provision. Costs were estimated to be most significant in the areas of personal protective equipment and training. (Since government clinics were not surveyed, rates of equipment usage and estimates of current practice used in performing the calculations for physicians' offices were used in computing cost estimates for clinics.) As explained above for physicians' offices, rates of compliance for gowns were found to be low, as were rates of compliance for training. Glove use was a significant cost item due to frequency of use.

TABLE VII–21.—GOVERNMENT OUTPATIENT CLINICS

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Exposure Control Plan	202,697	506,742	709,439	65.13
Medical Provisions	228,791	1,222,996	1,451,787	133.28
HB Vaccination	228,791	307,713	536,504	49.25
Exposure Follow-up	0	915,283	915,283	84.02
Personal Protective Equipment	0	3,893,082	3,893,082	357.39
Gloves	0	1,507,078	1,508,078	138.35
Gowns	0	1,699,008	1,699,008	155.97
Masks	0	563,355	563,355	51.72
Goggles	0	97,792	97,792	8.98
Kits	0	0	0	0.00
Respirators	0	25,849	25,849	2.37
Training	594,322	2,453,354	3,047,676	279.78
Housekeeping	32,711	483,923	516,634	47.43
Sharps Disposal	32,711	61,999	94,709	8.69
Biowaste bags		63,928	63,928	5.87
Waste Hauling		357,997	357,997	32.86
Engineering/Work Practice Controls		790,219	790,219	72.54
Handwashing/Glove Change		341,994	341,994	31.40
Safety Syringes		448,225	448,225	41.15
Recordkeeping	30,605	217,969	248,574	22.82
Totals	$1,089,126	$9,568,286	$10,657,412	$978.37

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Blood/Plasma/Tissue Centers. Total annual incremental costs for the 730 affected establishments identified were estimated to be $4 million. OSHA judged all establishments to be affected, since employees were reported to be exposed to blood or other potentially infectious materials in 99 percent of establishments surveyed.

Table VII–22 presents costs for affected facilities by provision. As shown, personal protective equipment and engineering and work practice controls account for almost 80 percent of the total annual cost for this sector. OSHA believes the cost for glove use would be significantly higher if the standard required mandatory glove use for phlebotomists. Average overall cost per affected establishment was estimated to be $5,496.

TABLE VII–22.—BLOOD/PLASMA/TISSUE CENTERS

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Exposure Control Plan	13,584	33,960	47,543	65.13
Medical Provision	63,561	235,716	299,277	409.97
HB Vaccination	63,561	82,908	146,469	200.64
Exposure Follow-up	0	152,808	152,808	209.33
Personal Protective Equipment	0	1,949,073	1,949,073	2,669.96
Gloves	0	556,902	556,902	762.88
Gowns	0	866,114	866,114	1,186.46
Masks	0	488,347	488,347	668.97
Goggles	0	35,977	35,977	49.28
Kits	0	0	0	0.00
Respirators	0	1,732	1,732	2.37
Training	49,207	282,189	331,395	453.97
Housekeeping	2,469	87,964	90,434	123.88
Sharps Disposal	2,469	4,680	7,149	9.79
Biowaste bags		12,619	12,619	17.29
Waste Hauling		70,666	70,666	96.80
Engineering/Work Practice Controls *		1,193,678	1,193,678	1,635.18
Handwashing/Glove Change		74,073	74,073	101.47
Safety Syringes		293,285	293,285	401.76
Recordkeeping	9,266	91,512	100,778	138.05
Totals	$138,066	$3,874,092	$4,012,178	$5,496.13

* Includes $826,320 for leakproof containers.

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Personnel Services. Total annual incremental costs for the 1,348 personnel service establishments affected by the standard were estimated to be $13.3 million. Based on OSHA's multi-sector survey, 3,847 establishments were estimated to incur no cost, since employees were not reported to be exposed to blood or other potentially infectious materials.

Table VII–23 presents costs for affected facilities by provision. Personal protective equipment, particularly gowns, will be the most significant cost item for these establishments.[7] Training will also be needed, due to the high number of affected employees (over 163,000), high turnover, and poor baseline profile.

[7] OSHA notes that compliance with personal protective equipment provisions for temporary service workers was assumed to be zero (no usable survey data were received for this worker category).

TABLE VII–23.—PERSONNEL SERVICES

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Exposure Control Plan	50,167	62,709	112,876	83.74
Medical Provisions	797,004	817,017	1,614,021	1,197.34
HB Vaccination	797,004	745,830	1,542,834	1,144.54
Exposure Follow-up	0	71,187	71,187	52.81
Personal Protective Equipment	0	8,068,434	8,068,434	5,985.49
Gloves	0	1,060,494	1,060,494	786.72
Gowns	0	5,549,215	5,549,215	4,116.63
Masks	0	1,165,084	1,165,084	864.31
Goggles	0	283,819	283,819	210.55
Kits	0	0	0	0.00
Respirators	0	9,822	9,822	7.29
Training	264,670	3,100,654	3,365,324	2,496.53
Housekeeping	0	0	0	0.00
Sharps Disposal	0	0	0	0.00
Biowaste bags		0	0	0.00
Waste Hauling		0	0	0.00
Engineering/Work Practice Controls		11,926	11,926	8.85
Handwashing/Glove Change		11,926	11,926	8.85
Safety Syringes		0	0	0.00
Recordkeeping	87,668	88,496	176,165	130.69
Totals	$1,199,509	$12,149,237	$13,348,746	$9,902.63

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Funeral Services. Total annual incremental costs for the 19,890 funeral homes and crematories affected by the standard were estimated to be $8.8 million. OSHA estimated 1,046 establishments to incur no cost; OSHA's survey indicated that in 5 percent of establishments surveyed, employees were not exposed to blood or other potentially infectious materials.

Table VII–24 presents costs for affected facilities by provision. Major areas of expenditure for establishments in this sector include personal protective equipment and training, which together account for over 60 percent of overall compliance costs.

OSHA's compliance profile indicated that in each of the three major areas of personal protective equipment (gloves, gowns, face protection), a majority of establishments were currently complying at a rate exceeding 90 percent. With regard to training, however, low current practice (0 to 10 percent) was indicated for most establishments. These figures suggest that for this sector, the level of effort required to bring establishments into compliance with the standard will not vary widely among affected entities.

TABLE VII–24.—FUNERAL SERVICES

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Exposure Control Plan	185,057	925,283	1,110,339	55.82
Medical Provisions	319,661	1,183,720	1,503,382	75.58
HB Vaccination	319,661	403,430	723,091	36.35
Exposure Follow-up	0	780,291	780,291	39.23
Personal Protective Equipment	0	2,423,908	2,423,908	121.87
Gloves	0	545,032	545,032	27.40
Gowns	0	1,361,826	1,361,826	68.47
Masks	0	459,079	459,079	23.08
Goggles	0	57,972	57,972	2.91
Kits	0	0	0	0.00
Respirators	0	0	0	0.00
Training	760,566	2,220,828	2,981,395	149.89
Housekeeping	1,203	578,115	579,318	29.13
Sharps Disposal	1,203	2,280	3,483	0.18
Biowaste bags		67,745	67,745	3.41
Waste Hauling		508,089	508,089	25.54
Engineering/Work Practice Controls		50,208	50,208	2.52

TABLE VII-24.—FUNERAL SERVICES—Continued

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Handwashing/Glove Change		39,467	39,467	1.98
Safety Syringes		10,741	10,741	0.54
Recordkeeping	32,560	162,039	194,599	9.78
Totals	$1,299,047	$7,544,102	$8,843,149	$444.60

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Health Units in Industry. Total annual incremental costs for the 202,540 industrial establishments affected by the standard were estimated to be $67.9 million.

Table VII-25 presents costs for affected facilities by provision. Training will require additional resources to comply with the standard. Costs for development of the infection control program and costs associated with exposure follow-up will also comprise a large percentage of overall compliance costs. Average costs for establishments in this sector were estimated to be relatively low ($334).

OSHA's compliance profile indicated low current practice with respect to training. Current compliance with follow-up procedures, gown use, and use of face protection were also areas where improvement by a majority of establishments would be needed, while compliance with glove use was already high.

TABLE VII-25.—HEALTH UNITS IN INDUSTRY

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Exposure Control Plan	3,778,931	9,447,328	13,226,259	65.13
Medical Provisions	825,705	14,214,074	15,039,779	74.06
HB Vaccination	825,705	1,178,909	2,004,614	9.87
Exposure Follow-up	0	13,035,165	13,035,165	64.19
Personal Protective Equipment	0	5,265,303	5,265,303	25.93
Gloves	0	2,842,622	2,842,622	14.00
Gowns	0	1,349,418	1,349,418	6.64
Masks	0	261,916	261,916	1.29
Goggles	0	260,592	260,592	1.28
Kits	0	0	0	0.00
Respirators	0	550,756	550,756	2.71
Training	8,546,094	14,730,391	23,276,485	114.62
Housekeeping	9,387	4,794,294	4,803,681	23.65
Sharps Disposal	9,387	17,791	27,178	0.13
Biowaste bags		561,942	561,942	2.77
Waste Hauling		4,214,561	4,214,561	20.75
Engineering/Work Practice Controls		3,719,231	3,719,231	18.31
Handwashing/Glove Change		188,058	188,058	0.93
Safety Syringes		3,531,172	3,531,172	17.39
Recordkeeping	90,039	2,483,549	2,573,588	12.67
Totals	$13,250,156	$54,854,170	$67,904,326	$334.37

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Research/Production Facilities. Total annual incremental costs for the 1,453 research and production laboratories affected by the standard were estimated to be $6.3 million. Based on its survey, OSHA estimated 1,372 commercial, noncommercial, and pharmaceutical establishments to incur no cost, as employees were not reported to be exposed to blood or other potentially infectious materials. OSHA also estimated about 800 publicly administered establishments would incur no cost, since these establishments were located in states without state occupational safety and health plans.

Table VII-26 presents costs for affected facilities by provision. The great majority of costs were estimated to be fairly evenly distributed among three cost areas: the hepatitis B vaccine, personal protective equipment, and training.

OSHA's compliance profile indicated that labs were generally meeting glove and gown requirements consistently, while face protection and vaccine requirements were essentially not being met by many affected establishments. Most labs will require significant to moderate improvement in bringing training programs into compliance.

TABLE VII-26.—RESEARCH/PRODUCTION FACILITIES

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Exposure Control Plan	27,037	67,594	94,631	65.13
Medical Provisions	556,449	734,352	1,290,801	888.37
HB Vaccination	556,449	716,123	1,272,572	875.82
Exposure Follow-up	0	18,229	18,229	12.55

TABLE VII-26.—RESEARCH/PRODUCTION FACILITIES—Continued

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Personal Protective Equipment	0	2,751,244	2,751,244	1,893.49
Gloves	0	771,114	771,114	530.70
Gowns	0	1,392,135	1,392,135	958.11
Masks	0	520,588	520,588	358.26
Goggles	0	67,407	67,407	46.39
Kits	0	0	0	0.00
Respirators	0	0	0	0.00
Training	194,347	1,666,099	1,860,446	1,280.42
Housekeeping	39,194	63,303	102,497	70.54
Sharps Disposal	39,194	63,303	102,497	70.54
Biowaste bags		0	0	0.00
Waste Hauling		0	0	0.00
Engineering/Work Practice Controls		150,111	150,111	103.31
Handwashing/Glove Change		99,267	99,267	68.32
Safety Syringes		50,843	50,843	34.99
Recordkeeping	54,684	18,493	73,178	50.36
Totals	$871,712	$5,451,196	$6,322,908	$4,351.62

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Linen Services. Total annual incremental costs for the 1,250 linen service establishments affected by the standard were estimated to be $1.9 million. Data indicated an equal number of establishments to incur no cost, due to the absence of worker exposure.

Table VII-27 presents costs for affected facilities by provision. As shown, costs associated with personal protective equipment will be most significant.

Though OSHA did not survey linen service establishments, information in the record indicated compliance is high in all areas. OSHA assumed that most facilities would incur about $1,554 in additional costs due to the standard.

TABLE VII-27.—LINEN SERVICES

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Exposure Control Plan	23,260	58,150	81,410	65.13
Medical Provisions	188,393	205,929	394,322	315.46
HB Vaccination	188,393	183,683	372,075	297.66
Exposure Follow-up	0	22,246	22,246	17.80
Personal Protective Equipment	0	1,088,947	1,088,947	871.16
Gloves	0	109,710	109,710	87.77
Gowns	0	750,375	750,375	600.30
Masks	0	225,112	225,112	180.09
Goggles	0	3,750	3,750	3.00
Kits	0	0	0	0.00
Respirators	0	0	0	0.00
Training	52,409	215,753	268,162	214.53
Housekeeping	0	33,150	33,150	26.52
Sharps Disposal	0	0	0	0.00
Biowaste bags		3,900	3,900	3.12
Waste Hauling		29,250	29,250	23.40
Engineering/Work Practice Controls		924	924	0.74
Handwashing/Glove Change		924	924	0.74
Safety Syringes		0	0	0.00
Recordkeeping	23,048	51,976	75,024	60.02
Totals	$287,109	$1,654,830	$1,941,939	$1,553.55

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Medical Equipment Repair. Total annual incremental costs for the 1,076 medical equipment repair establishments affected by the standard were estimated to be $6 million. OSHA estimated 2,184 establishments will incur no cost, as employees are not exposed to blood or other potentially infectious materials during routine performance of duties.

Table VII-28 presents costs for affected facilities by provision. OSHA identified personal protective equipment as the most significant cost area for these establishments. Due to the volume of repairs performed and a low rate of current compliance, costs for the use of protective gowns were estimated to comprise over one-third of overall compliance costs. Costs for glove use were also significant, though current practice estimates for this item were much higher. Costs for sharps disposal units were estimated to be about 10 percent of overall costs, due largely to the fact that only about 17 percent of establishments surveyed indicated that sharps disposal containers were available at all points of sharps use.

Compliance profile data indicated divergence in current practices. For example, 63 percent of all establishments surveyed were at a level of compliance of 80 percent or better with regard to glove use, while 14 percent were at a level of compliance of

20 percent or lower. In contrast, 93 percent of establishments surveyed were at a level of compliance of 10 percent or lower with regard to gown use. While many establishments will require additional expenditures for gloves and gowns, the level of effort required to achieve compliance will not be consistent across the industry.

TABLE VII-28.—MEDICAL EQUIPMENT REPAIR

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Exposure Control Plan	20,022	50,056	70,078	65.13
Medical Provisions	30,283	245,845	276,128	256.62
HB Vaccination	30,283	41,897	72,180	67.08
Exposure Follow-up	0	203,948	203,948	189.54
Personal Protective Equipment	0	4,543,377	4,543,377	4,222.47
Gloves	0	1,897,400	1,897,400	1763.38
Gowns	0	2,260,020	2,260,020	2,100.39
Masks	0	382,352	382,352	355.35
Goggles	0	3,605	3,605	3.35
Kits	0	0	0	0.00
Respirators	0	0	0	0.00
Training	62,106	191,398	253,503	235.60
Housekeeping	213,611	404,874	618,485	574.80
Sharps Disposal	213,611	404,874	618,485	574.80
Biowaste Bags		0	0	0.00
Waste Hauling		0	0	0.00
Engineering/Work Practice Controls		213,104	213,104	198.05
Handwashing/Glove Change		213,104	213,104	198.05
Safety Syringes		0	0	0.00
Recordkeeping	3,233	35,348	38,581	35.86
Totals	$329,255	$5,684,001	$6,013,256	$5,588.53

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Law Enforcement. Total annual incremental costs for the 4,946 law enforcement departments affected by the standard were estimated to be $10.9 million. OSHA estimated a similar number of departments to incur no cost, as employees were located in states without state occupational safety and health plans.

Table VII-29 presents costs for affected facilities by provision. Costs associated with training and personal protective equipment, including PPE "kits," represented almost 70 percent of overall compliance costs. Vaccination costs were also significant.

The large size of the affected workforce, 341,546 employees, explains the magnitude of industry wide cost for this sector. Cost per department was estimated to average about $2,194.

OSHA's compliance profile indicated about 34 percent of departments surveyed offered hepatitis B vaccine to all exposed workers free of charge. Most other departments will incur costs in this area. Current training practices were estimated to vary widely, though most departments will also require substantial improvement with respect to this provision. With regard to personal protective equipment, current compliance with gown and face protection requirements was estimated to be very low for most departments.

TABLE VII-29.—LAW ENFORCEMENT

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Exposure Control Plan	92,035	230,088	322,123	65.13
Medical Provisions	1,133,375	1,104,053	2,237,428	452.37
HB Vaccination	1,133,375	883,466	2,016,841	407.77
Exposure Follow-up	0	220,588	220,588	44.60
Personal Protective Equipment	0	3,311,809	3,311,809	669.59
Gloves	0	13,363	13,363	2.70
Gowns	0	1,717,598	1,717,598	347.27
Masks	0	100,455	100,455	20.31
Goggles	0	197,910	197,190	40.01
Kits	0	1,282,484	1,282,484	259.30
Respirators	0	0	0	0.00
Training	659,794	3,529,405	4,189,199	846.99
Housekeeping	10,867	41,478	52,344	10.58
Sharps Disposal	10,867	17,552	28,419	5.75
Biowaste bags		23,926	23,926	4.84
Waste Hauling		0	0	0.00
Engineering/Work Practice Controls		195,410	195,410	39.51
Handwashing/Glove Change		7,917	7,917	1.60
Safety Syringes		187,493	187,493	37.91
Recordkeeping	167,136	378,461	545,597	110.31
Totals	$2,063,208	$8,790,703	$10,853,911	$2,194.48

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Fire and Rescue. Total annual incremental costs for the 3,174 fire and rescue establishments affected by the standard were estimated to be $15 million. OSHA estimated a similar number of departments to incur no cost, as employees were located in states without state occupational safety and health plans.

Table VII–30 presents costs for affected facilities by provision. Due to the frequency and severity of emergency situations encountered, personal protective equipment was estimated to be the most significant cost area for this sector. The large number of affected employees identified, over 252,000, also resulted in estimates of significant incremental costs for training and hepatitis B vaccination.

Estimates of current practice for this sector indicated high compliance for EMTs with regard to glove use, though considerable effort will be required by all occupational categories to achieve compliance with gown and face protection provisions. Also, OSHA's compliance profile indicated most establishments to be either complying at rates over 90 percent or under 10 percent with respect to glove use, use of face protection, provision of the vaccine, and training. Since most compliance costs were estimated to be associated with these items, certain departments may experience costs varying considerably above or below the average for these provisions.

TABLE VII–30.—FIRE AND RESCUE

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per department
Exposure Control Plan	59,062	147,654	206,716	65.13
Medical Provisions	1,206,997	1,501,566	2,708,562	853.36
HB Vaccination	1,206,997	1,187,823	2,394,820	754.51
Exposure Follow-up	0	313,743	313,743	98.85
Personal Protective Equipment	0	9,573,585	9,573,585	3,016.25
Gloves	0	1,497,481	1,497,481	471.80
Gowns	0	5,924,957	5,924,957	1,866.72
Masks	0	1,084,507	1,084,507	341.68
Goggles	0	217,141	217,141	68.41
Kits	0	0	0	0.00
Respirators	0	849,498	849,498	267.64
Training	214,007	1,695,580	1,909,586	601.63
Housekeeping	3,493	70,368	73,862	23.27
Sharps Disposal	3,493	6,621	10,115	3.19
Biowaste bags		63,747	63,747	20.08
Waste Hauling		0	0	0.00
Engineering/Work Practice Controls		216,141	216,141	68.10
Handwashing/Glove Change		183,233	183,233	57.73
Safety Syringes		32,908	32,908	10.37
Recordkeeping	130,186	195,299	325,485	102.55
Totals	$1,613,744	$13,400,192	$15,013,937	$4,730.29

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Correctional Facilities. Total annual incremental costs for the 1,895 correctional facilities affected by the standard were estimated to be $4.9 million. Approximately 900 additional facilities were estimated to incur no cost, as employees were located in states without state occupational safety and health plans.

Table VII–31 presents costs for affected facilities by provision. OSHA estimated costs for personal protective equipment to be most significant, followed by training and medical provisions costs. Costs for gloves and PPE "kits" accounted for over one-half incremental costs for personal protective equipment. ("Kits" contain a complete set of disposable items, including gloves, gown, and face mask, and were estimated to be used by the largest occupational category, correctional officers.)

As indicated for many sectors, current practice with regard to glove use was found to be much closer to the requirements under the standard than current practice with regard to other items of personal protective equipment and training. Compliance profiles suggest most facilities will require considerable improvement in both in-service and turnover training, with very few facilities in full compliance with the standard. Compliance with regard to personal protective equipment was found to be more widely varying, with many facilities complying at rates better than 90 percent. Compliance with respect to follow-up procedures was generally high.

TABLE VII–31.—CORRECTIONAL FACILITIES

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Exposure Control Plan	32,825	82,061	114,886	65.13
Medical Provisions	471,313	851,077	1,322,391	749.65
HB Vaccination	471,313	499,526	970,839	550.36
Exposure Follow-up	0	351,551	351,551	199.29
Personal Protective Equipment	0	1,581,115	1,581,115	896.32
Gloves	0	520,441	520,441	295.03
Gowns	0	439,421	439,421	249.10
Masks	0	127,375	127,375	72.21
Goggles	0	91,805	91,805	52.04

TABLE VII-31—CORRECTIONAL FACILITIES—Continued

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Kits	0	399,681	399,681	226.58
Respirators	0	2,392	2,392	1.36
Training	194,999	1,243,952	1,438,951	815.73
Housekeeping	2,503	151,475	153,978	87.29
Sharps Disposal	2,503	4,043	6,546	3.71
Biowaste bags		17,345	17,345	9.83
Waste Hauling		130,087	130,087	73.75
Engineering/Work Practice Controls		93,437	93,437	52.97
Handwashing/Glove Change		9,422	9,422	5.34
Safety Syringes		84,016	84,016	47.63
Recordkeeping	65,714	145,563	211,278	119.77
Totals	$767,354	$4,148,681	$4,916,036	$2,786.87

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Lifesaving. Total annual incremental costs for the estimated 100 emergency rescue departments affected by the standard were estimated to be $473,872. Locations where departments would be affected by the standard include beach rescue services in states with state occupational safety and health plans, such as California, South Carolina, North Carolina, Virginia, Maryland, Connecticut, New York, and Hawaii. OSHA estimated an equivalent number of departments in Florida, Georgia, New Jersey, or other states without state occupational safety and health plans, which would incur no costs.

Table VII-32 presents costs for affected facilities by provision. Incremental costs were estimated to be greatest for medical provisions followed by training. Personal protective equipment, in the form of portable kits, was also estimated to be a significant cost area, though the conditions under which an ocean lifeguard must perform his duties may limit its use.

Based on information gathered during public hearings, OSHA estimated the level of current practice to be about 25 percent of the effort required under the standard with respect to training and personal protective equipment, and 50 percent with regard to follow-up procedures and appropriate sharps disposal devices.

TABLE VII-32.—LIFESAVING

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per facility
Exposure Control Plan	1,860.8	4,652	6,513	65.13
Medical Provisions	60,772	96,852	157,623	1,576.23
HB Vaccination	60,772	78,395	139,167	1,391.67
Exposure Follow-up	0	18,456	18,456	184.56
Personal Protective Equipment	0	84,375	84,375	843.75
Gloves	0	0	0	0.00
Gowns	0	0	0	0.00
Masks	0	0	0	0.00
Goggles	0	0	0	0.00
Kits	0	84,375	84,375	843.75
Respirators	0	0	0	0.00
Training	14,166	125,167	139,333	1,393.33
Housekeeping	0	73,300	73,300	733.00
Sharps Disposal	0	60,300	60,300	603.00
Biowaste bags		13,000	13,000	130.00
Waste Hauling		0	0	0.00
Engineering/Work Practice Controls		503	503	5.03
Handwashing/Glove Change		503	503	5.03
Safety Syringes		0	0	0.00
Recordkeeping	5,092	7,134	12,225	122.25
Totals	$81,890	$391,982	$473,872	$4,738.72

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Schools. Total annual incremental costs for the 6,321 school agencies affected by the standard were estimated to be about $6 million. An additional 10,742 agencies were estimated to incur no cost, as employees were located in states without state occupational safety and health plans.

Table VII-33 presents costs for affected agencies by provision. Training was estimated to be the area requiring the most significant commitment of additional resources. Information in the record suggested that very little training was currently provided; thus, OSHA estimated a baseline level of 0 percent for this provision.

Incremental costs for gloves and medical provisions, principally exposure-follow-up, were also estimated to be significant cost areas. Current compliance with respect to follow-up was also estimated to be zero. Current compliance with regard to personal protective equipment was estimated to be 25 percent.

Due to the limited quantities of potentially infectious fluids which workers would be expected to encounter in this sector, costs for personal protective equipment items other than gloves were small. No incremental costs for housekeeping were estimated, since

very few potentially infectious waste items are expected to be generated.

TABLE VII-33.—SCHOOLS

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost	Annual cost per distnct
Exposure Control Plan	117,621	294,053	411,674	65.13
Medical Provisions	145,549	1,253,214	1,398,763	221.29
HB Vaccination	145,549	235,357	380,906	60.26
Exposure Follow-up	0	1,017,858	1,017,858	161.03
Personal Protective Equipment	0	1,717,971	1,717,971	271.79
Gloves	0	1,457,390	1,457,390	230.56
Gowns	0	260,581	260,581	41.22
Masks	0	0	0	0.00
Goggles	0	0	0	0.00
Kits	0	0	0	0.00
Respirators	0	0	0	0.00
Training	458,727	1,644,514	2,103,241	332.74
Housekeeping	0	0	0	0.00
Sharps Disposal	0	0	0	0.00
Biowaste bags		0	0	0.00
Waste Hauling		0	0	0.00
Engineering/Work Practice Controls		146,412	146,412	23.16
Handwashing/Glove Change		146,412	146,412	23.16
Safety Syringes		0	0	0.00
Recordkeeping	22,866	173,411	196,277	31.05
Totals	$744,763	$5,229,575	$5,974,338	$945.16

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

Waste Removal. Total annual incremental costs for waste removal operations affected by the standard were estimated to be $1.9 million. OSHA was not able to estimate the number of affected establishments and public refuse disposal organizations; however, 13,300 employees were estimated to be covered by the rule. Thus, costs were estimated to average $141 per affected employee.

Table VII-34 presents costs by provision. Personal protective equipment, in the form of portable kits, were estimated to comprise approximately three-quarters of overall compliance costs. Use was estimated to be quite frequent (one kit per week per affected worker). No costs were estimated for housekeeping, as workers in this sector do not generate potentially infectious waste items.

TABLE VII-34.—WASTE REMOVAL

Standard provision	Annualized first-year cost	Recurring cost	Total annual cost
Infection Control Plan	930	2,326	3,256
Medical Provisions	67,996	154,965	222,960
HB Vaccination	67,996	152,990	220,986
Exposure Follow-up	0	1,975	1,975
Personal Protective Equipment	0	1,383,200	1,383,200
Gloves	0	0	0
Gowns	0	0	0
Masks	0	0	0
Goggles	0	0	0
Kits	0	1,383,200	1,383,200
Respirators	0	0	0
Training	16,959	232,124	249,083
Housekeeping	0	0	0
Sharps disposal	0	0	0
biowaste bags		0	0
Waste Hauling		0	0
Engineering/Work Practice Controls		0	0
Handwashing/Glove Change		0	0
Safety Syringes		0	0
Recordkeeping	7,353	3,328	10,681
Totals	$93,238	$1,775,942	$1,869,180

Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

F. Economic Impacts and Regulatory Flexibility Analysis

OSHA developed quantitative estimates of the economic impact of the rule on the affected sectors. Data on profits are presented to illustrate the scale of affected industries and do not necessarily represent their ability to pay for the controls in question. Ability to pay is not related directly to profits because, as reported here, they do not net out all opportunity costs. The data on profits are calculated without making any adjustments for the normal rate of

return that investors and entrepreneurs would demand for making risky investments of capital, time, effort and talent.

Our analysis is limited in that it does not distinguish between the average firm or unit and the marginal firm or unit. Although costs of compliance may be small for the representative firm in a particular sector, for a firm whose profitability is marginal and may be on the brink of financial distress, the costs of compliance could be more important.

Opportunity Cost and Resource Allocation of Social Regulation

The opportunity cost of an action is the value of the foregone alternative action. Ultimately, the concept of opportunity cost refers to foregone benefits. When action 'A' is chosen over action 'B', then the expected benefits of action 'B' should be counted as an opportunity cost of choosing action 'A'. Opportunity cost is generally equal to the greatest expected benefit that could be gained among possible alternatives.

The opportunity cost of the regulation for consumers is the value of the foregone purchases or investments that would otherwise be made. Consumers may adjust the quantity of goods purchased to increase total utility, which may include purchasing less health care. In any event, the opportunity cost is represented by the foregone benefits of spending the estimated compliance costs in other ways.

In the case of public institutions, such as fire stations, price increases for services rendered may not apply. Budgets are usually fixed (in the short run), and compliance costs are paid by reducing funds for other items in the budget. The opportunity cost of the standard, represented by the estimated compliance costs, is then the foregone benefit realized by spending this amount on other activities. Foregone benefits may include improvements in public safety, health and rescue services, etc. While the cost of compliance reduces funds otherwise available for many different worthy causes, compliance with the regulation provides significant benefits and is necessary for reducing significant risks to health care workers.

It should be noted that there are practical boundaries which limit the theoretical applicability of social opportunity costs. It would be inefficient and impractical, for example, to recommend a tax on health care providers enough to realize over $800 million in revenue which could then be applied to realizing more beneficial social goals than those achievable under the rule.

Nevertheless, opportunity cost remains a useful analytical tool, but within the more narrow bend of selecting the most socially beneficial goal from a limited range of social investments realistically open to health care providers. No evidence was presented to OSHA during the public hearings or submitted to the record on this rulemaking which stated that funds should be redirected away from occupational disease prevention and control to other more desirable and beneficial projects affecting health care workers. Greater benefits achievable through such a redirection were simply not identified.

This regulation will prevent illnesses and fatalities, which reduces total health care costs in addition to producing large nonmonetizable benefits for society. The benefits are concentrated in the health care sector, potentially increasing the efficiency of health care providers. Pain and grief avoided by otherwise infected workers combine with other direct benefits to employers including reduced insurance premiums, increased productivity, and lower employee turnover rates.

From a regulatory impact perspective, OSHA has identified the costs of compliance with the bloodborne diseases standard. Compliance costs include expenditures for engineering controls, work practices, personal protective equipment, training, vaccination, post-exposure follow-up, and other areas of risk reduction. As a result of these expenditures, health care providers in the private and public sectors will help to eliminate the risk of transmission of infectious diseases, thereby preventing a significant number of deaths and illnesses. In terms of economic impact, compliance expenditures represent a cost to society as a whole that will result in some combination of higher prices for health services, a reduction in profits (to some private health care providers) or limits on alternative public services.

In the private sector, compliance expenditures will, in the short term, direct resources toward risk reduction technologies in the field of bloodborne diseases. OSHA believes that unreasonable risk currently exists with regard to these health hazards and that anticipated compliance expenditures are appropriate and justified. In an economic sense, the social decision to regulate constitutes corrective action needed to offset imperfect market conditions unintentionally created, but nonetheless real, which have allowed health care providers to avoid costs associated with protective health measures for employees in the work place. Cost avoidance has resulted because necessary perfect market preconditions (which must exist in order for opportunity cost analysis and decision making to be optimal) have been compromised (worker compensation limiting employer liability) or do not exist (perfect information about risk and labor mobility). The absence of perfect market conditions and the accompanying need for corrective social regulation has been more fully discussed in the RIA section on Nonregulatory Alternatives.

In response to this rule, OSHA expects that resources in the private sector will be shifted from lower risk activities to risks associated with infectious diseases. In effect, time, equipment and personnel will be devoted less, in the short run, to activities with negative health impacts less clearly defined or with risks not as pronounced as the risks identified in this RIA. OSHA recognizes that although this resource reallocation may impose transactions costs (costs of learning, establishing contacts with vendors, trainers, etc.) on the private sector and on society, these costs are not expected to significantly impede the functioning of health care markets and the institutional relationships between providers, patients, equipment suppliers and customers.

To the extent the costs can be passed through the system, minor price increases may be felt by patients, customers and other downstream recipients of health services. OSHA believes that spillover benefits will accrue to society apart from the direct benefits attributed to the standard. The emergence of new types of equipment and technologies to prevent transmission of infectious diseases are a likely outcome of investments stimulated by this rule. Newer, more efficient PPE and engineering controls will replace older systems; new technologies and applications should lead to reductions in risk in other types of health care. Increased information transfer is expected, creating stronger health networks and a more highly developed system for communicating advances in the field.

Very little employment reallocation is envisioned under this standard. Enterprises may consider cutbacks in their employment of receptionists, lab technicians, laundry workers, etc., perhaps by reducing the number of hours the enterprises are open. But this will be countered by increased spending, under the standard, for goods and services—including lab tests and

laundering of PPE garments by the same enterprises.

In sum, OSHA recognizes that government faces opportunity costs when it chooses to regulate or not to regulate. Where the costs and benefits of private actions accrue solely to those who take those actions, the government ought to leave those actions alone. But where private and public actions have externalities in the form of harm to private citizens, society can intervene to assure that the costs of adverse consequences will accrue to entities which cause them. In the case of occupational safety and health, public policy makers face opportunity costs in the choice of acting to intervene or not acting. Government action imposes cost on firms and/or their customers. Government inaction leaves the cost and nonmonetizable burdens of inadequate safety and health on workers and the general public.

The standard, in effect, "internalizes external costs" that would otherwise be borne by society and individual workers and their families. The standard reduces costs to employers of workers getting infected (lower turnover, absenteeism, training costs and insurance premiums). Finally, in a practical sense, no alternative social initiatives affecting health care workers provide benefits which exceed those projected under the rule. The opportunity cost test of choosing the option which maximizes benefits and minimizes the foregone advantages of rejected options has been met for health care workers.

Quantitative Economic Impacts

Quantitative estimates of the economic impact of the rule on each affected sector were based on the cost figures presented above, information contained in the public record, and other published financial data. Impacts were computed at the industry level and are summarized in Table VII-35.

TABLE VII-35.—SUMMARY OF ECONOMIC IMPACTS

Industry	Revenue, budget [a] ($ million)	Profits [a] ($ million)	Annual costs ($ million)	Costs/ revenue (%)	Costs/ profits [a] (%)
Offices of physicians	90,080	[b] 5,539	143.99	0.160	2.602
Offices of dentists	31,678	[b] 2,014	87.43	0.276	3.580
Nursing homes	45,872	1,159	69.78	0.152	4.577
Hospitals	220,000	1,012	321.91	0.140	8.996
Medical/dental labs	4,446	325	12.32	0.277	3.797
Home health care [c]	8,900	503	11.45	0.119	2.106
Hospice care	325.5	19	0.99	0.182	3.109
Hemodialysis centers	1,200	87	2.31	0.192	2.637
Drug rehabilitation	744	45	0.41	0.056	0.926
Government clinics [d]	2,400	N/A	10.66	0.444	N/A
Blood/plasma/tissue centers	1,500	N/A	4.01	0.267	N/A
Residential care	3,166	[e] 75	4.38	0.138	4.874
Personnel services	5,400	210	13.35	0.247	6.342
Funeral services	6,782	608	8.84	0.130	1.454
Health units in industry	[f]	[f]	67.90	N/A	N/A
Research labs	3,500	[g] 54	6.32	0.181	3.991
Linen services	4,800	99	1.94	0.040	1.962
Medical equipment repair	1,900	72	8.01	0.801	8.283
Police [d]	17,200	N/A	10.85	0.063	N/A
Fire & rescue [d]	4,000	N/A	15.01	0.375	N/A
Corrections [d]	8,509	N/A	4.92	0.058	N/A
Licensing [d]	140	N/A	0.47	0.338	N/A
Schools [d]	2,774	N/A	5.97	0.215	N/A
Waste removal	985	22	1.87	0.214	4.245

N/A Not Applicable.
[a] Revenue totals represent affected facilities only; profit totals reflect estimated pre-tax 1989 totals for proprietary establishments, unless noted otherwise.
[b] Revenue data represent non-public agencies only.
[c] Revenue data represent public agencies only.
[d] Based on profit margin of nursing home sector.
[e] Health care budgets not estimated.
[f] Represents commercial, noncommercial, and pharmaceutical labs.
[g] Ratio reflects proprietary firms, unless noted otherwise.
Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

The financial information appearing in column one of the table was obtained from the sources described earlier in the Industry Profile section of this Regulatory Impact Analysis, and were adjusted to exclude facilities not affected by the standard.

The information appearing in column two (estimated pre-tax profits) was also presented earlier, and was generated by OSHA based on Dun and Bradstreet financial reports and corporate tax schedules. For example, with regard to physicians' offices, Dun and Bradstreet information indicated a post-tax profit margin (exclusive of physicians' salaries) of 5.5 percent. To calculate pre-tax profits, OSHA first applied this rate of post-tax profitability to the estimated overall revenue of affected establishments ($90 billion) to obtain post-tax profits. Next, OSHA used corporate tax schedules to estimate pre-tax profits.

As shown in the table, compliance costs as a percentage of sector revenue (or budgets) ranged from 0.04 to 0.7 percent for affected establishments. Estimates of compliance costs as a percentage of pre-tax profits were less than 7 percent for most sectors; medical equipment repair facilities would experience the largest reduction in profit (6.4 percent). These estimates apply to the average firm in each sector. To the extent that compliance costs reduce profits, the burden on the marginal firms may be greater.

The degree to which affected firms will either incur or shift compliance costs depends largely on the competitive environment in which the firms operate and on the price elasticity of demand for the firms' services. Where the services offered are not very sensitive to price, affected firms can successfully raise prices to offset increased costs.

In general, when considered against recent indicators of the demand for and the costs of the types of services provided by establishments which would be affected by the rule, the economic impacts of the standard were not judged to be of sufficient magnitude to threaten the existence of any affected sector, nor were impacts judged sufficient to disrupt or otherwise adversely alter industry structure.

OSHA presents evidence below of strong demand for health care services. Recent trends show increasing expenditures on health care services during a period of rising costs to consumers. As described below, expenditures on health care services generally were estimated to have increased at rates ranging from 8 to 15 percent per year between 1987 and 1990. During the same period, costs to consumers also increased, at rates ranging from 6 to 11 percent. Recent cost-containment strategies have resulted in trends toward more cost effective health care delivery mechanisms, such as outpatient services. Establishments offering such services will continue to experience strong demand. OSHA believes that while cost containment is a growing concern in health care sectors, some portion of the costs of compliance associated with this rule will be passed forward to consumers. Strong demand will also assure most establishments of long term viable financial position with the associated ability to absorb compliance costs, if necessary, without experiencing undue harm.

Some have expressed concern that the provisions of the standard could result in a decrease in the productivity of health care workers. However, OSHA believes that familiarization with the requirements and techniques will restrict time lost. Furthermore, OSHA believes any decrease in productivity will be offset by the peace of mind associated with a safer work setting.

OSHA developed a composite compliance indicator to assess the effect of current practices, or baseline position, on potential differential impacts within industries affected by the rule. In contrast to the sometimes widely divergent profiles of current practice obtained in connection with specific items or provisions (discussed above, Costs of Compliance), OSHA's composite indicator showed that for most sectors, composite compliance which represented a weighted average of baseline position with respect to personal protective equipment, training, and hepatitis B vaccination, was normally distributed. This characteristic reduces the potential of a disproportionate economic impact among affected establishments. Consequently, the relative level of effort required among potential competitors to achieve compliance with the standard is not expected to vary widely for most sectors.[8]

An additional factor affecting concentration, differential impact due to size, was also considered; however, no significant effect was found (see Regulatory Flexibility Analysis).

Following is a sector by sector assessment of the impacts of the OSHA rule. In each case, OSHA examined each sector's ability to pass forward or absorb compliance costs from existing margins. Recent trends and prevailing economic conditions are addressed.

Physicians' Offices. Compliance costs were estimated to be 0.16 percent of affected physician office revenues and 2.6 percent of profits. This latter ratio, however, may not be a meaningful indicator of economic feasibility for this sector because most physician offices are owner-managed, and current tax laws provide strong incentives for distributing income as salaries or bonuses. Adjusting this ratio by adding an estimate of average physicians' income to the reported office profit shows that expected compliance costs represent less than 0.3 percent of total practitioner's income. Although costs of this magnitude would not result in a marked disruption in this sector even if borne entirely by these employers, evidence strongly suggests this sector will not bear the full cost burden.

According to the U.S. Department of Commerce, expenditures for physicians' services were estimated to increase at a rate of 15 percent between 1989 and 1990 [U.S. Industrial Outlook 1990, U.S. Department of Commerce, p. 49–1]. An increase of this magnitude in the expenditures for physicians' services during a period in which the costs of those services were estimated to have risen 7 percent (as reflected in the medical care services component of the 1989–1990 Consumer Price Index) indicates that fee adjustments in response to the OSHA rule can, to some extent, be passed forward to consumers and third party payers. (This option may be more limited in the future to the extent that Part B reimbursements under Medicare are restrained in an attempt to contain health care costs.)

Increases in the costs of physicians' services have led to the proliferation of managed care systems, which have enabled many consumers (those with health insurance) to retain access to care at reasonable cost. Though the increase in the cost of care attributable to the OSHA standard is estimated to be relatively minor, this regulation may reinforce this trend.

Cost pass-through in the form of higher premiums paid by consumers or higher co-payments for health services may lead some consumers to shift away from managed care plans or to forgo preventive care altogether [Ex. 6–612]. Thus, while the ability of establishments to pass-through some of the costs associated with the rule was indicated, certain establishments may choose to absorb a large portion of the costs of compliance. Current levels of net income were estimated to be sufficient to enable establishments to comply fully with the rule.

The relative level of effort required to achieve compliance from baseline conditions was not judged to be widely divergent across this sector; most affected establishments are at a modest baseline compliance position.

Dentists' Offices. Dental practices will incur compliance costs representing about 0.28 percent of revenues and 3.6 percent of estimated profits. After adjusting this ratio to reflect the average income of dentists, the expected compliance costs amount to less than 1 percent of total net income.

In contrast to physicians' offices, almost two-thirds of dental revenues are paid by direct consumer outlays [Ex. 13, IV–11]; thus, dentists may be less able than most other health care providers to pass forward the costs of compliance. However, impacts on net income were not estimated to be of sufficient magnitude to cause undue harm in this sector.

OSHA bases this conclusion on evidence of strong consumer demand for dental service. Evidence indicated consumer dental costs increased over 7 percent recently (as reflected in the medical care services component of the 1987–1988 Consumer Price Index); consumer expenditures also [U.S. Industrial Outlook 1990, U.S. Department of Commerce, p. 49–1]; and the number of dental practices remained fairly constant during the period (see Industry Profile above). The dental industry has been stable and competitive despite increasing costs to consumers which were an order of

[8] OSHA's composite compliance indicator represents three major requirements under the standard, and has been used as a proxy for overall baseline position for the purposes of this analysis. OSHA believes this statistic to be a reasonable indicator of overall compliance because incremental costs associated with the three provisions represented in the indicator were consistently found to constitute a high proton of affected establishments' overall incremental compliance costs (see Costs of Compliance).

magnitude above those required by the standard. OSHA concluded that a 0.28 cost to revenue increase could be absorbed or passed forward by the dental sector, and would not result in industry contraction or greatly limit the public's access to care.

In its post-hearing brief, the American Dental Association (ADA) argued that the standard would have substantial impacts on dentists' profits and, more importantly, would limit access to dental care [Ex. 295, pp. 46–52]. However, the ADA based its argument on preliminary estimates of the incremental costs of compliance, as calculated by OSHA and the Association. OSHA believes these preliminary calculations and conclusions do not present a representative picture of the effects of the standard on the industry. The ADA's arguments also demonstrated the Association's apparent misunderstanding of the requirements and intent of the rule.

First, new evidence indicated certain preliminary estimates incorporated into OSHA and ADA calculations tended to overstate incremental cost. For example, based on testimony and written submissions, OSHA revised downward its estimate of the unit cost of a disposable mask, a frequently used item in the dental profession (see Technical appendix C, Personal Protective Equipment). Also, OSHA's survey found rates of current compliance to be higher than originally estimated by either OSHA or the ADA.[6]

Second, the ADA noted that "OSHA's [preliminary] figure is understated in at least one important respect. It ignores costs for dentists who are not employees" [Ex. 295, p. 46]. Including incremental costs for non-employee dentists increased the ADA cost estimates by approximately 30 percent [Ex. 20-665, p. 28]. OSHA, however, correctly excluded non-employee dentists from its cost analysis, since the Agency may only enforce its standards when an employer-employee relationship exists. Dentists for whom the standard is not enforceable may voluntarily follow precautions required of employees, and are encouraged to do so, but no cost should be attributed to the standard for such voluntary activity.

Further, the ADA stated that "data * * * indicate that on average dentists who always use infection control methods charge 13.2 percent higher fees than dentists who use these methods less frequently" [Ex. 20-665, p. 29]. OSHA found this characterization of the potential impacts of the standard to be both vague and misleading. For example, the article referenced by the ADA concluded that "[i]n general, those dentists who always use [gloves, masks, gowns, and protective eyewear] charge higher fees than those dentists who use these methods less frequently" [Ex. 20-665, Appendix 6]. It is not clear from this conclusion how the author's use of the words "always" and "less frequently" relate to the requirements of the OSHA rule. The OSHA standard does not require employees to use gloves, masks, gowns, and protective eyewear at all times, but only to protect against blood exposure, which the ADA has stated occurs about 54 percent of the time [Ex. 295, p. 5, fn. 3]. Without more detailed explanation to clarify the referenced study, it is possible that dentists using the infection control measures "less frequently" are already in compliance with the standard. No indication of the relative frequencies of occurrence among dentists who "always" use the items as opposed to those who use the items "less frequently" is provided.

Finally, data reported by the ADA in connection with its 1988 survey of attitudes and behavior indicated that

[t]he most important reasons cited by general dentists for not using barrier techniques were: loss of tactile sense, low risk, and difficulty in adapting to new techniques. Cost was not an important factor in this decision—it was cited by only 1 percent of respondents as the most important reason. [Ex. 282, Attachment 2B, p. 336]

This finding is inconsistent with the notion that infection control procedures threaten the financial health of the dental sector.

Thus, OSHA did not find the ADA arguments persuasive, and relied instead on survey results and other available industry information in reaching its conclusion of no significant impact.

In addition to the direct costs of complying with the standard, dentists may also be subject to increases in the costs of equipment servicing. OSHA estimated that equipment repair firms would require a 0.8 percent increase in revenues in order to fully pass through the costs of the standard (see below). Assuming 50 percent of the costs of compliance for the medical equipment repair sector were attributable to servicing of dental equipment, and assuming 100 percent pass through to the dental sector, dentists costs for equipment servicing would increase from $84 million to about $87 million. Passing this cost through could result in an increase in dentists' fees of less than 0.01 percent.

Thus, OSHA concluded that the impacts of the standard will not result in disruption of the dental services sector. Data indicated that the incremental costs of compliance were not of sufficient magnitude to significantly alter either supply or demand for dental services.

Nursing Homes/Residential Care Establishments. Compliance costs for nursing homes were estimated to be 0.15 percent of revenue and about 4.6 percent of pre-tax profits. (Profits for proprietary homes were estimated to be 75 percent of total profits.) Compliance costs for residential care facilities were estimated to average about 0.14 percent of revenues and 4.7 percent of profits.

Nursing homes were reported to be heavily dependent on government reimbursement programs, particularly Medicaid [Exs. 20-1358, p. 5; 20-255, p. 2; Tr. 9/21/89, p. 46]. It was also reported that some medicaid programs may not be able to provide adequate reimbursement for all participants. United Health, Incorporated, testified that "[b]ecause of the demands for the allocation of limited medicaid dollars, the nursing home industry is often not provided adequate resources to meet the current care demands" [Tr. 10/18/89, p. 395]. Further, it is not likely that these facilities will benefit from increased reimbursements in the short term, as the portion of public resources allocated for health care continues to be limited in an effort to contain costs.

Though this dependency on government programs ensures that "the burden cannot entirely be passed on to consumers" [Tr. 9/21/89, p. 46], future conditions should favor the long term care establishments, as the demand for beds rises in response to growth in the elderly population and increased life expectancy (this demand is reflected by estimates that expenditures on nursing home care increased at an average rate of approximately 11 percent from 1987–90) [U.S. Industrial Outlook 1990, U.S. Department of Commerce, p. 49–1, –4]. Limited public funds and increasing demand could result in industry concentration with fewer but larger, financially stronger facilities. The trend of increasing expenditures in a period of scarce public resources, however, also provides evidence that at least some pass through to private payers should be possible among existing establishments.

OSHA's composite compliance indicator showed that, in the nursing home sector, over two-thirds of surveyed establishments were estimated to fall within the baseline range of 40 to

[6] In its post-hearing brief, the ADA disputes the validity of OSHA's multisector survey, from which rates of current compliance were estimated for use in this final analysis [Ex. 295, p. 20]. See Technological Feasibility for a complete discussion of the representativeness of the survey results.

80 percent. With regard to residential care facilities, about 14 percent of surveyed establishments were estimated to fall within the lowest baseline range (0–10 percent). Since incremental costs will be high for these establishments, the impact of the standard may tend to hasten consolidation in this sector.

Overall, OSHA found that the impacts associated with this regulatory action will not threaten the existence of the long term care industry, though restructuring may occur.

Hospitals. As shown in Table VII–35, OSHA estimated the cost of the standard at 0.14 percent of hospital revenues and 7.0 percent of hospital profits. Profit impacts were computed for proprietary hospitals only (estimated to constitute about 22 percent of the facilities in this sector) and were derived assuming an average total margin of 2 percent. Profits for hospitals were estimated to be $1.012 billion ($230 billion × 22% × 2%).

In assessing the ability of hospitals to pass the costs of compliance forward to consumers, OSHA examined recent data regarding hospital utilization, hospital expenses, and consumer expenditures. OSHA found that overall expenditures on hospital care were estimated to have increased steadily since 1987, on the order of 9 percent per year [U.S. Industrial Outlook 1990, U.S. Department of Commerce, p. 49–1]. At the same time, hospitals' costs rose 8–10 percent [1989 Hospital Statistics, American Hospital Association, p. xxxiii], and consumers paid 7.5 percent more for hospital services (as reflected in the medical care services component of the 1987–1988 Consumer Price Index). Revenues also increased 6.8 percent in 1987 and 9.3 percent in 1988 [1989 Hospital Statistics, American Hospital Association, p. xxxiii–xxxiv].

These data indicated that hospitals have succeeded in passing on to consumers a major portion of their increased expenses. As noted by OSHA in its preliminary analysis [54 FR 23108], third party payers bear a high percentage of the costs of hospital care, and it is likely that much of hospitals' cost increases were passed through to such payers. This conclusion is supported by the data presented above, which indicated demand for certain services remained strong despite significant increases in the costs of care.

However, to raise charges (prices) for inpatient services, hospitals rely on government programs, particularly Medicare, for increased reimbursements. Cost increases eventually result in higher reimbursements under the prospective payment system (PPS). Testimony indicated, however, that increases in federal medicare payments to hospitals for inpatient services are not likely to be sufficient to cover all cost increases [Tr. 9/27/89, pp. 58–59]. Thus, OSHA estimated that full pass-through would not be possible.

To more completely assess the impact of the standard in such an environment, a more detailed examination of the financial condition of hospitals and the prevailing trends in hospitals' health care delivery strategies was undertaken.

OSHA first examined hospitals' performance with respect to inpatient services. Average occupancy rates for hospitals averaged 65.5 percent in 1988, with the smallest hospitals (6–24 beds) reporting an average occupancy of 32.8 percent for the same year [1989 Hospital Statistics, American Hospital Association, p. xxxii]. Hospital admissions reported for 1988 declined 0.5 percent from the previous year, continuing a seven year downward trend [1989 Hospital Statistics, American Hospital Association, p. xxxi].

These reductions in admissions and accompanying drop in occupancy were largely due to PPS, which have set predetermined fee schedules intended to contain the escalating costs of hospital care. However, while the volume of inpatient services declined, cost per case continued to increase [1989 Hospital Statistics, American Hospital Association, p. xxxi].

Hospitals' inability to fully recoup cost increases through increased PPS reimbursements and increased patient charges (cost shifting) resulted in a period of consolidation, evidenced by increases in the closing of investor-owned facilities (which accounted for over 43 percent of community hospital closures in 1987) and by accelerated growth in the number of hospitals owned or managed by multi-hospital systems ["Prospective Payment Assessment Commission", Report to the Congress, June 1988, pp. 50, 51]. One example of a multi-hospital system is Presbyterian Health Care Systems. During testimony presented in Washington, D.C. Mr. Douglas Hawthorne of Presbyterian Hospital of Dallas, the "flagship" facility of the system, indicated that Presbyterian purchased rural hospitals in 1976 and 1984 [Tr. 9/27/89, p. 154].

To survive, hospitals increased their mix of services. One area where demand has grown significantly is outpatient services. In an effort to soften the financial impacts of cost containment strategies imposed on the industry by third party payers, hospitals began to treat more patients on an outpatient basis [1989 Hospital Statistics, American Hospital Association, p. xxv]. Consumer demand for outpatient care has continued to rise. According to the medical services component of the consumer price index, consumer costs for hospital outpatient services increased over 11 percent between 1989 and 1990; it appears that hospitals have been able to pass forward to outpatients some of their cost increases. (Increases in charges for outpatient services are also subject to approval by Medicare, (under Part B)).

Hospitals are also increasingly expanding their services to include long-term care [1989 Hospital Statistics, American Hospital Association, p. xxx], and some cost pass through should be possible in this area.

In contrast, hospitals will not be able to pass forward any of the costs of the rule in the area of uncompensated care. Hospitals are increasingly providing uncompensated care, and testimony presented during OSHA's informal public hearings emphasized this fact [Tr. 9/27/89, pp. 39, 229]. One study focused on the potential increase in uncompensated care in the treatment of AIDS patients [Ex. 6–637].

OSHA found it unlikely that compliance costs will be passed forward in full, although hospitals should be able to pass forward some portion of the costs of compliance. PPS updates have not increased reimbursement limits enough to fully compensate for hospitals' increased expenses with respect to inpatient care (and may not do so in the future). Hospitals have increased the volume of outpatient and long-term care services provided. Evidence indicated strong demand for these services, as recent trends clearly demonstrate that consumers and third party payers have borne some portion of hospitals' cost increases. Cost increases associated with the OSHA standard represent only a fraction of the recent cost increases experienced by hospitals and OSHA concludes that the effects of passing a portion of the costs of compliance forward will not result in a significant reduction in demand.

Hospitals' ability to absorb compliance costs which cannot be passed forward was also examined. As noted, a fair portion of hospitals' cost increases during the past several years were absorbed, resulting in declines in patient margins, some hospital closings and industry consolidation. (Patient margin is the percentage of patient revenue retained after expenses, in contrast to total margin, or the percentage of total revenue retained after expenses.) If the number of indigent patients increases, more

hospitals will experience financial problems [Trs. 12/19/89, p. 852; 11/14/89, p. 318].

These effects do not appear to be evenly distributed among the nation's hospitals. It was reported, for example, that during the 10 year period between 1978 and 1988 the number of urban community hospitals increased by 1 percent, while the number of rural community hospitals decreased by 12 percent [1989 Hospital Statistics, American Hospital Association, p. xxvi]. This was most likely due to population shifts and the differing characteristics of urban and rural hospitals; urban hospitals tend to be larger, on average, and are able to provide a greater variety of services; smaller hospitals tend to be more dependent on inpatient revenue and are less financially stable.

The regulatory impact will vary depending on a particular hospital's service area, current practices and means of financial support. For example, rural hospitals lag somewhat behind urban hospitals in current practices; thus, they may experience slightly greater impacts in attempting to comply with the standard due to weak baseline position. Also, some rural hospitals serving relatively isolated communities may not be able to alter their service mix to minimize costs and increase consumer expenditures. However, Congress and the Health Care Financing Administration (HCFA) identified sole community hospitals (SCH) as one group for which special treatment was justified with respect to PPS reimbursement limitations. SCHs, or those hospitals which constitute "the primary, and often the only, source of inpatient services for a market area" [Ex. 6-598, p. 3] are reimbursed in a manner which "gives greater weight to hospital-specific cost factors" and "become eligible for special payments in the event of a significant decrease in volume" [Ex. 6-598, p. 3]. Thus, it is likely that these hospitals may be able to pass forward, through third party payment, a larger portion of any cost increases resulting from the OSHA rule. It was also reported that rural hospitals often survive because of strong community support [Ex. 13, p. IV-13].

Patient mix will also affect a particular hospital's response to the rule. Hospitals with a larger medicare base and which provide significant amounts of uncompensated care may find it more difficult to pass costs forward, even as demand for services continues. One hospital's representative testified that 70 percent of all patients were medicare, and that 20 percent fell into the uncompensated classification [Tr. 9/27/89, p. 40]. The response of such hospitals to the OSHA rule will be to absorb a larger portion of the costs of compliance.

On balance, OSHA found the standard to be economically feasible for hospitals, but believes the rule will reinforce the present trend toward consolidation and service diversification. Though the volume of inpatient services has declined, the industry responded by consolidating to remove excess capacity, and by providing more outpatient services and long-term care. Demand for these alternative services should allow some portion of the costs of this standard to be passed forward to consumers, particularly in the case of larger hospitals, as they are more likely to be able to offer a diverse range of services. The reduction in excess capacity will result in a more financially stable industry better able to absorb costs which cannot be passed forward.

If it is assumed that substantial portions of the annual compliance costs incurred by blood collection and processing centers, personnel service agencies, linen services, and medical equipment repair establishments will be passed forward to hospitals (approximately $25 million), projected impacts would increase by only about 8 percent (an additional 0.01 percent of revenues, or 0.8 percent of profits). The magnitude of these impacts, when contrasted against past and prevailing financial trends in this sector, should not present hospitals with new, unmanageable burdens.

Also, many publicly administered hospitals will not be affected by the standard. It was estimated that about 10 percent of hospitals were state, county, or city funded [Ex. 266]. Such hospitals would also have a slight competitive advantage over non-public institutions. However, as noted above, the magnitude of cost increases associated with the standard were estimated to be relatively small, and should not create significant economic hardship for most affected hospitals.

Medical and Dental Laboratories. The impacts of compliance costs were estimated to be 0.28 percent of revenues, or 3.8 percent of profits for establishments in this sector.

The response of labs which provide testing services to other health care providers, such as physicians and dentists, will most likely be to attempt to pass costs forward to such health care professionals. Since data indicated that strong demand for health care services should enable providers to pass some portion of the costs associated with the rule on to consumers, OSHA estimated that some portion of the compliance costs incurred by medical and dental labs will be passed on as well. Labs billing consumers directly will also attempt to push costs forward.

Since some consumers may forgo preventive care in an environment of rising charges, labs will find that a fair portion of the costs will need to be financed through absorption. OSHA's calculations did not, however, indicate profit impacts to be sufficient to cause disruption in this sector. Differential impacts on establishments resulting from their low baseline position could occur, though any competitive impact would be mitigated by the overall weak baseline profile of the industry.

Other Health Care Facilities. Home health care, hospices, freestanding hemodialysis centers, and drug rehabilitation centers are included in this sector. As shown in Table VII-35, the impacts of compliance costs on revenues for establishments specializing in outpatient services range from less than one-tenth of 1 percent (drug rehabilitation centers) to just under 0.2 percent (hemodialysis centers). Compliance costs represent about 1 percent of profits for drug rehabilitation centers and about 3.1 percent of profits for hospices.

OSHA finds that current trends in health care delivery strategies favor providers which treat in the home or on an outpatient basis. The demand for home health services has grown steadily recently. The Commerce Department reported that "spending on home health care has been growing at an annual rate of about 20 percent for the past few years," reflecting both the advancing age of the population and incentives encouraging alternatives to institutionalization [U.S. Industrial Outlook 1990, U.S. Department of Commerce, p. 49-4]. Hospices also provide such an alternative.

There was little available information on dialysis and drug rehabilitation center. Since these establishments primarily provide services on an outpatient basis, OSHA judged the outlook for these sectors to be financially favorable. Recent financial information published by Dun and Bradstreet indicated dialysis centers were achieving good returns, with median firms earning in excess of 8 percent on sales (after taxes) in 1988 and 1989. Continued demand should ensure the ability of affected centers to finance the costs of the rule through a combination of pass-through and absorption.

Health Units in Industry. OSHA estimated total costs for health units in

manufacturing facilities to be almost $68 million. However, these costs will be shared by over 200,000 establishments. OSHA concluded that, since health units are typically found in large businesses, the costs associated with the standard will have a negligible impact on affected manufacturing plants and will not affect producers' market structure.

Personnel Services. Compliance costs for personnel firms supplying medical care staff and service employees are estimated at 0.25 percent of revenue and 6.3 percent of related profits.

Information regarding the demand for temporary staffing is limited and mixed. On the positive side, the continued emphasis being placed on outpatient and home care services should provide a growing market for temporaries. Information provided by the Home Health Services and Staffing Association (HHSSA) indicated, however, that, to the extent that families pay for home care services out of private funds, such services are "very price-sensitive" [Ex. 20–878, p. 3].

In contrast, the downturn in the demand for hospital inpatient services and the consolidation of both the hospital and long term care sectors have led to "a decline in the requests for temporary services in many areas of the country" [Ex. 20–878, p. 3].

Thus, OSHA concludes that total pass-through of compliance costs may not be possible for establishments in this sector. However, some avenues for pass-through should be available, and continued demand for home and long-term care should enable this industry to absorb the balance of the economic impacts of the standard.

OSHA's composite compliance indicator suggests that a substantial number of establishments may experience greater impacts due to a weak baseline position. OSHA estimated 28 percent of all surveyed establishments to have achieved an average level of current compliance which was 10 percent or below. However, since over 70 percent of establishments surveyed were estimated to have achieved a baseline position of 50 percent or below, the effects of a disproportionate allocation of incremental costs is not to be expected.

Other Related Services. These services include blood/plasma/tissue centers, linen supply services, medical equipment repair services, and funeral services. With regard to blood products, OSHA estimated compliance costs to represent 0.8 percent of total revenue. By the nature of their product and the structure of the blood services industry, full pass-through of compliance costs should be possible for this sector. The inelasticity of demand for blood products, coupled with the regional structure of the industry and the absence of a regulated pricing system, indicates that the 1 to 2 percent increase in costs associated with the standard will be passed forward to the consumers of health care, third party payers and, to a lesser extent, hospitals. In addition, OSHA's composite compliance indicator did not suggest a great potential for the disproportionate allocation of incremental costs.

In the linen services sector, increases in charges equivalent to 0.04 percent of revenue are expected to be passed forward to health care clients. This conclusion is supported by evidence in the record indicating a shift away from in-house laundries by hospitals toward contract laundry services. This trend, which has been taking place over the past 5 to 10 years, is expected to continue [Ex. 20–106]. The continued demand for linen services should enable linen service establishments to pass forward costs associated with the rule. The cost increase should not eliminate the advantage realized by health care establishments utilizing contract linen services.

Establishments servicing medical and dental equipment are also in a strong position to pass forward most or all of the costs associated with the rule. OSHA estimated that dental offices should be able to absorb any costs passed forward by equipment repair establishments, as the magnitude of such costs were estimated to be a very small portion of dentists' net income. Similarly, OSHA estimated the hospital sector to be able to manage increases in the costs of equipment repair associated with the rule, by using a combination of pass-through and absorption.

OSHA disagrees with the American Dental Trade Association's (ADTA) contention that the OSHA standard will "create a strong incentive for companies to cease repair operations" [Ex. 20–1144]. The need to maintain complex and expensive equipment will continue and support the continued demand for establishments with expertise in this area.

Some equipment repair establishments may find their poor baseline position to be a disadvantage, as thirteen percent of surveyed establishments were estimated to have achieved average compliance levels of 0 to 10 percent. The balance of affected establishments were estimated to have achieved average compliance levels of no more than 50 percent, however, thus reducing the potential of a concentrated impact of the rule.

The costs of compliance in the funeral homes sector were estimated to be 0.13 percent of industry revenue, or just under 1.5 percent of profits. OSHA estimates that continued demand for the services provided by establishments in this sector should enable them to push most costs of the rule through to buyers. With respect to the rule's possible effect on industry structure, OSHA's composite compliance indicator did not suggest a great potential for the disproportionate allocation of incremental costs.

Research and Production Facilities. OSHA estimated the costs of compliance to represent 0.18 percent of total revenues and 4 percent of profits for this sector.

Many research projects are supported by public funds, such as those conducted in state and local institutions of higher learning or in association with federal grant programs. However, corporate and private donations are essential in both public and private research. Though OSHA has no data on the sensitivity of these sources of support to increases in the costs of performing research, it is anticipated that the ability to pass costs forward would be greater for establishments relying more heavily on corporate funding than on public grants. Since evidence was presented indicating over one-half of the estimated research dollars are spent on research performed by private labs and labs in the pharmaceutical industry [Ex. 13, p. I–44], OSHA believes that some portion of the costs of compliance will be passed forward in the form of higher prices for corporate products or services.

Establishments relying primarily on public funding for research may be forced to absorb the costs in full. However, costs, as percentages of profits and revenues, are small and are not expected to have a significant effect on the ability of firms to operate.

Waste Removal. OSHA estimated the costs of compliance to represent just over 0.3 percent of industry revenues and approximately 4.2 percent of pre-tax profits.

Generators of regulated waste have three main alternatives with respect to disposal of such waste. First, wastes may be rendered noninfectious prior to disposal, thus enabling generators to use a general waste stream. A second way many generators dispose of regulated items is to incinerate on site. Generators not equipped to treat or incinerate items on site will be required to have regulated items collected and transported off site for subsequent disposal or treatment.

Relatively few of the establishments affected by the standard generate enough waste to justify investment in incineration equipment, with the exception of hospitals, on-site incineration would not be cost-effective for most facilities faced with a 0.3 percent increase in transportation costs. However, OSHA found many affected establishments operate autoclaves (steam sterilization equipment) on-site. Generators may find it cost effective to invest in new steam sterilization equipment, thus altering their current treatment/disposal strategy to minimize disposal costs.

In the case of hospitals, data from one survey indicated that 80 percent of infectious (regulated) items were treated before disposal [Ex. 6-609]. Many hospitals appear to have some ability to avoid increased collection/transportation costs in connection with regulated waste items.

Since generators of regulated waste can avoid some or all of the costs associated with collection and transportation of regulated items, OSHA estimates that the incremental costs of compliance incurred by waste removal establishments may be absorbed by affected firms. The impact of this absorption is not expected to be overly burdensome to this industry sector.

Public Service Sectors. Compliance costs for government clinics, corrections, police, fire and rescue operations, lifesaving, and schools were estimated to amount to less than 0.5 percent of the budgets in all cases. Though collective increases of this magnitude represent increases in public expenditures of less than $0.50 per capita for state-plan states, local governments may choose to forgo tax increases and procure additional resources for public services affected by the standard through shifting resources away from less essential services. Localities choosing to finance compliance costs through tax increases or service charges should find incremental tax burdens or service charges to be relatively small.

Regulatory Flexibility Analysis. Based on data presented by Jack Faucett Associates, OSHA preliminarily concluded that the impact of the rule on small businesses would be similar to that found for the affected universe as a whole, because the majority of businesses affected are small [54 FR 23107]. Table VII-36 shows the estimated percentage of affected establishments by sector reporting annual income of $3.5 million or less. The table reflects how hospitals differ from other affected industry sectors, and the majority of the revenues in five sectors is generated by larger establishments.

TABLE VII-36.—SECTOR COMPOSITION—SMALL ESTABLISHMENTS

Industry	Percent of firms with revenue of less than $3.5 million	Percent of revenue from small business
Offices of Physicians	99.32	88
Offices of Dentists	99.97	88
Nursing Homes	87.47	48
Hospitals	28.84	2
Medical/Dental Labs	96.59	58
Outpatient Care	96.02	45
Home Health Care		
Hospice Care		
Drug Rehabilitation		
Hemodialysis Centers		
Residential Care	97.60	75
Personnel Services	90.54	34
Funeral Services	99.61	90
Research Labs	91.63	14

Source: Jack Faucett Associates.

OSHA compared the composite compliance indicator profiles presented in Technical appendix B for seven employment-size categories in each surveyed sector (five employment-size categories were developed for the hospital sector).[10] By examining the baseline profiles of smaller establishments, or the extent to which smaller establishments have already implemented worker protection measures, insight was gained with regard to smaller establishments' relative abilities to supplement such measures to comply with the rule. OSHA used the profiles to generate the information presented in Table VII-37, the implications of which are explained below.

[10] Employment size categories for non-hospital sectors were 0-4; 5-9; 10-19; 20-49; 50-99; 100-249; >250. Employment size categories for hospitals were 1-49; 50-99; 100-249; 250-499; >500. Though OSHA's bloodborne pathogens survey was not designed to produce statistical estimates by size class, the compliance estimates discussed here are believed to be generally accurate and useful for illustrative purposes.

TABLE VII-37.—SMALL ESTABLISHMENT BASELINE ANALYSIS

Industry	Percentage of affected establishments with fewer than			Percentage of affected establishments falling within baseline ranges 0-30 with fewer than		
	10 employees	20 employees	50 employees	10 employees	20 employees	50 employees
Offices of Physicians	76	89	98	92	98	100
Offices of Dentists	91	98	99	94	100	100
Nursing Homes		2	17		3	17
Medical/Dental Labs	53	80	89	67	96	96
Home Health Care	15	31	64	13	27	60
Hospice Care	36	50	72	75	75	100
Drug Rehabilitation	11	30	60	0	33	100
Hemodialysis Centers	17	55	92	0	50	100
Blood/Plasma/Tissue Centers	14	41	70	23	54	92
Residential Care	11	29	55	17	45	76
Personnel Services	4	6	13	5	5	15
Funeral Services	88	96	99	100	100	100
Health Units in Industry	54	69	92	50	67	90
Research Labs	17	39	61	34	50	67
Medical Equipment Repair	50	74	97	53	73	100

* Percentage shown reflects percentage of establishments with fewer than 250 employees.
Source: Occupational Safety and Health Administration, Office of Regulatory Analysis.

As shown in the table, OSHA included in the analysis establishments employing fewer than 10, 20, or 50 employees. OSHA sought evidence that smaller establishments were overrepresented in the lower baseline ranges (0 to 30 percent average compliance). As shown in Table VII–37, for most sectors, this was not the case. For example, in dentists' offices, establishments were found in the lowest baseline ranges in proportion to their representation in the universe of affected establishments as a whole, regardless of employment-size class. This pattern was exhibited by many of the surveyed sectors, including nursing homes, home health care facilities, personnel service establishments, and medical equipment repair establishments. In three sectors (dialysis centers, blood centers, and residential care facilities), a trend toward larger establishments' overrepresentation in the lowest baseline ranges was found.

However, in physicians' offices, establishments employing 10 or fewer employees made up 92 percent of establishments falling into the lower baseline ranges but only 76 percent of the population of affected entities. Smaller establishments in the hospice and medical/dental laboratories sectors also appeared to lag behind larger establishments with respect to employee protection against infectious agents.

These figures suggested that, for most sectors, smaller establishments generally have not experienced greater difficulty in implementing employee protection measures relative to larger establishments. Nevertheless, in some sectors, smaller establishments may need a relatively greater effort than larger facilities in achieving compliance. However, OSHA's baseline profile also indicated that a substantial number of small facilities fall into the higher compliance ranges in these sectors; small size alone did not preclude implementation of voluntary employee protection measures. For example, 67 percent of surveyed physicians' offices with fewer than 10 employees were estimated to have achieved a baseline position exceeding 30 percent, and almost one-third were estimated to have achieved a baseline position exceeding 50 percent.

Thus, OSHA did not find smallness associated with an inability to comply with the rule or to necessarily place small establishments at competitive disadvantage under the rule.

With regard to the hospital sector, small firms make up about 29 percent of the affected universe when revenue is used as the primary criterion to establish size. However, OSHA's baseline analysis indicated only 4 hospitals have failed to achieve an average compliance level of 31 percent. Though these four hospitals all reported fewer than 250 employees and fewer than 300 operating beds, hospitals of this size constituted over 25 percent of all hospitals included in the analysis.

Thus, while smaller hospitals' limited ability to diversify could be a potential disadvantage in their attempts to pass compliance costs forward, it does not appear that they lag behind larger hospitals to any significant extent in their ability to provide employees with protection against infectious hazards.

These findings support OSHA's earlier assessment with regard to regulatory flexibility. Based on these findings, OSHA reaffirms its conclusion that impacts on small businesses will generally conform to the impacts of the standard upon the affected universe as a whole. Though some smaller establishments may experience impacts which exceed those placed upon competitors, differential impacts should not alter industry structure to any significant degree.

G. Nonregulatory Environment and Regulatory Alternatives

1. Introduction

Under the requirements of Executive Order 12291 and the Office of Management and Budget (OMB) guidelines for its implementation, regulatory agencies must consider nonregulatory alternatives when reviewing a standard. Many proposals have been advanced as solutions to the complex problem of reducing occupational health hazards and the attendant economic burden they place on affected workers, employers, and society at large. While these proposals form a continuum in their distribution of costs and benefits, they generally fall into categories based on the degree to which market forces are relied on to reduce workplace hazards.

2. Worker's Compensation and Tort Liability

Some market-based approaches for dealing with occupational illness rely on the theory that workers' compensation and tort liability provide adequate incentives for employers with high injury and illness rates to improve workplace conditions. Workers' Compensation programs, however, are generally not adequate to ensure an efficient allocation of health resources. The rates charged employers tend not to serve as an economic incentive as only 20 percent of all firms (mostly large firms) are experience rated. Since the universe of establishments affected by the bloodborne pathogens standard consists predominantly of small establishments, it would be unlikely that many workplaces would be rated.

Additional obstacles to Workers' Compensation providing incentives for workplace health and safety are the usual limitation of benefits to less than two-thirds of weekly wages, restricted permanent disability benefits, and limited survivor benefits.

This situation is further complicated by the nature of occupational diseases, which may take years to develop. For example, the long latency period prior to the development of acquired immunodeficiency syndrome (AIDS) may make it difficult to obtain Workers' Compensation benefits for occupationally induced illness.

In short, the Workers' Compensation system does not provide adequate incentives for employers to invest in a more healthful workplace because benefits are below the actual costs of injury, and because premiums for individual firms do not directly hinge on the level of risk they impose. The economic costs not borne by the employer are shifted to the employee, their families, or to society as a whole through social security or welfare programs.

The threat of litigation under tort liability has also been propounded as an effective market incentive to provide a more healthful work environment. The potential effectiveness of tort liability, however, is limited by the fact that, in most instances, workers are precluded from suing employers by Workers' Compensation statutes. Moreover, workers often cannot afford to forgo Workers' Compensation benefits while awaiting settlement, especially when there is a low probability of winning the lawsuit. In addition, workers may not be able to afford the costly legal fees associated with protracted litigation. Indeed, the threat of litigation may have the effect of suppressing information, especially when employers are vulnerable to third-party liability suits. Thus, the probability of a successful outcome from litigation involving an occupational illness is small due to the absence of definitive information concerning hazards and the related difficulty of proving employer negligence.

3. Private Markets

Neoclassical economics assumes that a perfectly functioning labor market will efficiently allocate occupational safety and health resources and that government intervention is warranted

only when a market failure occurs. According to this view, workers will bargain for wages which will compensate for their expected losses as a result of occupational risks, while employers will reduce the risks in order to reduce their labor costs. This theory typically assumes perfectly competitive labor markets in which workers, having perfect knowledge of job risks and being perfectly mobile between jobs, command wage premiums that fully compensate them for the risk of a future occupational illness. Theoretically, the cost of occupational illness is borne initially by the firms responsible for the unhealthy workplace and, ultimately, by the consumers who pay higher prices for the final goods and services produced by the firms. With all costs internalized, private employers have an incentive to reduce the level of risk in the workplace wherever the cost of doing so is less than the cost of the expected illness. The resultant level of health protection is considered "efficient" in that it minimizes the sum of the costs of health protection and of illness.

There is mixed evidence, however, on the extent to which workers are compensated for on-the-job health hazards. Although a number of wage surveys have found that many riskier occupations do receive wage premiums, no empirical studies necessarily imply that workers are fully compensated for bearing such risk. There are several reasons why wage differentials may not correspond to the actual occupational risk to which the worker is exposed.

Perfectly competitive markets, which require fully informed individuals, mobile resources and internalized costs, do not exist in all labor markets. While job health resources would be supplied by the private market under perfect market conditions, these conditions are rarely met. Thus, one rationale for the need for government regulation to reduce occupational illness is to correct for the "market failure" due to the absence of accurate risk information, the immobility of labor, and the externalization of part of the social costs of worker illness or death. These factors lead to an undersupply of investment in occupational health protection.

The problem of imperfect information regarding job hazards exists in many workplace settings. Most occupational illnesses are only statistically associated with specific jobs. The incidence of a particular malady in a group of workers is higher than in the general population. It is very difficult to predict illness on a case-by-case basis. Cause and effect analysis by long latency periods for many diseases. Persons exposed to particular risks may not know precisely what those risks are and may either overestimate or underestimate them. Without knowing exact levels of risk it is not possible to successfully negotiate wage differentials which adequately compensate for accepting that level of risk. Illness and health effects data often are of poor quality and private firms have little incentive to improve or disseminate them. Where data are available, they are seldom presented in terms that would help workers to make informed decisions. Moreover, even if such data were available, workers may not be able to translate them into a probability of disability or death. If workers cannot adequately evaluate their individual risks, their ability to bargain effectively with their employers for compensation or for healthier working conditions is severely impaired.

The problem of imperfect information dissemination, while common to all areas of safety and health, is particularly pronounced for health risks. Adverse health effects caused by exposure to hazardous substances may have symptoms similar to diseases which are not necessarily occupationally related. This complexity precludes informed decisions being made based on the likely consequences of occupational exposure to harmful substances or conditions.

Another cause of market inefficiency is inadvertently created by entitlements under Social Security disability and other social welfare programs. Although these programs do not affect occupational risk, they in fact absorb part of the loss produced by job-related illness and injury, in turn fixing part of the cost of occupational risk on the general public rather than on the workers and employers who negotiate in the labor market. To the extent that the public pays for the consequences of risk, workers in hazardous jobs will have a smaller incentive to bargain for compensating wage differentials. Reduced wage differentials lessen the incentive to abate the hazard. Thus, one of the reasons that the private market does not perform perfectly in reducing accident and illness rates is that workers and employers have been allowed to externalize the costs of workplace illness and injury to society in general.

A perfectly competitive labor market also requires that workers have the ability to move freely from job to job with few transaction costs. But, localized demand for occupational skills and widespread fears of unemployment restrict labor's ability to bargain for safer workplace conditions. Considering the substantial loss of income resulting from prolonged periods of unemployment, the practical choice for many workers is not between a safe job and a more hazardous but higher paying job, but rather between employment and unemployment at whatever the prevailing rate of pay and risk. The high cost of relocation, the cost of breaking family and community ties, and the growth of institutional factors such as pension plans and seniority rights also elevate the cost of job transfer. Thus, for situations in which wages are more responsive to the demands of more mobile workers (who tend to be younger and perhaps less aware of job risks), hazard premiums for the average worker will not be fully compensating, and the obtained level of health will be less than that required for economic efficiency.

4. Action taken by Employers Based on Non-enforceable Guidelines

In 1987, the Centers for Disease Control (CDC) of the United States Department of Health and Human Services (HHS) published guidelines for safety when working with blood or other potentially infectious materials. Though research performed by OSHA indicated that some level of worker protection has been instituted in most establishments where exposure to infectious substances occurs, this information, together with comments received by the public, clearly demonstrates that non-enforceable guidelines will not result in an adequate level of protection to the nation's health care and public safety workforce.

To ensure the best possible protection to the population at risk to bloodborne pathogens, an integrated system of controls, procedures, training, and medical measures are required, and the OSHA standard was designed to be implemented in such a fashion. Though current practices with regard to the use of gloves by affected workers were found to be largely in compliance with the OSHA rule, adequate levels of training were found less often. Training in the appropriate use of gloves is an important component of the rule.

In the absence of this regulatory option, significant gaps will remain in many establishments' worker protection programs. Enforceable workplace standards will ensure that employers will institute a complete set of risk reduction policies and procedures, the most effective and efficient way to maintain a safe and healthful workplace.

5. Other Regulatory Alternatives

Since universal precautions were introduced by CDC, the concept has received overwhelming support by worker and industry groups alike. In light of such evidence, OSHA concluded that the most effective regulatory approach for limiting exposure to bloodborne infectious agents was to mandate the adoption of universal precautions, a system whereby all blood and other materials which may contain bloodborne pathogens are considered potentially infectious.

However, while the concept of universal precautions is generally acknowledged as prudent and effective, OSHA determined that a more complete worker protection program would be required to ensure maximum worker protection. That is, while universal precautions are a necessary element in any comprehensive program where exposure to blood is to be limited, the concept is not in itself sufficient if worker safety is to be maximized.

Thus, OSHA has also required the hepatitis B vaccine to be offered to occupationally exposed employees free of charge. Three alternatives to this requirement were considered. First, OSHA considered limiting the population of workers offered the hepatitis B vaccine to that portion of the affected workforce occupationally exposed an average of once a month or more. OSHA's second alternative was to require all employers to offer the vaccine, free of charge, to occupationally exposed workers, regardless of frequency of exposure. A third alternative would be to mandate the vaccination of all exposed employees. However, this alternative would not protect workers from other bloodborne pathogens.

A review of public comment and testimony indicated strong support for the second of the three alternatives listed above. If vaccine eligibility had been based on monthly exposure, many workers at risk would not have qualified for the vaccine. OSHA chose to mandate that employers offer the hepatitis B vaccine to all occupationally exposed workers.

OSHA also considered mandating specific control methods or technologies for worker protection. However, while specification standards may be appropriate for processes or systems incorporating minimal variation in tasks and predictable hazards, such a regulatory approach would not be well suited to health and emergency care workplaces. Most sectors providing health care and related services require employees to confront an array of potentially hazardous scenarios, many of which are unpredictable or unanticipated. Prescribing strict procedural or technological requirements in a hospital, where workers consistently face unique and varied exposure situations, would invite conflict between specific rule requirements and the need to provide essential health care services. Strict requirements in association with such a dynamic environment would become outdated, as new treatments and advances in medical science are implemented.

Thus, OSHA has drafted a performance oriented standard, allowing employers to craft the most protective and cost effective programs possible. OSHA is confident that employers will be able to minimize risk to occupationally exposed workers by training workers to employ effective and efficient risk reduction techniques, such as work practices to reduce the potential for exposure, engineering controls, or proper use of personal protective equipment, when confronted with occupational exposure.

Two alternatives in connection with the requirement that employers provide post-exposure follow-up to employees following exposure incidents were considered. The first involved mandating that follow-up procedures be performed in accordance with standard recommendations for medical practice. The alternative to this option was to mandate that follow-up procedures be performed in accordance with Public Health Service (PHS) guidelines. OSHA chose the second alternative, since recommendations for standard medical practice generally follow PHS guidelines. This will ensure that workers are provided the best follow-up care as soon as possible.

VIII. Environmental Impact

The provisions of the standard have been reviewed in accordance with the requirements of the National Environmental Policy Act (NEPA) of 1969 [42 U.S.C. 432, et seq.], the Council on Environmental Quality (CEQ) NEPA regulations [40 CFR part 1500], and OSHA's DOL NEPA Procedures [29 CFR part 11]. As a result of this review, OSHA concluded that rule will have no significant environmental impact.

The rationale behind this assessment is based on information in the record which indicated that, although the volume of waste handled as infectious will increase under the standard, available treatment/disposal strategies are currently in use. Additionally, OSHA's survey found that most establishments are already treating the majority of their wastes in accordance with the requirements of the standard. These factors should minimize the potential adverse effects of incremental waste disposal activities associated with the rule.

As generators achieve full compliance, infectious waste previously entering the general waste stream will be shifted into one of the major treatment options used for the disposal of infectious waste, namely incineration or landfill. With regard to incineration, any incremental environmental impact resulting from the standard would be principally related to air quality and disposal of ash. However, incinerators are often operated by hospitals, and data in the record indicated that hospitals are currently complying at a rate in excess of 90 percent (see Technical appendix C, Housekeeping). Thus, any incremental impact on environmental quality associated with this disposal method was estimated to be minimal.

Incremental impacts on landfills will result from the increase in the use of disposable items required by the standard, such as personal protective equipment, syringes, and sharps disposal containers. OSHA estimated that an increase in tonnage of approximately 50,000 tons per year will result from this requirement.[11] This estimate does not take into account any shift away from disposable toward reusable items. Since total U.S. solid waste generation is about 160 million tons per year [Ex. L20–1272, p. 4], OSHA's bloodborne pathogens regulation is estimated to increase solid waste tonnage by less than 0.1 percent.

To the extent that infectious waste in the general waste stream is currently handled improperly, the rule may improve environmental quality as previously mishandled infectious waste is redirected toward preferred disposal alternatives.

[11] OSHA assumed all additional regulated waste items generated by non-hospital sectors in response to the standard and destined for treatment/disposal would be sent off site for landfill disposal.

XI. Summary and Explanation of the Standard

OSHA believes that the requirements set forth in this final standard are those, based on currently available data in the record, which are necessary and appropriate to provide adequate protection to employees exposed to blood and other potentially infectious materials. In the development of this final standard, OSHA has carefully considered the comments and testimony from interested parties given in response to the Proposed Standard and the Advance Notice of Proposed Rulemaking. In addition, numerous reference works, journal articles, and other data, collected by OSHA and others since the initiation of this proceeding have been taken into consideration in the development of this final standard. All of this information is in the rulemaking record.

Paragraph (a) Scope and Application

The standard applies to all occupational exposure to blood and other potentially infectious material as defined in paragraph (b) of this standard. The risk of infection with bloodborne pathogens is dependent on the likelihood of exposure to blood and other potentially infectious materials wherever that exposure occurs. A single exposure incident may result in infection and subsequent illness and in some cases, death. The hazard affects employees in many types of employment and is not restricted to the healthcare industry. By relating coverage to occupational exposure, OSHA hopes to protect all employees at risk regardless of their job title or place of employment.

Blood has long been recognized as a potential source of pathogenic microorganisms that may present a risk to individuals who are exposed during the performance of their duties. In 1983, the CDC published guidelines for controlling infections in hospitals (Ex 6-74). One section, entitled "Blood and Body Fluid Precautions," recommended that certain precautions be taken in handling the blood and body fluids of patients who were known or were suspected of being infected with bloodborne pathogens. Special precautions were recommended to be followed with these patients. The patients were identified using special placards, and their blood specimens were labeled in order to alert employees who had contact with the specimens. Specimens of blood from other patients whose infection status was unknown were collected and analyzed using no special precautions to protect the employee.

Although some patients could be identified as infected with HIV or HBV, allowing employees to be alerted to the increased risks present, it soon became apparent that many individuals infected with these viruses were either undiagnosed or their infection status was not known to the healthcare employee. Patients being treated for unrelated injuries or illnesses, dental patients, trauma victims, and blood donors are all examples of individuals whose infection status may not be known and whose blood may present a risk to the employees who come in contact with it. The possibility of undiagnosed infection combined with the increasing prevalence of HIV and HBV led CDC to recommend that blood and certain other body fluids from all patients be considered potentially infectious and that rigorous infection control precautions be taken to minimize the risk of exposure. This approach is called "Universal Precautions," and the CDC published this recommendation in its August 1987 guidelines (Ex. 6-153). This is the approach taken by OSHA in the final standard.

CDC/NIOSH supported this approach to the scope of the standard when they stated that "protection of workers against reasonably anticipated exposure to blood and other potentially infectious materials is the only practical approach" (CDC/NIOSH, Ex. 20-634). They explained their basis for this support in their comment on the proposed standard.

> The scope of the regulation should not be based on employment in one or a few specified industries. OSHA is correct in defining the scope in terms of reasonably anticipated occupational exposure to blood or other potentially infectious material. These exposures occur predominantly but not exclusively in the healthcare industry. Healthcare workers may therefore be most commonly at risk, but it is their blood exposure, not the industry in which they are exposed, that places them at risk. Regardless of the industry in which they may be exposed, all workers with reasonably anticipated occupational exposure to blood or other potentially infectious materials should be included in the scope of this rule. (CDC/NIOSH, Ex. 20-634, p.3)

The recommendations of the Immunization Practices Advisory Committee (ACIP), Protection Against Viral Hepatitis, published by the U.S. Public Health Service in 1990 also support the idea that employees who have blood exposure are at risk and should be protected. Recommendations for those at occupational risk were included as two of the 13 groups recommended for preexposure hepatitis B vaccination. The recommendations state:

> Persons at substantial risk of HBV who are demonstrated or judged likely to be susceptible should be vaccinated. They include the following:
>
> 1. *Persons with occupational risk.* HBV is a major infectious occupational hazard for health care and public safety workers. The risk of acquiring HBV infection from occupational exposures is dependent on the frequency of percutaneous and permucosal exposure to blood or blood products. Any health-care or public-safety worker may be at risk for HBV exposure depending on the tasks that he or she performs. If those tasks involve contact with blood or blood-contaminated body fluids, such workers should be vaccinated. Vaccination should be considered for other workers depending on the nature of the task.
>
> Risks among health-care professionals vary during the training and working career of each individual but are often highest during the professional training period. For this reason, when possible, vaccination should be completed during training in schools of medicine, dentistry, nursing, laboratory technology, and other allied health professions before workers have their first contact with blood.
>
> 2. *Clients and staff of institutions for the developmentally disabled* * * * Staff who work closely with clients should also be vaccinated. This risk in institutional environments is associated not only with blood exposure but may be consequent to bites and contact with skin lesions and other infective secretions * * * Susceptible clients and staff who live or work in smaller (group) residential setting with known HBV carriers should also receive hepatitis B vaccine * * * Staff of nonresidential day-care programs (e.g., schools, sheltered workshops for the developmentally disabled) attended by known HBV carriers have a risk of HBV infection comparable to that among health-care workers and therefore should be vaccinated. (Ex. 286G)

Many of the issues raised by commenters who disagreed with the Agency's approach to the "Scope of the Standard" related to coverage of workplaces where employees provide service to individuals who are not members of groups known to be at increased risk for HIV or HBV infection. OSHA recognizes that certain populations have more members who are infected with HIV or HBV than other populations. A hospital ward dedicated to the care of AIDS patients, for example, would be expected to contain a population that is 100% HIV positive. A group of young male trauma victims entering the emergency room of an urban hospital might reasonably be expected to have a higher percentage of HIV positive individuals than the population as a whole. Conversely, a group of repeat blood or plasma donors would be expected to have a relatively

low number of individuals who are HIV positive. However, even populations of volunteer blood donors are not free of infected individuals and considerable efforts are expended to identify and discard units donated by those individuals.

A similar assessment can be made of the risk for HBV. For example, immigrant and refugee populations from areas of high HBV endemicity have a high percentage of members who are hepatitis B surface antigen positive. In other words, they are carriers of the hepatitis B virus. Users of illicit parenteral drugs and household contacts of HBV carriers also have a substantially increased risk of being HBV carriers. Elderly nursing home residents would be expected to have fewer infected individuals, but it is clear that even an elderly population has individuals who are hepatitis B carriers often as the result of infections that occurred earlier in life.

Unlike AIDS, a substantial number of cases of hepatitis B infection have not been associated with a known risk factor. In CDC's Sentinel County Study, the percentage of cases where no known risk factor could be identified averaged 36% for the years 1982 to 1987. The risk factors remained unidentified, despite a thorough effort to pinpoint the source, as described below:

> Each patient with viral hepatitis is extensively interviewed for risk factors associated with acquiring the disease. In addition, to determine the actual source of infection for HB patients who have no identifiable source, attempts are made to obtain serum from household and sexual contacts of these patients. (Ex 6-245)

Some commenters contended that blood or other potentially infectious materials present a negligible risk after a few hours. The record contradicts this and contains evidence that the hepatitis B virus can survive for at least one week dried at room temperatures on environmental surfaces (Exs. 6-422; 6-458). Transmission of HBV infection as the result of exposure to contaminated environmental surfaces has been documented to be a major mode of HBV spread in certain settings, particularly hemodialysis units (Exs. 6-56; 6-446; 6-461; 6-480). Likewise, the death of the source individual does not result in the instantaneous inactivation of HIV or HBV that may be present in the individual's blood and body fluids. For example, HIV was recovered at autopsy from a person with AIDS who had died 18 hours earlier (Ex. 286M).

An LPN from rural Pennsylvania addressed another mistaken notion, the belief that people who are infected with HIV are only found in urban areas when she said:

> Don't be fooled by the statistics of our rural areas. AIDS patients are counted where they are diagnosed, not where they die. I've had patients from California, New York and Florida come home to die. It is vital that we treat every patient as if he or she has an infectious disease and then take the appropriate precautions. (Ms. Alice Donovan, Ex. 36)

Section 6(b)(5) of the OSH Act instructs the Secretary to promulgate a standard that protects an employee "even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life." An employee may have occupational exposure to blood or other potentially infectious materials from a large number of source individuals in a working lifetime. For example, the record contains several estimates of the number of hemoglobin determinations and phlebotomies that are performed per hour (for example, Dr. Tom Carson, ARC, Ex. 20-215; DuPage Hospital, Ex. 20-347). The estimates range from 8 to 24 per hour. If we use the lower end of the range with 10 patients per hour, the employee would have occupational exposure to the blood of 17,500 different source individuals per year and 87,500 different source individuals after 5 years [10 per hour × 7 hours × 5 days × 50 weeks × number of years]. The number of occupational exposures over a working lifetime of 45 years would be 787,500 source individuals. A single needlestick contaminated with blood containing HIV gives a risk of infection of 3 to 4 per 1,000. A single needlestick contaminated with blood containing HBV gives a risk of infection of 60 to 300 per 1,000. It is important to note, however, that an employee can become infected as the result of a single exposure incident. Infection does not require multiple exposures.

Both HIV and HBV infections have been reported in rural as well as urban populations and in every state and territory. The fact that the viruses are transmitted sexually and through the sharing of needles by I.V. drug users points to the fact that the viruses may be present in any group. Furthermore, the likelihood that infected individuals will become carriers means that individuals may continue to pose a threat of infection years after the initial infection takes place. In summary, the Agency knows of no population that is free of these infections.

Although OSHA does not intend to present an exhaustive list of job classifications that may be associated with tasks that have occupational exposure to blood and other potentially infectious materials, a brief discussion of some of the environments where occupational exposure may occur follows.

The 1985 CDC guideline recommending HBV vaccination for personnel at risk included these examples of occupational groups having frequent exposure to blood: medical technologists; operating room staff; phlebotomists and intravenous therapy nurses; surgeons and pathologists; oncology and dialysis unit staff; emergency room staff; nursing personnel; and staff physicians. CDC also cites the need for vaccination of students in schools of medicine, dentistry, nursing, laboratory technology and other allied health professions. This set of recommendations also included healthcare workers based outside hospitals such as dental professionals, laboratory and blood bank technicians, dialysis center staff, emergency medical technicians, and morticians (Ex. 4-9).

Hospitals: There is almost universal agreement that healthcare workers, such as nurses and physicians, who are employed in hospitals, provide patient care, and have occupational exposure are at risk for infection by bloodborne pathogens. Since their risks are so extensively documented (See Section IV: Health Effects), no additional discussion is provided here. The occupational exposure encountered by other hospital employees is discussed below under Laundry, Housekeeping, and Clinical/Diagnostic Laboratories.

Clinical/Diagnostic Laboratories: These include but are not limited to hospital labs, free-standing clinical or diagnostic labs, labs in dentists' or physicians' offices, blood and plasma center labs, dental labs, and laboratories preparing reagents from human blood or blood components. Laboratories that conduct research using blood or blood components but do not produce or use concentrated amounts of HIV or HBV also fall into this category. Employees who work in clinical or diagnostic laboratories that perform a variety of tests to aid in the diagnosis of disease and the management of treatment are also at risk if they have occupational exposure. In the United States, millions of blood specimens are collected and analyzed in these laboratories each year. One commenter referenced a report that 898 million blood collection tubes were sold in 1986 (3M, Ex. 233). Although not all laboratory tasks involve blood or other potentially infectious materials, a relatively high potential for exposure exists for employees who analyze and process these fluids and tissues. In

addition, environmental surfaces and equipment in clinical laboratory areas have been shown to be contaminated with HB surface antigen and present a potential risk for the laboratorian (Ex. 6–56). Several organizations and groups have devised procedures for reducing risks in the laboratory and these procedures are part of our record (for example, Exs. 6–153; 6–312; 11–71; 11–159; 11–280).

One expert witness described his experience in auditing laboratories over the preceding 14 years.

Since 1976, I have conducted many dozens of site visits to clinical and research laboratories to perform biosafety audits. These audits have included blood laboratories * * * For years it has been accepted that 15–30% of blood lab and hospital workers will contract hepatitis B over their lifetime as a result of exposure on the job. The attitude is that this risk goes with the territory. A few years ago only a modest number of blood samples per year were positive for HBV and/or HIV in a clinical laboratory. Today, based on my experience it is not uncommon to find one in fifty to one in every 100 clinical samples in a 24 hour run of thousands of samples in a metropolitan blood laboratory to be positive for HBV and/or HIV. As the pool of positive samples is growing rapidly, so also is the danger to those who must handle the blood specimens. (Dr. Joseph Coggin, Ex. 26)

Dr. Coggin's observation is supported by the study of Handsfield and colleagues. In 1987, they reported that a large number of serum and plasma specimens submitted for analysis to the clinical chemistry lab of an urban teaching hospital were positive for HIV or HBV. Specifically 6.3% were hepatitis B surface antigen positive and 3.0% were HIV antibody positive. Taking into account that some samples had both viruses, 8.7% of the samples contained at least one of these viruses (Ex. 6–351).

Although laboratorians may not have direct patient contact, most of those employed in clinical or diagnostic labs do have exposure to the blood and other potentially infectious materials of patients. An examination of the tasks performed by clinical laboratorians as they analyze human blood and other human body fluids as part of the diagnosis and treatment of disease makes it clear that these individuals have occupational exposure and, therefore, are at risk.

Housekeeping: The housekeeping workers in healthcare facilities may also be at risk of exposure to bloodborne pathogens. Individuals who perform housekeeping duties, particularly in patient care and laboratory areas, may be at increased risk for exposure when they perform tasks such as cleaning blood spills and handling infectious wastes. They often encounter carelessly discarded contaminated sharps. One witness testified:

Our members who work in the housekeeping departments often pick up waste baskets and bags which often contain needles. They continually face the possibility of needles which have been improperly discarded * * *. For instance, one of our members, who is now retired, was cleaning a room when she picked up some trash on a window sill and was stuck by a contaminated needle from an AIDS patient. The needle was lying in an alcohol pad. (Mr. Robert Moore, Ex. 36)

Laundry: Laundry workers may also be at risk of exposure to bloodborne pathogens. These individuals may be employed in either hospital laundries or in commercial laundries that service healthcare, public safety and other institutions where occupational exposure to blood or other potentially infectious material occurs. Laundry workers may be exposed to laundry contaminated with blood or to contaminated sharps inadvertently left in the laundry.

Laundry employees who testified at the public hearings gave examples of occupational exposure. For example, an employee of a hospital laundry told of the types of exposure that are found in these laundries.

I think the sorters who have to sort out the dirty linen, they are always finding needles, syringes, scalpels and other sharps in the dirty linen. Most of these instruments are bloody. Employees have been stuck because they don't always see the things until they've been stuck. Another thing, if sharps get by the sorters and find their way into the wash deck, this puts the washers who load and unload the machine at risk * * *. Like some of the surgery, we get a lot of congealed blood. We get a lot of different parts of the body * * *. You also get some from labor and delivery. You get different congealed blood in sheets and in blankets * * *. They have to handle all of this. (Ms. Georgia Davenport, Tr. 1/16/90, pp.779–780)

One witness told of receiving needle sticks from needles in the laundry. He said:

In my work as a sorter, I have been stuck twice by a needle, as recently as two years ago—once by picking up a plastic bag full of bloody surgery towels * * *. Myself and other employees in the laundry still encounter needles in the linen, mostly coming from surgery. The number has decreased in the last four years but there shouldn't be any at all. (Mr. Raymond Montez, Tr. 1/16/90, pp 788–789)

Most recommendations for minimizing or eliminating these hazards focus on limiting the risk by minimizing handling of soiled laundry. This practice not only reduces the likelihood of skin contact with blood-contaminated laundry, but also reduces the likelihood of a puncture wound from a needle or other sharp object. The risk of handling this laundry is present whether the servicing laundry is within the institution or at another site.

Personnel Services: These agencies provide nurses and other healthcare professionals to hospital and other healthcare facilities that require their services. The occupational exposure experienced by these employees would be expected to occur in hospitals, physician's offices, and other healthcare facilities, rather than in the facility of the Personnel Service. These employees' occupational exposure would be similar to other employees performing the same tasks and procedures in the healthcare facility that has contracted for their services.

Tissue Banks: Another potential source of bloodborne pathogens is human tissue that is removed for transplantation. The American Association of Tissue Banks, representing 700 individual and institutional members, supported the implementation of a standard and recommended including the category "tissue bank personnel" in the coverage (Exs. 11–50; 20–720). Examples of tasks and procedures that may result in occupational exposure in tissue banks were described by Dr. John Kateley, president of the American Association of Tissue Banks (AATB).

Tissue banking professionals are at risk for infection in a manner similar to laboratory technologists, phlebotomists, surgeons and other healthcare professionals dealing in patient care. Tissue banks are responsible for the removal, preparation and storage of bone, skin, ligaments, tendons, corneas, heart valves, and saphenous veins for transplantation. These tissues are surgically removed and then further processed in a tissue bank laboratory for storage and future transplantation. (Dr. John Kateley, AATB, Ex. 20–720)

The evidence in the record shows that tissue bank employees have exposures similar to those seen in hospital and medical laboratory personnel.

Drug Treatment Facilities: These facilities include hospitals, residential treatment programs, and outpatient treatment facilities. The types of occupational exposures that occur would range from those described above for hospitals to those associated with rendering first aid and performing phlebotomy in an outpatient clinic or residential setting.

Physicians' Offices: The physician's office is often the scene of blood collection, treatment of wounds, minor surgery, and other invasive procedures.

Physicians, nurses, nurse practitioners, physicians' assistants and other healthcare employees may be exposed in this setting. The office may also contain a laboratory where additional exposure may occur when blood and other potentially infectious materials are analyzed. Employees who perform these tasks have the same risk as their hospital-based colleagues.

Freestanding Clinics: A number of healthcare employees work in freestanding clinics that operate outside the hospital. For example, employees of hemodialysis clinics, urgent care clinics, health maintenance organization (HMO) clinics, and family planning clinics perform many of the same tasks that have traditionally taken place in either the hospital or the physician's office. Examples of these tasks include performing hemodialysis, phlebotomy, surgery, wound care and dressing changes. These tasks clearly carry the same risk whether they are conducted in a hospital or a free-standing clinic.

Clinics in Industrial, Educational, and Correctional Facilities: Many commenters made the point that healthcare is also being provided as a service to a larger facility, such as in industrial, in educational, and in correctional settings. These facilities often provide services such as emergency first aid, collection of blood, and cleaning and dressing of wounds, activities that may place the healthcare provider at risk for exposure to blood and other potentially infectious materials. (Exs. 11-111; 11-86; 11-216).

Dental Facilities: Dentists, dental hygienists, dental assistants and dental laboratory technicians are continually exposed to blood and bloody saliva during almost all dental procedures. Because saliva in dental procedures is so likely to contain blood, the CDC recommends personal protective equipment to practitioners for all dental procedures (Ex. 6-316). The record contains many references to occupational hepatitis B infections in dental health professionals. (Exs. 6-68; 6-441)

Ms. Karen Boulton, a dental hygienist who testified at the public hearings, gave examples of preventive dental hygiene services, including scaling and polishing of the teeth, periodontal root planing and subgingival curettage. She estimated that "almost 100 percent of [her] patients in private practice exhibit some extent of bleeding during routine treatment." (Tr. 1/16/90, pp. 563-565)

A number of commenters who considered this issue agreed that these dental employees are at risk and supported a standard for dental operations (Exs. 11-162; 11-177; 11-327). The position of the American Dental Association (ADA) regarding the scope of the standard and the major provisions was given by Dr. Enid Neidle in her testimony at the public hearing on the proposed rule. She stated, in part:

> The purpose of OSHA in protecting, through this proposed rule, the health care worker is clear, unequivocal, and laudable. The American Dental Association shares that purpose. Over the past 15 years, the Association has invested substantial resources in the development of educational materials to prevent the transmission of infection in the dental office. (Dr. Enid Neidle, ADA, Ex. 58)

However, the ADA stated its belief that OSHA overstated the risks to dental healthcare workers in the preamble to the proposed standard. In their posthearing comments (Ex. 282), they stated:

> Over the past several years, data have been amassed that suggest that the dental profession is at very low risk of contracting infectious bloodborne diseases. The following documented facts support this position:
>
> • Over the past five years, the American Dental Association Health Screening Program and other testing programs have done a total of 4,973 tests on dentists for antibodies to HIV. In 1988, Klein et al. reported that one dentist in their sample of 1,132 dentists • • • was seropositive; this case was subsequently adjudged by the Centers for Disease Control to meet the criteria for an occupational transmission. As shown in Table 1, of the total sample of 4,973 tests between 1985 and 1989, only two have been positive. Table 2 shows that the prevalence of HIV infection among dentists is low compared to the general population. Inasmuch as dentists have been treating HIV-infected patients for at least 15 years (and did not wear personal protective equipment for at least the first ten years), the occupational risk to dentists is extremely low.
>
> • In response to an inquiry from the Association, the Centers for Disease Control has stated that no dental staff members (hygienist, assistant, dental laboratory technician) have been reported to have been infected with HIV as a result of occupational exposure.
>
> • As of 1989, 71% of U.S. dentists had been vaccinated against HBV; this percentage has increased steadily since the vaccine first became available in 1982. (ADA, Ex. 282)

One of the difficulties in relating this information to the final standard is that it focuses almost entirely on dentists, who are more likely to be employers and not covered by the standard. It does not adequately address the status of dental hygienists, dental assistants, and dental laboratory technicians who make up 75% of dental healthcare workers who are employees and are therefore covered by this standard.

In any case, we will address the points made by the ADA to support their contention that OSHA has overestimated the occupational risk faced by dentists. First, it would be more complete to say that the Klein study, cited above in the quote from the ADA, found five (5) HIV infected dentists, not one (Ex. 6-366). Four of these individuals were found to have other risk factors leaving one occupational HIV infection in a group of 1,132 dentists. A finding of 1 occupational HIV infections in a group of 1,132 dentists, or 2 occupational HIV infections in a group of 4,973 for that matter, is not "extremely low" or "minimal" or "insignificant" as the ADA has argued. On the contrary, this finding is compatible with a finding of a 1 in 1,000 risk of a fatal illness as the result of an occupational exposure. In the "Benzene Decision," the Supreme Court clearly defined this as a significant risk. (See Section VI: Significance of Risk) This does not take into consideration the additional occupational risk caused by HBV. The ADA's contention that the HIV risk in dentists is lower than that of the general population is confusing and is not supported by the data the ADA cited in their posthearing comments. They use the figure "2 HIV infected dentists per 4,973" and as we have noted above, the Klein study alone found 5 HIV infected dentists (5 per 1,132). There is no information in the record to indicate how many other HIV positive dentists with other risk factors were found in the other groups that make up the total 4,973 tested individuals. Second, in the past it has been relatively uncommon for dental hygienists, dental assistants and dental laboratory technicians to be tested for HIV following occupational exposure. Since an HIV infection may be silent for many years before AIDS develops, it is highly unlikely that untested individuals would know whether or not they were infected with HIV. Third, OSHA agrees that the HB vaccine is a central component of any effort to control hepatitis B, and it is important to note that a relatively high percentage (71%) of dentists are vaccinated. However, the remaining 29% who have not been vaccinated continue to be at increased risk. An article from the Journal of the American Dental Association begins, "In the late 1970s, it became clear that dentists are at a risk three times greater than that of the general population for hepatitis B [ADA, Ex. 282-2b]] In addition, as the ADA acknowledged in their posthearing brief, other dental healthcare workers are considerably less likely to have been vaccinated (ADA, Ex. 295). For example, in 1989 only 15% of dental laboratory technicians had been vaccinated.

Clearly, dental health professionals perform tasks that place them at risk for infection due to their occupational exposure.

Institutions for the Developmentally Disabled: Although the overwhelming majority of cases of HBV and HIV infections occur in adults, one group of children have a high risk for hepatitis B infection. This group consists of developmentally disabled children who are or have been institutionalized. Surveys conducted in large state institutions indicate that the risk of a child contracting hepatitis B in one of these institutions ranges from 50% to 90% with 5% to 20% of those infected becoming hepatitis B carriers (Ex. 11-165, p. 4). The behavior of these children, including scratching, biting, and self-mutilation, may present a risk to those who teach or otherwise care for them. Developmentally disabled adults who are or have been institutionalized also have an increased risk for being infected with HBV. In 1990, the CDC recommended the hepatitis B vaccine for both the clients and the staff of institutions for the developmentally disabled (Ex. 286G).

Hospice: A hospice is one of several alternative health care programs open to the terminally ill, including terminally ill AIDS patients. Employees provide healthcare services to these patients which place the employee at risk for occupational exposure. The Hospice Association of America provided examples of the types of employees (and volunteers) who provide hospice care and some of the types of care rendered by these individuals that place them at risk.

> Hospice employees engaged in direct patient care include, but are not limited to, registered nurses, homemaker/home health aides, physicians, licensed practical nurses and various therapists. * * * Hospice services provided in the home include * * * dressing change, intravenous drug administration, blood specimen collection, intramuscular and subcutaneous injections, management of intrathecal, epidural, venous and arterial shunts and catheters and suctioning of tracheal and upper respiratory secretions. In other words, much of the direct patient care provided in the hospital is also provided in the home by hospice employees and volunteers. (Hospice Association of America, Ex. 11-202)

Hospice employees who perform the services outlined above as well as other duties that result in occupational exposure are at risk of infection by bloodborne pathogens.

Home Health Care: Another alternative to hospital care is home healthcare. There was recognition among the commenters that some employees who provide home health care have occupational exposure and are at risk of HIV and HBV infection. Tasks that home healthcare providers may be expected to perform include collecting a blood specimen, cleaning and dressing wounds, and managing intrathecal, epidural, venous and arterial shunts and catheters (National Association for Home Care, Ex. 11-203).

A common theme among the commenters concerned with home health care is the environment in which the care must be rendered. For example, one group stated:

> * * * Unlike other types of providers, home health agencies (HHAs) do not control the worksite. The worksite is the patient's home; the nurse, home health aide, or therapist is only a visitor. Attempts to apply universal precautions, decontaminate the worksite, and otherwise control the risk of infection by bloodborne pathogens must take this into account.
>
> A home nurse, for example, cannot control the level of general sanitation or cleanliness in the home. Some homes do not have amenities such as running water. Home health employees cannot ensure that patients and their non-professional caregivers will take precautions that they may find objectionable or bothersome. Many beneficiaries and their caregivers are quite elderly and confused, and would have great difficulty in following through on decontamination instructions (Amer. Fed. of Home Health Agencies, Inc., Ex. 20-544).

OSHA is aware that in most instances home healthcare must be provided in an environment and at a location that is not under the control of the employer. In addition to home healthcare employees, emergency medical service providers are another group who provide healthcare services in a variety of locations outside the employer's facility. However, it is clear that both types of employees have occupational exposure; are at risk for HIV and HBV infection; and must be provided the protection afforded by the provisions of the standard. OSHA has modified several provisions of the proposed standard to take into account the circumstances described above. For example, paragraph (d)(2)(iv) of the standard allows the use of antiseptic hand cleansers when handwashing facilities are not available.

Blood Banks/Plasma Centers: In blood banks and plasma centers, the potential for occupational exposure begins with the initial finger stick of the donor and continues until contaminated units are identified and destroyed. The blood and blood products in these facilities are regulated by the Food and Drug Administration (FDA), and all plasma and blood collection facilities have extensive written procedures for donor requirements, donor room procedures, and laboratory testing of the blood with blood components (ABRA, Ex. 11-71). However, the FDA does not set standards for the health and safety of the employees.

One witness, a nurse employed by the American Red Cross, testified concerning the likelihood of contact with blood.

> To the uninitiated, phlebotomy appears to be a clean operation. After all, we aren't performing surgery, emergency service, or even patient care. Instead, we're dealing with individuals who don't appear to be sick * * *. It may come as a surprise to some people, then, that mobile collection staff may come in contact with large amounts of blood on the job. I'm not just talking about needle sticks. Since we handle large amounts of blood all day long, the potential for contact is always present. (Pam Talbot, RN, Tr. 9/15, p. 157)

Dr. Robert G. Chapman, President of the Council of Community Blood Centers, agreed that occupationally exposed blood bank personnel should be offered the hepatitis B vaccine and other protection. He felt, however, that there should be a two tiered approach to protective clothing with less stringent requirements for, for example, phlebotomists drawing homologous donors in nonhospital blood banks. (Tr. 10/20/89, p. 731) Dr. Paul V. Holland, representing the American Association of Blood Banks, argued that the risk from voluntary blood donors is very low, that wearing gloves often presents a problem to the phlebotomist (applying labels, for example). He further stated that they require gloves for autologous patients and hepatitis B vaccination for employees in their laboratories (Tr. 10/20/89, pp. 764-765). The American Blood Resources Association (ABRA) has argued that workers in a plasma center are at a reduced risk of exposure to bloodborne pathogens because many plasma donors donate frequently, as often as twice a week, and therefore their antibody status is known (Ex. 11-71). Similarly, the American Red Cross stated that "its healthy blood donor population does not present any increased health risks to its employees and volunteers" (ARC, Ex. 11-280). However, despite prescreening, both blood banks and plasma centers have donors who are infected with HIV, HBV, and other bloodborne pathogens including non-A non-B hepatitis.

A 1990 study of intravenous drug users published in the Journal of the American Medical Association showed that 27% of a cohort of 2921 intravenous drug users had donated blood or plasma. Of this group 82.2% had donated after they had started using drugs and most

donated at commercial plasma centers. (Ex.299, attachment) In a study published in the New England Journal of Medicine in 1989, Leitman and her colleagues conducted an in depth analysis of a group of volunteer blood donors who were found to be infected with HIV. One of the issues studied was the donors' estimation of whether or not they were at risk for HIV.

The results of our study suggest that current measures for donor education and screening are not uniformly effective in eliminating people at high risk from the donor pool. The majority of our HIV-infected donors understood the definition of high-risk behavior but did not view themselves as having engaged in such behavior. Even more disturbing, a large proportion donated specifically in order to discover the results of HIV testing. Furthermore, less than 5 percent understood the purpose of the post-donation confidential unit-exclusion system and would have designated their units as solely for research. Clearly, both donor-education policies and interview strategies need to be strengthened. (Ex. 281-3)

Twenty six percent of the subjects of this study did not believe their earlier behavior placed them at risk, because they had changed their lifestyles and they remained in good health. A similar percentage attempted to donate blood in order to undergo HIV-antibody testing because they viewed the donor center as more pleasant, more accessible, and not associated with any stigma. Fifteen percent of the donors felt pressured to donate despite a history of high-risk behavior. Only 6 percent did not read or understand the informational material provided by the blood center that presumably would have led them to disqualify themselves. The authors concluded that a small number of persons with HIV infection continue to donate blood despite attempts to exclude them.

In any discussion of the risk to employees in the blood and plasma centers it is important to note that these facilities dedicate a substantial amount of their resources to identifying these contaminated units and ensuring that they are not released for transfusion or for other use. Units of blood from donors who test positive are discarded and do not present a risk to recipients of transfusions. However, employees engaged in the collecting, processing, and testing of these units are at risk for exposure.

Nursing Homes/Longterm Care: Nursing homes or other long term care facilities were cited by commenters as places of employment where employees are at risk for blood and body fluid exposure (ANA, Ex. 11-86; Exs. 11-74; 11-172). For example, employees provide care for decubitus ulcers and skin tears. Employees give insulin injections and perform finger sticks which present the added risk of handling contaminated sharps.

Information from the National Health and Nutrition Examination Survey II gave us the most recent in depth look at the prevalence of hepatitis B markers in people from age 6 months to 74 years and from different racial groups (Exs. 20-834, 6-340). In other words, it provided information that would tell what percentage of people in each age group have been infected with hepatitis B at some time in their lives. In the age group 65 to 74, 6.4 out of 100 white females had serological evidence of past hepatitis B infection, 7.5 out of 100 white males, 39.5 out of 100 black females, and 39.7 out of 100 black males. This indicates that many individuals who are of an age group that would be either residents of nursing homes or candidates for nursing homes have at some time in their lives had a hepatitis B infection. Most of these individuals would no longer be infected but a percentage of these individuals would be expected to have developed hepatitis B carrier status and would still be infected with the virus years after the initial infection. Further data from this same study indicates that in persons aged 45-74 years, approximately 3 out of 1,000 whites and 8 out of 1,000 blacks were carriers of hepatitis B surface antigen, and thus presented a risk to those who came in contact with their blood. This can be compared to hospital patients where one would expect approximately 10 out of 1,000 patients (1%) to be infected with hepatitis B (Ex. 6-427).

The Service Employees International Union urged OSHA not to exclude nursing homes from the standard. They stated:

An exclusion of nursing homes based on their current low AIDS population is inappropriate. Nursing home workers are as likely as other health care workers to be exposed to HBV. They also face other infectious diseases such as TB. Moreover, such a policy would be dangerously short sighted. CDC estimates that more than 1.5 million individuals are today infected with the HIV virus. The growing numbers of AIDS patients together with soaring hospital-based health costs will spur treatment in alternative healthcare settings like nursing homes and respite homes. (SEIU, Ex. 11-61)

The American Health Care Association, which represents more than 10,000 long term care facilities and allied health care providers, stated:

[L]ong term health care facilities should be included, [in the standard] but we believe that recognition should be given to the differences in both type of care and population served in long term care facilities as opposed to acute care facilities. (AHCA, Ex. 11-27)

In its posthearing comment, the American Health Care Association gave a number of reasons why they feel that the nursing home industry should not be subjected to the "wholesale application of the OSHA standard." Some of these are listed below: (AHCA, Ex. 278)

[W]e believe that nursing homes comprise a discreet segment of the health care industry where, due to the nature of the resident population and the types of care provided, there is no reasonable expectation of employee exposure to blood or other potentially infectious body fluids in the performance of normal job tasks. The proposed standard utterly ignores the fact that the average patient in a nursing home is an 84-year old woman who will be given care in a stable setting for over a year * * *. Furthermore, nursing homes do not encounter their residents under the transient acute episodic and emergency circumstances which characterize *all* [emphasis in the original] of the other high risk health care categories * * *. Nursing homes are unique among health care providers because continuous regulatory oversight, survey, and compliance actions are built into the federal certification process for participation in the Medicare and Medicaid programs (AHCA, Ex. 278).

OSHA does not agree that employees of nursing homes have no reasonable expectation of occupational exposure. First, based on evidence in the record, it appears that some employees in nursing homes and some other long term care facilities do have occupational exposure despite the AHCA statement to the contrary. However, it is reasonable to expect that some nursing home employees, for example those employed in the dietary department, may not have occupational exposure and would not be covered by the standard. Second, as discussed above, elderly individuals may be carriers of bloodborne pathogens, particularly HBV, as the result of an earlier infection. In addition, although the average patient may be an elderly woman, the population is not made up exclusively of elderly women, but includes men as well. In fact, the population may contain adults of all ages whose personal circumstances require more care than they are able to provide for themselves. For example, a nurse's assistant testified:

While it may be true many nursing homes fit [a] typical resident profile. In every home I've worked in, I've taken care of male as well as female patients, young as well as old

patients and short-term stays as well as long-term care of patients. There is a wide variety of patients in nursing homes, some of whom have history of behavior which would put them at high risk for HBV and AIDS . . . as well as people who have had blood transfusion in the past 10 to 15 years. (Ms. Kathy Lucas, Tr. 1/16/90, p.751)

Third, the nursing home industry is not unique among the covered industries in that long term care, as opposed to acute, episodic care, is provided. The staff of institutions for the developmentally disabled also provide long term care, and these individuals are also at risk when they have occupational exposure as discussed above.

Fourth, the fact that nursing homes are subject to infection control requirements imposed by the Health Care Financing Administration (HCFA) of the U.S. Department of Health and Human Services under the Medicare and Medicaid programs and to infection control requirements of states does not obviate the need to cover the employees of these facilities under this standard. These infection control requirements are primarily to protect the patients (residents).

The preamble to 42 CFR 438.65, which requires nursing homes to have infection control programs, states, "* * * [T]he emphasis we wanted to place was on the actual performance of a facility in *providing care* * * *" (emphasis added) 54 FR 5345 (February 2, 1989). The interpretative guidelines for this regulation suggest that HCFA surveyors ask whether the HIV/HBV infection control policies agree with OSHA requirements for protecting employees and current accepted standards of practice recommended by CDC. It does not appear that HCFA mandates compliance with OSHA requirements and CDC occupational health guidelines as a matter of its own regulations. To the contrary, HCFA in effect notes that nursing homes must comply with OSHA requirements. Thus, there is no conflict with HCFA or duplication of effort. Similarly, since States implement the same infection control requirements under 42 U.S.C. 139 6r (h), the same arguments apply to state regulations. State licensing agencies may possibly have different, additional occupational health requirements. See 42 U.S.C. 139 6r (h)(8). However, the purpose of the OSH Act is to provide uniform protection. *Usery* v. *Lacy*, 628 F. 2d 1226 (9th Cir. 1980). States which desire to address issues covered by OSHA standards must adopt a plan approved by Federal OSHA. 29 U.S.C. 667 (b). Finally, the Congress has expressly indicated that OSHA is to protect healthcare and public safety workers from HIV and HBV. The Congress mandated CDC to develop guidelines for protecting healthcare and public safety workers from HIV and HBV and to submit the guidelines to OSHA for its use in the development of this standard. 42 U.S.C. 300ee–2 (a)(1)(2) and (b).

Funeral Homes and Mortuaries: The CDC considers morticians to be healthcare workers who should observe precautions because of their exposure to blood (Ex. 4–9). From the beginning of the rulemaking, there was a consensus among the commenters that employees of mortuaries have been at occupational risk because they are exposed to blood and certain body fluids and should be covered by the standard (Exs. 11–161; 11–111; 11–293; 11–282; 11–240; 11–181; 11–169; 11–157; 11–165).

For example:

It is generally agreed upon within the funeral service profession that risk of occupational exposure to bloodborne pathogens exists to varying degrees during the handling of human remains prior to embalming and during the embalming process (National Funeral Directors Association, Ex. 311).

Mortuary workers are potentially exposed to large quantities of blood during the preparation of cadavers; there is also potential for certain abrasions (SEIU, Ex. 11–161).

Embalmers constitute a group of long ignored non-hospital based health care workers. During the embalming procedure they often come into contact with large amounts of uncontainerized blood as the vascular system is drained. Depending on the cause of death and whether an autopsy has been performed, they may be required to handle various body parts and tissues, as well as to make numerous incisions and subsequently suture the incised tissue. These procedures put them at risk of exposure. (AAOHN, Ex. 11–111)

Exposure in funeral homes during embalming and other procedures described above may result in exposures similar to those encountered in surgery and autopsy.

Research Labs and Production Facilities: Research and production facilities that produce or manipulate concentrated virus are also included within the scope of this standard. There are many researchers in academia, government and industry who are studying HIV and HBV. These individuals may be at even greater risk than healthcare providers because the concentration of virus is often greater than that found in blood or other body fluids. The record contains evidence that two individuals who worked with concentrated HIV in a production facility became infected as the result of occupational exposure (Exs. 6–187; 6–312; 6–368). The circumstances surrounding these infections were the subject of a thorough review by a committee of experts appointed by the Director of the National Institutes of Health.

Expert witness Jolanda Janczewski, formerly Biological Safety Officer for the AIDS Research Program at the National Cancer Institute, Frederick Cancer Research Facility (NCI-FCRF), described the events in her testimony at OSHA's public hearings on the proposed standard.

In 1984, the NCI–FCRF began to produce the large amounts of HIV–1 that were needed for assays to test the nation's blood supply. Subsequently, and to date, the NCI–FCRF production laboratory was employed to prepare large quantities of HIV–1 as an agent for structural, immunological, and biochemical studies. Other commercial laboratories took over the process of producing the concentrated virus needed for the FDA-approved blood testing kits. By 1987, and to date [9/12/89], seven laboratories within the United States were involved in large scale HIV–1 production and employ an estimated 150 workers.

In September 1987, the first occupationally-acquired HIV–1 infection of a worker in a large scale HIV–1 production facility was confirmed. A second worker was reported to be infected in October, of the same year * * * Dr. James Wyngaarden, Director, National Institutes of Health convened a Review Group to investigate the reported HIV–1 infection[s] * * *. The Review Group * * * concluded with recommendations for worker training, enforcement of safety practices, medical surveillance, and evaluation of processes and equipment. (Ex. 25)

The reporting of two infections as the result of occupational exposure in a group of employees that number less than 200 documents the potential for viral infection whenever employees concentrate or otherwise manipulate highly concentrated virus. The final standard incorporates many of the recommendations of the Review Committee described above and the provisions specific for these facilities are found in paragraph (e) and paragraph (g)(2)(ix).

Although at present, HBV cannot be grown in tissue or organ culture, this may be possible in the future. Any concentrated HBV prepared from human or animal blood or body fluids would also present a risk to the laboratorian or other researcher who had occupational exposure in the laboratory or production facility.

Medical/Infectious/Regulated Waste Operations: Although OSHA is not aware of any documented cases of HBV or HIV infection associated with the collection, transportation, and final

disposal of "regulated" waste, the potential for such an infection prior to final disposal of the waste is clear. The situation facing employees who handle "regulated" waste within healthcare and other facilities was described by Judith Gordon, testifying as an expert witness for OSHA. She stated:

At many worksites, concern for employee safety and health is directed primarily toward the professional and skilled workers, and the impact of work practices on the safety and health of the maintenance and janitorial staff is often overlooked. Yet, if the exposure to bloodborne pathogens that are present on blood-contaminated items constitutes an occupational hazard to, for example, the healthcare worker, it poses the same risk for the person who must handle the same blood-contaminated items when they are waste. Scientifically and logically, handlers of infectious waste are also at risk of occupational exposure to bloodborne pathogens.

Infectious waste management has many aspects including discard of the infectious waste, its collection and storage, and treatment of the waste before disposal. Each of these activities has an inherent risk of occupational exposure to bloodborne pathogens. The work practices of those who initially discard infectious waste have a direct effect on the potential for exposure and the risks faced by those employees downstream who handle the infectious waste. (Ex. 30)

Browning-Ferris Industries (BFI) described the types of occupational exposure that may occur after the employee of the medical waste company has picked up the medical ("regulated") waste.

BFI's medical waste employees perform a variety of tasks associated with transporting and disposing of medical waste. Unlike healthcare and medical laboratory workers who may be exposed to bloodborne pathogens through direct and indirect patient contact, specimen collection and processing, or handling dressing, linens, waste and medical equipment, BFI medical waste employees handle waste only after it has been packaged and/or placed in a plastic container (tub) for transport and disposal. Medical waste workers load packages for transport, off load packages and tubs at transfer stations and destination facilities, prepare packages and tubs for treatment or destruction, and operate equipment which moves waste into and through treatment or destruction processes.

BFI's assessment is that the greatest potential occupational exposure of our employees to bloodborne pathogens is through needle sticks from sharps not properly packaged by generators in rigid containers, or from sharps containers not properly sealed. Medical waste workers are also exposed through improperly packaged fluids, and through spill response activities. BFI's own packaging and handling practices, including reliance on mechanical waste handling, as well as state and federal packaging requirements, substantially reduce these exposure routes. (BFI, Ex.20-138)

These comments clearly indicate the nature of the occupational exposure of employees who have contact with regulated waste from its generation to its ultimate disposal.

Equipment Service and Repair: Several commenters pointed out the potential risk to employees who service or repair medical instruments or other types of equipment contaminated with blood or body fluids such as dialysis pumps, pacemakers, liquid chromatographs, and centrifuges (Millipore Corp., Ex. 11-3; American Dental Association, Ex. 11-43; IBT, Ex. 11-97; 11-282; HIMA, Ex.66; Ex. 85). These devices are often contaminated both externally and internally (ADA, 11-43; YSI, 11-7). This hazard may be encountered when the equipment is serviced on site (Ex. 11-282) or at the factory or service center prior to decontamination (Ex. 11-7).

Dr. Amiram Daniel, testifying on behalf of the Health Industry Manufacturers Association, described how employees who sell and service medical equipment may be exposed. He stated:

In our industry we employ about 200,000 workers. About 10% of these workers are engaged in labor which may put them in contact with potentially infectious material * * * Our field force, composed of sales, service and repair, quality assurance and teaching personnel, must come in contact with the patient in the hospital, clinic or home environment, or with contaminated devices. Some of our used products are returned to the manufacturer for a variety of reasons—replacements and failure investigation to mention but two. The manufacturing personnel handling these shipments do not always know the status of the devices, who used them and how, whether they were disinfected prior to shipping, etc. (Dr. Amiram Daniel, HIMA, Ex. 66)

One group opposed coverage of these employees. Mr. Timothy Fise, representing the American Dental Trade Association (ADTA), testified that it was the opinion of the ADTA that medical and dental companies that engage in equipment repair should be excluded from the standard because they contend that the risk of infection is remote. Mr. Fise stated:

Companies do these repairs either: (1) outside of the medical/dental facility, or (2) at a time substantially after the equipment was in use with exposure to any patient. With the likelihood that equipment is incapacitated for at least several hours (if done on-site) and more likely several days before repair (if the equipment is shipped to the medical/dental facility for repair) any HBV which may have been present on the equipment will long since have died, and the exposure/risk eliminated. As noted above, any risk was remote at worst (Mr. Timothy Fise, ADTA, Ex. 85).

This argument, that blood contaminated equipment does not present a hazard was addressed in the opening paragraphs of this section. It is well documented that HBV can remain viable on environmental surfaces for at least a week, and transmission of HBV infection from exposure to contaminated environmental surfaces has been documented to be a major mode of spread in certain settings, particularly hemodialysis units (Exs. 6-56; 6-440; 6-461; 6-480).

Public Safety and Emergency Medical Services: Other employees who may be exposed to blood and other potentially infectious materials include emergency medical service providers, firefighters, law enforcement personnel and correctional officers. These employees would be covered under the final standard if they have actual or potential occupational exposure to blood or other body fluids and if they are employed by the private sector, the federal government, or a state or local government in a state that has an OSHA-approved state plan. Employees of state and local governments, including those employed in public hospitals and health clinics, in states without state occupational safety and health plans are not covered by OSHA regulations. (For more information on states and territories with OSHA state plans, see Section II: Legal Authority)

Finally, the Congress has expressly indicated that OSHA is to protect healthcare and public safety workers from HIV and HBV. The Congress mandated CDC to develop guidelines for protecting healthcare and public safety workers from HIV and HBV and to submit the guidelines to OSHA for its use in the development of this standard. 42 U.S.C. 300ee-2 (a)(1)(2) and (b) (Ex. 15).

The following descriptions outline the occupational exposures that are common to Public Safety Officers and Emergency Medical Services personnel.

Emergency Medical Services: Individuals who render emergency medical services are clearly at risk for blood exposure incidents. Prehospital care is often rendered in a hostile or uncontrolled environment. Conditions beyond the control of the employee, broken glass and sharp metal at an accident scene, weapons at the scene of a violent crime, and inclement weather, may complicate the tasks and make them more hazardous. Many of the commenters considered the risk to these

providers of emergency medical service to be substantial (ANA, Ex. 11–86; AAOHN, Ex. 11–111; International Association of Firefighters, Ex. 11–125; Merck, Ex. 11–165). Moreover, recent CDC guidelines clearly apply to personnel rendering emergency medical service (Exs. 6–153; 6–199). A description of the hazards that may be faced by emergency medical responders was provided by Chief Ricky Davidson, Chairman of the Emergency Medical Services Committee for the International Association of Fire Chiefs.

The pre-hospital emergency care providers, unlike their counterparts in hospitals and other medical facilities, do not have the luxury of controlled clinical environments. As has already been stated, field delivery of medical care often involves the challenges of adverse operating conditions, limited equipment and resources, and limited time. The emergency medical providers must often contend with very hazardous situations, violent and uncooperative patients and hostile bystanders. The house call, once a regular part of a physician's practice, is now almost exclusively the duty of the emergency responder.

There is no such thing as a sterile work environment for emergency medical responders. Theirs is often one of untenable work conditions, whether attempting to safely deliver a baby on the floor of an abandoned tenement, strewn with human waste and drug paraphernalia, or crawling through the shattered window of a motor vehicle to treat an accident victim, contending with broken glass, jagged metal and leaking fuel. The explosive growth in drug use all over the United States now places the emergency rescuer directly on the battleground, often having to deal with the aftermath of a drug deal gone bad. The rescuer can do little to change the dynamics of the situation. This is the world in which we must operate. (Tr. 9/14/89, p.114–115)

Mr. Paul Maniscalco, Vice President of the National Association of Emergency Medical Technicians, said:

The EMS provider is called upon to render lifesaving techniques in what can be described as, at best, less than ideal situation. Some of these scenarios include, but are not limited to, hazardous materials incidents, overturned autos, inner-city tenements, or in rural areas many miles from any health care facility. These varying environments provide for problems that ate each highly unique, and nothing like the static environment that is offered by working in a fixed medical facility. For example, the potential for a needlestick to occur is greatly increased when an EMT is required, due to patient condition, to start an IV in a moving ambulance. (9/14/89 Tr. 121)

Fire Fighting and Law Enforcement: Many commenters urged OSHA to include fire fighters and law enforcement personnel within the scope of the standard (Mr. Richard Duffy, IAFF Tr. 9/14/89 p. 150; Mr. Clyde Bragdon 9/14/91 Tr 105; IBPO Ex. 20–1251; 11–86 ANA; 11–15 AFSCME; 11–74 NY State Dept of Health; 11–111 AAOHN; 11–165 Merck; 34 Int'l. Ass'n. of Fire fighters). When these individuals act as emergency first responders their risk is similar to that discussed earlier for emergency medical services. In addition, the potential for a hostile or uncontrolled environment at a fire or crime scene mandates special procedures in devising an adequate program of protection. The combination of broken glass, jagged metal and blood may present a hazard to the fire fighter who is attempting to extricate the victim of a motor vehicle accident. Even after the victim has been removed from the scene, the employee may have to remain in a blood contaminated environment while the investigation and cleanup continues. For law enforcement officers, weapons (including knives, ice picks and razor blades) and drug paraphernalia (including needles and syringes) encountered on a search may have to be collected as evidence. Also, facilities for personal cleanup can be inadequate or lacking altogether. In addition, the employee may have to work under time constraints when there is the threat of an explosion, the likelihood of a building collapse, or a hostage situation.

Mr. Clyde A. Bragdon, Jr., formerly Fire Chief of Los Angeles County and currently the Administrator of the United States Fire Academy, testified as to the duties of fire fighters that place them at risk. He stated:

Today's fire fighter is not just a fire fighter. He is also an emergency healthcare worker, often the first to arrive at the scene of an accident. In fact, 60 per cent of all field emergency medical care is provided by the fire service. The occupational exposures inherent to their jobs necessitates that the Rule cover all fire fighters, emergency medical technicians, and paramedics. (Tr. 9/14/89, 105)

Mr. Eric Lamar, a Fairfax County (Va.) fire fighter and emergency medical technician with more than 14 years service, described the changing role of the fire fighter.

I think that there may be, at least at some levels, some confusion about the applicability of the standard for fire fighters, and I think it's extremely important to re-emphasize again that, certainly in the time that I've been in the fire department, the nature of the job has changed dramatically in many ways, but the way it's changed the most is that we are now expected to be performing much more emergency medical service than we were before, and there's an incredibly high degree of integration that's occurring not only in urban areas but also in suburban areas, too.

I can also tell you that on a daily basis, some of us would be chagrined to admit to you that even though we consider ourselves to be fire fighters, that most of our calls are emergency medical calls. That's because in many municipalities we have tiered response where if an ambulance isn't available, the fire equipment is sent first since we are trained as emergency medical technicians. (Tr. 9/14/89, pp. 165–166)

Law enforcement officers and correctional officers may face a number of situations where there is occupational exposure to blood and other potentially infectious materials. In its publication "Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public Safety Workers" (Ex. 15), the CDC described some of these situations as follows:

Law enforcement and correctional facility officers may face the risk of exposure to blood during the conduct of their duties. For example, at the crime scene or during processing of suspects, law-enforcement officers may encounter blood-contaminated hypodermic needles or weapons, or be called upon to assist with body removal. Correctional officers may similarly be required to search prisoners or their cells for hypodermic needles or weapons, or subdue violent and combative inmates.

Law enforcement and correctional facility officers are exposed to a range of assaultive and disruptive behavior * * * Behaviors of particular concern are biting, attacks resulting in blood exposure, and attacks with sharp objects. Such behaviors may occur in a range of law-enforcement situations including arrests, routine interrogations, domestic disputes, and lockup operations * * * Hand-to-hand combat may result in bleeding and may thus incur a greater chance for blood-to-blood exposure * * * Criminal justice personnel have potential risk of acquiring HBV or HIV infection through exposures which occur during searches and evidence handling. Penetrating injuries are known to occur, and puncture wounds or needlesticks in particular pose a hazard during searches of persons, vehicles or cells and during evidence handling. (Ex.15 p.15–16)

The comment by the International Brotherhood of Police Officers listed a number of ways that occupational exposure may occur to law enforcement officers.

There are a variety of ways in which police potentially come in contact with blood-borne disease, the most dramatic of which is assaults by criminals wielding weapons. Frequently these criminals are drug users who are in one of the fastest growing populations of individuals infected by the AIDS and Hepatitis B virus. It is not uncommon for police officers to sustain cuts and abrasions in the course of these struggles and to come in contact with the criminal's blood and bodily products. Police are also at risk from needle sticks, while handling evidence samples and accident victims. (Ex. 20–1251)

Correctional Institutions: Many of the situations that place correctional officers at risk happen as the result of the violent behavior of the inmates, a group with a high prevalence of infection because of past and present high risk behavior. Studies of four prison populations in the U.S. revealed that approximately half of the prisoners had serological evidence of previous hepatitis B infection with 1.3% to 8.0% of the study population who were carriers (Ex. 8–132).

Mr. Jim Knapp, a correctional officer, testified to weapons made from silverware, razor blades, sharpened pencils, and pieces of steel and the inmates' use of needles and razors to tattoo other inmates. He and his coworkers have also found needles in searches for contraband, and they are often required to break up fights and then clean up the blood in the area (10/17/89 Tr. 71, 92). One witness, addressing himself to those who might be skeptical about whether correctional officers are exposed to blood, described the following incident that occurred two days earlier:

> People look at a correctional officer and say, "Well, you're not like a nurse. You're not like a health service [worker] or whatever. You don't have that much contact." Well, just to emphasize my point, Sunday morning I was working in my unit. We had a code call in the unit next door to us. I ran over. Here were two guys fighting over the phone. As I ran up to break them up, one of the guys threw a punch into the other guy's face and I had red splattered all over my eyeglasses. This was just Sunday. Luckily, I was wearing eyeglasses. (Mr. Glenn Rude 10/17/89 Tr. 81).

Not everyone agreed that public safety officers should be covered by the standard. Dr. Richard Vogt, testifying on behalf of the Council of State and Territorial Epidemiologists (CSTE), stated:

> [T]he initial rules should be confined to health care facilities, specifically health care providers * * * includ[ing] emergency medical technicians * * * [T]he risks of occupationally-related transmission of HIV and HBV to policemen, firemen and correctional facility personnel (also known as personal service workers) has never been demonstrated. (Ex. 132, p.3)

During questioning by the panel, Dr. Vogt disagreed with basing the scope of the standard on blood exposure but insisted that "actual data" be used.

OSHA must make the decision on whether or not to include employees on the basis of the best available evidence. These data, presented in both Section IV Health Effects and Section V: Quantitative Risk Assessment, demonstrate convincingly that it is blood exposure that is most closely correlated with risk of HBV. Furthermore, the likelihood of percutaneous exposure or exposure to mucous membranes further increases the risk. Clearly, these public safety officers not only have exposure to blood, but also have a risk for percutaneous exposures as described above. Therefore, the Agency concludes that they are at risk as the result of occupational exposure.

Ocean Lifeguards: Another group of employees, ocean lifeguards, were not included in the discussion of scope in the proposed standard and are added to this discussion of employees who have occupational exposure. OSHA was first made aware of the risks faced by ocean lifeguards in testimony by Mr. Ken Gunther representing a number of life saving associations and the Health Risk Duty Imperative of Ocean Lifeguards (HRDIOL) project. His testimony, first delivered at the Washington, D.C. hearings pointed to the occupational exposure to blood and other potentially infectious materials encountered by these employees (9/27/89 Tr. 300–313).

When OSHA held hearings in Miami, Florida on December 20, 1989, Mr. Gunther and 29 other lifeguards testified in detail as to the duties that place lifeguards at risk for blood exposure. Dr. Jim Dobbins, an epidemiologist, and a member of the Gulf Coast Region of the United States Life Saving Association, described the most common risk situations:

> In general, lifeguards are exposed in the course of their duties to blood and bloodborne pathogens in two ways. Contact exposure when both the victim and the lifeguard are cut in the process of a rescue near rocks and pilings in the water, and after the rescue during attempted resuscitation and stabilization of the victim. (12/20/89 Tr. 1211) These routine exposures are separate from the sort of incidents * * * that involve blood exposure through trauma and boating accidents, automobile crashes in the water or unusual injuries on the beach, or * * * plane crashes. (12/20/89 Tr. 1216)

Testimony from other lifeguards pointed out other conditions that injure swimmers or other beach patrons and require the assistance of the lifeguard, thereby resulting in occupational exposure to the lifeguard. Patrons suffer lacerations from rocks, shells, broken glass, fish hooks, or reefs (12/20/89 Tr.1298, Tr.1287, Tr.1234, Tr.1235, Tr.1284, Tr.1235, Tr.1305). Swimmers may be injured when the surf propels them into jetties, rock groins, piers, pilings covered with barnacles, or underwater rebars from demolished piers (12/20/89 Tr.1305, Tr. 1186, Tr.1192, Tr.1332, Tr.1357). Swimmers may be stung by a man-of-war or attacked by sharks, barracudas, blue fish or moray eels (12/20/89 Tr.1233, Tr. 1240, Tr. 1186, Tr. 1235, Tr.1236). Surfers may suffer head or body trauma or skeg cuts from surfboards (12/20/89 Tr.1229, Tr.1236, Tr. 1286). Fist fights and bottle fights are not uncommon (12/20/89 Tr. 1228, Tr.1236–1238), and motor vehicle accidents are a problem on beaches where vehicles are allowed (12/20/89 Tr.1185, Tr. 1295). Boating accidents are a common occurrence, and witnesses described several incidents that required the rescue of persons who had been run over by a boat with an outboard motor (12/20/89 Tr. 1251, Tr. 1307, Tr. 1340, Tr. 1285).

Other witnesses testified to rendering emergency medical assistance to swimmers who had been struck by lightning or shot with spear guns (12/20/89 Tr. 1245, Tr. 1295). One witness assisted in the care of an individual who had fallen to the beach from a hotel balcony (12/20/89 Tr.1187). Another witness described his attempt to rescue a terminally ill, despondent man who was attempting to commit suicide by drowning (12/20/89 Tr.1194). Several witnesses described their attempts to rescue pilots of planes that crashed just off shore (12/20/89 Tr. 1193, Tr. 1216–7, Tr.1246, 1295, 1336).

Some of the duties performed by these ocean lifeguards are similar to those performed by emergency medical technicians (EMTs) who are members of EMS, fire departments or rescue squads, and, indeed, many ocean lifeguards are EMTs and some are paramedics (12/20/89 Tr.1226,1233,1236,1290,1298). Unfortunately, these duties must be performed under hazardous or hostile conditions, in the water or in a boat and while wearing only a bathing suit. Despite the obstacles presented by a hostile environment and the difficulties associated with the use of protective clothing and equipment, OSHA believes that training, the hepatitis B vaccine, postexposure follow-up, and other provisions of the standard will reduce the likelihood of infection caused by occupational exposure to bloodborne pathogens.

OSHA has not attempted to list all of the operations/worksites and name all job classifications where occupational exposure may occur. The Agency anticipates that when the employer prepares the exposure determination required by paragraph (c) of the standard, the employer is likely to identify job classifications with occupational exposure in addition to those described above. Worksites in addition to those named above may also require that individuals employed there

perform duties that result in occupational exposure.

OSHA's conclusion is that employees who have reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of the employee's duties ("occupational exposure") are at risk of infection by bloodborne pathogens. This risk has been most thoroughly documented in healthcare workers employed in healthcare facilities such as hospitals; however, the risk is not confined to hospitals but is present whenever blood or other potentially infectious materials are present. Exposures do occur in worksites in addition to healthcare facilities and to employees who are not necessarily engaged in the direct delivery of healthcare (e.g. medical equipment repair). Therefore, the scope of the standard includes occupational activities that occur both in healthcare and non-healthcare facilities and in permanent and temporary work sites.

Examples of health care facilities include, but are not limited to: hospitals, clinics, dentists' and physicians' offices, blood banks and plasma centers, occupational health clinics, nursing (long term care) homes, hospices, urgent care centers, clinical laboratories, mortuaries and funeral homes, and institutions for the developmentally disabled. Examples of non-healthcare operations include, but are not limited to the service and repair of equipment, infectious waste disposal, virus research laboratories and production facilities, law enforcement and correctional institutions. In addition, examples of mobile (temporary) operations where there may be occupational exposure to blood and other potentially infectious materials includes mobile blood banks, crime scenes, and scenes of accidents or other trauma.

OSHA believes that under the scope of this standard each employee who has occupational exposure to blood or other potentially infectious material will be provided the necessary protection afforded by the proposed standard.

Paragraph (b) Definitions

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

"Blood" is defined in this standard as human whole blood; human blood components such as plasma or platelets; and human blood products such as clotting factors.

At least two commenters stated that some human blood products such as sterile human albumin or blood products manufactured using recombinant DNA technology do not present a risk and suggested the definition be amended. Both commenters offered alternative definitions for "blood." For example:

"Blood" means human blood, human blood components and products made from human blood. Exempt from this definition are those blood components and/or products that are sterile, approved by the FDA, or produced using recombinant DNA technology where the genetic construct meets the following criteria: a) the host organism is not regulated as a human pathogen under the U.S. Public Health Service [42 CFR Part 72] and b) the recombinant DNA does not code for a bloodborne pathogen or toxin therefrom (Mr. Richard D. Godown, Industrial Biotechnology Association, Ex. 20–289).

Blood means human blood, human blood components and products made from human blood that have not been treated to render bloodborne pathogens noninfectious. (Dr. Joseph Van Houten, Schering Laboratories, Ex. 20–543)

On the matter of the products of recombinant DNA technology, it is not the intention of the Agency to regulate under this standard the products of recombinant DNA technology absent blood or other potentially infectious materials. The only exception would be the use of the hepatitis B vaccine, a product of recombinant DNA technology.

OSHA is concerned that the words "treated to render bloodborne pathogens noninfectious" may present a problem because there is little or no information in the record that deals with such treatment. The standard does recognize that some blood and blood components and blood products present little or no occupational risk and an exception to the labeling requirement was made for these products. The exemption is found in paragraph (g)(1)(i)(F) which states:

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

"Bloodborne Pathogens" means pathogenic microorganisms that are present in human blood and that can infect and cause disease in persons who are exposed to blood containing these pathogens. The definition lists hepatitis B virus (HBV) and human immunodeficiency virus (HIV) as examples of such microorganisms.

Dr. Jeffery Squires and Mr. Andrew Montano requested that OSHA provide a specific list of bloodborne pathogens as part of the definition (Ex. 20–749; 20–1028). Section IV Health Effects includes a discussion of other diseases caused by bloodborne pathogens including hepatitis C, malaria, syphilis, babesiosis, brucellosis, leptospirosis, arboviral infections, relapsing fever, Creutzfeld-Jakob Disease, Human T-lymphotrophic virus Type I, and Viral Hemorrhagic Fever.

HBV and HIV are given as examples because they are the viruses of greatest interest and present the greatest risk. Adding additional examples to the definition would not improve the definition.

Another commenter suggested that the definition be modified to read "• • • microorganism and viruses • • •" because viruses are "not living creatures and the definition should include them." (Alpha Environmental Management, Ex. 20–115). It is true that viruses are not living cells. As a minimum, they are composed of nucleic acid protected by a protein or lipoprotein coat. As physical agents separated from a living host cell, they are incapable of reproducing or carrying on many of the functions that can be performed by bacteria and fungi. However, once they enter the cell they are capable of taking over the cellular machinery and reproducing themselves. The term "microorganism" is well understood to refer to viruses as well as bacteria and fungi (Ex. 6–74, p.7). In addition, the examples of HIV and HBV make the intention of the definition absolutely clear.

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

"Contaminated/Decontaminated" In the proposal, OSHA requested public comment on whether the terms "contaminated" and "decontaminated" needed to be defined. Of those who commented on this issue, a large number supported defining these terms, and several proposed definitions (CDC/NIOSH, Ex. 20–634; AHA, Ex. 20–353; Society of Hospital Epidemiologists, Ex. 20–1002; American Biological Safety Association, Ex. 241; Abbott Laboratories, Ex. 20–1227; American Society of Clinical Pathologists, Ex. 20–351; American Association of Blood Banks, Ex. 20–1059; American Association of Critical-Care Nurses, Ex. 20–1162; Baystate Medical Center, Ex. 20–22; Boone Hospital Center, Ex. 20–556; Connecticut Dept. of Labor, Ex. 20–157; Office of the Assistant Secretary for Defense, Ex. 20–847; Pharmaceutical Manufacturers, Ex. 20–729; South Carolina Dept. of Health and Environmental Control, Ex. 20–1160; State of Utah Dept. of Health, Ex. 20–605; Service Master Company, Ex. 20–21; Visiting Nurse Corporation, Ex. 20–1268). The problem anticipated by the Agency

was delineated clearly in the comment submitted by the Service Master Corporation which stated:

> The terms "contaminated" and "decontaminated" should be defined. While their definitions are understood by many healthcare personnel, there is still some misunderstanding. Even journal articles by healthcare professionals, e.g. physicians, have used the term "infected" for inanimate surfaces and water, where "contaminated" was the proper term to use. Likewise, the term "contaminated" has been used where "colonized" was the appropriate term. Such misunderstanding can be even more widespread outside the healthcare community. (Ex. 20-21)

The Agency carefully reviewed the definitions offered by the commenters. While no single criterion existed, many commenters urged OSHA to include some form of the concept of an infectious agent capable of causing disease. Several commenters recommended that contamination be defined on the basis of "visibility" of the contaminant (Abbott Laboratories, Ex. 20-1227; South Carolina Dept. of Health and Environmental Control, Ex. 20-1160; Visiting Nurse Corporation, Ex. 20-1268). While this approach would certainly cover some instances in which contamination was present, OSHA does not believe that being able to observe a contaminant on a surface is an adequate criteria for determining "contamination." Surfaces or items can be heavily contaminated by a substance (e.g., serum, plasma), yet show no readily observable signs of such contamination. Other suggested definitions of contamination employed criteria such as contact or exposure to blood or other potentially infectious materials (Connecticut Dept. of Labor, Ex. 20-157; American Society of Clinical Pathologists, Ex. 20-351); the ability of a material to produce or transmit an infectious disease in humans (Pharmaceutical Manufacturers Association, Ex. 20-729); the presence of microorganisms capable of producing disease in humans (Service Master Company, Ex. 20-21); the presence of a bloodborne pathogens of sufficient hazard and concentration on an item or surface to cause disease in persons exposed to the surface or item (American Biological Safety Association, Ex. 241); and the soiling with blood or other potentially infectious material (CDC/NIOSH, Ex. 20-634). All of these suggestions point to the concept that "contamination" should encompass the known or suspected presence of an infectious agent on a surface or item. OSHA agrees and therefore, the term "contamination" has been defined as the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

Since contamination is determined by the presence or reasonably anticipated presence of blood and other potentially infectious materials presumed to contain bloodborne pathogens, then it is reasonable to assume that "decontamination" represent the process of removing or inactivating these pathogens. (CDC/NIOSH, Ex. 20-634; American Biological Safety Association, Ex. 241; Service Master Company, Ex. 20-21). Therefore, OSHA is defining "decontamination," for the purposes of this standard, as the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is considered safe for handling, use, or disposal.

The term "contaminated laundry" was used in the proposed standard in the description of paragraph (d)(4)(iv) housekeeping, but no definition was provided for the term. The final standard contains a definition "contaminated laundry". This term is used to identify laundry which has been soiled with blood or other potentially infectious materials or may contain blood or other potentially infectious materials or may contain contaminated sharps.

Several commenters suggested the use of the word "soiled" to describe laundry which required special handling (Exs. 20-37; 20-108; 20-41,p.1; 20-1001). However, although "soiled" laundry would certainly include laundry that may contain blood or other potentially infectious materials or contaminated sharps, the term also describes items that are merely used or contain substances other than bloodborne pathogens, such as urine or feces. This standard applies only to bloodborne pathogens so in the absence of visible blood, this standard does not apply to urine and feces. Therefore, OSHA has concluded that "soiled laundry" is not specific enough for the purpose of the standard. The term "contaminated laundry" has been chosen to clarify OSHA's intent to differentiate linens which require special handling. Since "contaminated" has been defined to mean the presence or reasonably anticipated presence of blood or other potentially infectious material on an item or surface, nearly all laundry used in patient care can be considered contaminated. The potential presence of contaminated sharps in used laundry creates a unique hazard which emphasizes the need to handle certain laundry as contaminated.

"Contaminated Sharps" are defined in this standard as any object, contaminated with blood or other potentially infectious material, that is capable of penetrating the skin. The proposed standard defined "sharps", using examples of needles, scalpels and broken capillary tubes.

The Environmental Protection Agency (EPA), in its Standards for the Tracking and Management of Medical Waste; Interim Final Rule and Request for Comments defines sharps as follows:

> Sharps that have been used in animal or human patient care or treatment or in medical, research, or industrial laboratories, including hypodermic needles, syringes (with or without the attached needle), pasteur pipettes, scalpel blades, blood vials, test tubes, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). (Ex. 6-497)

Because EPA's definition would encompass a wider variety of sharps than OSHA intended to regulate with this standard, OSHA chose not to use EPA's definition. OSHA's goal, which is the reduction or elimination of occupational bloodborne infections, is different than that of the EPA, which is the regulation of medical waste, including unused medical waste. However, the need for additional explanation was recognized and OSHA's definition was amended in two ways.

First, the word "contaminated" has been added to the description of sharps to clarify that OSHA is concerned in this standard with the handling and discarding of only those sharps which have the presence or the reasonably anticipated presence of blood or other potentially infectious materials on them.

Second, examples of sharps are expanded to include not only needles and scalpels, but also broken glass and the exposed ends of dental wires.

There are a number of "sharps" that could cause injury to workers. Broken pieces of glass, particularly broken specimen tubes, such as capillary tubes, are hazardous. In dental settings, a unique hazard is the potential for injury from exposed ends of dental wires. When these sharps are contaminated, they can be the source of a parenteral exposure to blood and are, therefore, included as examples of "contaminated sharps" in the definition.

"Decontamination" is discussed above under "Contaminated/Decontaminated."

"Director" means the Director of the National Institute for Occupational Safety and Health, U.S. Department of

Health and Human Services, or designated representative.

"Engineering Controls" is defined as controls that isolate or remove a hazard from a workplace. Biosafety cabinets are examples of engineering controls since they not only remove contaminants through a local exhaust system but provide the added protection of confining the contaminant within an enclosed cabinet thereby isolating it from the worker. Other examples of engineering controls are sharps disposal containers which isolate contaminated needles or other sharps from employees.

Mr. Stanley Dub suggested that the definition of "Engineering Controls" should be changed to include controls "which substantially reduce the presence of the hazard in the workplace." (Ex. 20-516). He erroneously inferred that OSHA insists on "controls which completely isolate or remove the hazards." It is generally understood by the occupational health professionals, that engineering controls, such as local exhaust ventilation, remove air contaminants such as formaldehyde or ethylene oxide from occupational environment and thus reduce their concentrations in the workplace. This definition conveys the same principle. Therefore, the definition of "engineering controls" remains virtually unchanged for the purpose of this standard. The only modification is the addition of a few examples.

"Exposure Incident" means a specific exposure to the eye, mouth, other mucous membrane, non-intact skin, or parenteral exposure to blood or other potentially infectious materials that results from the performance of an employee's duties. Examples of an exposure incident include blood spattering into the eyes, splashing into the mouth or a puncture by a blood-contaminated needle.

As was pointed out by one commenter, the term "occupational exposure" has been used by others to describe the conditions that OSHA has labelled as an "exposure incident" (Klaman and Rao, Shadyside Hospital, Ex. 20-546). For the purpose of the standard, it is necessary to use one term, "occupational exposure," for reasonably anticipated exposure (which requires the implementation of protective measures) and another term, "exposure incident," for a discrete exposure event (which requires medical follow-up).

Although a small amount of blood on intact skin would not be considered an exposure incident under this definition, such an event should be a matter of concern to the employer. It may be an indication of inadequate personal protective clothing and equipment and the circumstances surrounding such events should be investigated to determine whether they can be prevented in the future.

"Handwashing Facilities" means a facility providing an adequate supply of running potable water, soap and single-use towels. The Agency anticipates that most employees will have access to a sink that can be used for handwashing. Clean paper towels, clean roller towels, or a hot air hand dryer may be used. In cases where the above described requirements are not feasible alternative methods are permitted. See discussion of paragraph (d)(2)(iv) below.

"HBV" means Hepatitis B virus.

"HIV" means human immunodeficiency virus.

"Licensed Healthcare Professional" means a person whose legally permitted scope of practice allows him or her to independently perform the activities required by paragraph (f) Hepatitis B Vaccination and Post-exposure Follow-up. Paragraph (f)(1)(ii)(C) requires that medical evaluations and procedures including the hepatitis B vaccine and post-exposure prophylaxis and follow-up are performed by or under the supervision of an appropriately trained and licensed healthcare professional. A definition for licensed healthcare professional has been added to the final standard because this term was not used in the proposed standard. The definition reads "a person whose legally permitted scope of practice allows him or her to independently perform the activities required by paragraph (f) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up."

Several commenters noted that a variety of healthcare professionals are capable of and, in fact, currently are administering the hepatitis B vaccine and post-exposure evaluation and follow-up to employees as required in the standard (e.g., Tr. 9/20/89, pp. 29,31; Ex. 20-1222; Ex. 20-141). The final standard requires that the persons delivering care to employees are appropriately trained and licensed to carry out the activities required by section (f) of the standard. These services include activities such as providing Hepatitis B vaccine, ordering appropriate laboratory tests, determining contraindications to vaccination, providing post-exposure prophylaxis and counseling. The legal scope of practice for this professional must allow the independent performance of all the procedures described in paragraph (f) hepatitis B vaccination and post-exposure evaluation and follow-up.

A variety of healthcare professionals may perform these functions. For example, in addition to licensed physicians, the majority of states have laws that enable advanced practitioners in nursing to provide medical services independently. Nurse practitioners and clinical nurse specialists are registered nurses prepared through a formal, organized education program and certified for an advanced practice role. This group of registered nurses provides primary healthcare that includes traditional medical services as well as nursing care.

A more complete discussion of this portion of the standard can be found in the Summary and Explanation of paragraph (f)(1)(ii)(C).

"Occupational Exposure" is one of the key terms upon which the standard rests. It contains the criteria which trigger application of the final standard.

The definition reads:

> 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.

Actual contact would be expected during an autopsy or surgery. In these cases, blood or other potentially infectious materials come in direct contact with the employee's gloves or other protective clothing. In other cases, contact may not occur each time the task or procedure is performed, but when blood or other potentially infectious materials are an integral part of the activity, it is reasonable to anticipate that contact may result. Examples of such tasks are phlebotomy and changing a surgical dressing.

The occupational exposure must be reasonably anticipated. For example, the employer would reasonably anticipate that contact with blood or other potentially infectious materials would occur when an employee is performing certain surgical, medical, dental, or laboratory procedures. On the other hand, the employer would not reasonably anticipate that contact with blood and other potentially infectious materials would occur when an employee is driving a bus down the highway or is processing insurance claims in an office setting.

In addition to being reasonably anticipated, the contact must result from the performance of an employee's duties. An example of a contact with blood and other potentially infectious materials that would not be considered to be an "occupational exposure" would be a "Good Samaritan" act. For example, one employee may assist

another employee who has a nosebleed or who is bleeding as the result of a fall. This would not be considered an occupational exposure unless the employee who provides assistance is a member of a first aid team or is otherwise expected to render medical assistance as one of his or her duties.

One commenter questioned whether "Good Samaritan" acts should be excluded from the standard and listed a number of reasons why one worker might come to the aid of another even though it was not part of their duty to do so (Ms. Ruth Christos, S.C. Dept. of Health and Environmental Control, Ex. 20–1160). Since accidents and unexpected illness can occur in any workplace, exposure to blood is a theoretical possibility in all working environments. Many worksites have employees whose duty is to provide first aid or medical assistance, and employers must provide them with the protection of the standard. However, OSHA has concluded that it would be needlessly burdensome to require that all employers, including those where none of the employees has duties that can reasonably be expected to result in contact with blood and other potentially infectious materials, implement the provisions of the standard based on the chance that an employee will have contact with blood and other potentially infectious materials while performing a task that he or she is not required to do.

The definition of "occupational exposure" that appeared in the proposed standard included a second sentence:

> The 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 (54 FR 23134)

A number of commenters found this second sentence confusing, contradictory or redundant. (Mr. V.J. Vincent, Boeing Support Services, Ex. 20–1150; Grady Memorial Hospital (Ohio), Ex. 20–834, Mrs. Ann Marie Witherow, Clearfield Hospital, Ex. 20–900; Dr. Carol Rice, MidWest Consortium for Hazardous Waste Worker Training, Ex. 20–892; AFSCME, Ex. 297). The terms "incidental exposure", "reasonably [expected]" and "routinely expected" were not defined. For instance, it was not clear whether the Agency intended to cover exposures that were not routine in nature. In addition, there was no guidance as to what constituted an incidental exposure or as to who would determine when one had occurred. "Incidental" can mean likely to happen or incurred casually in addition to the normal amount. For example, the State of Maryland Division of Labor and Industry submitted information indicating that certain funeral home operators among other employers believed that their exposures were incidental and therefore would not be covered by the standard (Ex. 20–1362). As discussed in "Scope," some funeral home employees can be expected to have occupational exposure.

Moreover, it was not clear whether "reasonably anticipated" from the first sentence meant the same as "reasonably expected" in the second sentence. Some commenters found the language contradictory in that there might be situations where the exposures are incidental or infrequent yet reasonably anticipated due to the nature of the employee's duties and thus, not excluded from coverage. Finally, some commenters pointed out that the language used in the second sentence was redundant in that the first sentence already defined occupational exposure as exposures to blood or other potentially infectious materials that may result from the performance of an employee's duties. Because the term "employee's duties" implies the performance of duties that are part of the employee's job description, the second sentence adds nothing by stating that exposure incidents not incurred by a worker in the normal course of his or her employment are not considered occupational.

In attempting to convey the idea that exposures, such as the "Good Samaritan" act described above, are not considered "occupational exposures" for the purposes of this standard, the wording of the definition in the proposal was confusing. Therefore, the Agency has concluded that the second sentence should be deleted.

The purpose of this standard is to prevent bloodborne infections by eliminating or reducing occupational exposure. In order to achieve this goal, it is necessary to know where and how such exposure can occur and who will be performing those tasks and procedures. In an ideal situation, no employee would ever have skin, eye, mucous membrane, or parenteral contact with blood and other potentially infectious materials. A definition of occupational exposure that was limited to events in which not only an exposure incident occurs but also occurs each time the task is performed, would not achieve the goal of the standard.

Despite the explanation in the proposal, some commenters interpreted the words "reasonably anticipated" to mean that contact with blood or other potentially infectious materials would have to occur each time the task was performed in order to be considered occupational exposure. For example:

> Furthermore, the AABB maintains that, in the performance of a phlebotomist's duties in bleeding a normal blood donor, it is not reasonably anticipated that the phlebotomist will have skin or other contact with blood. It is the exception, not the rule, that the phlebotomist will have skin or other contact with blood. (AABB, Ex. 20–1059)

In order for employees to be protected from actual exposures, protective measures must be instituted before the blood or other potentially infectious materials come in contact with the person. OSHA has concluded that the words "reasonably anticipated" give the employer clear guidance in determining which of his or her employees are covered under the standard. It is necessary for the employer to know who is potentially exposed so that the employer can assure that proper training, engineering and work practice controls, personal protective equipment and the other provisions of the standard are implemented. This requires that the employer examine the tasks and procedures and determine if it can be reasonably anticipated that exposure may occur. For example, it is reasonable to anticipate that when a needle is inserted into a vein for the purpose of withdrawing blood that some of the blood may contact the gloved or ungloved fingers of the phlebotomist. Such contact would not necessarily be expected to occur with each phlebotomy.

"Other Potentially Infectious Materials" consists of three primary categories of material which have the potential to transmit bloodborne pathogens. OSHA has used the term "potentially" to acknowledge that body fluids and tissues may or may not contain bloodborne pathogens. However, the provisions of the standard must be followed in any case. Under this definition, OSHA has included the body fluids specified by the CDC in their June 1988 update of guidelines for healthcare workers (Ex. 6–316). The fluids covered by this definition are: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, amniotic fluid, saliva in dental procedures, and any other body fluid that is visibly contaminated with blood. In support of utilizing universal precautions when contacting these body fluids, CDC stated:

> Universal precautions also apply to tissues and to the following fluids: cerebrospinal fluid (CSF), synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid. The risk of transmission of HIV and HBV from these fluids is unknown;

epidemiologic studies in the health-care and community setting are currently inadequate to assess the potential risk to health-care workers from occupational exposures to them. However, HIV has been isolated from CSF, synovial, and amniotic fluid , and HbsAg has been detected in synovial fluid, amniotic fluid and peritoneal fluid. One case of HIV transmission was reported after a percutaneous exposure to bloody pleural fluid obtained by needle aspiration. Whereas aseptic procedures used to obtain these fluids for diagnostic or therapeutic purposes protect health-care workers from skin exposures, they cannot prevent penetrating injuries due to contaminated needles or other sharp instruments. (Ex. 6-316)

Commenters generally agreed with using the CDC list. However, a number expressed the opinion that the focus should be on blood rather than other body fluids. Some representatives of the dental profession wondered why OSHA singled out saliva in dental procedures. For example:

[W]hy is saliva singled out in "dental procedures"? If saliva is to be considered a potentially infectious material only in dental procedures, then the diversity of dental procedures must be addressed. The paragraph could be changed to read: "saliva visibly contaminated with blood" and thereby eliminate an apparent inconsistency with the public view regarding the infectiousness of saliva. (Federation of Prosthodontic Organizations, Ex. 20-232)

While universal precautions do not generally apply to saliva, exception is made in the case of saliva in dentistry. Addressing this situation, the CDC states:

Special precautions, however, are recommended for dentistry. Occupationally acquired infection with HBV in dental workers has been documented, and two possible cases of occupationally acquired HIV infection involving dentists have been reported. During dental procedures, contamination of saliva with blood is predictable, trauma to health-care workers' hands is common, and blood spattering may occur. Infection control precautions for dentistry minimize the potential for nonintact skin and mucous membrane contact of dental health-care workers to blood-contaminated saliva of patients. (Ex. 6-316)

OSHA has concluded that the CDC guidelines of June 1988 provide the best guidance for determining which body fluids are included in the definition for other potentially infectious materials, and we have adopted that list.

The Agency requested comments as to whether other body fluids should be added to the list of other potentially infectious materials. With the exception of those commenters who encouraged OSHA to expand the standard beyond bloodborne pathogens, most commenters agreed that body fluids such as urine and feces should not be added to the list unless they were visibly contaminated with blood (For example, Hospital Assn. of N.Y., Ex. 20-381; Ms. Mary Wilson, Central Florida APIC, Ex. 20-57; South Seminole Community Hospital, Ex. 20-251).

Hoffman-LaRoche requested a clarification as to whether materials which have been obtained from donors that have undergone a prescreening process would qualify as "other potentially infectious materials" (Ex. 20-291). None of the body fluids listed would be exempted because the donor has been prescreened. However, after the blood has been tested and is available for transfusion or other clinical use, then it is exempted from the labelling requirements in paragraph (g).

CDC's guidelines for public safety officers state that when it is difficult or impossible to differentiate between body fluids all body fluids should be treated as if they are potentially hazardous (Ex. 15).

The unpredictable and emergent nature of exposures encountered by emergency and public-safety workers may make differentiation between hazardous body fluids and those which are not hazardous very difficult and often impossible. For example, poor lighting may limit the worker's ability to detect visible blood in vomitus or feces. Therefore, *when emergency medical and public-safety workers encounter body fluids under uncontrolled, emergency circumstances in which differentiation between fluid types is difficult, if not impossible, they should treat all body fluids as potentially hazardous.* (Emphasis in the original) (Ex. 15)

After reviewing the comments in the record on this issue, the Agency concluded that such a provision is needed in the standard. The definition of other potentially infectious materials has, therefore, been modified. The Agency also addresses this situation in Methods of Compliance, paragraph (d)(1).

The second category of other potentially infectious materials is "any unfixed tissue or organs (other than intact skin) from a human (living or dead)." These pose a risk because they may be contaminated with bloodborne pathogens. One example of a tissue is human bone which has transmitted HIV infection as the result of transplantation (Ex. 6-357). In the same document, CDC also notes reported transmission of HIV through "transplantation of kidney, liver, heart, pancreas, possibly by skin, and by artificial insemination. * * *"

Although tissues and organs may contain blood and body fluids, which may be the reason for the transmission hazard, they are not in reality "fluids". Therefore, to avoid confusion OSHA has listed them as a separate category. Since casual contact, including touching, does not pose a risk of transmission, intact skin is not considered to be "other potentially infectious materials."

CDC/NIOSH stated that the parenthetical words "other than intact skin" and "living or dead" should be deleted because they are superfluous (CDC/NIOSH, Ex. 20-634). OSHA agrees that, normally, one would want a simple definition without parenthetical elements. However, to avoid misinterpretation, the Agency has chosen to retain the parenthetical elements so that the meaning is clear.

The third group under "other potentially infectious materials" relates to the culture and propagation of HIV and HBV in laboratory cultures and experimental animals. This group contains HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV. This definition applies particularly to research activities and to production activities where concentrations of virus can be expected to exceed the concentration found in blood. Section IV—Health Effects discusses in detail the infection of two workers that resulted from occupational exposure to high concentrations of HIV virus in a production facility.

AFSCME, District Council 37 suggested that animal blood be included (Ex. 20-985). The current definition includes the blood of animals experimentally infected with HIV or HBV. It would not normally include the blood from companion animals (pets), other domestic animals, animals in zoos or research animals not infected with HIV or HBV. The record does not contain the information necessary to determine whether animal blood in these circumstances presents a significant occupational risk.

"Parenteral" refers to piercing the skin barrier (including mucous membranes), and the definition in the final standard is basically unchanged from the proposal; that is, parenteral refers to piercing the skin barrier. This route of transmission presents the greatest hazard to the employee (Ex. 6-430; 6-449). There was little comment on this definition during the comment period.

In the proposed rule, the definition of parenteral included examples of routes of parenteral exposure (e.g. subcutaneous, intramuscular, intravenous). In the final standard, examples of parenteral exposure are described again, but events rather than

routes are used as examples. Needlesticks are an easily identified example of an event in which "parenteral" exposure may occur.

Human bites are another example of a parenteral exposure event. There is evidence in the record that individuals have been infected with HBV as the result of a human bite, and it is reasonable to expect that some workers will be bitten (Ex. 6-316). For example, law enforcement and correctional officers may be subject to human bites during interaction with violent suspects or prisoners. Human bites also occur in the emergency room or psychiatric setting with patients who are violent or psychotic. In these instances, due to the violent nature of the occurrences, bleeding from the mouth (gums, teeth or soft tissue) of the source individual can be anticipated, exposing the worker to blood from the source individual. For these reasons, human bites have been included as examples of parenteral exposures. However, not all bites that occur in a workplace would be considered occupational exposure. For example, if two coworkers fight in the workplace, and one bites the other, this is not occupational exposure for either of these workers since neither is expected to incur bites as part of his or her job. Moreover, elementary and high school teachers, particularly those whose students do not include the developmentally disabled or mentally ill, would not reasonably anticipate being bitten as part of the performance of their duties.

Cuts and abrasions also represent examples of interruption in the skin barrier and another route of entry for bloodborne pathogens. Since exposure to non-intact skin is included as an "exposure incident", cuts and abrasions are listed here as examples of a "parenteral" route.

"Personal Protective Equipment" is specialized clothing or equipment worn by an individual to protect him or her from a hazard. For the purposes of this standard, this term includes, but is not limited to, clothing and equipment such as (a) gloves; (b) gowns, aprons, laboratory coats; (c) faceshields, protective eyewear and masks; and (d) mouthpieces, resuscitation bags, or other ventilation devices. General work clothes (e.g., uniforms, pants, shirts and blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment. A more detailed discussion concerning general work clothes and personal protective equipment can be found under the discussion of paragraph (d)(3)(i).

OSHA received one comment which suggested that the definition of the personal protective equipment should include clothing "placed on the patients" (Mr. Stanley Dub, Ex. 20-516). The example used by the commenter was a dental dam which is an example of an engineering control rather than personal protective equipment and would be covered under that definition.

"Production Facility" is defined as a facility engaged in industrial-scale, large-volume or high concentration production of HIV or HBV. The 1988 Agent Summary Statement for Human Immunodeficiency Virus was the source for this term (Ex. 6-312).

"Regulated Waste" was called "Infectious Waste" in the proposal. "Infectious Waste" was defined as blood and blood products, contaminated sharps, pathological wastes, and microbiological wastes. In this final standard, the analogous term "regulated waste" has been defined as: (1) Liquid or semi-liquid blood or other potentially infectious materials; (2) contaminated items that would release with blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; (3) items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; (4) contaminated sharps; and (5) pathological and microbiological wastes containing blood or other potentially infectious materials. Based upon the collected information, OSHA has concluded that these items are generally recognized as presenting a hazard of disease transmission and as such, warrant special handling.

During the hearings, CDC/NIOSH testified:

> The categories of items that we consider as potentially infectious and that should be handled in a special manner include microbiological waste, bulk blood or body fluid, contaminated blood, sharps or pathological waste, materials that contain those particular items would be defined by the CDC as infectious waste. (Ms. Polder—CDC/NIOSH, Tr. 9/14/89, p. 54)

CDC explains their position further in their written comment, stating:

> • • • As a related point of information, CDC considers it important to use the CDC definition of infectious waste, which has been adopted by OSHA in this proposed rule, in preference to the definition of medical waste adopted by EPA and used in the Medical Waste Tracking Act. The CDC definition is based on the epidemiology of disease transmission, whereas other definitions are much broader and include articles that should not require special handling. (CDC/NIOSH, Ex. 20-634)

With regard to EPA and their definition of wastes requiring special handling, some commenters expressed opinions similar to CDC and discouraged adoption of EPA's Medical Waste Tracking Act (MWTA) definition (e.g., APIC—Indiana, Ex. 20-139; McLeod Regional Medical Center, Ex. 20-527; Meadville Medical Center Ex. 20-624). However, other participants recommended that the MWTA definition be incorporated into the final standard (e.g. ADA, Ex. 20-665; Support Systems International, Ex. 20-1149). On a more general level, comments were also received which simply encouraged OSHA to assure that the final regulation's definition of "infectious waste" does not conflict with EPA's definition (e.g., AHA, Ex. 20-352; Tucson Medical Center, Ex. 20-141; Hospital of St. Raphael, Ex. 20-289).

In their comment on the proposal, EPA states:

> The proposed OSHA definition appears to be fairly consistent with the wastestreams EPA regulates in 40 CFR part 259, if the term "microbiological wastes" corresponds to Class 1 wastes in 40 CFR 259.30(a)(1) ("Cultures and stocks of infectious agents • • •"). EPA's rules also may cover a broader range of wastes, but generally do not refer to them as "infectious wastes" due to the wastes' widely varying infective capability. (EPA, Ex. 20-991)

Reviewing 40 CFR part 259 reveals that microbiological wastes, as OSHA has defined them in this final regulation, would fall under Class 1 since the presence of blood or other potentially infectious materials is, under universal precautions, assumed to indicate the presence of a disease-causing bloodborne pathogen. EPA goes on to remark that their rules may cover a broader range of wastes. OSHA does not feel that this presents a conflict of definitions since the wastes regulated under this rule are a subset of those regulated by EPA. The Agency has concluded that the wastes covered under this standard warrant special handling and are in accordance with both CDC and EPA definitions. Therefore, these categories of waste have been retained in this regulation with modifications adopted in response to public comment.

Several participants commented on the ability of medical waste to transmit disease (e.g., Good Samaritan Hospital, Ex. 20-1230; Anaheim Medical Center, Ex. 20-45; Lewis-Gale Hospital, Ex. 20-871). In conjunction with this, a number of commenters raised the issue of the necessity of regulating the handling of certain components of the medical wastestream such as blood-stained

bandages which could fall under the proposed definition but which they felt posed no threat of disease transmission (e.g., Palomar Pomerado Hospital, Ex. 20–1260; Rowan Memorial Hospital, Ex. 20–629; Community Hospital of Chula Vista, Ex. 20–761). Reviewing the record, it was noted that very little information is available on the potential for contracting disease as a result of contacting medical waste. The primary basis for comments that medical waste is no more infectious than household waste seems to be several German studies conducted in the early to mid–1980's comparing bacterial load of hospital wastes which are usually collected daiiy with that of household waste that was up to 7–days old (Exs. 286C; 286T; 286W). The Agency does not intend to debate the merits of these studies and has not conducted original research in this area. Hence, OSHA cannot offer a more definitive determination of the "infectiousness" of these materials. To eliminate the implication that OSHA has determined the "infectiousness" of certain medical wastes, the aforementioned waste categories have been grouped under the term "Regulated Waste" rather than "Infectious Waste." Non-sharp waste, such as bandages, can be contaminated with widely varying amounts of blood or other potentially infectious materials, ranging from a single drop to complete saturation. The proposal contained no specific reference to how blood-contaminated non-sharp waste was to be differentiated and handled but simply stated that blood and blood products were to be treated as infectious waste. During the informal public hearings, the Agency solicited information from participants regarding what criteria were currently being utilized to determine which of these types of wastes were treated as "infectious" and which wastes were placed into the general waste stream. Responses to this inquiry were widely divergent, ranging from considering only blood-saturated items as infectious waste (Nassau-Suffolk Hospital Council, Inc., Tr. 11/14/89, pp.466–467) to "red-bagging" all items contaminated with blood or body fluids (Baptist Medical Center Montclair, Tr. 9/19/89, p.98; Laura Williams—SEIU, Tr. 10/17/89, pp.66–67). In addition, several interested parties requested that OSHA clarify what wastes were encompassed by the phrase "blood and blood products" (e.g., Greater New York Hospital Association, Tr. 11/14/89, p.316; APIC-Greater Los Angeles, Ex. 20–213). It became obvious to the Agency that no generally-accepted criteria was being applied by those involved to classify which blood-contaminated non-sharp waste required special handling. Therefore, an easy-to-use, acceptable minimal benchmark would have to be developed to assure consistent compliance and enforcement in this area. A number of commenters offered suggestions as to what this benchmark should be. The majority of commenters who considered this issue suggested that only bulk blood be considered infectious waste (e.g., AHA, Ex. 20–352; Middle Tennessee Medical Center Inc., Ex. 20–105; Arizona Hospital Association, Ex. 20–69). The difficulty with this approach is that there is little agreement on how much blood constitutes "bulk blood." Some commenters recommended actual volume amounts of blood ranging from greater than 10 ml to more than 100 ml of blood (e.g., Kalispell Regional Hospital, Ex. 20–1212; Virginia Mason Hospital, Ex. 20–569; Providence Memorial Hospital, Ex. 20–744). The Agency has concluded that such a determination would be difficult to judge since the visual characteristics of a specific quantity of blood would vary based on the type and size of substrate on which it appeared. For example, 10 ml of blood on a bed sheet would appear as a spot while the same amount on a cotton ball would likely cause saturation and dripping. Suggestions offered by other participants included bulk blood and items heavily saturated with blood or which drip and splash (e.g., Redlands Community Hospital, Ex. 20–692; Mills-Peninsula Hospitals, Ex. 20–701; St. Anthony Hospital Systems, Ex. 20–221); waste heavily contaminated with blood (Cleveland Clinic Foundation, Ex. 20–563); blood soaked items—not blood stained items (e.g., Nassau-Suffolk Hospital Council, Inc, Tr. 11/14/89, p. 46); only bulk amounts of liquid or semi-liquid blood (i.e. pourable or ability to flow), excluding dried blood (e.g., APIC—Indiana, Ex. 20–139; APIC—Greater Omaha, Ex.20–943); and blood that readily separates from the solid portion of waste under ambient temperature and pressure (Paradise Valley Hospital, Ex. 20–217). The record indicates that a large number of commenters feel that bulk blood should be classified as infectious waste. Moreover, "bulk" blood seems to be generally associated with the ability to pour or flow. During the hearings, Ms. Polder of the CDC stated:

> • • • [I]n terms of blood, we really feel that the only type of blood that you need to be concerned about, in terms of transmission of disease, is bulk blood, or bulk fluids that may contain blood which means essentially liquids • • •. In terms of items that are contaminated with blood that may be dry or may be wet, but are contained in a material such as gauze or a bandage, the risk of transmission of a pathogen to a susceptible host is extremely unlikely, and therefore, that type of waste can be handled like any other waste that is collected in the community, that may be contaminated in the same fashion. (Tr. 9/14/89, p.92)

Consequently, this physical characteristic (i.e., the ability to pour, flow, drip, etc.) has been adopted as one of the attributes of waste being regulated under this standard.

Comments such as those submitted by APIC—Greater Omaha Area and Paradise Valley Hospital make it apparent that in some circumstances solid waste is capable of generating bulk (i.e. liquid or semi-liquid) blood (Exs. 20–943; 20–217). While an item which is freely dripping blood or other potentially infectious materials obviously falls into this category, some items may adequately contain these materials when in a static state yet liberate them when compressed. During accumulation of waste in a container, the weight of items toward the top of the container naturally compress those items beneath. Wastes may also be purposefully compacted in order to increase the amount of waste which can be placed into a single container. This compression could generate potentially infectious liquids which would then accumulate at the bottom of the container. If the container's barrier capability is compromised, these materials would be released, presenting an exposure and/or contamination hazard. An EPA guidance document addressing EPA's Medical Waste Tracking Act states:

> • • • Only those fibrous items that are completely saturated with blood (or would drip with blood if squeezed), or non-fibrous items that have enough blood present that they are dripping, are regulated medical waste • • •. (Ex. 224, Attachment A)

Both the EPA document and the statement by Ms. Polder of the CDC indicate that blood or other potentially infectious materials which are contained in non-sharp contaminated waste, such as bandages, do not become a concern until these liquids are liberated from the substrate. The ability of the substrate to contain these substances is the deciding factor as to their proper handling and disposal. OSHA has therefore concluded that items contaminated with blood or other potentially infectious materials which would release these substances in a liquid or semi-liquid state if compressed should be considered regulated waste.

Dried blood or other potentially infectious materials could also pose a

problem if these dried materials are released from a contaminated item during handling. A study by Bond et. al. (Ex. 20–634) showed hepatitis B virus could remain viable in dried material for up to seven days. Furthermore, CDC recognizes the potential for disease transmission by dried blood. In their 1989 document, Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers, CDC recommends to law enforcement personnel:

> Airborne particles of dried blood may be generated when a stain is scraped. It is recommended that protective masks and eyewear or face shields be worn by laboratory or evidence technicians when removing blood stain for laboratory analysis. (Ex. 15)

Based on this prolonged viability and potential for infection, items that are heavily contaminated or "caked" with dried blood or other potentially infectious materials have been included in those situations where such dried materials could flake or fall off of the item during handling.

In summary, the category "blood and blood products" contained in the proposal has been more specifically delineated in the final standard to read: (1) Liquid or semi-liquid blood or other potentially infectious materials; (2) items contaminated with blood or other potentially infectious materials which would release these substances in a liquid or semi-liquid state if compressed; and (3) items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling. This expansion and clarification provides easily-recognized criteria for determining OSHA's intent as to those wastes it considers, at a minimum, to require special handling.

Very little comment was received about the remaining three categories of (infectious) regulated waste. Marion Memorial Hospital appeared to be referring to sharps that have not been contaminated by bloodborne pathogens when they stated that many sharps are utilized in hospitals that are never exposed to a patient (Ex. 20–1269). In consideration of those circumstances in which contamination of a sharp by bloodborne pathogens is known not to exist, the term "sharps" has been revised to "contaminated sharps" in the final standard to clarify that, for the purposes of this standard, sharps which are contaminated with blood or other potentially infectious materials are the items with which OSHA is concerned. However, it should be noted that other local, State, and Federal agencies (e.g., EPA) may have more expansive regulations regarding sharps and their disposal based upon factors such as transmission of diseases other than bloodborne diseases, aesthetic concerns, or the physical puncture hazard of sharps in general.

As to the categories "pathological waste" and "microbiological waste," Boone Hospital Center requested a clarification on which pathological wastes are considered infectious while the State of Connecticut, Office of Policy and Management, commented that some microbiological wastes will not present a hazard to humans (Exs. 20–556; 20–796). These issues have been addressed by adding that it is those pathological and microbiological wastes "containing blood or other potentially infectious materials" which are regulated by this standard. Again, one should be aware that other agencies may have more stringent and inclusive regulations concerning these wastes.

"Research Laboratory" is defined as a facility engaged in activities such as producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in production facilities.

While Abbott Laboratories found the requirements for research and production facilities appropriate, they raised a question about the definition of "research laboratory." Specifically they said:

> We do find the use of the term "research laboratory" confusing since there are research laboratories where only clinical specimens are handled, and clinical or diagnostic laboratories where virus propagation for the purpose of diagnosis takes place (Abbott, Ex. 20–127).

Because the standard must address a number of different workplaces and activities, it has been necessary to define certain umbrella terms, such as "source individual" (see discussion below), "production facility" and "research facility". A "research facility is a facility that produces or uses concentrated virus, that is, virus in higher concentrations than would be found in human blood and body fluids. OSHA's intention in this matter is to parallel the intent of CDC/NIH quoted above.

On the second issue raised by Abbott, OSHA recognizes that there are laboratories that conduct research on blood and other body fluids and this research is unrelated to research on HIV or HBV. These laboratories are not considered research laboratories for the purpose of this standard. They would not be required to comply with paragraph (e), but would have to comply with all of the other provisions of the standard which are applicable.

"Source Individual" means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. This term includes a wide spectrum of people when one considers both the need for universal precautions and the multitude of healthcare and nonhealthcare settings in which occupational exposure may occur. Examples of such individuals include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of nursing homes or hospices; human remains; individuals who donate or sell blood or blood components.

In the proposed standard, human remains prior to embalming was one example of a source individual or patient. In the final standard, the words "prior to embalming" were deleted because there is no evidence in the record that demonstrates when or if embalming inactivates HIV or HBV.

Individuals who donate or sell blood or blood components includes individuals who donate or sell plasma, a blood component.

The Agency was sharply criticized for defining blood donors as "patients" in the proposal (Ms. Joan Elise Dubinsky, ARC, Ex. 20–784; Dr. Laurence A. Sherman, AABB, Ex. 20–1059; Mr. James P. Reilly, ABRA, Ex. 20–1090). However, none of the representatives of these groups was able to suggest an alternate term. As it became clear, the objections of many of the representatives of blood and plasma banks industry go beyond the use of the term, "patient." They want blood and plasma donors to be removed from the list entirely (Dr. Paul Holland, AABB, Tr. 10/20/89 pp. 768–775). As we discussed in "Scope," the Agency does not plan to exclude certain sectors, such as blood banks and nursing homes, because they provide services for individuals who are not at high risk for HIV and HBV infection. We do, however, agree that a more descriptive term than "patient" should be used. Therefore, we looked to the CDC for a more appropriate term.

In their recommendations, CDC has used several terms to refer to the individual whose blood or body fluids are a source of occupational exposure to the employee. In their August 1987 guidelines, they used the word "patient" (Ex. 6–153). In the more recent

documents, they have used the terms "source individual" (Ex. 286 J) and "source of exposure" (Ex. 286 G).

OSHA has chosen to use the term "source individual" because it provides the best description without the limiting qualities inherent in the word "patient." It is clear that any human can be a "source individual."

"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.

In their 1987 document, "Recommendations for the Prevention of HIV Transmission in Health-Care Settings," CDC states:

> Since medical history and examination cannot reliably identify all patients infected with HIV or other bloodborne pathogens, blood and body-fluid precautions should be consistently used for *all* patients. This approach, previously recommended by CDC and referred to as "universal blood and body-fluid precautions" or "universal precautions" should be used in the care of *all* patients, especially including those in emergency-care settings in which the risk of blood exposure is increased and the infection status of the patient is usually unknown (Ex. 6-153).

In their 1988 "Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings," CDC reiterates this concept in the statement:

> Under universal precautions, blood and certain body fluids of all patients are considered potentially infectious for human immunodeficiency virus (HIV), hepatitis B virus (HBV), and other bloodborne pathogens (Ex. 6-316).

The public safety worker guidelines issued by the Centers for Disease Control in 1988 extend the use of universal precautions to all body fluids in certain situations. These guidelines state:

> [W]hen emergency medical and public-safety workers encounter body fluids under uncontrolled, emergency circumstances in which differentiation between fluid types is difficult, if not impossible, they should treat all body fluids as potentially hazardous (Ex. 15).

While the final standard's definition of universal precautions does not include this extension, it has been incorporated and discussed in the definition of "other potentially infectious materials" and in paragraph (d)(1) of the Methods of Compliance section of this document.

OSHA's definition of universal precautions in the proposed standard is perfectly consistent with the CDC's statements. A number of the comments relating to the proposal's definition of universal precautions appear to relate not to the definition *per se* but are directed to the Agency's proposed methods of implementing this infection control concept contained in paragraph (d) of the proposal. Based upon a careful review of the aforementioned CDC documents, OSHA has concluded that the proposed definition of "Universal Precautions" is correct and should be retained without modification. Therefore, the final regulation defines "Universal Precautions" as a method of infection control in which all human blood and certain body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

"Work Practice Controls" are controls that reduce the likelihood of exposure by altering the manner in which a task is performed. As they relate to this standard, examples of some work practice controls include: (1) Adherence to the practice of universal precautions in all situations of occupational exposure; (2) prohibiting the recapping of needles or other sharps by a two-handed technique; and (3) prohibition of pipetting or suctioning by mouth. To give an example of a workplace control, the words "e.g. prohibiting recapping of needles by hand" was incorporated in the definition. In each of these examples of work practice controls, the possibility for exposure to blood, or other potentially infectious materials has been eliminated or minimized simply by alteration of the way in which the employee performs the task.

Paragraph (c) Exposure Control

Employees incur risk each time they are exposed to bloodborne pathogens. Any exposure incident may result in infection and subsequent illness. Since it is possible to become infected from a single exposure incident, exposure incidents must be prevented whenever possible. It is the goal of this standard to reduce a significant risk of infection by minimizing or eliminating occupational exposure to blood and other potentially infectious materials, providing the hepatitis B vaccine, and post exposure medical follow-up. The purpose of paragraph (c), Exposure Control, is to identify those tasks and procedures where occupational exposure may occur and to identify the positions whose duties include those tasks and procedures identified with occupational exposure.

In the proposed standard, paragraph (c) was entitled "Infection Control." However, the Agency has been reminded that the term "infection control" is typically used in health care to mean control of nosocomial infections, the aim of which is to prevent the transmission of pathogens to the client/patient by the employee (from cross-contamination).

> Throughout the standard the term infection control is used. Although this is accurate to a point, it implies that the plan implementation is under the aegis of the Infection Control Department. However, infection control personnel traditionally are concerned with patient care. Their teaching with employees is done with the emphasis on providing safe patient care; that is, protecting the patient, not the health care worker, from the potential hazards of medical care. (American Association of Occupational Health Nurses, 9/20/89, TR, pg. 7-37 and 7-38).

In addition, comments in the record regarding usage of the terms "infection control plan" and "infection control" indicated that these terms do not translate easily to settings other than hospitals (Abbott Laboratories, Ex. 20-1227; Health Industry Manufacturers Association (HIMA), Ex. 20-795), and may not be understood by workers in occupations outside of the health care industry (Pharmaceutical Manufacturers Association, Ex. 20-729).

Though the principles of controlling infection may be similar to those involved with controlling employee exposure, the focus of this standard is on protecting the employee from occupational exposure to bloodborne pathogens. Therefore, in order to most effectively express the intent of this standard, the Agency believes that a clarification of these terms is necessary. Since it is OSHA's intent to control or minimize occupational exposure, the title of paragraph (c) of the final standard is "Exposure Control", and paragraph (c)(1) is titled "Exposure Control Plan".

The Exposure Control Plan required by paragraph (c)(1) is a key provision of the standard because it requires the employer to identify the individuals who will receive the training, protective equipment, vaccination, and other provisions of this standard.

The American Association of Dental Schools (AADS) supported the proposed requirement that employers establish a Plan (Ex. 20-878). In addition, the Austin Area Infection Control Council supported the preparation and use of a Plan as a means of documenting current standards and operating procedures (Ex.

20–982). Some commenters suggested that employees should be encouraged to be involved with developing Plan policies (American Dental Hygienists Association, Ex. 20–256). However, this is not a requirement in the final standard.

Paragraph (c)(1)(i) of the final standard requires that the exposure control plan be written. The need for a written plan was supported by testimony at the public hearings.

It is only reasonable that the efforts to identify the population at-risk and the methods to reduce that risk be published within the facility so that employees will know what provisions are in place at their work establishments. A written, periodically reviewed, infection control plan is key to the proposed standard. (Elise Yiasemides, 9/13/89, TR, pg. II–42).

The reasons for having a written Plan are threefold. First, because exposure control must be practiced by everyone—employee and employer—it is imperative that employees be able to find out what provisions are in place in his or her workplace. According to testimony from NIOSH, having the Plan in writing,

• • • would serve as an on-site adjunct to the overall infection control plan, would reinforce educational programs, and should be used in mandated training programs. (NIOSH, 9/14/89, TR, III–27 & 28).

Secondly, that the Plan be in writing is also important for enforcement. By reviewing the Plan, the OSHA Compliance Officer will be able to become familiar with the employer's determination of tasks and procedures with occupational exposure, the job classifications whose duties include those identified tasks, and the implementation and revisions to the Exposure Control Plan. In addition, Paragraph (g)(2)(vii)(D) requires that the Exposure Control Plan be explained as part of the employee training program.

According to the record, many commenters were not opposed to the idea of having a written Plan, but rather, they objected to writing a whole new Plan, especially when similar plans already exist. Many commenters suggested incorporating the Exposure Control Plan into existing infection control plans currently in place (Frankfort Hospital, Ex. 20–211; Casa Colina Hospital for Rehabilitative Medicine, Ex. 20–284).

The Society of Hospital Epidemiologists of America commented that,

The requirement to establish "a written infection control plan" seems to imply that all applicable policies must be incorporated into a new, separate document. However, hospitals already have comprehensive Infection Control manuals which typically include many or all of the provisions required by OSHA (Ex. 20–1002).

The Veterans Administration requested that OSHA allow employers to integrate the intent of this standard into existing documents. Examples of existing documents that could be used are job descriptions, performance criteria, procedure manuals, and departmental guidelines in infection control manuals (Ex. 20–43).

The Wisconsin Association of Nursing Homes objected to the "intrusion upon systems that have already proven effective" and suggested that OSHA have some mechanism whereby existing plans could be evaluated for their effectiveness. Otherwise, they contend OSHA is essentially requiring that facilities go to the expense of reformulating infection control plans solely for the purpose of complying with a rule and not for the purpose of prevention of disease transmission (Wisconsin Association of Nursing Homes, Ex. 20–255).

The Pharmaceutical Manufacturers Association commented that OSHA should specifically allow the Plan required by the standard to be a component of a larger, overall plan. They said that establishing a separate plan would be burdensome and potentially confusing to personnel (Ex. 20–729).

It is not OSHA's intent for employers to duplicate current policies, however, if the Exposure Control Plan is incorporated into existing manuals, all requirements of the regulation must be followed. Dr. Hardin of NIOSH stated in his testimony that,

• • • compliance with this rule should be approached as a part of the larger program to control all health and safety hazards in health care and public-safety workplaces. When such plans exist, it would be an unnecessary and wasteful use of resources to develop independent plans, policies and procedures solely to administer the requirements of this rule. When they already exist, infection control plans, health and safety programs, training programs, and the like should be reviewed and modified as necessary to ensure that all of the requirements of this rule are addressed as an integral part of those more comprehensive plans. (NIOSH, 9/14/89, TR, pg. III–28 and 29, Ex. 13).

Therefore, the final standard requires a written Exposure Control Plan, but does not prohibit the plan from being part of a larger document. Paragraph (c)(1)(i) reads: "Each employer having an employee(s) with occupational exposure shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure."

The content of the Exposure Control Plan is stated in paragraph (c)(1)(ii) of the final standard which reads: "The Exposure Control Plan shall contain at least the following elements:

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

(B) The schedule and method of implementation for paragraphs (d) Methods of Compliance, (e) HIV and HBV Research Laboratories and production Facilities, (f) Hepatitis B Vaccination and Post Exposure Followup, (g) Communication of Hazards to Employees, and (h) Recordkeeping, of this standard, and

(C) The procedure for the evaluation of circumstances surrounding exposure incidents.

In the Final Rule, as in the proposal, the Plan must contain the exposure determination as described in paragraph (c)(2) of this standard. Exposure determination is a key element of the Plan. The rationale and support for the exposure determination is discussed under paragraph (c)(2).

In addition to the exposure determination, the Plan must include an explanation of when and how the employer will implement the other provisions of the standard in a manner appropriate to the circumstances in the employer's workplace. In the proposed standard, OSHA stated that an annotated copy of the final standard would be sufficient to meet the requirement for the Exposure Control Plan to state when and how the employer will implement the provisions of the standard. The requirement is in performance language, so that each employer can structure the plan to cover the circumstances in the employer's workplace.

Comment from the College of American Pathologists supported that "an annotated copy of the final standard would be sufficient to meet the requirements" for paragraph (c)(1)(ii)(B) (College of American Pathologists, Ex. L20–1688A).

Testimony from OSHA expert witness Elise Yiasemides indicated that an annotated copy of the final standard would be adequate for most small facilities. Larger facilities could develop a broad facility-wide program incorporating provisions from the OSHA standard that apply to their establishments (9/13/89, TR, pg II–41, Ex. 28).

In the final standard, the Exposure Control Plan also requires the employer to state the procedure for evaluation of exposure incidents. This requirement

was not included in the proposed rule. According to testimony by NIOSH:

> The Infection Control Plan needs to be expanded to include requirements for * * * evaluation of the circumstances of exposure incidents and significant failures of control procedures to determine whether changes in policies or practices are needed to prevent recurrences of similar incidents. * * * Formal, systematic protocols should be established to evaluate all exposure incidents and other failures of controls so that any contributory deficiencies in institutional policies and procedures can be identified and corrected (NIOSH, 9/14/89, TR, III-27 and III-28).

The need for a procedure to evaluate exposure incidents was also supported by AFSCME (Ex. 297) and SEIU (Ex. 299).

The procedure for evaluating the circumstances surrounding exposure incidents required by paragraph (c)(1)(ii)(C), could include the following elements: an evaluation of the policies and "failures of control" at the time of the exposure incident; the engineering controls in place at the time of the exposure incident; and, the work practices and protective equipment or clothing used at the time of the exposure incident. The goal of this evaluation is to identify and correct problems in order to prevent recurrence of similar incidents.

Other additional elements were suggested by commenters to be included in the plan. The University of Cincinnati Medical Center suggested that the Plan include a critique of emergency situations and follow-up, in addition to including initial and annual training, and Plan revision (Ex. 20-648). The Retail, Wholesale & Department Store Union contributed that the Plan must be a written site-and-task specific document and must include: the name of the designated employee, types of engineering controls in place, the personal protective equipment necessary for each task, and the standard operating procedures for that department and task (Retail, Wholesale & Department Store Union, AFL-CIO, Ex. L20-1505). In addition, the American Federation of State, County & Municipal Employees, AFL-CIO, commented that employers should designate someone to be responsible for carrying out the Plan during all working hours, and that there should be some minimal qualifications for the person or persons so designated (Ex. 20-685). Although not included in the final rule as elements of the Exposure Control Plan, many of these considerations are included elsewhere in the overall requirements of the rule (i.e., requirements for training, PPE, and maintenance of controls).

In addition to having a written Plan, paragraph (c)(1)(iii) requires that the Exposure Control Plan be accessible to the employee. The reason for this requirement is to assure that the employee can access and consult the Plan at any time. Testimony from the American Federation of State, County and Municipal Employees (AFSCME) suggested that all employees should have access to the Plan and that a single person responsible for the Plan should be designated within each facility (AFSCME, 9/15/89, TR, pg. 4-80.) The Service Employees International Union AFL-CIO commented that access to the Plan encourages workers to develop a complete understanding of the Plan and its application, assuring that the program is carried out by everyone—both employer and employee (Ex. 20-979). The Retail, Wholesale and Department Store Union commented that a copy of the Plan must be available in a central location on each floor of each facility covered by this standard so that employees may have access to the protocols when necessary (Ex. L20-1505). According to testimony offered by NIOSH, having the Plan available serves as an on-site adjunct to the overall infection control program and may reinforce educational and training programs (NIOSH, 9/14/89, TR, pg. III-27 and III-28).

OSHA agrees with the value of access that the commenters have stated, however, it does not wish take away from the flexibility or performance approach to compliance. As several commenters have suggested, and as discussed above, depending on the size and organization of a particular facility, elements of the Plan may be incorporated into existing overall infection control policies currently in place or the Plan may become a completely new and separate document. It is, however, OSHA's intention that while not dictating the specific form of the documentation comprising the Plan that it be in some manner a cohesive entity by itself or that a guiding document exist that states the overall policy goals and references elements of existing separate policies that comprise the plan. The "location" of the plan may also be adapted to the circumstances of a each particular workplace provided that the employee can access a copy of the plan at the workplace, during the workshift. For example, if the plan is maintained on a computer, access to the computer or hardcopy must be available to the employee. Likewise, if the Plan is comprised of several separate policy documents, copies of all documents must be accessible in addition to any general policy statement or guiding document that may exist.

Therefore, a new paragraph has been added to the final standard to assure employees that a written Exposure Control Plan, or a copy of the Plan, is accessible for employee use. Paragraph (c)(1)(iii) of the final standard reads: "Each employer shall assure that a copy of the Plan is accessible to employees."

Paragraph (c)(1)(iv) requires that the Plan be reviewed and updated periodically to reflect significant modifications in tasks or procedures. The purpose of this requirement is to assure that all new tasks and procedures are evaluated in order to determine whether they will result in occupational exposure. Testimony from NIOSH stated that the,

> * * * Plan needs to be expanded to include requirements for periodic review * * * to ensure that it remains current with the latest workplace practices and scientific knowledge pertaining to the bloodborne pathogens (NIOSH, 9/14/89, TR, III-27 and III-28).

It is also important that new and revised job classifications be included in this review and are added to the lists of job classifications and tasks and procedures identified in (c)(2)(i) of this standard.

Several comments in the record suggested that a specific period of time for such review and update be identified.

> Plans must be reevaluated, rewritten and updated at least every six months to reflect the current status of the program and any changes in the methods of compliance. The Plan must be flexible and reflect new information as it becomes available (Retail, Wholesale and Department Store Union AFL-CIO, Ex. L20-1505).

Some commenters suggested that the Exposure Control Plan should be reviewed at least annually, and updated as necessary (Tennessee Health Care Association, Ex. L20-1205; University of Cincinnati Medical Center, Ex. 20-648).

The American Hospital Association recommended that the Plan be reviewed biennially in light of new prevailing standards of infection control, and revised where significant changes in infection control procedures have been identified as effective (AHA, Ex. 20-352). The American Federation of Teachers (AFT) suggested that the Plan, its review and revisions be developed with a bargaining agent or designated representative of employees having occupational exposure. In addition, the AFT stated that OSHA should require that the review and updating process take place at least annually, or as needed (Ex. 20-257).

Because of the rapidly developing information and technology related to

the prevention of occupational illness due to bloodborne pathogens, OSHA believes that it is reasonable to require that the Plan be updated and reviewed at least annually. However, if there is a significant change, for example, if a medical center plans to open an HIV research laboratory where none existed before, then the Exposure Control Plan would need to be amended so that employees in those Job Classifications performing those tasks and procedures with occupational exposure are included in the Plan. Therefore, paragraph (c)(1)(iv) in the final standard reads:

> The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee job classifications with occupational exposure.

OSHA proposed that the Plan be made available to the Assistant Secretary and Director for examination and copying. The justification for this requirement is to allow the OSHA representative to review an employer's Plan and become familiar with the exposure determination that places employees at risk for occupational exposure. It was suggested by some commenters that this requirement be deleted because documents are already inspected regularly by JCAHO, AHA, and other regulatory organizations with greater medical experience than OSHA (Good Samaritan Hospital, Ex. 20–373). However, in this requirement, it is OSHA's intention that an authorized OSHA Representative may request to examine or to have a copy of an employer's Exposure Control Plan. For example, a Compliance Safety and Health Officer may request to see an employer's Plan, or to have a copy of the Plan, during the course of a workplace inspection. By examining the Plan, the Compliance Officer can conduct an inspection with the employer's procedures and program planning for the control of occupational exposures in mind. In such a situation, the employer must make the Plan available to the OSHA Representative upon his/her request.

To clarify this section of the proposal, the final standard incorporates this intent. Paragraph (c)(1)(v) in the final standard reads: "The Exposure Control Plan shall be made available to the Assistant Secretary and the Director upon request for examination and copying."

Paragraph (c)(2) of the standard requires the employer to perform an exposure determination. As stated in the proposal, the employer must know which tasks or procedures involve occupational exposure in order to determine what measures can be taken to eliminate or minimize exposure incidents. The Agency proposed that the standard require each employer having employees with occupational exposure to perform an exposure determination to identify and document the tasks and procedures where occupational exposure occurs, and to identify and document the job classifications whose duties include performing those tasks and procedures. This is necessary in order to assure that the employees who hold these job classifications are included in the training programs, are provided with personal protective equipment, are provided with post-exposure follow-up where appropriate, are included in the HBV vaccination program, and receive all other protection afforded by this standard.

Considerable comment was received regarding the requirements of listing all tasks and procedures, and OSHA has concluded that a more flexible approach to exposure determination and documentation can be allowed in the final standard. Comments generally indicated objection to listing individual tasks and procedures and suggested that broader categories of tasks and procedures or job classifications be used to identify employees at risk. OSHA has incorporated both of these recommendations in the final rule.

The American Hospital Association (AHA) indicated that developing this plan may be a monumental administrative burden if a detailed listing of all tasks is required for each job.

> • • • as a basis for the plan, employers should be permitted to use either broad categories of tasks or positions to determine which employees are at risk of exposure. This will permit the employer to identify who needs personal protective equipment and training to reduce risk. Most importantly, it will eliminate the administrative burden of documenting thousands of tasks and procedures, and constantly updating the list (AHA, Ex. 20–352).

Other commenters concurred with the AHA position that categories of responsibilities would be less of an administrative burden and at the same time provide adequate safety awareness (Montana Deaconess Medical Center, Ex. 20–380).

The Association for Practitioners in Infection Control (APIC) stated that the creation and maintenance of lists will not prevent injuries, needlesticks, or body fluid exposures, but will create paperwork (APIC, Ex. 20–55). Other commenters stated that identifying every task and procedure with occupational exposure would be an unreasonable burden (Tri-County Area Hospital District, Ex. 20–63; Augusta Hospital Corporation, Ex. 20–66; Leesburg Regional Medical Center, Ex. 20–67; Memorial Medical Center, Ex. 20–1111; Jefferson Park Hospital, Ex. 20–111A). The American Nurses' Association (ANA) recommended that OSHA clarify the extent to which tasks and procedures should be identified and documented (ANA, Ex. 20–953).

A number of other commenters also suggested that employers be allowed to group tasks into "broad categories" or "classify responsibilities". For example, the American Association of Blood Banks (AABB) stated that,

> The Association recognizes that employers need to assess which positions, tasks, and procedures involve occupational exposure so that the affected employees can be provided with the appropriate training, protective equipment and HBV vaccinations. However, the Association is concerned that the exposure determination and infection control plan as proposed simply places a massive administrative burden and additional unnecessary paperwork on its member blood banks.
>
> To identify and document for each position every task and procedure "where occupational exposures may take place" is a monumental undertaking. The Association recommends that OSHA allow for grouping or classifying responsibilities when conducting the exposure determination (AABB, Ex. 20–1059).

In addition, it was suggested by some commenters that if the purpose is to identify all employees who may have occupational exposure, that purpose can be accomplished without listing every task and procedure for every position (HIMA, Ex. 20–795; Abbott Laboratories, Ex. 20–1227). Another commenter stated that since precautions will be similar, many of the tasks could be categorized rather than listed separately (McGehee-Desha County Hospital, Ex. 20–58).

The Communications Workers of America, AFL–CIO, however, commented that although some employers have cited undue administrative burden as the reason for their opposition, this is not a compelling argument since employer personnel offices usually have written job classifications which include descriptions of employee duties which would aid employers in this process (Communications Workers of America, AFL–CIO, Ex. 20–273). In addition, some health care facilities commented that they have existing documents and manuals which already identify tasks and procedures with occupational exposure. (Norwood Hospital Ex 20–273; APIC TR 10–18; Mariana Memorial

Hospital 20–1269; Frick Community Health Care 20–292)

Many commenters suggested that job positions would be preferable to identify personnel at risk, and thereby eliminate the need for task identification (Veterans Administration, Ex. 20–635; Frankfort Hospital, Ex. 20–211; Pharmaceutical Manufacturers Association, Ex. 20–729).

Health care worker exposure determinations more readily lend themselves to categorization by duty title or job function. These categories already exist in healthcare. Utilizing an existing determination scheme will expedite the implementation of the standard. (APIC, Ex. 20–1118).

Some comments suggested that the exposure determination should be based on location; that is, employees working in "places where patients obtain care" (University of California, San Diego Medical Center, Ex. 20–156). However, another commenter disagreed with basing the plan on categories such as the "Emergency Room", because exposure is related to responsibility, not location. (Montana Deaconess Medical Center, Ex. 20–380).

Other comments regarding identification of job classifications with occupational exposure indicated similar concerns to those comments regarding task identification; that it would be an administrative burden (APIC, Middle Tennessee Chapter, Ex. 20–55; Casa Colina Hospital for Rehabilitative Medicine, Ex. 20–284).

Another approach suggested by NIOSH was that the exposure determination identify and document individual employees with occupational exposure (rather than using job titles).

It is not enough to simply identify those "positions" in which occupational exposures occur. It is essential to identify each individual who performs duties in which exposure to blood or other potentially infectious material can be reasonably anticipated. (NIOSH, Ex. 20–634).

OSHA has considered these suggestions and believes that grouping job classification according to location would not be sufficient to meet the requirement for task identification or for position identification with occupational exposure. For example, determining exposure by assignment to the "Emergency Department" does not identify the employee positions or the tasks that have occupational exposure. In addition, assignment to a "Patient Care Area" does not identify those tasks, procedures, or positions with occupational exposure. Also, this type of categorization excludes employees who may have occupational exposure, but hold a position outside of the patient care area, such as a laboratory technician or laundry worker.

On the other hand, OSHA believes that the listing of every employee's name would be burdensome for many employers. In addition, maintaining such a list of names would be time consuming for facilities with large number of employees and for those facilities where staff turnover is high. Furthermore, the identification of each employee's name would not sufficiently identify the job classifications whose duties include occupational exposure.

The Agency believes that the evidence supports allowing employers to identify and document those job classifications where employees have occupational exposure as basis of the required exposure determination. The employer, therefore, is not required by the final standard to list all tasks and procedures as originally proposed. OSHA does however, intend for employers to consider the duties, tasks, and procedures of all employees in each job classification, in each work area, in making the exposure determination. All personnel who hold positions determined to have occupational exposure are entitled to the protection of this standard.

Existing job titles and job descriptions could be used to identify the job classifications in which occupational exposure may occur. By identifying those job classifications with occupational exposure, the employer can then identify those employees who are entitled to the provisions of this standard.

It should be noted that in the proposed rule, OSHA used the term "position(s)" with reference to identification and documentation of employees at risk in the exposure determination. Other terms such as "Job Category", "Job Responsibility", "Job Function", "Job Title", "Job Description", "Position Description", and others, have also been used by commenters with reference to this identification. In the Final Standard, OSHA has chosen to use the term "Job Classification" because it has the broadest application to facilities both large and small and with both formal and nonformal designations of employment. Use of the term "Job Classification(s)" is not intended to alter the meaning, intent, or implications of previous comments or context of discussion by OSHA in terms of "Position(s)" or other similar terms.

The primary component of the exposure determination in the final rule is stated in paragraph (c)(2)(i)(A) which requires "A list of any job classifications in which all employees in those job classifications have occupational exposure;". For example, if a hospital determines that all employees within the job classification of "Nurse" have duties or responsibilities to perform tasks and procedures where occupational exposure occurs, the job classification of "Nurse" shall be listed in the exposure determination in accordance with paragraph (c)(i)(A) and subsequent listing of those tasks and procedures is not required with respect to exposure of "Nurse[s]".

Similarly in a small dental office, it is likely that the job classifications of "Dentist", "Dental Hygienist", and "Clinical Dental Assistant" would be identified in accordance with paragraph (c)(2)(i)(A) as job classifications in which all employees so designated have occupational exposure. It may be further determined that employees in other job classifications have duties that may occasionally require them to perform some tasks and procedures where occupational exposure occurs. If other employees, such as those classified as receptionist, bookkeepers, or office managers, for instance, assist at times in operative dental procedures, handle potentially contaminated impressions in the laboratories, or assist in cleaning the operatories or disposal of regulated waste, then those job classifications would be listed along with "Dentist", "Dental Hygienist", and "Dental Assistant" in accordance with paragraph (c)(2)(i)(A). If however, the employer determines that all employees in any job classifications clearly have no occupational exposure, then those job classifications need not be listed. For example, if the receptionist, the bookkeeper or the office manager do not have occupational exposure then the job classifications would not have to be listed.

If the employer determines that listing a particular job classification is not sufficiently specific to identify exposed employees, the employer may also, or instead, list the job classifications in which any (some, but not all) employees in those job classifications have occupational exposure and then clarify the exposures within those job classifications by listing the tasks and procedures or groups of closely related tasks and procedures associated with exposure for those job classifications.

This requirement is stated in paragraphs (2)(c)(i) (B) and (C) which state that the exposure determination shall also include:

(B) A list of all job classifications in which some employees have occupational exposure, and

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

For example, within a funeral home there are typically several employees classified as "Funeral Director[s]". Same, but not all, employees classified as funeral director may perform embalming, removals, or other tasks and procedures where occupational exposure occurs, whereas, other employees classified as "Funeral Directors" may have specific duties limited to making funeral arrangements or conducting services where occupational exposure does not occur. In this case, the job classification "Funeral Director" would be listed in accordance with paragraph (c)(2)(i)(B) and the tasks and procedures which place some, but all, "Funeral Directors" at risk would be listed in accordance with paragraph (c)(2)(i)(C).

Similarly, within a hospital Central Services and Supply Unit all Central Services Technicians may not have contact with potentially contaminated materials. For example some Central Services Technicians may have specific limited duties handling and distributing items after they are processed and sterilized and some Central Services Technicians may have specific duties where occupational exposure occurs such as decontaminating reusable instruments prior to sterilization. In this example, Central Services Technicians would be listed in the exposure determination in accordance with paragraph (c)(2)(i)(B) and those tasks and procedures which place some Central Services Technicians at risk for occupational exposure would be listed in accordance with paragraph (c)(2)(1)(c).

The final standard allows the exposure determination to be based primarily on list of job classifications. OSHA expects that some employers may, however, choose to list all tasks and procedures for all job classification identified. The employer will however, only be required to list tasks and procedures or groups of closely related tasks and procedures where necessary to identify certain employees within a job classification where some but not all, employees have occupational exposure.

In these cases where it is necessary to list certain tasks and procedures to identify exposed employees within a particular job classification, OSHA believes grouping of closely related tasks and procedures to be an effective and feasible method as suggested by several commenters (AHA 20–353; Bayshore Medical Center, 20–160; Hospital Employee Health, 20–627; Kaiser Permanente, 20–559). It is essential, however, that the tasks and procedures that are grouped must be related; that is, they must share a common activity. For example, tasks such as starting or discontinuing IV's, performing phlebotomy, accessing arteries, inserting central lines, could be grouped into the broad category of "vascular access procedures". Other examples might include tasks such as washing, cleaning, removing, disassembling, decontaminating, and disposing of contaminated, used needles, wires, knives, scalpels, blades, and razors which could be grouped into the broad task of "handling of contaminated sharps". Tasks such as *post mortem* removal or disposal of tubes, Ivs, and contaminated dressings; removal or disposal of contaminated clothing; collection of contaminated evidence; removing, lifting, transporting (carrying) and assisting with bleeding (bloody) post mortem bodies could be grouped into the broad task of "handling of deceased persons and their belongings".

In October 1987, the Departments of Labor and Health and Human Services issued a Joint Advisory Notice (52 FR 41818). One purpose of this document was to provide some additional guidance to employers to assist them in identifying employees at risk for occupational exposure. It suggested three categories of tasks that employees may perform. One of the difficulties with this approach has been the tendency to confuse the categorization of tasks with the categorization of employees or job classification. This sometimes results in ranking exposed employees with the result that some individuals are classified as being at greater risk than others. The purpose of paragraph (c) is not to determine whether one individual is at greater or lesser risk, but it is to identify all those employees who have occupational exposure and who are covered by the standard.

OSHA proposed that the standard require the exposure determination be made without taking into consideration the use of personal protective clothing or equipment. The reason for this is that several conditions must be met for personal protective equipment to effectively lessen exposures. First, the employee must be trained to use the equipment properly. Second, the personal protective equipment must be used each time the task is performed. Third, the equipment must fit properly and be appropriate for the task. Fourth, it must be free of physical flaws that could compromise safety. If even one of these conditions is not fully met, protection cannot be assured. For example, if blood covered gloves are not removed correctly, the hands may become contaminated. If utility gloves are torn or cracked, they will not provide protection. Therefore, all tasks that entail occupational exposure need to be included in the exposure determination, regardless of the personal protective equipment used, so that the workers who perform such tasks will receive training, HBV vaccination, and other provisions of this standard that will enhance their safety. Therefore, paragraph (c)(2)(ii) in the final standard reflects this and reads, "This exposure determination shall be made without regard to the use of personal protective equipment."

Paragraph (d) Methods of Compliance

Engineering and Work Practice Controls

Paragraph (d)(1) of the final standard states that universal precautions shall be observed to prevent contact with blood and/or other potentially infectious materials. It further requires that under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.

Several significant changes have been made in this provision in response to additional information submitted to the record. First, the exemption to the use of universal precautions has been moved to paragraph (d)(3)(ii), Personal Protective Equipment—Use. As stated in the proposal's Summary and Explanation, pages 23114–23116, it was the Agency's intent that this exemption apply only to the use of personal protective equipment and was not intended to provide an excuse for non-adherence to the overall concept of universal precautions. Universal precautions, as noted above in the definition, is a method of preventing disease by preventing transfer of blood and certain body fluids. Universal precautions' underlying concept is that all blood and certain other body fluids are considered to be infectious for bloodborne pathogens. In most situations, an employee will treat all blood and certain body fluids as though they contained bloodborne pathogens and would accomplish this through a variety of measures. In rare instances, such as unexpected medical emergencies, employees may not be able to put on gloves, don a gown, or tie a face mask immediately. In those

situations where some leeway must be accorded the provider of healthcare or safety services, the employees must not ignore the underlying concept of universal precautions (i.e., all blood and certain body fluids are to be considered to be infectious) nor should he or she decline to use any personal protective equipment simply because it is not practicable to use all the equipment appropriate to the task. To exempt an employee from universal precautions would subject the employee to needless risks in that some of the personal protective equipment can be donned.

OSHA requested comment on whether it was more appropriate to include this exemption under the section dealing with personal protective equipment in order to make the limitations of the exemption more clear. Numerous commenters raised concerns that, as written, the proposed exemption was too broad due to the use of vague terms such as "interfere with" and "proper delivery". More importantly, NIOSH/CDC pointed out that OSHA should state clearly that the exemption only covers the use of "personal protective equipment" (PPE) (Tr. 9/14/89, p. 31–2). NIOSH/CDC reiterated this concept in its post-hearing comment:

> The exception provided in this proposal applies not to the general concept of universal precautions, but to the use of personal protective equipment under rare and relatively limited circumstances. These circumstances and the exception to mandatory use of protective devices would be better addressed, in paragraph (d)(3) under a new subparagraph (ii) dealing specifically with the use of personal protective equipment. (Ex. 20–634).

Many other commenters supported this change. Service Employee International stated:

> SEIU recognizes that there are extraordinary circumstances where workers can't use protective equipment. However, the proposed standard would define those situations broadly as those that would interfere with the proper delivery of services, opening up a large loophole.
>
> SEIU recommends limiting the exemption to personal protective equipment and only if the worker determines that these precautions would prevent the proper delivery of health care or public safety services in extraordinary situations. Enforcing universal precautions and ensuring the availability of personal protective equipment must be the employer's responsibility. (Tr. 9/15/90, p.7).

OSHA's expert witness, Jolanda Janczewski, commented:

> Under paragraph (d) (1), OSHA proposes what appears to be an exemption to the use of universal precautions. However, in the summary and explanation section on page 32115, OSHA clearly states that the exemption refers to the use of personal protective equipment and not to the actual concept of universal precautions. In no way do I believe that OSHA should intend for the proposed regulation to provide an excuse for complete non-adherence to this very important principle of infection control.
>
> Only under extraordinary circumstances that are unexpected should employees have the option of deciding not to use personal protective equipment if they feel that such equipment will prevent the proper delivery of healthcare or public safety services or will create a greater hazard to their personal safety if they did not use such equipment. I agree with OSHA's statement in the preamble that the decision not to use personal protective equipment is to be made by the employee on a case-by-case basis and must be prompted by truly extenuating circumstances.
>
> The exemption should be rewritten to apply only to the use of personal protective equipment. The provision also should be narrowly constructed and be placed under section (d)(3) which deals with personal protective equipment so that there will be no confusion over when it is to be used. (Tr. 9/12/89, p. 46–7).

The American Federation of State, County and Municipal Employees also opposed the idea of having an exemption to universal precautions and supported the idea of moving the exemption to the personal protective equipment section. It specifically stated:

> Public safety workers, such as fire fighters, emergency medical techs, are always present in emergency situations. By writing a specific exemption into the standard, OSHA is in essence inviting employers and employees to find and use extenuating circumstances as a justification for not following universal precautions.
>
> In the event that OSHA decides that an explicit exemption is nevertheless necessary, AFSCME suggests that it be moved to the section under personal protective equipment, and I quote "The employer shall assure that the employee uses appropriate PPE unless doing so in a specific unexpected instance would in the professional judgment of the employee threaten the life or safety of the patient or worker or prevent the proper delivery of public safety services. Such exemptions shall be limited in extent and time, and shall not limit the employer's responsibility to comply with all other paragraphs of the section, nor should allow the employer under any circumstances to discourage employees from adhering to universal precautions." (Tr. 9/15/90, p. 83).

In addition, AFSCME stated:

> A final note on the subject of universal health care or public safety services in a particular circumstance.
>
> As defined by the Centers for Disease Control, universal precautions is an approach by which blood and body fluids from all patients are treated as if they are potentially infectious for blood-borne pathogens.
>
> Even if there is an extreme situation where it is totally impossible to use a particular preventive measure, the overall approach of using universal precautions and using those precautions that can be implemented should never be suspended. The language of the exemption as presently stated could be interpreted in a number of ways that are not in accordance with OSHA's intent for this section, as explained in the preamble which states that the exemption will serve as an exemption for the use of personal protective equipment in appropriate cases and is not intended to provide an excuse for complete non-adherence to the overall concept of universal precautions. (Tr. 11/14/89, p. 453).

OSHA agrees with NIOSH/CDC and the commenters who suggested that the exemption should only cover the use of personal protective equipment. Accordingly, the Agency has moved the exemption to paragraph (d)(3)(ii) which addresses the use of personal protective equipment.

The second modification of this provision is the addition of the requirement that all body fluids be considered potentially infectious materials in those circumstances where body fluid types are difficult or impossible to differentiate. In their June 23, 1989, document, "Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public Safety Workers," the Centers for Disease Control state:

> The unpredictable and emergent nature of exposures encountered by emergency and public-safety workers may make differentiation between hazardous body fluids and those which are not hazardous very difficult and often impossible. For example, poor lighting may limit the worker's ability to detect visible blood in vomitus or feces. Therefore, *when emergency medical and public-safety workers encounter body fluids under uncontrolled, emergency circumstances in which differentiation between fluid types is difficult, if not impossible, they should treat all body fluids as potentially hazardous.* (Ex. 15)

This exposure control approach was supported by the American Federation of State, County, and Municipal Employees (Tr. 11/14/89, pp. 455–456). Situations arise in which treating all body fluids as potentially infectious is the most prudent means of protecting employees against exposure because it may not be possible to differentiate between body fluids. For example, EMTs rendering aid to a car accident victim on a dark, rain-soaked roadway would find it extremely difficult to distinguish whether the victim's trousers are wet with blood, urine, or rain water. Consequently, the best method of assuring proper protection under these circumstances is to treat all fluids as potentially infectious. Recognizing this, OSHA has concluded that adding this provision to paragraph (d)(1) is

appropriate and necessary to assure employee protection against occupational exposure to bloodborne pathogens.

One of the most important methods of compliance is the implementation of "Universal Precautions" as recommended by CDC. "Universal Precautions" requires the employer and employee to assume that all blood, and other potentially infectious materials are, indeed, infectious and must be handled accordingly. This infection control concept and suggested methods of implementation were discussed in detail in CDC's August 21, 1987, MMWR supplement "Recommendations for Prevention of HIV Transmission in Health-Care Settings" (Ex. 6-153). The Centers for Disease Control bases the rationale of universal precautions on the following:

> Since medical history and examination cannot reliably identify all patients with HIV or other blood-borne pathogens, blood and body fluid precautions should be consistently used for all patients. This approach, previously recommended by CDC and referred to as "universal blood and body fluid precautions" or "universal precautions" should be used in the care of all patients, especially including those in emergency-care settings in which the risk of blood exposure is increased and the infection status of the patient is usually unknown. (Ex. 6-153)

Use of universal precautions and protecting against exposure to blood and other potentially infectious materials as a means of eliminating or minimizing occupational transmission of bloodborne diseases was given specific support by a number of commenters who addressed this issue (e.g., AHA, Ex. 20-352; SEIU, Ex. 299; National Funeral Directors Association, Ex. 311; AARC, Ex. 20-107; AFSCME, Ex. 297; ANA, Tr. 9/20/89, p.122; APIC—Indiana, Ex. 20-139; Council of State and Territorial Epidemiologists, Tr. 11/14/89, p.216; Local 1199 Drug, Hospital and Health Care Employees Union, Tr. 11/14/89, p.372; New York Committee for Occupational Safety and Health, Tr. 11/13/89, p.15; George Washington University Hospital, Ex. 20-1203; Society of Hospital Epidemiologists of America, Ex. 20-1002). Only a few commenters voiced opposition to the use of universal precautions (American Association of Forensic Dentists, Ex. 20-109; Community Blood Center, Inc., Ex. 20-325; University of Washington, Department of Laboratory Medicine, Ex. 20-378; University of Medicine and Dentistry of New Jersey, New Jersey Dental School, Ex. 20-647). For example, the University of Washington comment stated that one of the reasons they opposed implementation of universal precautions was that too much reliance was placed on barrier precautions, primarily gloves. They stated:

> • • • health care workers, including physicians, are increasingly seen wearing gloves when they are clearly not needed, eg., when punching computer buttons, handling telephones and doorknobs. Environmental contamination will increase throughout hospitals, laboratories and other public facilities. (Ex. 20-378)

This type of situation is addressed by other provisions of the standard (e.g., removal of personal protective equipment upon leaving the work area, decontamination of environmental surfaces) and the Agency does not feel that the arguments put forth are sufficiently compelling to delete the requirement for utilization of universal precautions.

OSHA agrees with CDC and the commenters who supported universal precautions, especially with those who had successfully implemented universal precautions in their workplaces. The Agency has, therefore, retained the general requirement for use of universal precautions in occupational exposure situations.

Body Substance Isolation (BSI) is a method of infection control in which all body fluids and substances are considered to be infectious. A number of respondents supported utilization of BSI rather than universal precautions for preventing employee exposure (Exs. 20-105; 20-1325; 20-130; 20-46; 20-886; 20-591; 20-316; 20-527; 20-609; 20-1304). The fluids and materials listed in the definitions of "Blood" and "Other Potentially Infectious Materials" in paragraph (b) of this standard are derived from those substances which CDC recommends handling with universal precautions (Ex. 6-153) and which OSHA believes present the potential for occupational transmission of bloodborne diseases. Since BSI incorporates not only the fluids and materials covered by this standard but expands coverage to include all body fluids and substances, BSI is an acceptable alternative to universal precautions provided facilities utilizing BSI adhere to all other provisions of this standard.

Throughout the comments, OSHA was urged to define Universal Precautions in accordance with CDC or to simply reference CDC's definition of this term (e.g., Society of Hospital Epidemiologists of America, Ex. 20-1002; AHA, Tr. 9/19/89, p. 129; Cedars-Sinai Hospital, Tr. 12/21/89, p. 1467; Good Samaritan Hospital, Tr. 12/21/89, p. 1431; Nassau-Suffolk Hospital, Tr. 11/14/89, p. 464; Exs. 20-148; 20-292; 20-557; 20-587; 20-692; 20-694; 20-701; 20-708; 20-716; 20-730; 20-744; 20-371; 20-932; 20-911; 20-967; 20-972; 20-978; 20-884; 20-992; 20-999; 20-514). Since the proposal's definition was taken directly from CDC's guidelines (Ex. 6-153), OSHA has concluded that commenters were not referring to an incorrect definition of the term on the Agency's part, but were referring instead to the means of implementing universal precautions. This conclusion is supported by several participants who specifically noted this view in their recommendations (Exs. 20-182; 20-556; 20-1247; 20-122; 20-220; 20-131; 20-582; 20-186; 20-1262; 20-158; 20-1223; 20-633; 20-1325; 20-343; 20-134; 20-546; 20-94; 20-184). Therefore, the controversy of conflicting OSHA requirements and CDC guidelines does not appear to focus on the concept of universal precautions but rather on methods for implementing the concept. For example, they may have disagreed with proposed requirements for the use of gloves for phlebotomists. As a result, OSHA sees no reason to modify its definition of universal precautions or rescind the requirement for general use of universal precautions in occupational exposure circumstances.

Engineering controls serve to reduce employee exposure in the workplace by either removing the hazard or isolating the worker from exposure. These controls encompass process or equipment redesign (e.g., self-sheathing needles), process or equipment enclosure (e.g., biosafety cabinets), and employee isolation. In general, engineering controls act on the source of the hazard and eliminate or reduce employee exposure without reliance on the employee to take self-protective action. Once implemented, engineering controls protect the employee permanently, subject only, in some cases, to periodic replacement or preventative maintenance. By comparison, work practice controls reduce the likelihood of exposure through alteration of the manner in which a task is performed. While work practice controls also act on the source of the hazard, the protection they provide is based upon the behavior of the employer and employee behavior rather than installation of a physical device such as a protective shield.

These two control methodologies frequently work in tandem because it is often necessary to employ work practice controls to assure effective operation of engineering controls. For example, a sharps disposal container provides no protection if an employee persists in recapping needles by hand and disposing of them in the wastebasket. Proper work practices and engineering

controls must both be utilized to ensure safe, acceptable sharps disposal.

In addition to engineering controls and work practices, administrative controls can be used to minimize employee exposure. Examples of administrative controls include methods such as scheduling of tasks to reduce exposure.

Paragraph (d)(2)(i) of the final standard requires the employer to institute engineering and work practice controls as the primary means of eliminating or minimizing employee exposure. Moreover, where occupational exposure remains after institution of these controls, employers must provide and assure employees use personal protective equipment as supplemental protection. Primary reliance on engineering controls and work practices for controlling exposure is consistent with good industrial hygiene practice and with the Agency's traditional adherence to a hierarchy of controls. This hierarchy specifies that engineering controls and work practices are to be used in preference to personal protective equipment.

The proposed standard did not specifically state that a preferential reliance on engineering controls and work practices over the use of personal protective equipment was required although it was not the Agency's intent to abandon its longstanding policy of hierarchy of controls in the control of exposure to bloodborne pathogens. During their testimony in Washington, DC, the American Federation of State, County, and Municipal Employees (AFSCME) expressed concern over the apparent neglect to require adherence to the control hierarchy. They stated:

> For reasons that are unknown to us, OSHA has seemingly abandoned its long-standing preference for engineering and work practice controls. OSHA tries to single out this standard as different, noting that in some circumstances engineering controls are not feasible. However, the hierarchy of controls clearly allows for a combination of controls to be used when engineering controls and work practices alone are not sufficient or feasible.
>
> In fact, engineering controls are explicitly preferred in other OSHA standards, even where a combination of controls is needed in most situations. Therefore, there is no breach of the traditional hierarchy or of traditional OSHA practice in allowing the use of protective equipment to supplement employee protection.
>
> There are several reasons why engineering controls must be a principal focus of this rulemaking:
>
> First, work practices and personal protective equipment will not adequately reduce injuries from needles and other sharp objects. OSHA admits that as many as 60 percent of needle stick injuries will be unaffected by improved work practice procedures.
>
> Secondly, a single exposure incident can lead to illness and death. Therefore, OSHA must require every feasible measure to reduce the incidence of accidental needlesticks and other sharp object injuries.
>
> And third, the lifetime risk of occupational HIV transmission is not well-characterized. Therefore, it is likely that current risk estimates underestimate actual risks over a working lifetime. (Tr. 9/15/89, pp. 95–97)

In their post-hearing comment, AFSCME again urged OSHA to insert the requirement that employers must adhere to the hierarchy, stating:

> That engineering controls are the best method to protect employees is an important, longstanding, tested principle of industrial hygiene. Although OSHA attempts to single out this standard by claiming that engineering controls would rarely be the *only* control method used, the fact is that a combination of engineering controls, work practices, and personal protective equipment are needed to control almost any chemical as well. * * * [T]his position should be clearly stated in the body of the standard so that there is no possibility of misinterpretation by employers. (Ex 297)

Strong support for the hierarchy of controls and/or development of safer equipment was also registered by a number of other sectors, including government agencies [NIOSH, Ex. 298; State of Michigan Advisory Committee on Occupational Exposure to Bloodborne Pathogens, Tr. 10/17/89, p. 20], labor unions (Local 1199—Drug, Hospital and Health Care Employees Union, Tr. 11/14/89, p. 376; Retail, Wholesale, and Department Store Union, Tr. 11/14/89, p. 428; SEIU, Tr. 1/16/90, p. 692; UAW, Tr. 11/13/89, p. 34; USWA, Tr. 11/13/89, p. 99; CWA, Ex. 20–273; FAST, Ex. 281), professional organizations (AORN, Tr. 9/20/89, p. 66; AAOHN, Tr. 9/20/89, p. 36–39; College of American Pathologists, Tr. 11/13/89, p. 191; American Association of Critical-Care Nurses, Tr. 12/19/89, p. 956; APHA, Ex. 20–1361; American Society for Microbiology, Ex. 20–1186), manufacturers (Habley Medical Technology, Tr. 1/18/90 p. 841; Labco, Tr. 9/22/89 p. 90; On-Gard, Tr. 9/26/89 p. 38; Health Industry Manufacturers Association, Tr. 10/17/89, p. 128; Hoffman-LaRoche, Ex. 20–291), and other commenters (NY Committee for Occupational Safety and Health, Tr. 11/13/89, p. 23; Northwest Center for Occupational Health and Safety, Ex. 20–528; MidWest Consortium for Hazardous Waste Worker Training, Ex. 20–892; Medical Arts Laboratory, Ex. 20–638). As stated in the proposal, OSHA recognizes that in many instances a combination of control methodologies (i.e. engineering controls, work practices, personal protective equipment) may be required to adequately protect employees against exposure. However, it is the Agency's intent, in paragraph (d)(2)(i), to clarify that primary reliance shall be placed upon engineering controls and work practices to eliminate or minimize employee exposure. In those circumstances where occupational exposure remains after institution of these controls, personal protective equipment is to be used.

Relative to the use of engineering controls to protect employees against occupational exposure, paragraph (d)(2)(ii) requires that engineering controls be examined and maintained or replaced on a regular schedule to ensure their effectiveness. This provision remains unchanged from that put forth in the proposal under paragraph (d)(2)(i). Regularly scheduled inspections are required to confirm that engineering controls such as protective shields have not been removed or broken; that ventilation systems are operating properly; that filters, sharps disposal containers, and so forth are being replaced on a sufficiently frequent interval; and that other physical, mechanical, or replacement-dependent controls are functioning as intended.

The American Hospital Association (AHA) stated in their comments:

> The provision requiring regular examinations of engineering controls in this section leaves too much discretion to OSHA inspectors, who are not usually qualified to make determinations about how health care should be delivered. Without a limit on the frequency of examination, the rule may permit unreasonable numbers of reviews of engineering controls by compliance officers.
>
> *Recommendation:* Alter Sec. 1910.1030 (d)(2)(i) to require engineering controls to be examined on an annual basis, and changed where a reasonable alternative can be identified which can be expected to limit worker exposure, while not interfering with the delivery of medical care. (Ex.20–352)

It should be noted that responsibility for the regular examination and maintenance of engineering controls falls upon the employer, not an OSHA compliance officer, since the employer is required to assure proper protection of his or her employees. Therefore, an OSHA compliance officer (CSHO) would not be making regularly-scheduled inspections of a facility to examine engineering controls. However, a CSHO could be expected to ascertain the effectiveness and proper functioning of engineering controls during a normal inspection of a facility. While the AHA questions the qualifications of a CSHO to perform such inspections, the Agency does not believe that any specialized

medical expertise is required to determine if, for example, the ventilation system of a biosafety cabinet is functioning properly, if the splash shield covering the segmenting unit of a hematron is broken or missing, if sharps disposal containers are overfilled, and if similar controls are functioning effectively.

Limiting examination of controls to a frequency of once per year is also inappropriate. Because not all controls are the same, differing frequencies of examination are required to assure proper functioning. For example, it would probably not be necessary to check the ventilation performance of a biosafety cabinet on a daily basis, while sharps disposal containers in some high use areas may need to be checked and replaced several times per day. Therefore, it is left to the employer to determine what frequency of examination is necessary for each control to assure that the protection it is intended to provide is maintained. In addition, the phrase "replaced on a regular schedule" is not meant to imply that an engineering control is to be regularly replaced by some alternative control method. It means, instead, that any portion of the control necessary for proper functioning of the control is to be replaced on whatever regularly-scheduled frequency is required to maintain the control's effectiveness.

OSHA has long recognized handwashing as a major precept of infection control. This viewpoint was amply supported by ANPR respondents such as the CDC (Ex. 6-153), the American Hospital Association (Ex. 11-233d), the American Blood Resources Association (Ex. 11-71) and the American Association of Occupational Health Nurses (Ex. 11-111). Therefore, paragraph (d)(2)(ii) of the proposal stated that employees must 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. This provision has been expanded in the final standard and renumbered as paragraphs (d)(2)(iii), (d)(2)(iv), (d)(2)(v), and (d)(2)(vi) to address several issues which arose in the course of public comment.

While the proposal required handwashing, the Agency overlooked requiring that a means of handwashing be provided to employees. This oversight was brought to OSHA's attention by several commenters (CDC/NIOSH, Ex. 20-634; American Biological Safety Association, Tr. 9/21/89, p.100; Food and Allied Service Trades, Ex. 20-888; Retail, Wholesale, and Department Store Union, Ex. 20-1505). OSHA's expert witness in infection control, Ms. Elise Yiasemedes, stated in her testimony:

> Because gloves may not provide complete protection, basic handwashing remains a fundamental element of infection control practices. Facilities for proper handwashing need to be readily available in all areas where occupational exposure to bloodborne pathogens is anticipated. (Tr. 9/13/89, p. 49)

As with any provision which requires the use of ancillary equipment, OSHA also believes that such equipment should be located where employees have easy access to it, thereby increasing the likelihood of use, minimizing the amount of time that contamination must remain in contact with the skin, reducing contaminant migration resulting from employees traveling to remote locations in order to wash hands, and fostering an attitude of compliance due to accessibility of proper facilities. Therefore, paragraph (d)(2)(iii) has been added requiring employers to provide handwashing facilities which are readily accessible to employees.

However, exposures can occur in a number of environments in which sinks and running water are not available for handwashing. In their written testimony, the American Ambulance Association stated:

> We support the requirement to wash hands immediately after handling a patient. However, ambulances are not outfitted with sinks, and in many instances paramedics and EMTs must immediately return to service following delivery of a patient. We urge OSHA to consider the allowance of alternative methods in this and other instances where ambulance design and work practice make compliance with the regulation impractical. We suggest that substitute hand cleaning supplies which are not dependent on water for use. (Ex. 283)

In addition to ambulance-based paramedics and EMTs, other employees, such as firefighters, police, and mobile blood collection personnel, may find themselves exposed to blood or other potentially infectious materials with no means of washing up. In the proposal, OSHA requested information on whether an acceptable substitute for handwashing existed which could be used in these situations and, if so, did it provide protection that is equivalent to handwashing. The Association for Practitioners in Infection Control (APIC)—National responded:

> There are effective substitutes for handwashing when sinks and running water are not available. These products include alcohol-based rinses, foams, and impregnated paper wipes. Data on these products support their efficacy when handwashing facilities are not available. (Ex. 20-1118)

Commenters supporting the existence of adequate substitutes included the American Red Cross—National Headquarters (Ex. 20-784), the American Society for Microbiology (Ex. 20-1188), the Johns Hopkins University (Ex. 20-17), and the University of California, San Diego (UCSD) Medical Center (Ex. 20-156). A number of other participants supported allowing handwashing substitutes although they added the caveat that regular soap and water handwashing must be performed as soon as possible after use of such alternative methods (CDC/NIOSH, Ex. 20-634; International Association of Firefighters, Tr. 9/14/89, p. 154; American Association of Critical-Care Nurses, Ex. 20-1162; The Service Master Company, Ex. 20-21; Veterans Administration—Prescott, AZ, Ex. 20-31). For example, Mr. Richard Duffy of the International Association of Fire Fighters testified:

> We believe that handwashing must be stringently enforced. Hands and other exposed surfaces must be washed, obviously, with a non-abrasive soap and running water after any direct patient contact and as soon as patient care allows.
>
> We also believe that because running water and non-abrasive soap is not always available in the emergency setting, that other types of immediate disinfection be available, such as alcohol wipes or other disinfectant wipes, on the emergency vehicle, so that they can be utilized until such other handwashing, such as water and so forth, are available. (Tr. 9/14/89, pp. 154-155)

This sentiment is echoed by the comment of CDC/NIOSH:

> Handwashing with soap and water, alone or in combination with application of decontaminants, is preferred. When normal handwashing facilities (a sink with running water and soap) cannot be made available, the employer should be required to provide for handwashing using an antiseptic hand cleaner that does not require the use of water, or disposable disinfectant towelettes. A variety of products is available, but handwashing with soap and water should follow as soon as possible. Towels, either paper or cloth, should be provided in all cases. (Ex. 20-634)

While handwashing substitutes are available, their efficacy may be compromised in proportion to the amount of contamination present (Calgon-Vestal Laboratories, Ex. 20-49). The Service Master Company stated:

> Proper handwashing is the most important means for preventing cross-infection and must not be overlooked or neglected even when handwashing facilities are not available. *There are substitutes for handwashing facilities that have a water*

supply, such as the use of alcohol foams or gels that require no water. These can be substituted for soap and water "handwashing", *but there should not be a substitute for handwashing itself, even when gloves are worn.* Emergency vehicles, mobile blood collection vehicles, etc., can be supplied with a "waterless" handwashing product and paper toweling, as well as a glove supply, just as they are supplied with a first aid kit.

The waterless handwashing products provide good antiseptic activity, at least equivalent to handwashing products that require the use of water. However, the flushing/rinsing away of gross amounts of blood or other materials that is provided by a running water supply is not possible with the waterless products. Nevertheless, in the absence of water, handwashing with the waterless products provides adequate protection, especially if gloves are worn in the presence of gross amounts of blood or body fluids. (Ex. 20–21) (Emphasis in the original)

In view of the information received, the Agency accepts the use of alternative handwashing methods as an interim measure when soap and water are not a feasible means of handwashing. OSHA has concluded, however, that handwashing with soap and running water must still be performed as soon as possible, particularly in cases of gross contamination, to adequately flush contamination from the skin. Therefore, paragraph (d)(2)(iv) has been added to the final standard. This provision states that when handwashing facilities are not feasible, the employer must provide either an appropriate antiseptic hand cleaner in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible.

Paragraph (d)(2)(ii) of the proposal would have required employees to wash their hands immediately or as soon as possible after removal of gloves or other personal protective equipment and after hand contact with blood of other potentially infectious materials. The final standard has split this proposed requirement into two provisions, paragraphs (d)(2)(iv) and (d)(2)(v).

While the proposal only required that hands be washed after contact with blood or other potentially infectious materials, this provision has been expanded in paragraph (d)(2)(iv) of the final to state that employers shall ensure that employees wash hands and any other skin with soap and water, or flush mucous membranes with water, immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials. In addition, this provision has been expanded to clarify that hands are not the only body area that needs to be washed upon contamination but also any other skin or mucous membrane which has had contact with blood or other potentially infectious materials. This will minimize the amount of time blood is in contact with potential routes of exposure such as mucous membranes or breaks in the skin.

Paragraph (d)(2)(v) requires that employers shall ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment. This portion of the proposed requirement remains essentially unchanged. The addition of the words "the employer shall ensure" merely make explicit what was implicit in the proposal, which is that the employer is responsible for making sure employees wash their hands as required.

CDC's "Guidelines for Handwashing and Hospital Environmental Control, 1985" states:

> Moreover, handwashing is indicated, even when gloves are used, *after* situations during which microbial contamination of the hands is likely to occur, especially those involving contact with mucous membranes, blood and body fluids, and secretions or excretions, and *after* touching inanimate sources that are likely to be contaminated, such as urine-measuring devices. (Ex. 8–35) (Italics in original)

At the San Francisco hearings, Dow Chemical Company testified that they perform approximately 80 fingerpricks in a day every week or two as part of their monitoring program for cholinesterase inhibition (Tr. 1/11/90, p. 356). While they change gloves between each individual, Dow feels that requiring handwashing along with each change of gloves would sharply increase the amount of time required for testing and would be burdensome. While OSHA recognizes that handwashing between glove changes would, naturally, take more time than a simple glove change, the Agency concluded that this is not a compelling argument to disregard handwashing after removal of gloves. OSHA believes that handwashing after removal of gloves or other personal protective equipment is consistent with CDC's handwashing guidelines and is an appropriate frequency for preventing occupational exposure.

OSHA requested comment in the proposal as to whether handwashing should be required upon leaving the work area. Several commenters supported this handwashing practice (American Biological Safety Association, Tr. 9/21/89, p. 100; Association of Operating Room Nurses, Ex. 20–862; Ortho Diagnostic Systems, Ex. 20–989). The ServiceMaster Company, commented:

> There may be many occasions when an employee will enter a work area where there is a potential for hand contamination, but with no intention of touching materials, surfaces, or persons that are contaminated. For example, there is no reason to require gloving when reading a medical chart, checking supply levels in a patient room, dispensing certain medications, etc. However, while in the work area, *the employee may have to make unplanned hand contact during an emergency or a request for assistance. There should be a requirement that employees wash their hands upon leaving the work area if they have touched any items that may be contaminated or have touched any patients.* (Ex. 20–21) (Emphasis in original)

The initial situations described in ServiceMaster's comment would not require handwashing since no occupational exposure occurred. The second scenario, which involves unplanned hand contact during emergency assistance would necessitate handwashing; however, this type of circumstance is already covered under paragraph (d)(2)(iv) of the final standard. It is not the Agency's intent to mandate unnecessary washing of hands that have not been potentially contaminated. Therefore, the standard does not to require handwashing upon leaving the work area unless, prior to leaving the work area, contact with blood or other potentially infections materials has occurred or gloves or other personal protective equipment have been removed.

Needlesticks are a very efficient means of transmitting bloodborne diseases. As stated in the Health Effects section, the chance of becoming infected after a single needlestick from a hepatitis B source individual ranges from 7% to 30%. With regard to this hazard, CDC's Recommendations for Prevention of HIV Transmission in Health-Care Settings states:

> • • • To prevent needlestick injuries, needles should not be recapped, purposely bent or broken by hand, removed from disposable syringes, or otherwise manipulated by hand. (Ex. 8–153)

In developing the proposed standard, OSHA adopted this philosophy and required that used needles and other sharps shall not be sheared, bent, broken, recapped, or resheathed by hand. In addition, used needles were not to be removed from disposable syringes. While the basic reasoning has been retained, the final provision has been revised to clarify intent and address the comments of interested parties.

Paragraph (d)(2)(vii) requires that contaminated needles and other contaminated sharps shall not be bent, recapped, or resheathed except as noted in paragraph (d)(2)(vii)(A) and (d)(2)(vii)(B) below. Shearing or breaking of contaminated needles is prohibited. This provision does not totally prohibit recapping or removal as the proposed standard was mistakenly interpreted to require by a number of respondents (e.g., AHA, Ex. 20–352; SEIU, Ex. 299; McLeod Regional Medical Center, Ex. 20–527; Guthrie Clinic, Inc., Ex. 20–1222; The Medical Center, Ex. 20–125). The phrase "by hand" is intended to mean "two-handed" or "hand-toward-hand" actions and is not intended to imply that "one-handed" techniques or use of special devices/mechanical means to accomplish recapping or removal are prohibited. A large number of commenters supported prohibition of "by hand", "manual", or "two-handed" recapping or removal and/or urged that alternative methods (i.e., one-handed techniques and use of devices/mechanical means) be permitted (e.g., ADA, Ex. 20–665, Tr. 9/21/89, p.164; Society of Hospital Epidemiologists of America, Ex. 20–1002; SEIU, Ex. 299; CDC/NIOSH, Ex. 20–634; Greater Houston Hospital Council, Ex. 20–1252; APIC—Greater Detroit, Ex. 20–662; Frick Community Health Center, Ex. 20–292; Texas Health Care Association, Ex. 20–636).

Many comments were received which stated that certain medical procedures or practices necessitated recapping or removal of contaminated needles (e.g., AHA, Ex. 20–352; CDC/NIOSH, Ex. 20–634; SEIU, Ex. 299; Society of Hospital Epidemiologists of America, Ex. 20–1002; ADA, Ex. 20–665; APIC, Tr. 10/18/89, pp.198–200; Hahnemann University Hospital, Ex. 20–356). Examples given included blood gas analysis, inoculation of a blood culture bottle, and administration of incremental doses of a medication (e.g., an anesthetic) to the same patient. OSHA recognizes that certain procedures or circumstances may require recapping and removal; however, it should not be construed that these two actions are acceptable as a general practice. The Agency believes that use and immediate discard into a readily accessible sharps container is the safest practice to minimize employee exposure. This belief is supported by the fact that some of the commenters urging allowance to use one-handed or mechanical means of recapping or removal qualified their recommendation by phrases such as "in certain circumstances," "limited use," or "in some instances" (e.g., Judith G. Novak, CEO, HCA, Ex. 20–1191; Tucson Medical Center, Ex. 20–141; Camden Clark Hospital, Ex. 20–200; East Alabama Medical Center, Ex. 20–89; Eliza Coffee Memorial Hospital, Ex. 20–220). CDC/NIOSH was more specific in that they recommended that OSHA should:

> * * * permit use of devices for the mechanical removal and disposal of needles, permit the resheathing of needles for medical practices for which there are no alternatives (e.g., blood gas syringes, blood cultures), and permit removal of resheathed needles during those procedures that require it. (Ex. 20–634)

In their post-hearing comment SEIU supported the approach of CDC/NIOSH. They stated:

> SEIU recognizes that certain procedures require re-capping (e.g., blood gas analysis). We support the position of NIOSH that re-capping should be permitted in those instances where there is no alternative and re-capping is required by a specific medical procedure. In those cases, mechanical devices should be used to assist in re-capping and to reduce the likelihood of needlestick injuries. (Ex. 299)

After considering these comments, the Agency concluded that it is correct in the belief that recapping or removal should not be acceptable as a general practice, however, certain situations exist where these actions are necessary. Therefore, paragraph (d)(2)(vii)(A) of the final standard requires that contaminated needles and other contaminated sharps shall not be removed or recapped unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical procedure. In addition, paragraph (d)(2)(vii)(B) stipulates that such recapping or needle removal must be accomplished through the use of a mechanical device or one-handed technique.

Some sharps are not disposable and are intended to be reprocessed and reused, for example, some large bore needles, scalpels, and saws (Norwood Hospital, Ex. 20–967; UCSD Medical Center, Ex. 20–156). Even though these items are reusable, they pose the same percutaneous exposure hazard as disposable sharps and must be contained in a manner that eliminates or minimizes this hazard until they are reprocessed. Since contaminated sharps, whether reusable or disposable, present the identical hazard, the containers into which they are placed need to possess the same characteristics. Therefore, paragraph (d)(2)(viii) requires that immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers must be: (A) puncture-resistant; (B) labeled or color-coded in accordance with this standard; (C) leakproof on the sides and bottom; and (D) in accordance with the requirements set forth in paragraph (d)(4)(ii)(E).

Puncture-resistance prevents the sharps from penetrating the container and protruding from the sides while labeling or color-coding warns employees of the containers' hazardous contents. Requiring the containers to be leakproof on the sides and bottom prevents any residual liquids from penetrating to the exterior where it would present the possibility of employee exposure and environmental contamination. These three characteristics are also required of containers used for the discarding of contaminated sharps and a more detailed discussion of the rationale behind these requirements can be found under paragraph (d)(4)(iii)(A)(*1*). The fourth required characteristic stipulates that the containers must be in accordance with the provisions of paragraph (d)(4)(ii)(E) of this standard. This paragraph states that reusable sharps, that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed. By eliminating the need for employees to reach into containers holding contaminated sharps, the chance of percutaneous injury and its associated risk of disease transmission is reduced.

Containers for reusable sharps have not been required to be closable as is required for containers for disposable sharps. It is anticipated that the containers used for collecting and holding reusable sharps will, themselves, be reusable. As such, paragraph (d)(4)(iii)(A)(*4*) under "Contaminated Sharps Discarding and Containment" stipulates that reusable containers (containing contaminated sharps) shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.

While there is no documented evidence showing transmission of HIV by environmental surfaces, there is evidence that surface contamination is a mode of HBV transmission. As stated in Laboratory Safety: Principles and Practices:

> Hepatitis transmission, especially type B hepatitis, can occur by indirect means via common environmental surfaces in a laboratory, such as test tubes, laboratory benches, laboratory accessories, and other surfaces contaminated with infectious blood.

serum, secretions, or excretions which can be transferred to the skin or mucous membranes. The probability of disease transmission with a single exposure of this type may be remote, but the frequency of such exposures makes this mechanism of transmission potentially an efficient one over a long period of time. Activities in laboratories such as nail biting, smoking, eating, and a variety of hand-to-nose, -mouth, and -eye actions contribute to indirect transmission. (Ex. 6-344)

The Agency believes that this type of exposure exists in any environment containing contaminated surfaces and is not confined to only laboratories. Therefore, paragraphs (d)(2)(ix) and (d)(2)(x) of the final have been retained essentially unchanged from the proposal in order to eliminate or minimize such indirect transmission.

Paragraph (d)(2)(ix) states that eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood for occupational exposure. This prohibition is supported by several sources (CDC/NIH, Ex. 6-338; AHA, Ex. 6-75; National Committee for Clinical Laboratory Standards, 11-159; American Red Cross, Ex. 11-280). The only change in this provision as opposed to that originally contained in the proposal is that the phrase "potential for occupational exposure" has been changed to "reasonable likelihood for occupational exposure." As discussed previously, this substitution for the word "potential" is consistent throughout this document and has been implemented for the purpose of clarification.

St. Vincent Hospital and Medical Center inquired whether the prohibition on application of cosmetics extended to applying hand cream in these areas, particularly when considering that frequent handwashing and/or glove usage may lead to chapped, irritated hands in some individuals (Ex. 20-524). Hand cream application is permitted provided hands are thoroughly washed immediately prior to application. It should be noted, however, that a workshop report submitted by the Northwest Center for Occupational Health and Safety contained a statement of direct concern relative to use of hand creams and gloves. It stated:

> Information presented by Dr. T. Lowe of the Food and Drug Administration (FDA) at the Fourth Conference on Occupational Hazards to Health Care Workers (University of Washington, May 1989) addressed not only the FDA's current efforts to establish efficacy criteria for latex surgical and examination gloves, but also noted the significant deterioration of such gloves when exposed to petroleum-based lubricants. This was new information to most participants at the Conference and illustrates an added dimension of barrier protection, the degradation of performance which may be caused by contact with other materials, such as disinfectants, cleaning materials and lubricants. (Ex. 20-526)

Therefore, when hand creams are utilized, particular attention should be directed to the cream's formulation and the effect it has on barrier properties of the gloves.

Several participants associated with ambulance services commented that the prohibition on eating and drinking in the work area could present a problem if "work area" is interpreted to include the cab of an ambulance (Mercy Ambulance, Tr. 10/20/89, p.832; American Ambulance Association, Tr. 1/17/90, p.884-885; Professional Ambulance Inc., Ex. 20-2758; Campbell-Superior Ambulance Service, Ex. 20-2647A). Ms. Jeanne Herson of the American Ambulance Association testified:

> • • • In active system status management plans, which is now currently used in many cities, ambulances are not based in stations but are constantly roving in areas which statistically have the highest incidence of calls. This system allows for quicker response times than otherwise would be achieved. In these circumstances ambulance workers, paramedics, and EMTs are often confined for long periods of time in the cab of the ambulance. In times of heavy call volume the worker may not have a chance to take a break for food. A clear definition that the cab is exempt is needed. (Tr. 1/17/90, pp.884-885)

In his testimony, Scott Bradley of Mercy Ambulance supported the comment that employees of ambulance services may, as a result of a high volume of calls, be too busy to suspend service in order to eat or drink (Tr. 10/20/89, p.832). However, both hearing participants also stated that the potential exists for contamination of the cab area if an employee entered the cab while wearing contaminated clothing. Ms. Herson testified:

> I think that if they had blood on their clothing and did not change it and went back into the cab the potential exists. I think that that could be removed by writing policies, procedures and standard operating procedures that that did not happen, that they were to change their clothing if they were exposed. We want them to change their clothing if they've got blood on their clothing. That could be written in. The potential there exists. (Tr. 1/17/90, pp.903-904)

Addressing the same issue, Mr. Brady stated:

> When—our company policy is that when an employee is exposed and the blood—and the universal precautions do not protect the employee, the employee is released from duty or given time to clean up and change uniform. (Tr. 10/20/89, p.842)

The Agency interprets this testimony as demonstrating that ambulance services find it feasible and, in fact, support an employee's changing contaminated clothing prior to entering the cab and resuming duties.

With regard to delineating what constitutes the "work area" of an ambulance, the Agency asked Mr. Brady if the cab is generally separate from the area where the patient would be transported. In response, Mr. Brady stated:

> Yes, it is. Currently, there are three types of vehicles used in our industry. Type 1, Type 2 and Type 3.
>
> Type 1 being a pick-up type cab with a box in the back. Type 2 being a normal van chassis, you would have like a conversion van, and Type 3 is a cab, van-type cab on the front with a box on the back. All of them, to my knowledge, right now are under federal KKK-1822(b) requirements, require that the cab and the patient area have some method of closing the—separating those two areas. So, there is a door, usually an opening or something, and a door that can be closed to separate the two areas. (Tr. 10/20/89, p.841)

Ms. Herson also testified that the cab and patient area are separated, permitting limited patient contact and then only with difficulty (Tr. 1/17/90, p.904).

Reviewing the testimony, the Agency recognizes that circumstances could arise which would require employees to remain in ambulances for extended periods of time. It is not the Agency's intent to prohibit these employees from eating or drinking during such extended periods. Therefore, eating and drinking in ambulance cabs is permitted under the final standard provided the employer has implemented procedures to permit employees to wash up and change contaminated clothing prior to entering the cab. In addition, employers must prohibit the consumption, handling, storage, and transport of food and drink in the rear of the vehicle. Such procedures ensure that patients and contaminated material remain in the rear area of the vehicle (behind the separating partition).

Consistent with the above provision, OSHA has required, in paragraph (d)(2)(x), that food and drink shall not be kept in refrigerators, freezers, shelves, or cabinets, or on countertops or benchtops where blood or other potentially infectious materials are present. In addition to contamination of the mucous membranes of the mouth, one must consider that food and beverage containers may also become contaminated, resulting in unsuspected contamination of the hands.

In the proposal, food and drink were also not permitted to be stored in "other areas of possible contamination." Verdugo Hills Hospital (Ex. 20-573) felt that this phrase was so broad that it was, in reality, meaningless. Although it is not OSHA's intent to prohibit employees from keeping their lunch in or on their desk or other such areas, this phrase could be misinterpreted and thereby severely restrict where consumables may be kept. However, the Agency does not want food and drink to be kept in areas where it or its packaging may be contaminated through processes such as leakage/spilling of specimen containers, contact with contaminated items, or performance of activities (e.g., lab analysis) that could generate splashes, sprays, or droplets of blood or other potentially infectious materials. Therefore, for the purpose of clarification, the phrase "other areas of possible contamination" has been eliminated in favor of the more specific statement "on countertops or benchtops."

Paragraph (d)(2)(xi) requires that all procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances. This requirement will not only decrease the chances of direct employee exposure through means such as spraying into the eyes of splashing onto the face or arms, but will also reduce contamination of surfaces (e.g., benchtops, instruments) in the general work area.

The term "aerosolization," which was contained in this provision in the proposal, has been replaced with "generation of droplets." Aerosols are solid or liquid particles, ranging in size from submicrometer to multi-micrometer, which are suspended in a gas. This suspension can last from a few seconds to a day or more. In their testimony and written submissions, Dr. Don Jewett and Ms. Patricia Heinsohn of the University of California at San Francisco, presented the results of preliminary research that they have been conducting regarding the generation of blood-containing aerosols during orthopaedic surgery. Their studies indicate that inspirable aerosols containing hemoglobin (the marker used to determine the presence of blood) are produced by power tools used during surgical procedures. Dr. Jewett and Ms. Heinsohn go on to discuss their recovery of blood-containing aerosols in personal breathing zone samples collected during actual hip replacement operations; the results of other researchers which indicate recovery of viable HIV from known HIV-positive blood/tissue in some, but not all, aerosols generated by surgical power tools, lasers, and electrocautery devices; the ability of a number of other viruses to be transmitted by aerosols; the possibility of infection through alveolar deposition of blood-containing aerosols; and quantification of risk of infection by calculating the number of Tissue Culture Infective Doses (TCID) contained in their air samples. Utilizing this information, they conclude that a potential respiratory hazard exists with the inhalation of blood-containing aerosols and that inhalation exposure must be controlled. A few other commenters supported this viewpoint (AFSCME, Ex. 297; Dr. Gerald Johnson, Tr. 1/12/90, pp.508-509).

However, a number of other participants commented that respiratory protection against aerosols did not appear to be warranted (CDC—Dr. Steven Hadler, Tr. 9/14/89, p.21 & p.80; CDC/NIOSH, Ex. 20-634; AHA, Ex. 20-352; AORN, Ex. 20-882; Medical Arts Laboratory, Ex. 20-638; Abington Memorial Hospital, Ex. 20-943; Association for Practitioners in Infection Control—National, Ex. 20-1118; The Cleveland Clinic Foundation, Ex. 20-563; Society of Hospital Epidemiologists of America, Ex. 20-1002; VA—Hines, Illinois, Ex. 20-961). During his testimony, Dr. Stephen Hadler of the Centers for Infectious Diseases at CDC stated:

> • • • Although there has been concern about potential infectivity of aerosols generated by dental, medical, and laboratory equipment, HBV has not been detected in such aerosols, and risk is posed primarily by large particles of "spatter" that travel only short distances. (Tr. 9/14/89, p.21)

Later, in response to questioning, Dr. Edward Baker of NIOSH stated:

> • • • There have been no documented cases in the literature, to the best of our knowledge, of HIV transmission via aerosols. Furthermore, there have been studies designed to culture aerosols and these viruses, both HIV and HBV have not been isolated.
>
> To the best of our knowledge, • • • there have been no cases, either of transmission or of clear evidence of exposure. (Tr. 9/14/89, p.80)

CDC/NIOSH expands on this stance in their written comment which goes on to say: (Ex. 20-634)

> Aerosols are not known to present a risk of transmission of bloodborne pathogens in the healthcare environment. There are no known instances in which bloodborne pathogens have been transmitted to workers by way of respirable particles generated during medical procedures, nor are other instances known in which airborne particulates containing bloodborne pathogens have presented a risk to healthcare workers. Therefore, use of respirators for protection against bloodborne pathogens is not recommended.
>
> The possibility that healthcare workers might be infected via inhalation of aerosolized bloodborne pathogens has been investigated, focusing on hepatitis B. Almeida et. al. [1971] reported possible airborne spread of hepatitis B in a dialysis unit following a spill of HBsAG-positive blood. However, experimental studies [MRC 1975] using tracer organisms (*Bacillus Globigii* spores and T3 phage) in a simulated dialysis unit suggested that aerosolization was not a probable route of transmission. Neither blood nor HBsAG could be detected in air samples collected in dialysis units [Peterson et. al. 1976] or during dental procedures [Peterson et. al. 1979]. The Immunization Practices Advisory Committee [ACIP 1985] did not mention inhalation of aerosols in their discussion of the modes of transmission of HBV in healthcare settings. The current opinion of experts is that, while aerosol transmission is a theoretical possibility, it does not contribute measurably to occupational transmission of HBV, which is attributed to direct blood exposure or contamination of environmental surfaces [Peterson 1980; Favero 1987, 1989].
>
> Splattering of blood onto skin or mucous membranes is a recognized mode of transmission of hepatitis B. Protection of the mucous membranes of the face and upper respiratory tract against large droplet spattering is needed. As required by OSHA in this draft rule, glasses, goggles, face shields, and surgical masks, alone or in combination as appropriate to the task being performed, can provide that protection.
>
> Some workers have requested and some employers have attempted to provide respiratory protection against possible inhalation exposure to bloodborne pathogens in healthcare workplaces. Some manufacturers and suppliers of surgical masks have responded to these potential markets with sales programs implying that surgical masks offer respiratory protection. Reported filtering efficiencies of the mask material are sometimes offered as evidence that a product offers respiratory protection.
>
> Surgical masks, designed and approved for use in the healthcare industry, including use in sterile environments, were not designed or approved as respiratory protective devices. The minimal testing specifications for surgical masks do not appear to measure filter efficiency accurately, precisely, or reproducibly, and do not require face fit testing. Whatever the filtering efficiencies of the mask material, most surgical masks do not form an occlusive seal to the face and therefore are not expected to be efficient respiratory protective devices. However, as previously stated, respirators are not recommended for protection against bloodborne disease because there is no evidence that bloodborne pathogens can be or have been transmitted in the healthcare workplace by the respiratory route.

In addition to comments recommending control of aerosol

exposure and those that stated aerosols do not present a hazard, others expressed concern over aerosols and some of them suggested that more research would have to be performed to accurately assess the risk (Northwest Center for Occupational Health and Safety, Ex. 20–526; Hoffmann-LaRoche Inc., Ex. 20–291; Roche Biomedical Laboratories, Ex. 20–1157; American Biological Safety Association, Ex. 241; Lutheran General Hospitals, Park Ridge and Chicago, Ex. 20–655). More specifically, the American Biological Safety Association stated:

In most situations, aerosols do not appear to present a risk of transmission of bloodborne diseases, however, there are some high energy devices which may produce respirable aerosols. Although evidence is inconclusive, preliminary results from researchers at the University of California San Francisco suggest the possibility that cell-free human immunodeficiency virus (HIV) may be present in blood-containing aerosols generated during some surgical procedures. Examples of such devices include the use of bone saw and a laser. Additional studies are needed to assess the risk to employees in such areas, and to recommend appropriate respiratory protection. (Ex. 241)

With reference to the clinical laboratory setting, Roche Biomedical Laboratories commented:

* * * It is acknowledged that little research has been done regarding aerosol production from routine clinical laboratory procedures. These procedures as a whole should pose little potential. However, the ones that do have the greatest potential which are commonly performed throughout the clinical laboratory industry should be identified and evaluated by NIOSH. Until such time, "aerosol" should not be used in the same context as splatters and splashes. (Ex. 20–1157)

The topic of "aerosols" has undergone careful review by the Agency. The information provided by Dr. Jewett and Ms. Heinsohn is disquieting to OSHA, however, the Agency lacks sufficient information in some important areas which it feels must be obtained before it can require employers to control exposures to aerosols. For example, it may be inappropriate to assume that transmission of HIV and HBV may be analogous to other viruses transmitted by the airborne route. While Dr. Jewett and Ms. Heinsohn cite evidence of HIV viability in aerosols, CDC and NIOSH stated that they are unaware of research indicating viability of these viruses in aerosols. Also, the proportional relationship between TCID and the dose necessary to result in human infection through inhalation is not known. In a written supplementary statement to his testimony, Dr. Jewett stated:

It should be noted that it is not known how many TCID are necessary to infect a human by any route, including recognized routes of transmission. With respect to SIV (Simian Immunodeficiency Virus) a dose less than one TCID (less than that which will infect a tissue culture) can infect a macaque monkey. The minimal infectious dose of HIV in humans is not known, but is likely to be very small. Some think that only a single HIV can be infective [23]. (Ex. 269)

Aerosols of blood can be generated by a number of processes in the healthcare setting. In addition to the use of surgical power tools, aerosols can result from activities such as removal of the rubber tops from evacuated blood collection tubes, blood spills, and automatic pipetting instruments. Assuming a "worst case" of single virion infectivity and knowing the capability of minute aerosols to remain suspended in air and therefore spread widely throughout a facility, respiratory protection would be necessary for essentially every person within the facility. However, if such a situation were true, the Agency would expect seroconversion rates to be drastically increased among those exposed; but this does not appear to be the case. However, even if the controversy over respiratory protection for aerosols were settled, questions would remain regarding what concentration of blood-containing aerosol should trigger its use and what monitoring should be done to ensure exposures do not exceed this level.

The hierarchy of controls provision, paragraph (d)(2)(i), of this standard requires employers to implement engineering controls and work practices prior to relying on personal protective equipment for protecting employees against exposure.

In their post-hearing comment, Dr. Jewett and Ms. Heinsohn state that they know of no effective engineering controls to address aerosol exposure. Specifically, Ms. Heinsohn commented:

We know of no engineering controls and physical containment devices which can effectively prevent breathing zone contamination in the operating room which can allow surgeons and others the close patient contact required. The suction tube held at the operative site throughout each operation was clearly ineffective in capturing the aerosols generated. Administrative controls are not feasible; the surgeons, first assistants, and other personnel finish the procedures they start. Respiratory protection remains as the most viable control measure. (Ex. 269)

At the San Francisco hearings, however, Dr. Gerald Johnson presented an electrosurgical pencil equipped with a sheath surrounding the tip whereby the smoke generated during the use of the pencil was evacuated through the sheath's suction ports. While the device Dr. Johnson presented was his personal property, he had sold the design to a manufacturer who was, at the time of the hearings, in the pre-development phase of manufacture. Dr. Johnson also testified that he had read that similar integral evacuators for surgical lasers were planned or were in the planning stages but he did not know of any that were commercially available at that time (Tr. 1/12/90, p.521). In response to a question from the OSHA panel, Dr. Jewett stated:

* * * I fully expect that there will be studies in which the power tools themselves would be changed to possibly reduce the amount of aerosol generated. That methods of trapping the aerosol near the source can also be devised and so my comment [that surgical power tool users should be wearing respirators] applies only to the present situation in which we are using the power tools that we have tested and the data that we have * * *. (Tr.1/9/10, p.102) *[Bracketed information added by OSHA]

OSHA is not aware of specific engineering controls and work practices that are currently available to address control of aerosols. If such controls are available, the question remains as to what airborne concentration of blood-containing aerosol they should be designed to achieve.

With regard to the respiratory protective devices themselves, the Northwest Center for Occupational Health and Safety discusses several areas that need further investigation. They state:

High priority should be given to research to characterize the respirable and non-respirable airborne particles that are generated during various medical procedures and to determine whether these particles present a risk of infection. Research is also needed to determine the permeability and penetration of body fluids or resuspension of body fluids through surgical masks. Current performance standards for industrial respirators should be evaluated for appropriateness of application to surgical masks. Minimal performance criteria should be established for surgical masks, with particular emphasis on face seal leakage criteria. (Ex. 20–526)

In addition to the concerns about surgical masks registered in the above statement, OSHA also lacks information on the appropriateness of face mask respirators in the healthcare setting (e.g., their impact on the vision of the surgeon and/or speech communication between operating staff, ability of particular respirators and/or filter cartridges to provide proper protection, etc.).

As stated previously, the information presented by Dr. Jewett and Ms. Heinsohn suggests the potential for

airborne transmission may exist. Conversely, CDC and NIOSH, both recognized experts in their respective fields, have stated that there are no cases traceable to airborne transmission. These conflicting opinions, coupled with the aforementioned lack of information, prevent OSHA from formulating a firm scientific opinion on this matter. Consequently, the Agency does not believe it is justified in pursuing regulation of aerosols at the current time. However, OSHA does believe that airborne transmission of these viruses through blood-containing aerosols needs to be thoroughly investigated with particular consideration being given to independent research currently being conducted. Therefore, the Agency will refer these matters to NIOSH for further study. If their findings indicate that respiratory protection against aerosol exposure is warranted, the final standard can be amended after appropriate rulemaking on the issues discussed above.

Paragraph (d)(2)(viii) of the proposal stated that mouth pipetting/suctioning would be prohibited. This provision remains unchanged in paragraph (d)(2)(xii) of the final regulation. The use of cotton plugs or other barriers does little to reduce the hazards of mouth pipetting. Even a technician who is skilled in mouth pipetting may inadvertently suck blood or other potentially infectious materials into the mouth which could result in bloodborne pathogens coming into contact with the mucous membranes of the mouth as well as any blisters, cuts, abrasions, or other lesions in the mouth or on the lips.

Paragraph (d)(2)(xiii) addresses the employer's obligations when specimens are placed in containers. A similar provision was put forth in the proposed standard under the housekeeping provisions. Upon review, however, the Agency feels that it is more appropriate to include this type of requirement under "Engineering and Work Practice Controls" because it is a work practice rather than a housekeeping concern. The original provision of the proposal also contained several requirements within one paragraph. For clarification, these requirements have been separated into individual paragraphs in this final standard.

Paragraph (d)(2)(xiii) of the final standard requires that specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, and shipping. The proposed standard required that specimens be placed in "leakproof" containers prior to being stored or transported. The American Hospital Association commented:

> • • • [T]he rules distinction between "leak*proof*" and "puncture resistant" is blurred. The performance-based standard of "leak *resistant*" is a far more realistic and appropriate standard for the health care setting • • •. (Ex. 20-352)(Emphasis in original)

This sentiment was reiterated by Dr. M. Scott Stirton, a Seattle pathologist, who stated:

> • • • The use of "leakproof" containers for all specimens is again, very costly and needless. Only specimens not in a closed container or those in a closed container with contamination on the outside need to be placed in a leakproof container. Throughout the document, "leakproof" should be changed to "leak resistant" since there are no "leakproof" containers, gowns, etc. (Ex. 20-565)

For the final standard, the term "leakproof" has been changed to "prevents leakage during collection, handling, processing, storage, transport, and shipping." The intent of this requirement is to eliminate or minimize the possibility of inadvertent employee contact with blood or other potentially infectious materials which have leaked out of the container, contaminating the container's exterior surface and/or surrounding surfaces. The Agency believes that this modification increases the performance orientation of the provision by permitting more latitude in the selection of containers based upon the type of specimen and the handling it would be anticipated to undergo. For example, a screw top container, maintained in an upright position, would most likely prevent leakage during collection and processing. However, a screw top container placed on its side in a bin or envelope for shipping to an outside lab may not be able to prevent leakage of its contents.

In addition to preventing leakage of blood and other potentially infectious materials from containers, employees must be warned that these substances are present so that proper handling precautions can be taken. Therefore, paragraph (d)(2)(xiii)(A) stipulates that the container for storage, transport, and shipping shall be labeled or color-coded according to paragraph (g)(1)(ii) of this standard and closed prior to being stored, transported, or shipped. The label or color-coding serves to alert those coming into contact with the container that the specimen contains blood or other potentially infectious materials. Requiring that the container be closed prior to being stored, transported, or shipped assures not only that the specimen will remain in the container if it is tipped over or jostled but also prevents other objects (e.g. charts, clothing) from contacting the specimen and becoming contaminated.

OSHA believes it is vitally important to the safety of workers for them to know they may be handling bloodborne pathogens. For many facilities, the only practical way to accomplish this is to label the specimen containers. NIOSH supports OSHA's proposal to require labeling to alert workers "• • • when handling materials or containers of materials that require observation of universal, or barrier precautions." (Dr. Bryan Harden, NIOSH, Tr. 9/14/89, p. 29).

In general, the commenters who considered labeling raised three major concerns:

(1) That the labeling of specimens HBV or HIV positive would encourage employees to take precautions only when handling those specimens known to be infectious;

(2) That the use of the biohazard label on all containers would make it such a familiar symbol as to negate its effectiveness; and

(3) That the labeling requirement is unnecessary and, some noted, inconsistent with universal precautions.

With regard to the first concern, the American Federation of State, County, and Municipal Employees (AFSCME) stated in their post-hearing brief:

> Some commentors have recommended that a special Biohazard symbol be used on samples that contain known bloodborne pathogens. This additional labeling, so the argument goes, will provide workers with greater incentives to take protective measures above and beyond those associated with universal precautions.
>
> However, we are concerned that differential labeling will encourage employees to become lax with samples that are not explicitly marked but may also be infectious (Ex. 297).

The University of Connecticut wrote in their comment:

> • • • Universal precautions require that human blood and body fluids always be handled using barrier protection. Tentative Guidelines of the National Committee for Laboratory Clinical Standards on Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids, and Tissue (M29-T, Vol. 9 No. 1, Jan. 1989) states, "[i]mplementing universal precautions also eliminates the need for using specific warning labels on specimens obtained from patients infected with HBV or HIV • • • The use of special labels may create a false sense of security that nonlabeled blood is not infectious • • •." (Ex. 20-191)

OSHA agrees with AFSCME, the University of Connecticut and other

commenters who were concerned that in such a tiered system of specimen handling, employees who fail to take precautions with specimens of unknown seropositivity status will be at increased risk from those unidentified HIV and HBV positive specimens. The purpose of the label is only to indicate the presence of blood or other potentially infectious materials in the specimen. OSHA is not requiring the seropositivity of a particular specimen be on its label.

Similar concerns were raised by other commenters who argued that labeling specimens which contain blood or other potentially infectious materials would create a false sense of security and/or result in a deterioration in handling of unlabeled specimens. (e.g., Montana Deaconess Medical Center, Ex. 20-380; University of Connecticut Health Center, Ex. 20-191; Michigan Advisory Committee on Occupational Exposure, Tr. 10/17/89, p. 25).

Several commenters suggested the labeling requirements would lead to too many labels in the workplace. Specifically, the Society of Hospital Epidemiologists and The George Washington University Medical Center believe that the proposed rule would result in overlabeling which would erode the meaningfulness of the biohazard symbol. (Tr. 10/18/89, p. 354; Ex. 20-1303). Ms. Patricia Lynch, a representative for the American Hospital Association and Infection Control Coordinator for Harborview Medical Center testified that:

> We found in our implementation that there was a marked difference in the behavior of the laboratory personnel when they received things that had coded labels of some sort on them, that they started doing additional stuff, and they stopped doing the precautions that we wanted them to use with everything. So, over a period of a year, or so, we withdrew our entire labeling system after a brief flirtation with labeling everything, which proved to be very burdensome. (Tr. 9/19/89, pp.163-164).

OSHA has considered this view but has decided that the chance that overlabeling could occur in a particular workplace is far outweighed by the need for employees to be readily informed about the potential hazards posed by bloodborne pathogens in specimens.

Many commenters stated that the proposed specimen labeling requirements were inconsistent with universal precautions and/or all specimens should be handled as if they were infectious (APIC—National, Ex. 20-1118; APIC—Dade County, Ex. 20-371; Baptist Medical Center, Ex. 20-148; Christine Bellefontaine, RN, BSN, Daniel Freeman Marina Hospital, Ex. 20-987; Independence Regional Health Center, Ex. 20-230; Shadyside Hospital, Ex. 20-546; VA—Kansas City, Ex. 20-167; Kaiser Permanente—Panorama City, Ex. 20-60; LASSA NW Ex. 20-680; Meadville Medical Center, Ex. 20-624; Memorial Hospital of Dodge County, Ex. 713; New England Medical Center Hospitals, Ex. 20-511; Norwood Hospital, Ex. 20-967; Saline Community Hospital, Ex. 20-869; Sequoia Hospital, Ex. 20-538; Stanford University, Ex. 20-984; University of Michigan, Ex. 20-1306; St. Luke's Hospital, Ex. 20-114). Many of these facilities expressed concern about being required to differentially label specimens containing blood or other potentially infectious materials when universal precautions were being followed in the handling of all specimens.

OSHA has considered these comments and believes they have merit. Handling all specimens with universal precautions is essentially the infection control method known as Body Substance Isolation which can provide more protection to employees and, in some facilities, be simpler to implement. Accordingly, in this final standard, OSHA is allowing workplaces where all specimens are handled with universal precautions to not label. However, since the hazards are great to employees who do not know they are handling bloodborne pathogens, OSHA has drawn this exception to the general labeling requirements narrowly. Specifically, employers may avoid labeling only if all employees who may have contact with specimen containers are able to recognize them as containing specimens requiring the use of universal precautions and all of these employees have been trained to follow universal precautions in handling these specimens. Moreover, OSHA believes that it is not sufficient to simply utilize universal precautions in the handling of all blood specimens in order to be exempt from labeling/color-coding. Other materials, some of which have no resemblance to blood or in which blood may not be readily observed, may also be potentially infectious (e.g., plasma, amniotic fluid). Therefore, the standard requires that the concept of universal precautions be applied to all specimens in order for the labeling/color-coding exemption to be permitted. This exemption only applies while such specimens/containers remain within the facility. Labeling or color-coding in accordance with paragraph (g)(1)(i) is required when such specimens/containers leave the facility. Labeling or color-coding the specimen container when it leaves the facility assures that employees outside the facility who may have contact with the specimen/container will be warned of its contents so that proper precautions can be taken.

Paragraph (d)(2)(xii)(B) states that if outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and that it is labeled according to the requirements. The requirement for a secondary container received several comments, all of which appear to interpret the provision as mandating double containers on all specimens (American Association for Clinical Chemistry, Ex. 20-368; AHA, Ex. 20-352; Christine Bellefontaine, RN, BSN, Daniel Freeman Marina Hospital, Ex. 20-987; Laboratory of Pathology, Ex. 20-718). Secondary containers are required only on those specimens in which the primary container is likely to be contaminated on its outside surface, as may occur by handling the container while wearing bloody gloves, or when it is reasonably anticipated that the primary container may not be able to prevent leakage. For example, a tissue specimen which is so large that it will not permit closure of the available primary container to the point of preventing leakage would necessitate a secondary container. OSHA believes, therefore, that secondary containers are necessary in situations such as those discussed above to prevent contaminant migration and inadvertent employee exposure.

If the specimen could puncture the primary container, paragraph (d)(2)(xii)(C) requires that the primary container be placed within a secondary container which is puncture-resistant in addition to the above characteristics (i.e., prevents leakage during handling, processing, storage, transport, or shipping and which is labeled or color-coded), again, to prevent inadvertent contaminant migration and employee exposure. The American Hospital Association recommended that this requirement be limited to only those circumstances when sharps are present in the specimen (Ex. 20-352). The term "sharps" encompasses a distinct set of items for the purposes of this standard and the Agency believes that items not contained within the definition of "sharps" could puncture a primary container. For example, a specimen containing a pointed bone sliver could puncture a plastic bag type container yet the bone would not be considered a "sharp" per se. Therefore, while it is not OSHA's intent to have all specimens placed in puncture-resistant containers, the Agency is not limiting implementation of this provision to only

those situations where sharps are present. This course of action has been chosen in order to assure that other items which could cause puncture, such as a bone sliver, will trigger the use of a puncture-resistant container.

Equipment used for diagnosis, treatment, research and other applications may become contaminated with blood or other potentially infectious materials. Examples of such equipment include blood gas analyzers, mechanical pipettes, suctioning devices, centrifuges, and liquid chromatographs. During the development of the proposed standard, several sources recommended instruments and equipment be decontaminated prior to repair in the laboratory or shipment to the manufacturer for servicing (CDC, Ex. 6–153; ABRA, Ex. 11–71; NCCLS, Ex. 11–159A). In addition, Waters Chromatography Division of Millipore Corporation (Ex. 11–3) and YSI Incorporated (Ex. 11–7), both of whom are involved with instrument servicing, addressed the potential for exposure of repair personnel.

OSHA responded to these comments by proposing that such equipment be checked and decontaminated as necessary and prior to servicing or shipping. The intent behind this proposed requirement was to minimize the possibility of employees and servicing and shipping personnel becoming exposed due to leakage of potentially infectious materials from the equipment or through contact with interior/exterior contamination. The Agency believes that this requirement and the underlying reasoning remain valid and has retained the provision in the final standard. Therefore, paragraph (d)(2)(xiv) states that equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible. This provision was supported by the Health Industry Manufacturers Association (HIMA) (Exs. 85).

Several commenters, while not disagreeing with the proposed provision, stated that it may not always be possible to decontaminate equipment prior to servicing or shipping (William W. Backus Hospital, Ex. 20–911; Norwood Hospital, Ex. 20–967; American Red Cross Blood Services—Appalachian Region, Ex. 20–215; APIC—National, Ex. 20–1118; Medical Arts Laboratory, Ex. 20–638). The American Red Cross Blood Services commented:

> In some instances this may not be feasible. Blood Center personnel operate technologically advanced equipment. They may not have the necessary training and experience to take apart technologically advanced equipment. (Ex. 20–215)

The Association for Practitioners in Infection Control (APIC) also voiced the concern that equipment design may prevent its effective cleaning in their statement:

> The requirement to decontaminate equipment prior to servicing or shipping is stated "as necessary". Realistically, this should say "as possible". It is not always possible to effectively clean equipment prior to servicing because of equipment design. Therefore biomedical equipment engineers are taught to practice precautions until the equipment can be disassembled and cleaned. Computer keyboards in the clinical laboratory are an example of equipment that cannot be effectively cleaned by the user. (Ex. 20–1118)

Although the Maryland Safety and Health program felt that contaminated equipment should be automatically disinfected before servicing and recommended eliminating the phrase "as necessary", OSHA agrees that complete decontamination may not always be possible, particularly when equipment is highly technical, very sensitive, and/or presents limited access to contaminated parts (Ex. 20–1362). However, the Agency believes that there are few, if any, circumstances in which at least partial decontamination (e.g., flushing lines, wiping the exterior) cannot be accomplished. Therefore, an exemption to decontamination is not warranted. OSHA has concluded that the requirement to decontaminate equipment prior to servicing or shipping is appropriate and should only be limited by feasibility.

When decontamination of equipment or parts of equipment cannot be performed, it is necessary to warn those who may come in contact with the equipment of the hazard so that appropriate precautions can be taken. Consequently, paragraph (d)(2)(xiv)(A) mandates that whenever decontamination of such equipment or portions of such equipment is not feasible, a readily observable label in accordance with the requirements of paragraph (g)(1)(i)(H) shall be attached to the equipment. It should be noted that in addition to the other requirements of paragraph (g), the label is to state which portions of the equipment remain contaminated. This will assist individuals who may contact the equipment in determining what precautions need to be taken and when they should be implemented.

Consistent with the other hazard communication provisions of this standard, responsibility for transmitting this warning falls upon the employer. Paragraph (d)(2)(xiv)(B), therefore, requires the employer to assure that this information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken. This provision is particularly important when equipment is being shipped or transported to an off-site servicing/repair facility to assure that downstream individuals are forewarned of the hazard.

Personal Protective Equipment

OSHA's requirements for personal protective equipment contained in paragraph (d)(3), have been set to assure adequate protection during task performance. In their response to the ANPR, the National Institute for Occupational Safety and Health (NIOSH) stated:

> The purpose of personal protective clothing and equipment is to prevent or minimize the entry of materials into the worker's body. This includes entry via apparent or inapparent skin lesions or entry through the membranes of the eye, nose, or mouth * * *. Appropriate protective clothing and equipment should * * * be selected based on the specific work and exposure conditions that will be encountered and the anticipated level of risk. (CDC/NIOSH, Ex. 11–187)

This approach to the selection of protective barriers is echoed by CDC in their June 1988 guidelines:

> * * * The type of protective barrier(s) should be appropriate for the procedure being performed and the type of exposure anticipated. (Ex. 6–316)

Personal protective equipment plays an important role in this standard. As discussed previously, when engineering controls and work practices are insufficient to eliminate exposure then personal protective equipment must be utilized to address the remaining exposure potential. Hence, paragraph (d)(3)(i) states that when there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. This provision also states that personal protective equipment will be considered "appropriate" only if it does not permit blood or other potentially infectious

materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.

The proposed standard required employers to provide personal protective equipment when employees had the "potential for" occupational exposure. Again, a number of commenters questioned the interpretation of the word "potential" and/or recommended that it be replaced or deleted (Shriner's Hospital for Crippled Children, Ex. 20–254; St. Francis Regional Medical Hospital, Ex. 20–360; Mayo Clinic, Ex. 20–378; San Antonio Community Hospital, Ex. 20–530; Lutheran General Hospitals, Park Ridge and Chicago, Ex. 20–655; Iowa Lutheran Hospital, Ex. 20–885; Osteopathic Medical Center of Philadelphia, Ex. 20–1342). For clarification, the term "potential" has been deleted from the provision as has been done in other portions of the standard. Provision of personal protective equipment is based, therefore, upon the existence of occupational exposure which, by definition, is "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.

It has been the Agency's longstanding policy to hold the employer responsible for controlling exposure to hazards in his or her workplace and to fulfill this responsibility at no cost to the employee. Therefore, the financial burden for purchasing and providing personal protective equipment rests upon the employer just as it does for all other control measures (e.g., engineering controls). Support for this provision was registered by a number of commenters (SEIU, Ex. 299; RWDSU, Tr. 11/14/88, pp 432–433; Communication Workers of America, Ex. 20–787; American Association of Critical-Care Nurses, Ex. 20–1182; ADHA, Tr. 1/18/90, p.570; Douglas Kline, MCM, CIC, Ex. 20–87; Lee Hospital, Ex. 20–183; Abington Memorial Hospital, Ex. 20–557; Lutheran General Hospitals, Park Ridge and Chicago, Ex. 20–655). Some participants apparently interpreted the proposed regulations on provision of personal protective equipment to mean that all work clothing was to be provided by the employer (Tennessee Christian Medical Center, Ex. 20–54; Lutheran General Hospitals, Park Ridge and Chicago, Ex. 20–655). Specifically, Dr. Murray D. Batt, Chairman, Infection Control Committees, of Lutheran General Hospitals commented:

> In the area of infection control it is clear that the hospital has responsibility to provide gloves, goggles where appropriate, masks where appropriate, waterproof aprons, protective gowns, etc. It is by no means clear that the employer should also make available clothing for its employees and I wonder why this is included in the rule making. (Ex. 20–655)

In discussing this provision, the Society of Hospital Epidemiologists of America suggested:

> Simple cloth garb such as lab coats or scrub suits are commonly used for convenience, appearance, and to prevent routine soiling of street clothes, rather than for personal protection from the risk of bloodborne infection. It should be made clear that use in this manner (rather than to comply with the provisions of this standard) is not required, and if permitted by the employer, does not impose a duty on the employer to supply or clean the garments. (Ex. 20–2082)

The Agency is aware that some employees purchase their own uniforms and/or lab coats for use as general work clothes. It is not the intent of this provision to obligate employers to provide general work clothes to employees, however, the employer is responsible for providing personal protective equipment. If an item of clothing is intended to protect the employee's person or work clothes or street clothes against contact with blood or other potentially infectious materials then it would be considered as personal protective equipment and must be provided by the employer. With particular regard to lab coats (or gowns) and uniforms, if a lab coat is used to prevent an employee's uniform from becoming contaminated with blood or other potentially infectious materials then the lab coat is personal protective equipment and must be provided by the employer. If an employee's uniform is intended to protect the employee's body against contamination, then the uniform is personal protective equipment and is to be provided by the employer. Whether or not an item of clothing is considered personal protective equipment supplied by the employer, depends on its use. For example, a uniform is personal protective equipment if its purpose is to protect the employee from occupational exposure. If, on the other hand, a lab coat or protective gown is donned over the uniform, then the uniform is not protective clothing. Therefore, the employer's obligation to provide a particular item is based upon whether or not an item is to function as protection against contamination with blood or other potentially infectious materials.

A number of commenters expressed concern that strict interpretation of this requirement would require employers to provide all employees with all of the personal protective equipment mentioned in the standard and/or require them to use it, regardless of the task being performed, or employees would inappropriately utilize such equipment, resulting in unnecessary overuse of personal protective equipment (AHA, Ex. 20–352; ADA, Ex. 20–665; American Association for Respiratory Care, Ex. 20–107; Blood Systems Inc., Ex. 20–341; Southgate Medical Laboratory Systems, Ex. 20–577; Episcopal Hospital, Ex. 20–886; APIC—Greater Omaha, Ex. 20–943; AHCA, Tr. 9/21/89, p.61–62; American Association of Orthodontists, Tr. 11/14/89, pp.496–497; American Board of Orthodontists, Tr. 11/14/89, pp.501–502). For example, the American Association for Respiratory Care stated:

> • • • We strongly urge OSHA to remain flexible in requiring the extensive use of protective equipment. By the very nature of the profession, the respiratory care practitioner, following strict OSHA standards would need to be gloved, gowned, goggled, and masked throughout the entire work shift. This is clearly over-prescriptive.
>
> We support OSHA's requirement for employee education, for mandatory infection control plans, for the requirement that the employer must provide easy access to a variety of protective equipment and clothing, but we believe that, guided by Universal Precautions, the individual should decide the extent of the protective items needed, based on the procedure and type of exposure anticipated. (Ex. 20–107)

The American Hospital Association, in addressing this issue, commented:

> • • • [B]y enumerating requirements to wear other protective equipment like masks, face shields, goggles, and aprons, but not limiting application to situations when exposure can reasonably be anticipated, the rule is vague enough to be construed to require such equipment for all patient encounters, regardless of the potential for exposure • • •. (Ex. 20–352)

It is not the Agency's intent that employees be outfitted in all possible personal protective equipment or a "moon suit" for all tasks or procedures that they perform. The protective equipment utilized is simply to be chosen to protect against contact with blood or other potentially infectious materials based upon the type of exposure and quantity of these substances which can be reasonably anticipated to be encountered during performance of a task or procedure. This approach to selection of the type of

personal protective equipment to be utilized in a particular instance is supported by several commenters in addition to the recommendations of NIOSH and CDC cited at the beginning of this discussion (AHA, Ex.20–352; Hospital Laundry Services, Ex. 20–1225; APIC—Pittsburgh, Tr. 9/27/89, p.265; Elise Yiasemides, Tr. 9/13/89, p.63).

In the proposal, under paragraph (d)(3)(vii), "Gowns, Aprons, and Other Protective Body Clothing", OSHA stated:

> 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.

The Agency then proposed, in three subsequent provisions, to delineate minimal characteristics of such protective body clothing based upon types of exposure. That is, gowns, lab coats, aprons or similar clothing were to be worn if the potential for soiling of clothes with blood or other potentially infectious materials existed; fluid-resistant clothing was to be worn if there was a potential for splashing or spraying; and fluid-proof clothing was to be utilized if there was a potential for clothing to become soaked with the substances of concern. In response, a large number of commenters requested that OSHA clarify or define the terms "fluid-resistant" and "fluid-proof" (Association of Operating Room Nurses, Inc., Ex. 20–882; AFSCME—New York, Ex. 20–985; American Association of Critical-Care Nurses, Ex. 20–1162; American Society for Microbiology, Ex. 20–1188; South Carolina Department of Health and Environmental Control, Ex. 20–1160; The Hospital Association of Pennsylvania, Ex. 20–874; The ServiceMaster Company, Ex. 20–21; Abington Memorial Hospital, Ex. 20–557; Mayo Clinic, Ex. 20–376). Other commenters, however, informed the Agency that there was no industry-accepted definition for these terms and, in fact, no generally recognized, standardized test methodology was employed to determine fluid-resistance (AHA, Ex. 20–352; Superior Surgical Manufacturing Co., Ex. 20–41; Abbott Laboratories, Ex. 20–1227; Surgikos, Ex. 20–252; APIC, Tr. 10/18/89, p.189; Joint Committee on Health Care Laundry Guidelines, Tr. 10/20/89, p.801; W.L. Gore and Associates, Inc., Tr. 9/25/89, p.180). Surgikos commented:

> In the quest for standards on liquid repellency, the manufacturers of protective clothing vary greatly as to methodology for determining levels of liquid repellency. In the marketplace today, several fabrics exist that exhibit a threshold (market proven) level of liquid repellency. Design enhancements, such as sleeve and chest reinforcements exist, providing additional levels of liquid repellency. These design enhancements can render the fabric impervious (plastic reinforced). Additionally, liquid challenges to protective clothing vary greatly according to the procedure being performed. In the past, committees made up of surgeons and nurses, but primarily of manufacturers, have assembled with the goal of establishing liquid repellency standards. To date, no standards are available * * *. (Ex. 20–252)

The American Hospital Association also addressed this issue in their statement:

> OSHA's attempt to differentiate between splashing, spraying, and soaking is specious, and will only burden workers and the health care facility, who must attempt to use this basis to determine when to use "fluid proof" or "fluid resistant" protective clothing. Because there is no method to assess the ability of a material to resist penetration of fluids and thus no scientific measures of barrier effectiveness against bloodborne pathogens, nothing can be gained by attempting to differentiate between fluid proof and fluid resistant garb * * *. (Ex. 20–352)

Conversely, the National Office of the Association for Practitioners in Infection Control felt that the distinction between fluid-resistant and fluid-proof was clear and the selection of such barrier properties based upon exposure (e.g. splashing, soaking) was appropriate (Ex. 20–1118). The Society of Hospital Epidemiologists of America also supported use of fluid-resistant and fluid-proof garb, but urged OSHA not to set stringent definitions for these terms. They commented:

> The distinction between *fluid-resistant* and *fluid-proof* is reasonable. Currently available gowns represent different degrees of protection along this spectrum, and some institutions make several types available in accord with anticipated exposure. However, as noted, gowns are not either "fluid-resistant" or "fluid-proof"; the spectrum is continuous, and the degree of protection varies even within the garment (back vs chest vs elbows, etc). Recommendation: require that provided gowns offer a degree of fluid protection appropriate to the anticipated exposures, such that strike-through is unlikely. Do not establish standards for "fluid-resistant" and "fluid-proof". (Ex. 20–1002) (Emphasis in original)

A similar approach was recommended by The Service Master Company in their comment:

> *Characteristics of personal protective equipment should be performance oriented.* The specification of characteristics of construction or fabric for personal protective equipment for each particular task would be monumental if it was to be all-inclusive. Furthermore, such specifications would be more limiting both in selection of current items available and acceptance of new items or materials as they are developed and became available. Performance-oriented characteristics provides for greater latitude and flexibility while still providing the desired employee protection. (Ex. 20–21) (Emphasis in original)

It appears from the comments that affected parties generally recognize that differing exposures (i.e., type of exposure and quantity of fluid) demand different levels of protective capability in a garment. While it was OSHA's intent in the proposal to assure that adequate protection was afforded employees by requiring the use of fluid-resistant and fluid-proof clothing based on exposure circumstance, the absence of a recognized industry standard for these characteristics has created confusion among both manufacturers and users of such garments. OSHA was informed that the American Society for Testing and Materials (ASTM) is working toward standardized methods of testing, terminology, classification, and performance specifications for resistance of clothing to biological hazards (ASTM, Ex. 20–51; American Reusable Textile Association, Ex. 20–1272). This work, however, is still under development and was not accepted and available for OSHA to refer to during development of this standard. Therefore, the Agency has decided to be more performance-oriented in the standard and the terms "fluid-resistant" and "fluid-proof" have been eliminated from the final regulation.

Relative to this performance-oriented approach, the State of Maryland Occupational Safety and Health program (Ex. 20–1362) recommended that protective equipment should form an effective barrier under anticipated conditions of exposure. The Agency does not believe that the phrase "effective barrier" provides adequate instruction to those covered by the standard since this term was used in the proposal and a large number of commenters asked for it to be clarified or defined (APIC—National, Ex. 20–1118; Northwest Center for Occupational Health and Safety, Ex. 20–526; Clayton General Hospital, Ex. 20–661; Abington Memorial Hospital, Ex. 20–557; Anaheim Memorial Hospital, Ex. 20–523; Children's Hospital of Orange County, Ex. 20–568; Children's Hospital of San Francisco, Ex. 20–545; Hoag Memorial Hospital, Ex. 20–673; Pacific Hospital of Long Beach, Ex. 20–633; Healthcare Medical Center, Ex. 20–618). After reviewing several of the comments, OSHA believes that the endpoint to be achieved is for the chosen personal protective equipment to adequately protect the employee's skin, clothing and

mucous membranes against contact with blood or other potentially infectious materials (Society of Hospital Epidemiologists of America, Ex. 20–1002; APIC—Indiana, Ex. 20–139; Parkview Memorial Hospital, Ex. 20–136; VA—Edward J. Hines Jr. Hospital, 20–961). Therefore, performance criteria have been added to paragraph (d)(3)(i) delineating the characteristics of "appropriate" personal protective equipment. This provision states that personal protective will be considered "appropriate" only if it does not permit blood or other potentially infectious materials to pass through to or otherwise reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used. OSHA has concluded that this provision increases the performance-orientation of the regulation, supplies the criteria necessary for proper selection of equipment, and increases flexibility in attaining compliance. Since this endpoint is the purpose of any personal protective equipment, it should be noted that the provision refers to *all* personal protective equipment rather than a particular item (e.g., gowns, masks, aprons, etc.).

Two other issues were raised during the public comment period relative to provision of personal protective equipment. The first is directly related to the concept of "appropriate" in choosing personal protective equipment. Several commenters urged OSHA to insert a requirement concerning "quality" of equipment provided to employees (AFSCME, Tr. 9/15/89, p.100, Ex. 297; Repack Surgical Enterprises, Tr. 10/20/89, p.886; SEIU, Ex. 299; Frick Community Health Center, Ex. 20–292; John L. McClellan Memorial Veteran's Hospital, Ex. 20–548; VA—Southwestern Region, Ex. 20–549). A review of the record did not reveal quality specifications for specific items of personal protective equipment but, in any case, the Agency concludes that the final regulation adequately addresses this issue by requiring that protective equipment maintain its protective characteristics "under normal conditions of use and for the duration of time which the protective equipment will be used". Under this performance-oriented standard, a paper gown which ripped or fell apart under normal use would not be considered to be "appropriate."

The second query involved provision of protective equipment (particularly gowns, aprons, and other body clothing) in general. A number of commenters asserted that transmission of bloodborne diseases has not been shown to occur through intact skin and some argued that the effectiveness of such equipment to prevent transmission has not been demonstrated (APIC—Central Ohio, Ex. 20–1158; G.S. Naylor, M.D., & K.A. Yates, R.N., Ex. 20–255; UCSD Medical Center, Ex. 20–156; Dakota Hospital, Ex. 20–632; LASSA N.W., Ex. 20–680; Mission Bay Hospital, Ex. 20–666; Scripps Memorial Hospital, Ex. 20–522; The United Hospital, Ex. 20–682; Tucson Medical Center, Ex. 20–141). However, the CDC's "Recommendations for Prevention of HIV Transmission in Health-Care Settings" states:

> 1. All health-care workers should routinely use appropriate barrier precautions to prevent skin and mucous-membrane exposure when contact with blood or other body fluids of any patient is anticipated * * *.
>
> 2. Hands and other skin surfaces should be washed immediately and thoroughly if contaminated with blood or other body fluids * * *. (Ex. 6–153)

In their follow-up document, "Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings," the CDC continues to recommend preventing skin exposure and utilization of personal protective equipment.

> Protective barriers reduce the risk of exposure of the health-care worker's skin and mucous membranes to potentially infective materials. For universal precautions, protective barriers reduce the risk of exposure to blood, body fluids containing visible blood, and other fluids to which universal precautions apply. Examples of protective barriers include gloves, gowns, masks, and protective eyewear * * *.
>
> 2. Use protective barriers to prevent exposure to blood, body fluids containing visible blood, and other fluids to which universal precautions apply * * *.
>
> 3. Immediately and thoroughly wash hands and other skin surfaces that are contaminated with blood, body fluids containing visible blood, or other body fluids to which universal precautions apply. (Ex. 6–428)

With regard to preventing not only skin and mucous membrane contact but also contamination of work clothes or street clothes with blood or other potentially infectious materials, the CDC's document "Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers" recommends to fire and emergency medical services:

> * * * Gowns or aprons should be worn to protect clothing from splashes with blood. If large splashes or quantities of blood are present or anticipated, impervious gowns or aprons should be worn. An extra change of work clothing should be available at all times. (Ex. 15)

This same document, under Law-enforcement and Correctional Facilities, states:

> * * * In case of blood contamination of clothing, an extra change of clothing should be available at all times. (Ex. 15)

The CDC recommends, therefore, that personal protective equipment should be used to protect not only skin and mucous membranes against contact with blood and other potentially infectious materials but should also be utilized to prevent contamination of clothing. Considering these recommendations, the Agency has concluded that requiring provision of personal protective equipment to prevent work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes from contact with blood or other potentially infectious materials is justified and appropriate.

With respect to preventing mucous membrane contact, the proposed standard required that emergency ventilation devices also fall under the scope of personal protective equipment and hence be provided by the employer for use in resuscitation. OSHA based this requirement on the possibility of employee exposure to blood or other potentially infectious materials in the mouth or in fluids that may be expelled by the patient during resuscitation. As little as one cubic centimeter (cc) of HBsAg positive blood can contain one hundred million infectious doses of Hepatitis B virus. As far as HIV is concerned, in their August 1987 guidelines, the CDC states:

> 4. Although saliva has not been implicated in HIV transmission, to minimize the need for emergency mouth-to-mouth resuscitation, mouthpieces, resuscitation bags, or other ventilation devices should be available for use in areas in which the need for resuscitation is predictable. (Ex. 6–153)

Provision of these devices was also supported by the American Federation of State, County, and Municipal Employees (AFSCME). (Ex. 11–157)

The International Association of Fire Fighters (IAFF), during its public hearing testimony, commented that provision of resuscitation devices was a necessity. Mr. Richard Duffy, Director of Occupational Health and Safety for the IAFF, stated:

> We have given the use of respiratory assistance equipment considerable thought. We certainly believe that unprotected mouth-to-mouth resuscitation should not be used by

any emergency response personnel. To this end, we believe that mechanical respiratory devices, such as a bag-valve mask or an oxygen demand valve resuscitator, be available on all fire department emergency vehicles that respond or potentially respond to medical emergencies or victim rescues—hence, almost every vehicle in a fire department.

Additionally, pocket masks designed to isolate emergency response personnel from contact with victim saliva, respiratory secretions, vomitus, blood or body fluids must be provided to all personnel who provide or potentially provide emergency treatment. (Tr. 9/14/89, p.155)

In further support, Dr. Thomas Robins, Chair of the State of Michigan Advisory Committee on Occupational Exposure to Bloodborne Pathogens, testified that Michigan's draft regulation on occupational exposure to bloodborne pathogens would require provision of emergency ventilation devices (Tr. 10/17/89, p.22). The Centers for Disease Control retained their recommendation for use of these devices in their June 1989 document "Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers" which states:

> Mechanical respiratory assist devices (e.g., bag-valve masks, oxygen demand valve resuscitators) should be available on all emergency vehicles and to all emergency response personnel that respond or potentially respond to medical emergencies or victim rescues.
>
> Pocket mouth-to-mouth resuscitation masks designed to isolate emergency response personnel (i.e., double lumen systems) from contact with the victim's blood and blood-contaminated saliva, respiratory secretions, and vomitus should be provided to all personnel who provide or potentially provide emergency treatment. (Ex. 15)

Rondex Products Inc. (Ex. 20–47) commented that some of the devices falling under the nomenclature of "masks", "mouthpieces", "resuscitation bags", and "shields/overlay barriers" may not be protective or could be improperly used by non-medical personnel. OSHA is reluctant, however, to prohibit use of specific types of resuscitation devices simply because some may not be protective under certain circumstances. There are many different personal protective equipment designs currently being marketed or being developed. OSHA believes that by choosing to apply a blanket prohibition to certain device types, the standard could become technology-limiting and it is not the Agency's intent to discourage development of safer and more protective devices. Moreover, it should be remembered that the same test of "appropriate" applies to emergency resuscitation devices as it does to other personal protective equipment. OSHA also believes that the issue of improper use of these devices has been addressed by paragraph (g)(2)(vii)(G) of this standard which requires that employees be trained in the types, proper use, location, removal, handling, decontamination, and disposal of personal protective equipment.

Based upon the information provided in the comments, OSHA has concluded that minimization of mouth-to-mouth resuscitation is prudent practice and that the most effective means to do so is to require ventilation devices be provided for resuscitation. Consequently, these devices have been retained under the requirements for provision of personal protective equipment. In addition, as required by paragraph (d)(3)(iii) of this standard, these devices are to be readily accessible to employees who can reasonably be expected to resuscitate a patient.

Paragraph (d)(3)(ii) of the standard requires the employer to ensure that the employee uses appropriate personal protective equipment. Furthermore, this provision states that the employee may temporarily and briefly decline to use personal protective equipment if, under rare and extraordinary circumstances, it is the employee's professional judgement that in the specific instance its use would prevent the delivery of health care or public services or would pose an increased hazard to the safety of the worker or co-worker. This exception to the use of personal protective equipment under certain circumstances was supported by a number of commenters (e.g., CDC/NIOSH, Ex. 20–634, Tr. 9/14/89, pp.31–32; ANA, Tr. 9/20/89, p.79; American Public Health Association, Ex. 20–1361; SEIU, Tr. 9/15/89, p.7). OSHA believes that in order to ensure that employees are adequately protected, the employer has the responsibility to not only provide personal protective equipment but also to ensure that it is utilized when necessary. The word "ensure" is used in this final standard in view of this responsibility because it holds the employer to a higher and more consistent level of performance.

OSHA believes that the personal protective equipment required by this standard is the minimum equipment dictated by the exposure circumstances requiring its use. By permitting employees to judge, individually, what protective equipment they will utilize could result in such a wide variance of equipment used for the same task (e.g., from no equipment to a "moon suit" approach) that those minimum standards of protection may not be met. Also, the Agency does not believe that the employee should be entirely responsible for his or her personal safety. Section 5(a)(1) of the OSH Act stipulates that the employer is responsible for furnishing "employment and a place of employment which are free from recognized hazards that are likely to cause death or serious physical harm to his employees." Therefore, the OSHAct places the onus of protecting employees upon the employer since the hazard(s) are present in the workplace under his or her control. The Agency interprets this to mean not only that the employer provide training, personal protective equipment, engineering controls, and so forth, but also that the employer has the responsibility to take necessary measures to insure that employees adhere to safety and health procedures.

A large number of commenters expressed concern that the employer would be held responsible to "assure" that employees use appropriate personal protective equipment. Of these, some thought that employees should be permitted to judge for themselves what protective equipment should be worn for each procedure, based in whole or in part, upon their training, experience, skill, knowledge, procedure, and anticipated exposure (e.g., American Society for Medical Technology, Ex. 20–990; American Association for Respiratory Care, Ex. 20–107; APIC—Greater Omaha Area, Ex. 20–843; Lee Hospital, Ex. 20–103; United Steelworkers of America, Tr. 11/13/89, pp.104–105). Other participants felt that the employer should not be required to assure use of personal protective equipment and that this responsibility for self-protection should be shouldered by the individual employee (e.g., APIC—Virginia, Ex. 20–750; American Society for Microbiology, Ex. 20–1168; The State Medical Society of Wisconsin, Ex. 20–276). Furthermore, still other commenters stated that requiring the employer to "assure" use of personal protective equipment was a requirement that the employer would find difficult if not impossible to fulfill since there was no way to monitor all employees to assure total compliance all of the time (e.g., Kaiser Permanente—Panorama City, Ex. 20–80; Medical Arts Laboratory, Ex. 20–638; Stanford University Hospital, Ex. 20–664; California APIC Coordinating Council, Tr. 1/10/90, p.187). The University of Cleveland Hospitals questioned the methods required of employers to assure use of personal protective equipment. They inquired if a nurse, who had been properly educated and understood the

risks yet still disregarded the rules, should be fired and they questioned what other option was available to assure use of proper personal protective equipment (Ex. 20–663). The Guthrie Clinic Ltd. expressed similar thoughts and urged OSHA to modify this provision to require that employers "endeavor to assure" use of personal protective equipment (Ex. 20–1222). The AHA supported this "endeavor to assure" approach in their statement:

> • • • [R]equire only that the employer take "reasonable efforts" to direct employees to use personal protective equipment, and to provide the training necessary for them to use it. (Ex. 20–352)

It is not OSHA's intent that each employee be constantly monitored for compliance, however, the Agency does not believe that the employer is powerless to have employees follow specific rules. Most certainly, employers have other policies such as reporting to work on time, working a particular minimum number of hours a day, notifying the employer when the individual is unable to report to work, taking certain precautions to prevent nosocomial infections, and so forth that they require employees to follow. These basic procedures are assuredly not left to the employee's discretion as to whether or not they are followed and the employer must have some process to reinforce their adherence. While such a process may be a multi-stage disciplinary process, this is not necessarily the only alternative. Methodist Hospital of Southern California, for example, suggested that an employee's compliance rate be tied-in with the individual's performance evaluation (Ex. 20–246). More simply, increased compliance may possibly only require additional education efforts or a positive reinforcement approach. The Agency does not find the arguments to rescind this provision to be compelling and, therefore, has retained the requirement that employers ensure that the employee uses appropriate personal protective equipment. This requirement is also consistent with other recent OSHA standards such as Coke Oven Emissions, 29 CFR 1910.1029; 1,2-dibromo-3-chloropropane (DBCP), 29 CFR 1910.1044; Ethylene Oxide, 29 CFR 1910.1047; and Formaldehyde, 29 CFR 1910.1048.

During the public comment process, several dental organizations raised the issue of exempting dentists from use of personal protective equipment, in whole or in part, while treating young children in order to prevent scaring the child (ADA, Ex. 20–665; American Association of Orthodontists, Tr. 11/14/89, pp.496–497; American Association of Orthodontists, Tr. 9/22/89, p.57; American Academy of Pediatric Dentistry, Tr. 10/19/89, p.467; Florida Academy of Pediatric Dentistry, Tr. 12/19/89, pp. 1075–1076; SEIU, Dr. Norma Solarz, Tr. 1/16/90, pp.663–664). Testimony presented by Dr. Thomas Floyd on behalf of the Florida Academy of Pediatric Dentistry urged OSHA to afford the dentist flexibility in deciding if a child will be overly frightened by use of a mask and goggles (Tr. 12/19/89, pp.1075–1076). In response to OSHA's question about his normal protective equipment, however, Dr. Floyd responded:

> Routinely, all examinations and all treatment are with gloves. We utilize the rubber dam routinely, and when we are using a rotary instrument and have the possibility of an aerosol, we will use a mask and a shield with protective eye covering. I wear glasses anyway for close up work • • •. (Tr. 12/19/89, p.1089)

When asked if he felt that this garb was appropriate for pediatric dentistry, Dr. Floyd stated:

> If it has been explained properly and is accepted by the child, yes. There are certain situations where it could become threatening and then the practitioner has to utilize his judgement. We never relinquish the gloves. We never relinquish the glasses. We never relinquish the clinic jacket. Sometimes the faceshield, but we will wear the mask, and I do not think that we have frightened anyone to the point of running out of the office at this point. (Tr. 12/19/89, p.1089)

Ms. Karen Boulton of the American Dental Hygienists Association stated that she normally wore a ¾ length sleeve lab coat, gloves, mask, and prescriptive eyewear. When asked if she found this equipment scared children under her care, she responded:

> • • • I personally don't find it to be a problem. I think its all in the education process to the child and you know certainly you can speak with the parent before the child comes in for actual treatment, but I have not found that to be a problem at all. In fact you can kind of make it a fun game with the child when you put your mask on, you can even draw a smile on the mask. I haven't found that to be a problem. (Tr. 1/16/90, pp.560–561)

In addition, Ms. Mary Kelly, a dental hygienist appearing at the Chicago hearings, testified that she had cleaned the teeth of children down to two and a half years of age and that they did not mind her use of protective equipment (Tr. 10/19/89, p.718). This testimony, gathered from practitioners who treat or have treated children while utilizing protective equipment, demonstrates to the Agency that use of personal protective equipment during dental care of children can be accomplished without frightening the patient. Also, children, like adults, can be infected with HBV and HIV without manifesting external signs and, therefore, should be treated with universal precautions. Consequently, the Agency has concluded that exemption or deviation from required personal protective equipment during dental treatment of children is not warranted.

Paragraph (d)(3)(ii) of the standard, however, does contain a limited exemption to the use of personal protective equipment. It requires that the employer shall ensure that the employee uses appropriate personal protective equipment unless the employer shows that the employee temporarily and briefly declined to use personal protective equipment when, under rare and extraordinary circumstances, it was the employee's professional judgement that in the specific instance its use would have prevented the delivery of health care or public safety services or would have posed an increased hazard to the safety of the worker or co-worker. In addition, when the employee makes this judgement, the circumstances must be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future.

OSHA stated in the proposed standard that it recognized that on occasion particular circumstances arise in which the use of personal protective equipment may interfere with the proper delivery of health care or public safety services or create a significant risk to the personal safety of the worker. The following scenarios represent examples of when such a situation could occur:

1. A sudden change in patient status such as when an apparently stable patient unexpectedly begins to hemorrhage profusely, putting the patient's life in immediate jeopardy;
2. A firefighter rescues an individual who is not breathing from a burning building and discovers that his/her resuscitation equipment is lost/damaged and he/she must administer CPR;
3. A bleeding suspect unexpectedly attacks a police officer with a knife, threatening the safety of the officer and/or co-workers.

The first two scenarios are examples of situations which may be immediately life-threatening to the patient while the third illustrates circumstances in which the personal safety of the worker or co-workers could be compromised. In evaluating each of the above situations, it may be judged that the time required to don personal protective equipment is critical to the patient's life or preventing

case or affixing the equipment more securely to the firefighter's clothing. Therefore, the employer is required to investigate and document the circumstances surrounding those instances when an employee invokes the exemption to the use of personal protective equipment in order to determine if changes can be instituted that would prevent a reoccurrence of such a situation in the future. In addition, the employer is not relieved of the responsibility to assure that personal protective equipment is readily accessible at all times and shall not discourage adherence to universal precautions or the appropriate use of personal protective equipment.

Paragraph (d)(3)(iii) of the final standard requires the employer to ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the worksite or is issued to employees. In addition, hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives are required to be readily accessible to those employees who are allergic to the gloves normally provided.

It is of great importance that personal protective equipment is easily accessible and of proper size. The consistent use of such items hinges, in part, upon the employee's motivation and acceptance. However, if access of the equipment is difficult, its use may be perceived as too time consuming and burdensome. Proper fit of personal protective equipment also plays a major role in its utilization by employees. If it is too large or too small it may be uncomfortable or could interfere with proper task performance, resulting in frustration and non-use. Ms. Delores Pfohl of the Communication Workers of America testified:

> • • • We've had problems getting people to wear gloves while they change a dressing or make a bed because they say that the gloves don't always fit well. They're awkward to use • • •. (Tr. 11/14/89, p. 250)

Proper employee protection rests upon utilization of this equipment, therefore, provision of proper sizes and accessibility must be maintained to ensure and promote its use. Several commenters supported this provision (SEIU, Tr. 11/13/89, p. 131; American Association of Critical-Care Nurses, Tr. 12/19/89, pp. 852, 858; AFSCME, Tr. 1/16/90, p. 604; Drug, Hospital, and Health Care Employees Union—Local 1199, Tr. 11/14/89, pp. 396–397; RWDSU, Tr. 11/14/89, pp. 432–433; Surgikos, Ex. 20–252). In addition, some participants in the hearing provided examples of how accessibility of personal protective equipment is currently being achieved in their workplace (AFSCME, Tr. 10/17/89, p. 83; AFSCME, Tr. 1/16/90, p. 600; Presbyterian Hospital of Dallas and Presbyterian Healthcare System, Tr. 9/27/89, p. 177; St. Paul Medical Center, Tr. 9/27/89, p. 209). Roxborough Memorial Hospital and the Tennessee Health Care Association asked that accessibility be clarified (Exs. 20–820; 20–1205). Based on the evidence in the record, the Agency has concluded that appropriate protective equipment must be located so that acquiring it does not hinder performance of the task or be inconvenient to the point of discouraging use. For example, Mr. Martin Rosen, a paramedic and representative of SEIU, testified that blood-soaked clothing cannot always be changed before proceeding to the next emergency call. He stated that the company encouraged employees to keep a second change of clothing in their car at the ambulance's home base but that the ambulance may not return to base for prolonged periods, possibly the entire shift (Tr. 1/16/90, pp. 778–779). The Agency would not consider this to be ready accessibility of personal protective equipment. OSHA agrees with Mr. Paul Maniscalco of the National Association of Emergency Medical Technicians who testified that he felt "accessible" would be on-scene, either on an individual's person or on the vehicle, depending upon the nature of the equipment (Tr. 9/14/89, pp. 133–134). In the case related by Mr. Rosen, the second set of clothing could be kept on the ambulance or employees could be provided with several sets of replaceable coveralls to be kept on the vehicle. The employer's responsibility to ensure accessible personal protective equipment for employees at non-fixed worksites cannot be overemphasized. Adequate planning and reinventory should ensure that the necessary equipment is present on the response vehicle or on the employee's person. Based upon the evidence submitted, it is OSHA's opinion that maintenance of ready accessibility in both fixed and non-fixed worksites is feasible.

The Society of Hospital Epidemiologists of America urged OSHA to clarify that barrier precautions which would not be expected to be needed in a particular area would not, consequently, be required to be readily accessible in that area (Tr. 10/18/89, p.357; Ex. 20–1002). It is not OSHA's intent that the entire array of personal protective equipment be readily accessible to all work areas; only that equipment which can be reasonably anticipated to be needed based upon the types of occupational exposure expected in a work area must be provided. For example, head and shoe covers would not be expected to be readily accessible in an area where gross contamination of the head or shoes would not be reasonably anticipated.

The Agency is aware that use of gloves as a protective barrier is a major part of this standard's methods of preventing occupational exposure. In addition, it is known that some employees may exhibit an allergic dermal reaction to the gloves normally provided to workers or the powder that the gloves contain. To prevent exacerbation of such allergic dermatitis and thereby permit these individuals to continue working, the proposal required employers to make hypoallergenic gloves readily accessible to those employees who exhibited allergic reactions to the gloves normally provided. A number of commenters acknowledged that some type of concession should be made for employees who manifest allergic reactions to gloves (APIC—San Francisco Bay Area, Tr. 1/10/90, pp.168–169; AAOHN, Ex. 20–882; Infection Control Coordinators Conference—Connecticut Hospitals Association, Ex. 20–275; Kaiser Permanente—Fontana, CA, Ex. 20–551; St. Vincent Hospital, Ex. 20–524; William W. Backus Hospital, Ex. 20–911; MD Anderson Cancer Center—University of Texas, Ex. 20–390; Verdugo Hills Hospital, Ex. 20–573; El Camino Hospital, Ex. 20–879; Surgikos, Ex. 20–252). However, information was provided that hypoallergenic gloves may not be the proper solution or, at least, the only solution available to address such reactions and several alternatives were given including powderless gloves, glove liners, and simply changing to another brand of glove (Tr. 1/10/90, p.169; Exs. 20–524; 20–249; 20–390; 20–879; 20–109). The final standard, therefore, expands this provision to afford employers with the flexibility to provide their employees with hypoallergenic gloves, glove liners, powderless gloves, or similar alternatives to deal with allergic reactions rather than restrict them to the single recourse of hypoallergenic gloves.

Paragraph (d)(3)(iv) of the standard requires that the employer clean, launder, and dispose of personal protective equipment required by paragraph (d), Methods of Compliance, and paragraph (e), HIV and HBV Research Laboratories and Production Facilities, of this standard, at no cost to the employee. In addition, paragraph (d)(3)(v) stipulates that the employer must repair or replace personal protective equipment as needed to

maintain its effectiveness, at no cost to the employee. These requirements remain basically unchanged from those contained in the proposal except for the addition of "at no cost to the employee." This addendum has been included to clarify that the employer's responsibility does not end with provision of personal protective equipment but is an ongoing responsibility to clean, maintain, and dispose of such equipment.

The first provision ensures that these items remain within the control of the employer and, therefore, will be properly disposed of, cleaned, or laundered consistent with that employer's control program. This will prevent contamination outside of the work area (e.g., non-work areas such as the employee's home). The requirement to repair or replace the protective equipment is needed to ensure proper functioning of these items and, thereby, proper employee protection. Moreover, requiring that the employer be responsible for this activity provides further insurance that the items will remain under the control of the employer who will make this a part of his or her overall program to control occupational exposure. Support for these specific provisions was received from several commenters (Minnesota Nurses Association, Ex. 20-995; Society of Hospital Epidemiologists of America, Ex. 20-1002; Rose Marie Unrein, Ex. 20-140; Fairfax County Fire Department, Tr. 9/14/89, p.179; RWDSU, Ex. 20-1505; Kathy Lampe, Ex. 20-1; State of Maryland, Division of Labor and Industry, Ex. 20-1362; ServiceMaster Company, Ex. 20-21).

Some confusion appears to exist as to the employer's responsibility (e.g., cleaning, repair, replacement) for employee-procured uniforms, lab coats and other items of clothing as evidenced by the number of participants requesting clarification of or stating opposition to this issue (APIC, Ex. 20-1118; American Association of Critical-Care Nurses, Ex. 20-1182; Exs. 20-523; 20-532; 20-1332; 20-568, 20-545, 20-661; 20-908; 20-105; 20-633, 20-320; 20-390; 20-548; 20-618; 20-967; 20-529; 20-1194; 20-43; 20-557; 20-886; 20-673; 20-11; 20-538; 20-527; California APIC Coordinating Council, Tr. 1/10/90, pp. 187-188). As stated previously in the discussion of "provision" of personal protective equipment, the employer's responsibility is based upon the intended function of an item. If an item is to function as personal protective equipment, then it is the employer's responsibility to provide that item, clean it, repair it, replace it, and dispose of it. These requirements imposed on the employer as part of his or her ongoing responsibility for employee personal protective equipment are consistent with other recent OSHA standards (Formaldehyde, 29 CFR 1910.1048; Asbestos, 29 CFR 1910.1001).

The record clearly indicates that some employees are currently laundering contaminated personal protective equipment at home (Frankford Hospital, Ex. 20-211; Hahnemann University Hospital, Ex. 20-356; ADA, Ex. 20-665; Oregon Dental Association, Ex. 20-1320; Kathy Lampe, Ex. 20-1; SEIU, Tr. 1/16/90, p.795; Dr. Frederick Preis, Tr. 9/25/89, p.12; Dr. Henry Finger, Tr. 9/22/89, p.39). In addition, some participants felt that contaminated clothing could be safely washed at home and that there was no evidence of disease transmission to support requiring that employers clean contaminated personal protective equipment (MetroHealth Medical Center, Ex. 20-190; Albert Einstein Medical Center, Ex. 20-945; Eisenhower Memorial Hospital, Ex. 20-1217; Laboratory of Pathology, Ex. 20-565; Lassa NW, Ex. 20-680; Osteopathic Medical Center, Ex. 20-1342).

The Agency does not believe that washing contaminated personal protective equipment at home is acceptable. Insurance of proper laundering procedures is one of the major reasons why the Agency believes that contaminated personal protective equipment must remain under the control of the employer. By permitting home laundering, the employer, obviously, cannot assure himself or herself that proper handling or laundering procedures are being followed. Moreover, as stated previously, home laundering could lead to migration of contaminants to non-work environments. Relative to the lack of evidence of disease transmission from washing contaminated equipment at home, reference to the "Laundry" section of this document will show that a large number of commenters believe that all contaminated laundry should be considered to be infectious and should be handled with universal precautions. This position is supported by ServiceMaster which listed the shortcomings of home laundering and recommended against allowing such practices (Ex. 20-21).

The Agency recognizes no distinction between dealing with contaminated institutional linen (e.g., bedsheets, surgical drapes) and the procedures for cleaning, laundering, and disposal of contaminated personal protective equipment. Therefore, OSHA concludes that while there are no specific studies linking disease transmission to home laundering, careful handling and cleaning of contaminated items is adequately supported to justify these provisions.

Paragraph (d)(3)(vi) stipulates that if a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible. This provision has been added to the final standard in response to a comment from CDC/NIOSH recommending insertion of a subparagraph stating:

> Employees shall immediately wash hands and any other skin or mucous membrane that becomes contaminated with blood or other potentially infectious material. In the event that outer garments are penetrated by blood or other potentially infectious material, the contaminated clothing shall be removed and the skin washed immediately or as quickly as practicable. (Ex. 20-634)

The logic behind adoption of this provision is to (1) Minimize further penetration of blood or other potentially infectious materials onto underlying garments and/or skin or mucous membranes and (2) minimize the amount of time these materials remain in contact with skin or mucous membranes if these materials have penetrated to the point of contacting the individual's skin or mucous membranes. It should be noted that if the latter case occurs (i.e., contact with skin or mucous membranes), the affected body areas are to be washed or flushed as required by paragraph (d)(2)(vi) of this standard.

The final standard, in paragraph (d)(3)(vii), requires that all personal protective equipment be removed prior to leaving the work area. This provision will minimize migration of contamination beyond the work area to such places as lunchrooms and offices. Several commenters and other documents in the record provided support for this provision (NIH, Ex. 6-338; NCCLS, Ex. 11-159A; Rose Marie Unrein, Ex. 20-140; American Society for Microbiology, Ex. 20-1188; Laurence R. Foster, Oregon State Epidemiologist, Ex. 20-832; St. Vincent Hospital, Ex. 20-524; State of Maryland, Division of Labor and Industry, Ex. 20-1362; American Red Cross, Ex. 11-280).

Upon removal of personal protective equipment, paragraph (d)(3)(viii) requires it to be placed in an appropriately designated area or container for storage, washing, decontamination or disposal. This ensures that the personal protective equipment will remain in a recognized area(s) and helps ensure that it will be dealt with by employees who have been trained in the proper handling of these items.

Performance of the majority of tasks that could result in occupational exposure usually requires some type of manual manipulation. Consequently, it is the individual's hands which have the highest probability for coming in contact with blood or other potentially infectious materials. Utilization of gloves has become the most widely used barrier precaution against transmission of infection, not only from employee-to-patient but also from patient-to-employee. Therefore, paragraph (d)(3)(ix) requires that gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin; when performing vascular access procedures [except as specified in paragraph (d)(3)(ix)(D)]; and when handling or touching contaminated items or surfaces. Examples of tasks which require the use of gloves include dentistry, surgery, phlebotomy [except as specified in paragraph (d)(3)(ix)(D), starting IVs, laboratory analysis of blood or other potentially infectious materials, clean-up of blood spills, and rendering emergency medical assistance to individuals with traumatic injury. OSHA concludes that use of gloves is a basic precept of prevention of occupational transmission of bloodborne pathogens. Gloves act as the primary barrier between an employee's hands (and any attendant skin lesions or breaks) and contact with blood and other potentially infectious materials, thereby minimizing exposure to these substances. Overall, use of gloves as a barrier precaution is advocated by a number of recognized sources and interested parties (e.g., CDC, Exs. 6–153, 6–316, 15, Tr. 9/14/89, p.20; AHA, Tr. 9/19/89, p.120, Ex. 20–352; ADA, Tr. 10/19/89, p.443, Ex. 20–665A; Academy of General Dentistry, Tr. 9/22/89, p.17; NCCLS, Ex. 11–152A; CDC/NIOSH, Ex. 20–634; AFSCME, Ex. 297; SEIU, Ex. 298; International Association of Fire Fighters, Tr. 9/14/89, p.153).

Further support for the feasibility of glove usage can be found in the compliance statistics and recommendations provided as part of the information provided by several participants. For example, the American Association of Orthodontists support the use of gloves (Ex. 20–355, Dr. David McKenna, Tr. 11/14/89, p.997). The Academy of General Dentistry's 1987 survey showed that 75% of its members glove for all patients (Tr. 9/22/89, p.14). The American Board of Pediatric Dentistry found glove compliance in pediatric dentistry to be approximately 90% (Tr. 10/19/89, p.476). Ms. Pat Lynch, infection control coordinator at Harbor View Medical Center and an American Hospital Association representative, stated that a study conducted at Harbor View showed compliance with glove usage to be greater than 80% (Tr. 9/19/89, p.120). Moreover, a 1988 survey conducted by the American Dental Association and summarized in their post-hearing brief reported the following usage rates: Dentists—76%, Hygienists—97%, and Assistants—78% (Ex. 282). Compliance rates from OSHA's survey can be found in the Regulatory Analysis section of this document.

While gloves are a generally-accepted method of protecting against exposure, a number of commenters took issue with requiring the use of gloves when performing phlebotomy and forwarded a number of arguments in support of their opinion. With specific regard to drawing blood, participants commented that inclusion of this task conflicted with the recommendations of CDC and urged the Agency to adopt the language of the CDC guidelines (e.g., AHA, Ex. 302; CDC/NIOSH, Ex. 20–634; Norwood Hospital, Ex. 20–987). Some also stated that employees, particularly skilled phlebotomists, should be allowed to decide for themselves whether or not gloves should be used (e.g., Iowa Lutheran Hospital, Ex. 20–885; Flint Osteopathic Hospital, Ex. 20–1154; Hurley Medical Center, Ex. 20–762).

In their 1988 document, Update: Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Bloodborne Pathogens in Health-Care Settings, CDC wrote:

> • • • In universal precautions, *all* [Emphasis in the original] blood is assumed to be potentially infective for bloodborne pathogens, but in certain settings (e.g., volunteer blood-donation centers) the prevalence of infection with some bloodborne pathogens (e.g., HIV, HBV) is known to be very low. Some institutions have relaxed recommendations for using gloves for phlebotomy procedures by skilled phlebotomists in settings where the prevalence of bloodborne pathogens is known to be very low.
>
> Institutions that judge that routine gloving for *all* [Emphasis in the original] phlebotomies is not necessary should periodically reevaluate their policy. Gloves should always be available to health-care workers who wish to use them for phlebotomy. In addition, the following general guidelines apply:
>
> 1. Use gloves for performing phlebotomy when the health-care worker has cuts, scratches, or other breaks in his/her skin.
>
> 2. Use gloves in situations where the health-care worker judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative patient.
>
> 3. Use gloves for performing finger and/or heel sticks on infants and children.
>
> 4. Use gloves when persons are receiving training in phlebotomy. (Ex. 6–316)

The above statement does not say that gloves are unnecessary for phlebotomy, simply that some institutions have chosen not to follow CDC's 1987 guidelines (requiring gloves for all phlebotomies) and have relaxed recommendations for the use of gloves by skilled phlebotomists. It is not a blanket statement about all settings (e.g., hospitals, clinics) where phlebotomies are *performed nor does it* refer to all vascular access procedures, only phlebotomy and, in particular, phlebotomy in volunteer blood donation centers. This specific setting is addressed in paragraph (d)(3)(ix)(D) below.

With regard to permitting skilled phlebotomists, in general, to decide when to use gloves, it is not the Agency's policy to base compliance with a regulation upon an employee's perception of his or her skill or experience at avoiding a hazard. Such an action would be analogous to permitting employees to enter a toxic atmosphere without respiratory protection based upon their belief that they could hold their breath long enough to accomplish the task at hand. The CDC recommends that gloves be used in situations where the healthcare worker judges that hand contamination with blood may occur. Evidence in the record indicates that a judgement of this sort would be simply an arbitrary selection on the part of the worker. For example, Ms. Carol Rogers, a physician's assistant and representative of AFSCME, who testified that she performed "a lot" of phlebotomies, stated:

> • • • Sometimes when there's a tourniquet, the vein is under so much pressure that when you put the needle in, the blood spurts out. It's—I mean, that's a good stick, too. It just happens. (Tr. 9/15/89, p.183)

In addition, Ms. Pam Talbot, a staff nurse for the American Red Cross who has twelve years experience drawing blood (and who feels herself to be a skilled phlebotomist) testified that she got blood on her hands when changing from test tube to test tube:

> • • • Sometimes three or four days it won't [happen] and sometimes one day it'll happen every time. (Tr. 9/15/89, p.175)

Dr. Joseph H. Coggin, one of OSHA's expert witnesses stated:

> In a clinical setting, I witnessed a phlebotomist drawing blood in the emergency

room from a gentleman with chest pains. Several ounces of blood were released onto the emergency room table while changing tubes on the needle set * * *. (Tr. 9/12/89, p.52)

These statements demonstrate that during blood drawing, even by an experienced phlebotomist, predicting when an occupational exposure could occur would be extremely difficult if not impossible.

Many participants criticized the proposal's requirement for gloves during phlebotomy on the grounds that gloves did not prevent needlesticks (e.g., American Society for Clinical Pathologists, Ex. 20–351; American Blood Resources Association, Ex. 20–1090; Glendale Memorial Hospital, Ex. 20–9; St. Joseph Hospital, Ex. 20–913; St. Vincent Medical Center, Ex. 20–529). OSHA recognizes that gloves will not protect against needlestick and proposed this requirement to prevent contamination of the hands with blood. This was the intent of CDC's original recommendation (as stated in Ex. 6–316, CDC's Update: document) and is also recognized by the American Hospital Association. When asked by OSHA's Dr. Susan Harwood if the AHA understood that it was not CDC's intent for gloves to protect against needlesticks but, instead, to prevent hand contamination, AHA's representatives Mr. Dennis Brimhall and Ms. Margaret Hardy responded that this was their understanding. Dr. Harwood then asked if a skilled phlebotomist with a cooperative adult patient should base utilization of gloves on whether or not the patient was known to be infected with HIV or HBV. Mr. Brimhall responded:

Well, according to the spirit of universal precautions, the answer to that would have to be no. The precautions ought to be taken regardless of the knowledge of the status of the patient. You have to assume that you don't know the status, you have to assume that you [are] providing protection against unknown status. (Tr. 9/19/89 p.161–162)

Ms. Hardy and Mr. Brimhall continued that if this course of action was not adhered to then one was not truly protecting the worker and it was not, in actuality, universal precautions. St. Vincent Medical Center also felt that requiring gloves for phlebotomy would not increase worker safety since they felt needlesticks were the major hazard (Ex. 20–529). In general, most people have breaks in the hand's skin barrier (e.g., damaged cuticles, scrapes, microcuts, dermatitis) as a matter of course and the Agency does not believe phlebotomists to be any different in this respect. OSHA has concluded, therefore, that gloves increase worker protection by minimizing contact of blood or other potentially infectious materials with such breaks in the skin.

One of the major concerns voiced by interested parties regarding mandated glove usage was that gloves decrease tactile sensation, decreasing dexterity and possibly resulting in an increased hazard for failed task performance or needlestick (e.g., Department of Defense, Armed Forces Blood Program Office, Ex. 20–161; American Association of Blood Banks, Ex. 20–1059; Dr. Stutt, American Association of Orthodontists, Tr. 9/22/89, pp.65–66; Dr. Stephen D. Carter, DDS, Ex. 20–277). Information submitted does not support this opinion, however. Ms. Ellen Redick of the American Association of Critical-Care Nurses testified:

* * * [W]henever you change your practice, there is that learning curve and that at first you may have a little bit of fumbleitis, but because you know that you are using something new, you have got a pair of gloves that are too big or what ever the problem is, you are going to be more careful. I personally have never had an experience or heard of an experience where someone has caused themselves and or the patient harm because they were using protective equipment * * *. (Tr. 12/19/89, pp.958–959)

Three employees whose responsibilities include phlebotomy also commented on this issue. Ms. Pam Talbot stated:

* * * [I]f they fit properly * * * the gloves don't present any hinderance in drawing blood, as far as I'm concerned. I have no problems with them if they fit properly. (Tr. 9/15/89, p.163)

In a later discussion with the OSHA panel, as to why phlebotomists do not want to wear gloves or are not currently wearing them, Ms. Talbot responded:

The only thing that I can see is sometimes they don't fit properly. If they don't fit properly, if there's none in your size, then it's impossible to do a needlestick with gloves that are too big that are falling off your hands. (Tr. 9/15/89, p.184)

Similar sentiment was expressed by Ms. Carol Rogers when asked about the difficulty of changing from ungloved to gloved phlebotomy:

* * * [I]t was more psychological difficulty than—it was just really more thinking of using the gloves when you were performing phlebotomy * * *. I don't think its harder with gloves that fit than without them. (Tr. 9/15/89, p.179)

Ms. Nan Kaeser, an Assistant Head Nurse for the American Red Cross, Greater Hartford Chapter, with approximately thirty years phlebotomy experience commented:

I can't overemphasize how important fit is. The other day I went into someone else's unit to help out with a phlebotomy, and I used one of their gloves. The glove was huge—you could have played baseball with it. I couldn't feel anything and had to put on a different pair before I could begin.

Our glove policy hasn't caused any major problems at our center, and now its like second nature. I wouldn't think of touching anyone without them. (Ex. 130)

Phlebotomy is not the only venous access procedure performed by workers. In this regard, Dr. Arnold Berry, Associate Professor of Anesthesiology at Emory University School of Medicine, stated:

* * * In my experience, anesthesia personnel have been slow to adopt the use of gloves because of a perception that they will interfere with their ability to perform these procedures where tactile perception is necessary. In my practice, I have learned to perform these tasks while wearing gloves, although I was not trained in these techniques during my residency. (Ex. 230)

It should be noted that all of the above individuals have switched from ungloved to gloved performance of their duties, demonstrating that use of gloves is feasible and can be successfully accomplished. In addition, proper fit of gloves obviously plays a central role in achieving proper task performance and acceptance of glove usage among employees. This factor has been addressed previously in paragraph (d)(3)(iii) which requires that employees be provided with personal protective equipment in appropriate sizes.

The American Red Cross submitted data that related to the number of unsuccessful collections (UN) that resulted when phlebotomists were required to wear gloves (American Red Cross, Ex. 238). Unfortunately, they did not give actual numbers for UN but rather gave percentages. It is unclear whether a UN rate that rose 100% represented 1 UN without gloves and 2 UN with gloves or 40 UN without gloves and 80 UN with gloves or some other number. In any case, the rate of unsuccessful collections dropped essentially to zero (0.2%) after four months. This supports the idea that it is a matter of learning a skill and not an intrinsic problem with the use of the gloves. Since the standard requires the use of gloves for all vascular access procedures, we conclude that phlebotomists will soon learn to perform phlebotomy using gloves with the same skill they previously showed using a bare handed technique.

In further reference to tactile sensation, the American Dental Hygienists' Association (ADHA) submitted a study entitled: Gloved Versus Ungloved Dental Hygiene Clinicians: A Comparison of Tactile

Discrimination (Ex. 275). In the study, subjects were to differentiate between grits of sandpaper using dental explorers while gloved and ungloved. Visual and auditory clues were blocked by a blindfold and stereo headphones. The following excerpts illustrate the conclusions of the study:

A decrease in tactile sensitivity is the primary reason dental practitioners prefer not to wear gloves. However, gynecologists, ophthalmologists, neurosurgeons and other medical personnel who require a high degree of tactile sensitivity wear gloves when performing examinations as well as in surgical procedures. A survey conducted by Solovan et. al. to determine operator effectiveness in performing scaling procedures while wearing gloves revealed that scaling efficiency was not affected. This finding supports King's study which indicated that wearing gloves did not impair the clinician's ability to achieve an accurate clinical diagnosis while using a vitalometer * * *.

The results of this study suggest that there is no statistically significant difference between the gloved and ungloved operator in detecting surface roughness when using either the #17 of CH-3 explorer. Although the majority of the subjects (62.5%) responded that gloves affected their ability to accurately discriminate, the results of the gloved and ungloved test scores did not confirm this. These findings support the studies of Solovan and King which indicated that gloves did not impair operator effectiveness when performing clinical skills * * *.

* * * The reluctance to wear gloves may be based more on habit than on actual loss of tactile sensitivity. (Ex. 275)

The American Association of Forensic Dentists (AAFD) on the other hand, submitted a study by Dr. E.J. Nelberger, DDS, entitled: Manual Dexterity and Associated Problems of 50 Practicing Dentists Using Latex Gloves (Ex. 20-109, C2). One of the aspects investigated in the study was the effect of latex gloves on light touch perception. This test was conducted by measuring the amount of force required for the test subject to first detect contact of the stylus of a dynamometer with his or her index finger. Tests were performed with the individual both wearing and not wearing gloves. Comparison of the force required to elicit response of the subject while wearing gloves with that required in the ungloved subject indicated a decrease in light touch perception. In addition, the AAFD study compared the average time required by the sample cohort to complete two assigned tasks while gloved and ungloved. While the average ungloved times were slightly faster (tenths to hundredths of a second) than the average gloved times, some individual subjects measured faster with gloves. None of the subjects failed in performing the assigned tasks.

The Agency is less concerned with definitive measurements of touch perception or maximum speed, than with actual ability to perform tasks while wearing gloves. The study submitted by the ADHA more accurately measures this parameter. Also, the testimony of witnesses supports the conclusion that employees can properly perform required tasks while utilizing gloves.

Reviewing the record, it is evident that employees who have not previously utilized gloves can successfully adapt to their use and that tasks can be properly performed while wearing gloves. It appears, in fact, that glove usage is already a widely-accepted practice among healthcare workers. OSHA has concluded, therefore, that the standard's required use of gloves is feasible and justified.

The proposal did not specify that a particular type of glove be utilized. Most of the gloves in use today are either latex or vinyl. However, representatives of SEIU testified in the hearings that they had been given plastic film food handling gloves ("baggie" gloves) to use in conducting exposure-related tasks (Tr. 1/16/90, pp.751-752). Such gloves are not strong enough to provide protection to the hands nor would they fit the employee as required by paragraph (3)(d)(iii). Therefore, such gloves would not be considered to be appropriate.

The American Association of Operating Room Nurses submitted an article, Integrity of Vinyl and Latex Procedure Gloves, which compared the barrier qualities of latex and vinyl (Ex. 20-882A). CDC/NIOSH specifically addressed the issue of vinyl versus latex in their post-hearing brief as follows:

A number of questions or comments were directed toward the degree of protection offered by gloves. Data are not sufficient to clearly distinguish benefits among various glove materials available (vinyl, latex, etc.). The collective experience in health-care settings during the last several decades indicates that gloves guard against transmission of infection. However, there are no documented differences related to type of material. (Ex. 298)

Because data in the record is inconclusive as to whether vinyl or latex gloves provide better protection, the final standard does not specify use of a particular material. The Agency concludes that both vinyl and latex are appropriate materials for glove use. However, one should realize that no barrier is 100% effective, therefore, handwashing after glove removal [as required by paragraph (d)(2)(v)] is very important.

Gloves may have to be replaced in order to ensure adequate protection for the employee and limit contamination. Paragraph (d)(3)(ix)(A) requires that disposable (single use) gloves such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised. Replacement of disposable gloves when contaminated will reduce inadvertent contamination of items throughout the work area such as door knobs, telephones, computer keyboards, and so forth (Ex. 6-344). Since the glove acts as the primary physical barrier between blood and other potentially infectious materials and the employee's skin, any tear, puncture, or similar defect compromises the integrity of this barrier, dictating replacement to ensure maintenance of protection (CDC, Ex. 6-153; American Association of Critical-Care Nurses, Ex. 20-1162; ADA, Ex. 20-665A; American Red Cross, Ex. 11-280).

Interested parties did not appear to disagree with this provision and it remains basically unchanged from the proposed requirement. Several commenters did point out possible interpretation problems with the proposed provision and the Agency has reworded the requirement to address these comments and clarify its intent. Replacement of gloves when visibly contaminated may not be workable in procedures where continuous blood contact is anticipated, as for example, in surgery (APIC—Northwestern Wisconsin, Ex. 20-108; American Association of Critical-Care Nurses, Ex. 20-1162; VA—Department of Medicine and Surgery, Ex. 20-95). Moreover, requiring that gloves be changed "as soon as possible" when visibly contaminated does not allow for procedures (e.g., surgery, deliveries) where it may be "possible" to change gloves but it may not be practical to interrupt the procedure to do so (Dr. Jared Schwartz, Presbyterian Hospital—Charlotte, NC, Ex. 20-812; Office of the Assistant Secretary of Defense, Ex. 20-847). OSHA recognizes that some critical procedures cannot be interrupted to change gloves as soon as visibly contaminated. In addition, all contamination may not be visible (e.g., blood plasma). Some materials on gloves may not be contamination as defined by this standard, but may be other materials such as iodine stains. The provision has, consequently, been revised to clarify the Agency's intent. Disposable gloves are to be replaced as soon as practical when contaminated

and as soon as feasible when their barrier properties are compromised.

Several participants urged OSHA to require gloves be changed between patient contacts (e.g., VA—Alexandria, LA, Ex. 20–39; Mercy Hospital of Johnstown, Ex. 20–628; District of Columbia Hospital Association, Ex. 20–342). While this is good infection control practice, the transmission being addressed is patient-to-patient and not patient-to-employee. Therefore, addition of such a provision to this document is beyond the scope of the OSH Act.

Paragraph (d)(3)(ix)(B) stipulates that disposable (single use) gloves shall not be washed or decontaminated for re-use (CDC, Ex. 6–316; ADA, Ex. 20–665A; Surgikos, Ex. 20–252). The CDC in its June 1988 Guidelines states that disinfecting agents may cause deterioration of the glove material while washing with surfactants could result in "wicking" or enhanced penetration of liquids into the glove via undetected holes, thereby transporting potentially infectious materials into contact with the hand (Ex. 6–316).

Utility gloves, often called "rubber" gloves, such as those which may be used for housekeeping chores, are of more substantial construction than surgical or examination gloves. The proposed standard, in agreement with CDC's recommendations, permitted disinfection and re-use of utility gloves provided they exhibit no signs of deterioration or their ability to function as a barrier was not compromised. The majority of commenters supported the use of utility gloves for housekeeping and laundry personnel and agreed with permitting their decontamination and re-use provided the gloves' integrity was maintained (e.g., AFSCME—NY, Ex. 20–985; CDC/NIOSH, Ex.20–634; American Society for Microbiology, Ex. 20–1188; ServiceMaster Company, Ex. 20–21; Society of Hospital Epidemiologists of America, Ex. 20–1002; American Biological Safety Association, Ex. 241). OSHA has concluded, therefore, that the proposed regulation was appropriate and, in paragraph (d)(3)(ix)(C), has stated that utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised, however, the gloves must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.

A few participants expressed reservations about decontamination of utility gloves (Tillotson Rubber Company, Ex. 20–1294; Calgon Vestal Laboratories, Ex. 20–49; Northwest Center for Occupational Safety and Health, Ex. 20–526). Tillotson commented that utility gloves should not be disinfected unless the method used can be validated to assure that the gloves are safe to use (i.e., could not contaminate co-workers or the environment with extended use). Similarly, Calgon Vestal Laboratories felt that it is the responsibility of glove manufacturers to supply users with appropriate decontamination procedures that do not compromise the integrity of the gloves. Calgon also felt that, in some cases, bloodborne pathogens may still reside on the glove's outer surface and, therefore, employees should be trained about accidental transmission. The Northwest Center for Occupational Safety and Health recommended that guidelines be set for how long utility gloves can be used, what types of utility gloves can be cleaned and re-used, and under what circumstances re-use is permitted.

OSHA believes "Decontamination", by definition, stipulates that the item must be safe for handling, use, or disposal. If the decontamination process compromises the gloves' integrity, they are to be discarded. Other provisions provide additional safeguards. Contamination migration is minimized since the standard requires that gloves are to be removed upon leaving the work area [paragraph (d)(3)(vii)] and that employees must wash their hands after glove removal [paragraph (d)(2)(v)]. With regard to setting guidelines for length of use time, the variability between gloves, tasks, and decontamination procedures would significantly affect how long gloves would be able to be used. Hence, a uniform time limitation would be extremely difficult to determine. However, appropriateness of re-use has been delineated by stipulating that gloves be discarded upon signs of deterioration or loss of barrier properties. Therefore, other provisions in this standard address the preceding concerns and ensure adequate protection of employees.

OSHA also sought comment on whether utility gloves should be required to be puncture-resistant. Several commenters supported this additional requirement (Society of Hospital Epidemiologists of America, Ex. 20–1002; Support Systems International, Ex. 20–1149; Visiting Nurse Corporation, Ex. 20–1288; AFSCME, Tr. 9/15/89, p. 140; State of Michigan Advisory Committee on Occupational Exposure to Bloodborne Pathogens, Tr. 10/17/89, p. 22). However, a large number of participants felt, for various reasons, that inclusion of such a requirement would be problematic. Some stated that puncture-resistant gloves would decrease dexterity to the point of impairing an employee's ability to function (Hospital Laundry Service, Ex. 20–1225; Lakeland Regional Hospital, Ex. 20–37; Superior Surgical Manufacturing Company, Ex. 20–41; ServiceMaster Company, Ex. 20–21; Angelica Corporation, Tr. 1/12/90, pp. 531–532). Other parties stated that such gloves were unnecessary if proper sharps disposal practices were followed (Lutheran General Hospitals, Park Ridge and Chicago, Ex. 20–655; National HealthCorp, Ex. 20–856; ServiceMaster Company, Ex.20–21). Still other commenters stated that puncture-resistant gloves which would prevent a needle's penetration were either unknown to them or were not feasible (Carmen C. Birk, Ex. 20–106; Iowa Lutheran Hospital, Ex. 20–885; Superior Surgical Manufacturing Company, Ex. 20–41; Angelica Corporation, Tr. 1/12/90, pp. 531–532). In her testimony, Ms. Jill Witter of the Angelica Corporation stated:

> I have with me several types of gloves which we have experimented with in our laundries, and as you can see, they range from a disposable to a reusable glove. This glove is the closest that you can just about come to on a puncture-proof glove and yet, a needle at the right angle will still go through this glove. This glove is not acceptable and does not work because we can't figure out how to disinfect the glove. So, it's certainly not a disposable glove and its far too expensive to treat it as such. It also has virtually no dexterity to it. That means that if the employee were to find on the soil sort line a needle or a sharp instrument, he could not pick it up and properly dispose of it without first taking off the glove....None of these, as you can see, would be impervious to a needle going through them and we have not been able to find a glove that is puncture-resistant. (Tr. 1/12/90, pp. 531–532)

With regard to puncture-resistant gloves, CDC/NIOSH commented:

> No gloves are puncture-proof, and none are tested or certified for puncture-resistance * * *. (Ex. 20–634)

The record contains no definitive evidence that puncture-resistant gloves (i.e., capable of substantially resisting penetration by a needle) are currently available or that standards for puncture resistance exist. In view of this, the Final Standard does not address the use of puncture-resistent utility gloves.

Responding to the proposed standard, CDC/NIOSH urged OSHA to permit latitude in glove use for phlebotomy (Ex. 20–634). In consideration of this comment and to increase consistency with CDC guidelines, a new provision has been added in the final standard which permits a limited exception to the

use of gloves for phlebotomy when this activity is performed in volunteer blood donation centers. Paragraph (d)(3)(ix)(D) states that if an employer in a volunteer blood donation center judges that routine gloving for all phlebotomies is not necessary, then the employer must: (1) Periodically reevaluate this policy; (2) make gloves available to all employees who wish to use them for phlebotomy; (3) not discourage the use of gloves for phlebotomy; and (4) require that gloves be used for phlebotomy in the following circumstances: (i) When the employee has cuts, scratches, or other breaks in his or her skin; (ii) when the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and (iii) when the employee is receiving training in phlebotomy. It is important to note that this exception has been strictly limited to phlebotomy performed in volunteer blood donation centers and does not apply to phlebotomy conducted in other settings such as plasmapheresis centers or hospitals. As has been extensively discussed above under general glove usage, the Agency has concluded that glove usage for venous access procedures (including phlebotomy in all settings except volunteer blood donation centers) is feasible and justified.

Exposure of mucous membranes to blood or other potentially infectious materials is a recognized route of transmission of bloodborne diseases. In his testimony, Dr. David Bell of the Centers for Disease Control stated:

> • • • available data indicate that • • • transmission of HIV infection to healthcare workers has followed occupational exposure to HIV-infected blood via percutaneous inoculation or via contact with mucous membranes or non-intact skin • • • (Tr. 9/14/89, p. 15)

Also, Dr. Stephen Hadler of CDC's Hepatitis Branch testified:

> HBV infection is spread by several modes: parenteral, by direct inoculation through the skin; mucous membranes, blood contamination of the eye or mouth; sexual contact and perinatally, from infected mother to infant • • • . One cubic centimeter of blood may contain 100 million infectious doses of HBV; thus, extremely small inocula may transmit infection • • • . (Tr. 9/14/89, pp. 19–20)

The final standard, therefore, retains the proposed provision requiring, in paragraph (d)(3)(x), that masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated. This overall requirement is supported by CDC/NIOSH who commented:

> Splattering of blood onto skin or mucous membranes is a recognized mode of transmission of hepatitis B. Protection of mucous membranes of the face and upper respiratory tract against large droplet spattering is needed. As required by OSHA in this draft rule, glasses, goggles, face shields, and surgical masks, alone or in combination as appropriate to the task being performed, can provide that protection. (Ex. 20–634)

Additional support for the provision was provided by sources such as the Centers for Disease Control (Exs. 6–153; 15); American Association of Dental Schools (Ex. 20–876); ADA (Ex. 20–665A); AHA (Ex. 6–75); Minnesota Nurses Association (Ex. 20–995); Association of Operating Room Nurses (Ex. 20–882); and the South Carolina Department of Health and Environmental Control (Ex. 20–1160).

By way of clarification, the final standard specifically states that if glasses are the chosen method of eye protection, they are to be equipped with solid side shields. "Solid" should not be interpreted to mean opaque but has been stipulated simply to preclude the use of mesh or perforated side shields (Association of Operating Room Nurses, Ex. 20–882; New England Medical Center, Ex. 20–511). In addition, if protective eyewear is chosen over use of a face shield, the eyewear must be worn in conjunction with a face mask since the aim of this requirement is to provide protection for the eyes, nose, and mouth.

Many of the comments on this provision were proffered by dentists, dental hygienists, and their professional associates. Therefore, OSHA's response uses the dental operatory to illustrate what is required and why. However, the regulation covers all situations where eyes, nose or mouth contamination can be reasonably anticipated. With specific reference to eyewear, The American Board of Pediatric Dentistry felt that clear side shields would impede peripheral vision (Tr. 10/19/89, p.471). Also, the ADA commented that it was rare to have blood or saliva spray into the dental health care worker's eyes during routine procedures; that protective eyewear did not fit over some prescription glasses and could interfere with the use of magnifier loops; and that available side shields would not fit on thin-framed glasses (Tr. 9/21/89, p.158; Ex. 20–665).

Relative to the absence of spatter, Ms. Karen Boulton, representative for the American Dental Hygienists Association, responded to OSHA's inquiry during the hearings:

> • • • it is definitely an education to take off this face shield when I wasn't wearing it and see the amount of splatter that does occur during treatment. Anything that you've got can be splattered, is physically splattered. (Tr. 1/16/90, p.580)

Ms. Boulton also stated that it was her personal feeling that protective eyewear should be mandated and that since exposure could occur through the sides of glasses, side shields were probably a good precautionary measure (Tr. 1/16/90, p. 570, 584). Dr. Mary Quinn, a clinician and dental infection control consultant, also stated during the hearings that she had gotten pieces of amalgam behind her glasses and felt that some type of side shield was necessary (Tr. 10/19/89, p.601). Dr. Sheldon Wallack, President of the Illinois Society of Oral and Maxillofacial Surgeons, testified that while some products did distort vision, he was aware of a type side shield glasses used by surgical assistants which provided lateral protection and good vision (Tr. 10/19/89, p.566). Full face shields were advocated by Dr. Derrick Hars who commented that they did not distort vision if the shield's curvature was large enough (Tr. 10/19/89, pp.722–723). Moreover, Ms. Mary Kelly, a dental hygienist and dental office practice consultant, stated that she felt side shields were necessary, that she used them and that they did not impede her vision (Tr. 10/19/89, p.711, 718). The Agency has concluded from this testimony that facial exposure, from directly in front and from the side, does occur in the dental setting and that protective eyewear that provides side protection (e.g., side shields, curved face shields) are warranted. In addition, evidence indicates that there are products available which provide such protection without impeding vision.

From the statements in the ADA's comment, it appears that the association interpreted the proposed regulation to require protective eyewear to be worn over prescription glasses; presumably, because the Agency normally refers to protective eyewear in the context of meeting certain impact-resistance requirements in addition to preventing liquids and/or particles from entering the eye. However, the primary purpose of protective eyewear in this standard is to prevent blood or other potentially infectious materials from entering the eye through splashing, splattering, spraying, and so forth. Impact resistance would only become an Agency concern in those situations where projectiles (e.g., bone fragments) may be generated.

Therefore, OSHA envisions that in most routine dental procedures prescription eyewear with side shields (either permanently affixed or of the "add-on" type) would be adequate protection. Also, the Association has stated that 66% of dentists currently wear prescription glasses (Ex. 20-665). Consequently, OSHA has concluded that prescription glasses with side shields will not interfere with the use of magnifying loops since this problem evidently does not exist with "unshielded" prescription glasses.

The Agency has determined that mucous membrane (i.e., eyes, nose, mouth) exposures occur in the occupational environment and must be prevented. The regulation provides employers with flexibility in choosing the types of protective measures to address the hazard and acceptable products which provide adequate protection with out impairing task performance are currently available. OSHA has concluded, therefore, that this provision is appropriate, feasible, and justified.

Gowns, aprons, and other protective body clothing minimize contaminant migration away from the work area and assist in eliminating skin exposure. Hence, paragraph (d)(3)(xi) requires that appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments shall be worn in occupational exposure situations (i.e., when contact with blood or other potentially infectious materials is reasonably anticipated). As with all personal protective equipment, the type of clothing (e.g., lab coat, gown) and its characteristics (i.e., protective capabilities) will depend upon the task being performed and the degree of exposure anticipated (i.e., quantity of blood or other potentially infectious materials). Utilization of protective body clothing is advocated or is currently being used by many of the participants in the rulemaking (e.g., CDC, Exs. 6-153, 15; CDC/NIOSH, Ex. 20-634; American Biological Safety Association, Ex. 241, ADA, Ex. 20-665; Society of Hospital Epidemiologists of America, Ex. 20-1002; Angelica Corporation, Tr. 9/18/89, p.178; American Dental Hygienists Association, Tr. 1/16/90, p. 571).

The proposal contained three provisions relative to protective body clothing which would have required specified barrier characteristics, such as "fluid-resistant" and "fluid-proof", based upon the amount of blood or other potentially infectious materials anticipated to be encountered (e.g., soiling, splashing/spraying, soaking). As discussed previously under "Provision" of this section, the terms "fluid-resistant" and "fluid-proof" generated confusion among interested parties. The Agency has decided not to use the terms "fluid-resistant" and "fluid-proof" in the Final Standard. This assures that the employee will be protected and gives the employer flexibility in complying. The employer must evaluate the task and the type of exposure expected and based upon this determination, select appropriate personal protective clothing. "Appropriate" protective clothing must prevent contamination of an employee's skin or clothing by blood or other potentially infectious materials (See discussion under "Provision" paragraph of this section).

Paragraph (d)(3)(xii) requires that surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated. Circumstances where the use of such equipment may be necessary would include autopsies and orthopedic surgery. Wearing head and/or shoe covers in these situations is required to minimize contamination migration and the possibility of transmission through either direct routes (e.g., through non-intact skin resulting from dermatitis of the head or foot) or indirect routes (e.g., an individual's hand contacts blood in their hair and subsequently is put near their eyes or mouth). Use of these coverings for particular procedures is supported by several commenters (AHA, Tr. 9/19/89, pp.157-158, Ex. 6-75; CDC, Ex. 15; National Committee for Clinical Laboratory Standards, Ex. 11-159A; Dr. Donald Jewett, Tr. 1/9/90, p.108; APIC, Tr. 10/18/89, pp.188-189; Rocky Mountain Infection Control Association, Ex. 20-192).

According to the record, head coverings and shoe coverings have traditionally been utilized to protect the patient against infection from the caregiver's loose hair and to eliminate static electricity, respectively (e.g., Albert Einstein Medical Center, Ex. 20-945; The United Hospital, Ex. 20-550). However, information gathered in response to the proposal indicates that there are some situations where it is appropriate to protect the head and feet/shoes against contamination by blood and other potentially infectious materials. Dr. Donald Jewett, an orthopedic surgeon with the University of California—San Francisco, testified that he supported the use of waterproof shoes in orthopedic surgery (Tr. 1/9/90, p.108). Moreover, a study of contamination of surgeons and other surgical personnel during 102 separate operative procedures, conducted by Dr Edward Quebbeman, Associate Professor of Surgery at the Medical College of Wisconsin, showed 16 instances of contamination of the foot area and 14 instances of head area contamination (Tr. 1/17/90, pp.866, 875-876). During discussions with the OSHA panel, representatives of the American Hospital Association stated that heavy shoe covers were worn in the operating room, trauma surgery, and urology where there often is a considerable amount of blood and, in addition, boots were worn in autopsy. The representatives agreed that there were occasions when such protective equipment was appropriate (Tr. 9/19/89, pp.157-158). Lauer and colleagues in their study entitled: Transmission of Hepatitis B Virus in Clinical Laboratory Areas, stated:

> • • • Contamination of the head region of a person could lead to direct inoculation or, more likely, to indirect inoculation when he grooms his hair or touches his face during breaks or lunch periods • • •. (Ex. 6-56)

A large number of participants commented that the use of head covers and shoe covers as personal protective equipment was unnecessary (e.g., APIC—Palmetto, Ex. 20-581; Bowman Gray School of Medicine, Ex. 20-941; Baptist Medical Center, Ex. 20-146). Other commenters stated that use of these items was unnecessary outside of limited clinical settings such as the operating room, the morgue, or trauma care (e.g., Georgetown University Hospital, Ex. 20-833; Children's Hospital of Orange County, Ex. 20-568; APIC—Greater Omaha, Ex. 20-943; Abington Memorial Hospital, Ex. 20-557).

From the comments received, the proposed requirement for head covers and shoe covers was apparently misinterpreted as requiring their use in general clinical settings. However, the Agency's intent is to utilize these items only in circumstances where large quantities of blood or other potentially infectious materials are anticipated to be encountered. The Agency has revised this provision in the final to clarify its intent by requiring that such coverings are to be utilized in "instances when gross contamination can reasonably be anticipated."

A few interested parties commented on the permeability of shoe covers and it was suggested that fluid-resistant covers should be permitted (Lisa D'Amico, APIC—Pittsburgh, Tr. 9/27/89, p.283; Baxter Health Care Corporation, Tr. 10/20/89, p.870; Association of the Nonwoven Fabric Industry, Tr. 12/22/89, p.1651). The Association of Operating

Room Nurses commented that shoe covers will not keep an individual's socks and feet dry in the presence of a large quantity of blood as would be encountered in urological, vascular, or trauma procedures and that contaminated shoes could be cleaned with a disinfectant (Ex. 20–882).

Selection of personal protective equipment is performance-oriented. Consequently, fluid-resistant equipment would be acceptable provided it meets the criteria of "appropriate" discussed above. Only that equipment necessary to protect against reasonably anticipated exposure associated with a specific task is required to be provided for performance of that task. Selection of the type and characteristics of necessary personal protective equipment is based upon the exposure anticipated to be associated with the task. In those instances where such equipment was incapable of halting penetration of blood or other potentially infectious materials normally encountered during a procedure, then a more resistant barrier (e.g., rubber boots) would be required. Decontamination of shoes in the situation described by the AORN (i.e., soaking of the sock and/or foot) would be inappropriate. While decontamination of the outside of the shoe may be possible, proper decontamination of the shoes' interior would be extremely difficult. In addition, the primary intent of this provision would not have been achieved, that is, prevention of foot exposure.

The Agency has concluded that circumstances exist in which gross contamination of the head or feet or both occur. Therefore, the use of head covers and/or shoe covers in such instances is required to prevent contaminant migration and the possibility of direct and indirect disease transmission.

Housekeeping

Paragraph (d)(4)(i) requires employers to ensure that the worksite is maintained in a clean and sanitary condition. The employer must determine and implement an appropriate written schedule for cleaning and a method of decontamination based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks and procedures being performed. The term "worksite" refers not only to permanent fixed facilities such as hospitals, dental/medical offices, clinics, and so forth but also covers temporary non-fixed workplaces. Examples of such facilities include, but are not limited to, ambulances, bloodmobiles, temporary blood collection centers, and any other non-fixed worksites which have a reasonable possibility of becoming contaminated with blood or other potentially infectious materials.

This requirement has been adopted from CDC's Guideline for Handwashing and Hospital Environmental Control, 1985 and Recommendations for Prevention of HIV Transmission in Health-Care Settings where it is reiterated (Exs. 6–188; 6–153). Specifically, CDC states that while extraordinary attempts to disinfect or sterilize environmental surfaces such as walls and floors are rarely indicated, routine cleaning and removal of soil are recommended. In addition, it is stated that cleaning schedules and methods will vary according to the factors outlined in the provision. OSHA recognizes that different types of surfaces and soiling exist throughout a facility and that the employer is in the best position to evaluate the condition of his or her facility. Therefore, the employer must determine and implement the appropriate written schedule of cleaning and decontamination based upon the location within the facility (e.g., surgical operatory versus patient room), type of surface to be cleaned (e.g., hard-surfaced flooring versus carpeting), type of soil present (e.g., gross contamination versus minor spattering), and tasks and procedures being performed in the area (e.g., laboratory analyses versus normal patient care). The requirement for a written schedule of cleaning and method of decontamination is twofold: (1) The schedule will assist in ensuring that routine cleaning, as recommended by CDC, is performed and that the method of decontamination deemed appropriate by the employer is followed; and (2) the employees can utilize the schedule to determine when such cleaning should be done and what method they should use to properly accomplish the task.

Several comments were received urging OSHA to specify what disinfectants/procedures are effective or which questioned the need for using a "tuberculocidal" disinfectant (e.g., Abington Memorial Hospital, Ex. 20–557; Huntington Laboratories, Inc., Ex. 20–1328; S.C. Johnson & Sons, Inc., Ex. 20–639; AFSCME, Tr. 9/15/89, p.103; Elise Yiasimedes, Tr. 9/13/89, p.48). The Agency has not specified particular disinfectants or procedures due to the wide variance of circumstances in which housekeeping tasks occur. For example, routine cleaning of the floor in a clinical laboratory may only require a "low-level" germicide to achieve decontamination while a more powerful germicide may be required in the operatory due to, for instance, the increased amount of blood contamination. Specifying particular disinfectants and procedures in the final may have the effect of limiting the use of new products and of discouraging the development of new information relative to adequate decontamination. Hence, this provision states that the schedule for cleaning and method of decontamination are to be "appropriate." OSHA has concluded that the level of cleaning required under this performance-oriented provision will adequately ensure that risk of employee exposure is minimized.

Contamination of items and surfaces was investigated in the study Transmission of Hepatitis B Virus in Clinical Laboratory Areas (Ex. 6–56). The conclusion of the investigators was that "transmission of HBV in the clinical laboratory is subtle and mainly via hand contact with contaminated items * * *." In addition to individual items such as marking devices and pipetting aids, contamination was found on analytical instruments and surfaces around instruments. Dr. Steven Hadler of CDC's Hepatitis Branch addressed and acknowledged hepatitis B transmission via contaminated surfaces in his testimony:

> Spread of HBV in the workplace may occur in ways that are less apparent than direct inoculation of infectious blood by needlesticks or puncture wounds. Preexisting lesions on hands from injuries or from dermatitis may provide a route of entry for the virus. Although gloving will not stop direct puncture injuries, it can prevent the virus from contacting existing lesions. Transmission of HBV from contaminated environmental surfaces have been shown to be a major mode of HBV spread in certain areas such as hemodialysis units. The HBV can survive for at least one week in dried blood on environmental surfaces or contaminated needles and instruments. (Tr. 9/14/89, pp. 20–21)

As discussed previously under paragraph (d)(2)(ix), Favero, Peterson, and Bond also state that environmental contamination is an effective method of disease transmission (Ex. 6–344). Therefore, paragraph (d)(4)(ii) requires that all equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials. This will minimize inadvertent employee exposure and contaminant migration resulting from contaminated items and surfaces.

Though there exists a broad range of work environments and circumstances where a work surface may become

contaminated, OSHA has concluded that there are certain circumstances where decontamination procedures must be implemented to maintain cleanliness and minimize employee exposure and contaminant migration. Hence, paragraph (d)(4)(ii)(A) requires that contaminated work surfaces shall be decontaminated with an appropriate disinfectant (1) after completion of procedures; (2) immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and (3) at the end of the work shift if the surface may have become contaminated since the last cleaning.

Cleaning contaminated work surfaces after completion of procedures has been required to ensure that employees are not unwittingly exposed to blood or other potentially infectious materials remaining on a surface from previous procedures (CDC, Ex. 6-153). Some commenters stated that this requirement could be unduly burdensome on facilities such as laboratories which may perform a large number of procedures in a single shift or day (MetroHealth Medical Center, Ex. 20-190; Grady Memorial Hospital, Ex. 20-84). Where procedures are performed on an essentially continual basis throughout a shift or day, as may be the case of a clinical lab technician performing blood analyses, it is not the Agency's intent for the work surface to be decontaminated before the technician can proceed to the next analysis. This provision is intended to ensure that after procedures are completed, which in the above example would include a set of analyses, contaminated work surfaces are decontaminated. The completion of procedures might also occur when the employee is going to leave the work area for a period of time. In this instance, the work surface will not present a source of contamination to the employee upon his or her return, to employees who may enter the area, or to items which may be placed upon the surface. It should be noted that decontamination is not required after each patient care procedure as some parties have interpreted, but simply after procedures resulting in surface contamination (AHA, Ex. 20-352; Grady Memorial Hospital, Ex. 20-84).

Work surfaces must also be decontaminated immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials. Little comment was received relative to this provision but information and the few comments in the record which addressed this requirement indicate that it is generally recognized that decontamination is appropriate in circumstances of obvious overt contamination and spills (e.g., CDC Exs. 6-153, 15; Providence-St. Margaret Health Center, Ex. 20-46; Research Medical Center, Ex. 20-74; APIC—Kansas City, Ex. 20-689). The proposal required that work surfaces be decontaminated immediately in these circumstances. However, OSHA recognizes that there may be some instances where "immediate" decontamination may not be practical as in, for example, an operating table during surgery. Therefore, the final requirement has been modified to state "immediately or as soon as feasible" to address these situations and avoid holding employers to a sometimes unachievable standard.

In the third instance of mandated work surface decontamination, the proposal required that this be performed at the end of the work shift. A large number of commenters objected to this provision as redundant, citing that decontamination was already required to be done after completion of procedures and following overt contamination or spills (e.g., APIC—Greater Kansas, Ex. 20-294; Society of Hospital Epidemiologists of America, Ex. 20-1002, Tr. 10/18/89, pp. 357-358; Baptist Medical Center, Ex. 20-146). OSHA has determined that these comments have merit and has revised the provision to require that decontamination is to be performed at the end of the work shift if the work surface may have become contaminated since the last cleaning. For example, if contaminated instruments or specimens had been set down on the surface since the last cleaning, the surface would need to be decontaminated.

Several other general issues were raised relative to the decontamination of work surfaces. First, some participants erroneously believed that all surfaces were being required to be decontaminated (Society of Hospital Epidemiologists of America, Ex. 20-1002; Children's Hospital—Richmond, VA, Ex. 20-587; Stanley M. Dub, Ex. 20-516; Wisconsin Association of Nursing Homes, Inc., Ex. 20-255). However, the requirement applies only to contaminated work surfaces and therefore would not encompass desks, countertops, and so forth in the area, provided they remained uncontaminated. Second, several commenters inquired whether this provision applied only to labs or stated that this requirement was inappropriate for patient-care areas (APIC—National, Ex. 20-1118; APIC—Kentuckiana, Ex. 20-948; Casa Colina Hospital, Ex. 20-284; McLeod Regional Medical Center, Ex. 20-527). In response to these comments, OSHA has determined that contaminated work surfaces present the same hazard regardless of where they are located in a facility. Hence, this provision is based upon the existence of a contaminated work surface rather than a particular worksite location. It should be noted that the above are minimum requirements and additional decontamination may be performed any time that it is deemed necessary.

Paragraph (d)(4)(ii)(B) of the final allows equipment and environmental surfaces to be covered with protective coverings such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper. When utilized, such coverings must be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the work shift if they may have become contaminated during the shift. Use of protective coverings was initially adopted from the dentistry precautions portion of CDC's Recommendations for Prevention of HIV Transmission in Health-Care Settings (Ex. 6-153). However, protective coverings may also be used in other settings such as on laboratory benchtops. This approach to protecting an item or surface against contamination could prove particularly useful in a situation where a piece of equipment would be very difficult to decontaminate yet could be protected by a cover. As with decontamination of work surfaces above, comments were focused primarily on the necessity of changing coverings at the end of the shift (AHA., Ex. 20-352; Society of Hospital Epidemiologists of America, Ex. 20-1002, Tr. 10/18/89, pp. 357-358; University of Connecticut Health Center, Ex. 20-191). Consequently, the provision has been modified to require that protective coverings be removed and replaced at the end of the work shift if they may have become contaminated during the shift. Interested parties also stated that to prevent cross-contamination coverings should be changed between patients or recommended that equipment should be wiped with an appropriate disinfectant between patients rather than being covered (Office Sterilization and Asepsis Procedures Research Foundation, Ex. 20-797; VA—Salt Lake City, UT, Ex. 20-635; Rocky Mountain Infection Control Association, Ex. 20-192). Use of protective coverings is not required by the standard but is merely being permitted as an acceptable method of protecting items and surfaces

against contamination. If this option is chosen, however, the final does require that they be removed and replaced at the stated minimum intervals. Relative to changing such coverings between patients, it should be remembered that, while this is prudent infection control practice which the Agency supports, OSHA's mandate is to protect employee health. Therefore, changing between patients has not been required as it falls into the realm of patient protection. These provisions represent housekeeping requirements directed toward ensuring that employee exposure to bloodborne pathogens is minimized; additional, more stringent decontamination rules that may be imposed to further infection control are not preempted.

In some cases, bins, pails, cans, and so forth, which are intended for re-use may be utilized in a manner which presents the potential for their becoming contaminated with blood or other potentially infectious materials. For example, a reusable metal trash can may be lined with a disposable plastic regulated waste bag. By virtue of a plastic bag's construction, the possibility for leakage is inherent and the can could become contaminated. If the can is not decontaminated, the contamination may be spread by leakage or spillage from the can or by fouling the outside of succeeding bags. Mr. Donald Gibbons, currently of United Linen Management and a former owner/operator of a laundry for institutional linen, also spoke of large plastic carts used to collect and transport soiled and cleaned linens. He stated that these transports, although contaminated with blood or other potentially infectious materials, were rarely cleaned (Tr. 9/25/89, pp. 71–72). Paragraph (d)(4)(ii)(C) addresses this situation by requiring that all bins, pails, cans, and similar receptacles intended for re-use which have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination. This provision is consistent with OSHA's existing standard regarding maintenance of waste disposal containers, 29 CFR 1910.141(a)(4)(i).

This requirement generated conflicting comments from interested parties. Some felt that the provision should be deleted as there has been no implication of these containers in disease transmission (UCSD Medical Center, Ex. 20–156; Good Samaritan Hospital, Ex. 20–373; Norwood Hospital, Ex. 20–967). Others commented that reusable bins, pails, cans, and so forth should be decontaminated only upon visible contamination (AHA, Ex. 20–352; William W. Backus Hospital, Ex. 20–911; VA—Edward Hines Jr. Hospital, Ex. 20–961). Still others asserted that decontamination should be performed on a regular schedule rather than upon visible contamination (CDC/NIOSH, Ex. 20–634; Grady Memorial Hospital, Ex. 20–84). Finally, the proposed provision was supported, in essence, by other participants (DCI Laboratory, Ex. 20–664; San Antonio Community Hospital, Ex. 20–530).

Of those supporting the provision, DCI Laboratory commented that every time biohazard bags are removed from receptacles, the receptacles are inspected for leakage and so forth and contamination is cleaned and disinfected immediately. They felt that semi-annual or annual cleaning, in addition to this routine inspection and cleaning, appeared to be adequate (Ex. 20–664). San Antonio Community Hospital stated that requiring receptacles to be inspected and cleaned regularly and upon visible contamination was reasonable while regularly-scheduled disinfection was unreasonable. They felt that disinfection of these containers was unnecessary and that soap and water wash was adequate with the ultimate goal to be achieved being that all receptacles be sufficiently cleaned and processed to make them safe for their intended use (Ex. 20–530). This is the intent of the Agency and has been clarified by rewording the provision to state "decontamination" rather than "disinfection" of these containers.

In response to the other commenters, deletion of the provision is not appropriate since contamination presents the same hazard whether it exists on a work surface, on the exterior of a waste bag, or on the inside of a reusable container. Deletion of this provision falsely implies that contamination on bag exteriors or inside reusable containers should not be of concern to employees who must handle these items. Limiting the requirement to only visible contamination disregards the evidence that imperceptible quantities of blood or other potentially infectious materials may still harbor large quantities of HBV. On the other hand, adhering to only regularly-scheduled cleaning while ignoring visible contamination is in conflict with recommendations for decontamination of other surfaces and the principle that viral content increases with increasing quantity of blood. Hence, the Agency has concluded that both regularly-scheduled inspection and decontamination in addition to decontamination upon visible contamination are warranted to protect workers.

Paragraph (d)(4)(ii)(D) stipulates that 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 brush and dust pan, tongs, or forceps. Contaminated broken glass is capable of inflicting percutaneous injury and direct inoculation of bloodborne pathogens into the bloodstream. Prohibiting picking up this glass directly with the hands eliminates or minimizes risk of such an injury and thereby the possibility of occupational transmission of bloodborne disease. This provision has been retained from the proposed standard with the exception of utilizing a vacuum cleaner or cotton swabs as an acceptable method of pick-up. Cotton swabs have been deleted to avoid confusion between swabs attached to a stick and a cotton ball-type "swab." Using a cotton ball-type swab is inappropriate as this type of swab can be penetrated by broken glass. Since an individual would normally hold such a "swab" directly with the fingers, injury or exposure could result. The American Society for Microbiology and Verdugo Hills Hospital commented that vacuum cleaners should not be used for clean-up as they could spread contaminant through their exhaust stream (Exs. 20–1188; 20–573). The Agency has concluded that vacuum cleaners and cotton swabs may not be appropriate for clean-up of contaminated broken glass and has deleted them from the examples of possible pick-up methods. It should also be remembered that tools used in clean-up must be properly decontaminated or discarded after use and the broken glass placed in a proper sharps container as required by other provisions of this standard.

The proposal required that reusable equipment, such as glassware or hand instruments, was to be decontaminated prior to washing and/or reprocessing. The rationale behind this proposed requirement was to rid such items of contamination before they entered the overall cycle of washing and reprocessing, thereby limiting the number of employees who must handle these contaminated items to only those performing the decontamination procedures. The great majority of comments received objected to this provision (e.g., AHA, Ex. 20–352; Society of Hospital Epidemiologists of America,

Ex. 20–1002; APIC—New England, Ex. 20–216; Humana Hospital—Orange Park, Ex. 20–367; Ft Sander Regional Medical Center, Ex. 20–1214; Parkview Memorial Hospital, Ex. 20–136). The most frequently stated reason for objection was that proper decontamination cannot be achieved in the presence of organic debris (e.g., blood) as it interferes with the efficacy of the disinfecting/sterilizing process (e.g., Thomas Jefferson University Hospital, Ex. 20–363; Douglas E. Kline, MCM, CIC, Ex. 20–87; Anaheim Memorial Hospital, Ex. 20–523). Reviewing CDC's guidelines, it is noted that cleaning of reusable items prior to disinfection/sterilization is the recommended sequence of reprocessing. Specifically, these guidelines state:

> Items must be thoroughly cleaned before processing, because organic material (e.g., blood and proteins) may contain such high concentrations of microorganisms. Also, such organic material may inactivate chemical germicides and protect microorganisms from the disinfection or sterilization process. (Ex. 6–188)

In addition, several commenters pointed out that the proposed requirement would, in actuality, result in *more* employees handling contaminated items (due to required cleaning prior to being sent for reprocessing) and that these employees would not be as well-trained and proficient in the decontamination process as reprocessing technicians (e.g., APIC—Middle Tennessee, Ex. 20–55; Eileen Upton, RN, ICP, Ex. 20–630; Presbyterian Hospital—Charlotte, NC, Ex. 20–912; VA—Salisbury, NC, Ex. 20–1317).

A few participants supported disinfecting prior to cleaning (e.g., Caltech Industries, Ex. 20–12; Clinical Research Associates, Ex. 20–910; Sterling Drug Company, Ex. 20–40). However, the number of products which can successfully penetrate a heavy bioburden appears to be very limited—Clinical Research Associates cites only two of all products tested (Ex. 20–910).

Considering this information, the Agency has concluded that requiring reusable items to be decontaminated prior to washing/reprocessing may not accomplish the proposed intent (and, indeed, may have the opposite effect); is contrary to recognized, recommended procedures; and may be of limited feasibility. Therefore, this requirement has been dropped from the final standard.

With respect to decontamination of reusable items, however, a hazardous situation was related during the public hearings. Mr. Ivan Ruez, an employee in the central supply department of a metropolitan hospital, spoke of the process used in his facility to gather contaminated reusable items for reprocessing. Mr. Ruez testified:

> Everybody coming into Central Supply you understand has to go through the process of orientation. In the process of orientation one of the first jobs that we do is decontamination. This is a process by which all the soiled used items retrieved from the floors must be sorted. Among those items, I'll give examples, are used trays, spinal needles, dirty commodes, suction machines, air mattresses, syringes, and any such items used by patients that can be recycled * * *.
>
> All soiled items are dumped into central locations on the floors which are called soil utility rooms. Now a person going up to the floor to do the decontamination, what's called DC for short, has to actually physically reach into these bins. They're putting themselves at extreme risk when they do this, * * *.
>
> Now when they extract this equipment, a lot of the times the stuff is covered by wrapping paper which is what we use for wrapping the tray, reprocessing. There's no way that you know what is underneath that paper, just like on the floors. You go to pick up a sheet, there will be a needle, you're stuck. The same thing with the paper, you go to reach in as most people would do because you have to actually stretch it to get into the bin. Right there you're setting yourself up for contamination, for a puncture and this has happened in my department quite a few times, just within the year and a half because like I said before I was in nursing. Just a year and a half I've been in this department. This has happened over and over and over. (Tr. 11/14/89, pp. 390–392)

Percutaneous injury by a contaminated item is the most efficient occupational method of contracting bloodborne diseases; therefore, at no time should an employee have to place his or her hand into a container which could contain items capable of causing injury (e.g., sharps). With regard to this hazard, paragraph (d)(4)(ii)(E) has been added to the final standard. It states that reusable sharps that are contaminated with blood or other potentially infectious materials, shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed. This provision will eliminate or minimize the risk of percutaneous injury resulting from reaching into containers of contaminated sharps.

Contaminated Sharps Discarding and Containment

Needles and sharps have been documented as prime mechanical agents of employee inoculation with both HIV and HBV. Therefore, their handling and discarding warrant special attention. Needles and sharps are capable of transferring infectious bloodborne pathogens directly into the bloodstream through accidental injuries such as needlesticks or scratches. The AHA states in their recommendations Management of HTLV–III/LAV Infection in the Hospital:

> As with other bloodborne diseases, the potential for transmission is greatest when needles and other sharp instruments are used in patient care. Therefore, needles and syringes should be disposed of in rigid, puncture-resistant containers. (Ex. 6–75)

This position is maintained in the AHA's comment to the proposed standard (Ex. 20–352).

Several CDC documents address disposal of sharps and needles (Exs. 6–27; 6–153; 6–312). In addition, recommendation (4)(b) of CDC's publication The Center for Disease Control's Recommendations on Infectious Waste states:

> Disposable syringes with needles, scalpel blades, and other sharp items capable of causing injury should be placed intact into puncture-resistant containers located as close as is practical to the area in which they were used * * *. (Ex. 6–395)

CDC/NIOSH also retains their stance on proper disposal of contaminated sharps as evidenced by their written comment and their 1989 guidelines for public safety workers (Exs. 20–634; 15).

In the final standard, paragraphs (d)(4)(ii)(A)(*1*) through (d)(4)(iii)(A)(*4*) deal specifically with management of disposable contaminated sharps. The proposal contained provisions addressing disposal container characteristics, accessibility, and maintenance. While the final also contains provisions relative to these aspects of sharps management, this section has been expanded and separated to clarify the Agency's intent and to address public comment. In addition, OSHA has decided to use the term "discarding" instead of "disposal" in order to more clearly show that what OSHA is addressing is the placement of the sharp before final disposal. This is consistent with EPA.

Paragraph (d)(4)(iii)(A)(*1*) puts forth the requirements for actual discarding of sharps and the physical characteristics of the container. It states that contaminated sharps shall be discarded immediately or as soon as feasible in containers that are: a) closable; b) puncture-resistant; c) leakproof on the sides and bottom; and d) labeled or color-coded in accordance with this standard. Containers must be closable in order to ensure that contaminated sharps remain inside the disposal unit while it is being transported and handled prior to terminal disposal (e.g. SHEA, Ex. 20–1002; CDC/NIOSH, Ex. 20–634; SEIU, Ex. 299; EPA, Ex. 6–497).

The Association for Practitioners in Infection Control commented that by requiring containers be closable, the Agency failed to recognize the risk to the healthcare worker posed by the closure devices of some of the containers (Ex. 20–1118). However, OSHA believes workers receiving needlesticks as the result of a container's closure is most likely due to either overfilling of containers or poor container design. Both of these problems can be addressed. More frequent container replacement, as required by paragraph (d)(4)(iii)(A)(*2*)(*iii*), will eliminate needlesticks resulting from overfilling. If design of a container is leading to needlesticks from problems such as excessive manipulation of the sharps or container closure during discarding of the sharps or sharps becoming stuck in the container's opening upon discard, the employer should investigate and change to a different container design. Various designs are currently available.

Puncture-resistance is necessary to prevent the points of needles or other sharps from puncturing the container and protruding through the side of the container where they can present a hazard to unsuspecting staff (e.g., nurses, technicians, housekeepers). Ms. Judith Gordon, OSHA's expert witness on waste disposal, testified that puncture-resistance is the most important requirement for sharps containers (Tr. 9/13/89, pp.97–98). This requirement was also supported by several other sources (CDC/NIOSH, Ex. 20–634; AHA, Ex. 6–75; CDC, Ex. 6–153, 6–395; SEIU, Ex. 299, Toni Camasura, Tr. 1/16/90, p. 731; IAFF, Tr. 9/14/89, p.152; EPA, Ex. 6–497). During the hearings, Dr. Diane Fleming of the American Biological Safety Association stated that she currently chairs an ASTM committee which is developing a standard for puncture-resistance of sharps disposal containers and urged OSHA to identify specifications for these containers (Tr. 9/21/89, p.97). During development of the Medical Waste Tracking Act, EPA was also requested to delineate specific performance standards for containers. EPA decided that such action was inappropriate for the following reason:

> • • • [T]he Agency believes that it is inappropriate to specify specific performance standards for such containers, since packaging materials vary extensively in their physical and mechanical properties. For instance, it is quite possible that a 1-mil-thick film of one polymer material will be more puncture, impact, and abrasion resistant that a 2-mil-thick film of a different polymeric material. The physical properties can be affected further by the manufacturing process, such as extrusion and injection molding. The most appropriate manner of determining the suitability of a particular container with respect to its ability to resist puncture, leakage, and/or breaking under individual usage conditions is to subject the container to those conditions. (Ex. 6–497)

OSHA believes that the work of ASTM is valuable, and when completed, will provide users with specific criteria related to the puncture-resistance of containers. However, the Agency agrees with EPA and views the requirement of puncture-resistance to be one of performance-orientation. Thus, OSHA has concluded that requiring the container to be "puncture resistent" adequately informs the employer that the material and construction of the container must prevent sharps from protruding through the container.

Containers must be leakproof on the sides and bottom to prevent residual liquids which drain from syringes and pool in the container from leaking out onto countertops, floors, cart tops, and so forth, thereby spreading contamination. This requirement also prevents employee hand contact with liquids which could otherwise leak through and contaminate the outside of the container. Dr. Eric Steiner of On-Gard Systems Incorporated stated that it was his experience that it was commonplace to find residual liquids in the bottom of sharps containers (Tr. 9/26/89, p.61). EPA's MWTA also recognizes that residual liquids may collect in sharps containers and requires that all sharps be placed in leak-resistant containers (Ex. 6–497). The Agency has concluded that residual liquids can collect in sharps containers and that requiring containers to be leakproof on the sides and bottom is both justified and feasible.

Sharps containers must be labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard. This requirement serves essentially two purposes: (1) It allows the containers to be easily identified by employees having contaminated sharps to discard by clearly distinguishing the containers from others in the area; and (2) It gains the attention of other staff, such as housekeepers, by virtue of the readily recognizable label or color, thereby warning them of the potential hazard and signaling that special handling precautions are necessary. Labeling or color-coding of sharps containers was supported either specifically or in general in the recommendations of several participants (CDC/NIOSH, Ex. 20–634; SEIU, Ex. 299; EPA, Ex. 6–497; Judith Gordon, Tr. 9/13/89, p.98). In view of the particular hazard presented by contaminated sharps, OSHA has concluded that labeling or color-coding of containers is an appropriate requirement which is necessary to attract an employee's attention and warn him or her of the potential hazard.

Paragraphs (d)(4)(iii)(A)(*2*) and (d)(4)(iii)(*A*)(*3*) contain provisions relative to sharps containers during use and when moving them from the area of use as would occur when filled containers are being replaced. During use, sharps containers must be: (a) Easily accessible to personnel and located as close as feasible to the area where sharps are used or can be reasonably anticipated to be found (e.g., laundries); (b) maintained in an upright position throughout use; and (c) replaced routinely and not allowed to overfill. When sharps discarding is perceived as inconvenient, chances are increased that needles and sharps will be left in bed linens, on night stands, or thrown into waste baskets, making them potential hazards for other staff such as laundry workers and housekeepers. In addition, the possibility of an accidental needlestick is greater if an employee must carry an uncapped needle or sharp to a remote location in order to discard it.

The proposed standard required that sharps containers be located in "the immediate area of use." A significant number of participants commented that it may be unwise or impossible to place sharps containers in certain areas, such as pediatric units, psychiatric units, areas where patients are confused or mentally impaired, or correctional facilities [e.g., AHA, Ex. 20–352; Donna Richardson, ANA, Tr. 9/20/89, p.80, 81; Toni Camasura, SEIU, Tr. 1/16/90, p. 731). OSHA recognizes that there may be circumstances, such as in a correctional facility, which may not permit a sharps container to be located in the immediate area of use. However, Baylor University Medical Center stated that they have not found problems with having sharps containers in pediatric and psychiatric wards (Tr. 9/27/89, p. 83). In order to provide the proper flexibility to address these situations, this provision has been modified to state that containers for contaminated sharps shall be located "as close as feasible to the immediate area where sharps are used • • •." It should be realized that this revision is not intended to permit sharps containers to merely be located in the general area. For example, SEIU presented videotaped testimony of "Jane Doe," a nurse who HIV seroconverted after receiving a needlestick. The needlestick occurred when "Jane" attempted to insert the needle of a used IV set-up into the set-up's rubber port to

protect it while she moved the set-up across the room and into the bathroom where the sharps container was located.

In terms of the actual incident that occurred, two things would have made a very significant difference, if not have prevented the thing entirely. The first is that the sharps containers, which are placed in the bathrooms, could be placed at the bedside, in which case I standing there with a contaminated needle would have been able to turn several inches and place the needle directly into the sharps container. I would not have had to entertain the possibility of walking through what I felt was an obstacle course, possibly tripping and impaling myself to get to the bathroom. (Tr. 1/16/90, p. 667)

According to testimony, sharps containers are uniformly located in the bathrooms throughout the basic medical and surgical floors of the facility (Jean Smith, SEIU, Tr. 1/16/90, p. 702). This tragic incident supports OSHA's contention that when discarding of contaminated sharps is perceived to be, or in actuality is, inconvenient, the chance of improper sharps handling and the potential for needlestick is increased.

There are alternatives to locating a standard sharps container at the bedside of patients in the above situations. Containers can be used which are lockable or are designed to prevent removal of syringes while still maintaining easy accessibility for discarding. Several participants in the rulemaking, including a mental health facility, commented that another alternative was to have the healthcare worker bring a sharps container to the site, perform the procedure, and then remove the container upon leaving (APIC—National, Ex. 20–1118; Society of Hospital Epidemiologists of America, Ex. 20–1002; CDC, Ex. 15, Mendota Mental Health Institute, Ex. 20–794; Judith Gordon, Tr. 9/13/89, p.123; Norwood Hospital, Ex. 20–967).

This provision was also revised to require that sharps containers be located not only where sharps are used but also in areas where it can be reasonably anticipated that contaminated sharps could be found. Several participants involved with laundering of linens stated that contaminated sharps are found among these items (Angelica Corporation, Tr. 9/18/89, p. 160; Georgia Davenport, SEIU, Tr. 1/16/90, p. 766; Raymond Montez, SEIU, Tr. 1/16/90, pp.770, 782). Specifically, Mr. Montez, a laundry worker stated:

Myself and other employees in the laundry still encounter needles in the linen, mostly coming from surgery. The number has decreased in the last four years but there shouldn't be any at all. There are no containers in the sorting room to put needles in. I have been told by my supervisor to give them to him but many times he is not there and I don't know if he follows up and complains to the proper department about it.

I recently gave him one of these needles and he said he would take care of it and he left it on the ironing machine. The next day I picked it up. (Tr. 1/16/90, p.770)

This testimony helps illustrate why the Agency concluded that it was necessary to require sharps containers in areas where sharps are not normally used but may be found in order to provide affected employees with an appropriate method of discarding of these sharps. The design of the tops of a number of sharps containers will permit leakage if the container is tipped on its side or turned upside down, a fact substantiated by several parties (Judith Gordon, Tr. 9/13/89, p.99; American Biological Safety Association, Tr. 9/21/89, p.103; Winfield Corporation, Tr. 1/17/90, pp.913–914; On-Gard Systems, Ex. 20–645, Tr. 9/26/89, p.42; APIC—Northwestern Wisconsin, Ex. 20–108). The Agency has concluded, therefore, that the additional provision in paragraph (d)(4)(iii)(A)(*2*)(*ii*), which requires that sharps containers be maintained in an upright position throughout use, is necessary to prevent contaminant migration and inadvertent employee exposure through leakage from tipped containers.

A major concern when utilizing sharps containers is that they be replaced routinely and not allowed to overfill. The reason for this is twofold. First, a full container necessitates discarding of the sharp in some manner other than in the proper container, again leading to sharps being placed on night stands, thrown into waste baskets, and so forth. Mr. Carson Limbrick, a licensed practical nurse and representative of AFSCME stated:

As it stands now, we have one box and that's in the immunization room. What all the nurses do or the nurses that give immunizations they basically collect the needles in their rooms or offices where they give the shots. And whenever they find time to dispose of them they just take them to the immunization room and put them in the box that's there. If that box is full, then we find other areas to dispose of them. We find these little baggies and put them in the trash can, we put them in the trash can baggies. We have to find someplace to secret them away. We have kids who run through the clinic and whatnot so that's always a problem * * *. (Tr. 10/17/89, p.88)

This statement illustrates how overfilled containers directly contribute to improper discarding of contaminated sharps. It also demonstrates the improper actions necessitated when sharps containers are not easily accessible to the area of sharps usage.

Second, the employee may be tempted to get "just one more" sharp into the container by forcing it in by hand. In doing so, the possibility for an accidental needlestick increases, particularly if some of the discarded sharps are pointed toward the opening of the container. Several participants cited problems with overfilling and supported the requirement for routine replacement and prevention of overfilling (Diane Moats, Communication Workers of America, Tr. 11/14/89, p.292; Ruth Jeffries, AFSCME, Tr. 1/16/90, p.592; Joan Emslie, SEIU, Tr. 1/16/90, p.681; Toni Camasura, SEIU, Tr. 1/16/90, p.731; CDC/NIOSH, Ex. 20–634; SEIU, Ex. 299; AFSCME, Ex. 297). OSHA has concluded that replacement of containers before overfilling occurs is an appropriate requirement and reduces the chance of accidental needlestick by promoting proper handling and discarding of sharps.

When sharps containers are to be moved from the area of use, paragraph (d)(4)(iii)(A)(*3*) requires that they be closed. A proper closing will ensure that if the container should become tipped or overturned, employees will not be exposed to contaminated sharps which may otherwise spill out. In addition, sharps containers must be placed in a secondary container if leakage is possible. This secondary container must be: (i) closable; (ii) constructed to contain all contents and prevent leakage during handling, storage, transport, and shipping; and (iii) labeled or color-coded according to paragraph (g)(1)(i) of this standard. From comments discussed above, it can be expected that at least some sharps containers will contain residual liquids and, based upon the particular container's design, may leak when tipped or overturned. These leaked fluids then present a contamination and exposure hazard which must be prevented. Judith Gordon urged addition of a provision specifying that measures must be taken to prevent exposures to spills and leaks from sharps containers during collection and transport (Tr. 9/13/89, p.99). In addition, Curtis Leland of Winfield Corporation stated the practice that most states recognize is that of immediately red-bagging filled sharps containers to prevent any residual liquids from spilling (Tr. 1/17/90, p.914). EPA also recognizes the potential for leakage from sharps containers in their Medical Waste Tracking Act and addresses this hazard as follows:

* * * If the container(s) cannot be sealed to prevent leakage, it must be placed in a

plastic bag or other leak-resistant container that can be sealed to prevent leakage. The intent is to ensure that sharps and associated residual fluids (often blood) are securely contained and the integrity of the packaging is maintained from the time the waste leaves the generator's site until the time the waste is disposed of or is treated and destroyed. (Ex. 6-497)

This information leads the Agency to conclude that all of the above requirements are appropriate, justified, and feasible.

While the proposal specifically required disposable sharps containers, the final standard permits utilization of reusable containers for discarding of contaminated sharps. However, the final standard places restrictions on the processing of these containers to ensure that employees who handle them are not exposed to the risk of percutaneous exposure. As such, paragraph (d)(4)(iii)(A)(4) requires that reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.

A number of participants urged OSHA to consider permitting use of reusable containers (e.g., CDC/NIOSH, Ex. 20-634; APIC—National, Ex. 20-1118; EPA, Ex. 20-991; Judith Gordon, Tr. 9/13/89, p.98; Florida Hospital Association, Tr. 12/19/89, pp.908-910; MedX Inc., Ex. 255, Tr. 12/21/89, pp.1587-1591; Biosystems Partners, Ex. 20-2887). CDC/NIOSH commented:

> Paragraphs (d)(4)(iii)(B) and (d)(4)(iii)(B)(2) should be revised so they do not preclude the possibility of employing reusable containers if procedures are devised that do not increase the risk of puncture wounds. (Ex. 20-634)

Also, Judith Gordon echoed the above in her written comments, stating:

> In my opinion, OSHA should look at other available systems. It may be appropriate to allow the use of sharps containers that are not disposable if their handling does not pose a risk of occupational exposure to the waste handlers. (Ex. 30)

In their comments to the proposal, EPA simply stated that while OSHA had stipulated disposable containers, EPA was allowing reusable rigid containers that had been decontaminated (Ex. 20-991). Obviously, even among some of those urging OSHA to consider reusable sharps containers, the potential for employee exposure is a concern. OSHA shares these concerns and this was a major point during consideration of this issue. Other participants provided information and comment which substantiated the Agency's concern.

Dr. Michael Decker, representing the Society of Hospital Epidemiologists of America, testified that the Society disagreed with permitting the use of reusable sharps containers. He stated:

> We view the greatest hazard as being sharps and the area where the most rigorous rule making is appropriate is sharps. And we would not encourage anyone to handle any sharp after use. If it's reusable, by definition somebody had to clean it out. Nobody should have to do that. We think sharps should go into impervious, relatively crush-proof * * * containers that are never thereafter reopened by anyone until they're terminally destroyed. (Tr. 10/18/89, p.352)

The Society reiterated this stance in their written comment by stating that permitting reusable containers implied that some worker would empty the containers—an activity whose risk far outweighed the trivial economic benefit (Ex. 20-1002).

Also during the hearings, Joan Emslie, a SEIU union representative, described a reusable container system that had been in use at local hospital facility. Essentially, the system consisted of locked, yellow, hard plastic boxes, lined with plastic bags, into which sharps were discarded. When full, a central supply technician removed the box, took it to central supply, unlocked it, and emptied it into a larger red box by up-ending the yellow box and allowing the plastic liner and contents to fall out. Full red boxes were then removed by an independent hazardous waste company (Tr. 1/16/90, pp.665-666). When asked to detail some of the problems with this system, Ms. Emslie responded:

> * * * once they open the lid like this they then grasp it by the sides, the lid comes all the way off and they grab it this way and dump it totally upside down. Now because of the size of the needles or the way they throw the needles in there, it actually goes through this plastic liner, the first few in, and it sticks into the bottom. So the needle is actually stuck into the plastic. So when they turn it upside down it does not always fall out. So then they would have to then set it back on the counter, lift the paper which is against the rules, but pull on the paper to get it out. In doing that if the needle comes loose quickly it could fly out at them. Also, if the needle that's disposed of in here has tape on it, it sticks to the side, you can't see that when you look inside. So when you turn it upside down some of the needles fall out and if the plastic doesn't fall out that needle then is swinging freely. Even if you had the glove on, which only goes to your wrist, the needle could swing out and hit you in the forearm, which it has done and at this particular arbitration we had testimony from an employee who was stuck just that way. Also, with the hole in the top the way it is, it is possible that when they go to remove the top if it's too full or a very large syringe is in here and in unlocking this and then unclamping it here it is possible to get stuck through the top. We also had testimony from a central supply worker who did get stuck that way as well. (Tr. 1/16/90, pp.660-661)

Moreover, Dr. Steiner of On-Gard Systems stated that he felt that a system requiring emptying of sharps containers was a totally ill-advised practice while the American Association of Critical-Care Nurses commented that disposable containers were safer since they reduced the number of people having to deal with the container (Tr. 9/26/89, p.73; Tr. 12/19/89, p.960).

MedX, Incorporated and Biosystems Partners, two companies supplying reusable sharps container services to facilities, presented an opposing viewpoint. Some of the advantages of reusable containers cited by these commenters included: higher quality container construction resulting in increased puncture-resistance; cheaper disposal costs for client facilities; reduced needlestick incidence within client facilities due to increased container replacement rate, minimizing overfilling; and a reduction in solid waste going to landfills or incinerators (Exs. 255, 20-2887). While these are certainly important benefits, OSHA shares the concern voiced by some of the previously-cited commenters relative to the risk of injury incurred by employees who open, empty, and/or clean the containers. Even though the occurrence of sharps injury may decrease in client facilities, the Agency cannot advocate transference of this risk to employees of the servicing company. This concern does not necessarily mean that utilization of reusable containers must be prohibited, however, and it is not the Agency's intent to eliminate a potentially viable alternative to disposable sharps containers, provided servicing employees are not placed at increased risk. In response to questions about viability of reusable container systems, Dr. Decker of the Society of Hospital Epidemiologists of America stated that he did not support individuals opening sharps containers; however, he continued by commenting:

> If there were containers that were designed to be hauled off and in some automated way emptied, cleaned, and sent back, I don't see anything wrong with that. Certainly its doable * * *. (Tr. 10/18/89, p.369)

Ms. Barbara Russell of Baptist Hospital (a MedX client), who had visited the MedX plant and observed their procedures, stated that the actual emptying of containers was done by machine (Tr. 12/21/89, p.1594). MedX stated in their post-hearing comment that a fully-automated container cleaning system that eliminates employee sharps exposure was expected to be put into service by

January 1991. MedX concludes their comment by stating:

It would create an undue hardship on companies such as MedX, who have devised reusable sharps container services, for OSHA to completely eliminate the service without first conducting a fair investigation. If the findings of an investigation demonstrate that some facet of the system presents an unreasonable risk, OSHA should demand that the industry modify the system appropriately. (Ex. 255)

After much deliberation, OSHA has concluded that reusable sharps container systems can be a viable alternative to disposable containers if the risk to servicing employees is eliminated. Based on the information presented, it is also the Agency's conclusion that it is currently feasible to alter the cleaning process to eliminate this risk. Therefore, reusable containers are permitted provided they are not opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.

Regulated Waste Containers

Paragraph (d)(4)(iii)(B) of the final standard puts forth the requirements for containing regulated wastes other than contaminated sharps, such as blood-saturated dressings. This waste must be placed in containers which are: (a) closable; (b) constructed to contain all contents and prevent leakage of fluids during handling, storage, transport, and shipping; (c) labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and (d) closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

Requiring the container to be closable is necessary to ensure that the waste is not spilled in the event of the container becoming tipped or upended (VA—Salt Lake City, Ex. 20-635; EPA, Ex. 6-497; CDC, Ex. 6-395). Simply being closed, however, is not enough to ensure that wastes are contained. For example, plastic bags containing waste may be torn due to rough handling, compaction, or punctures caused by pointed or sharp objects being placed into them. When the physical barrier surrounding the waste is compromised, the chance of employee exposure and work area contamination is increased. Mr. David Ares, a health and safety delegate for SEIU, stated that it was fairly common at the facility where he worked for waste-containing redbags to break and spill their contents (including liquid blood) into the work area and onto employees while being loaded into the incinerator hopper (Tr. 11/13/90, pp.176-177). Moreover, Ms. Lawrel Mueller, a certified nurse's assistant, described what resulted at her facility when plastic waste bags broke during handling. She stated:

• • • [A]t one time the porter would pick up from the floors. He would go around to all of the floors and he would take it out to the dock. This would be in plastic bags. Sometimes the bags would break and the blood would go all over him. That happened a number of times. They would throw it down the chute, blood products, I don't know how that happened but it did and one time I went down there, he called me and he was full of blood and the whole area where it had fallen into this huge cart, it was all over, the walls, the ceiling, everywhere, and all over the worker. (Tr. 1/16/90, p.783)

In some circumstances, duration of time that wastes remain in the container may also play a role in a container's ability to contain waste. Mr. Steve Whitney of Whitney Products testified that small-volume generators (e.g., doctors offices, clinics, or dentists offices), by virtue of the small amount of waste generated per day, may place waste into large holding boxes over the course of a number of consecutive days. These boxes may sit for weeks or months before they are picked up by specialized waste services (Tr. 10/20/89, p.927). Obviously, consideration would have to be given to the design of the container to ensure that it would be able to retain all wastes, including any liquids, for the period of time between pick-ups.

Other sources also indicated that some type of provision was needed to ensure proper waste containment. The comments of Ms. Bonnie Shacknies and APIC—Greater LA recommended that this provision state that containers or bags are to be of sufficient strength to prevent leakage and tearing in transport (Exs. 20-525; 20-213). Furthermore, EPA's Medical Waste Tracking Act requires that waste bags be of sufficient strength to prevent tearing and breaking and must be sealed securely to prevent leakage (Ex. 6-497). OSHA has reviewed the above information and agrees that a minimum performance requirement is necessary. Consequently, OSHA has stipulated in the final regulation that whatever containers are chosen for waste containment (e.g., boxes, plastic bags), they must be able to contain all contents and prevent leakage of fluids during handling, storage, transport, or shipping.

The proposed standard stated that waste containers had to be "leakproof." CDC documents also discuss "leakproof" and "impervious" containers (Exs. 15; 6-395). Several commenters, however, questioned the achievability of "leakproof" containers. The American Hospital Association wrote that no container was truly "leakproof" and that "leak-resistant" is a sufficient standard which permits enough flexibility for a facility to use heavier packaging when necessary (Ex. 20-352). The Cleveland Clinic recommended that "leakproof" be conditioned to apply to normal handling situations (Ex. 20-563). Moreover, the EPA commented that "leakproof" may be unattainable without further definition of the term (Ex. 20-991). Reviewing the Medical Waste Tracking Act, it was noted that EPA requires "leak-resistant" containers (Ex. 6-497). To reduce confusion and avoid requiring a possibly unachievable standard, the Agency has revised this provision to be more performance-oriented. The final standard requires that containers prevent leakage during handling, storage, transport, or shipping.

Regulated waste containers must also be labeled or color-coded in accordance with paragraph (g)(1)(i) of the standard in order to warn employees who may have contact with the containers of the potential hazard posed by their contents. Use of warning labels or color-coding was supported by several interested parties (EPA, Ex. 6-497; ADA, Ex. 20-665; AFSCME, Ex. 297; CDC/NIOSH, Ex. 20-634; APIC—Indiana, Ex. 20-139; Mohawk Valley Psychiatric Center, Ex. 20-950; American Biological Safety Association, Tr. 9/21/89, p. 101; Baxter Health Care Corporation, Tr. 10/20/89, p. 872). However, one commenter, Mercy Regional Medical Center, suggested that not all infectious waste would be required to be marked as such if it is handled on-site and the facility's policy is for all waste to be treated as infectious waste (Ex. 20-186). While OSHA believes that treating all waste as regulated waste is consistent with safe handling practices, elimination of all warnings on waste containers is not justified. Warning by label or color coding is still necessary for to alert employees who may not be aware of the facility's waste policy (e.g., new employees, employees who would not normally come in contact with wastes, employees from outside the facility). Facilities like Mercy can place all of their waste in labeled or color-coded containers. OSHA has concluded that such a policy does not warrant an exception to labeling or color-coding, particularly when considering the general recognition by commenters of the potential hazards posed by regulated waste.

OSHA proposed that if infectious waste was labelled rather than color-coded, the label include the biological hazard symbol. EPA supports the use of

the biohazard symbol as evidenced by the fact that it is one of the three choices given to generators for designating regulated waste (Ex. 6-497). Dr. Michael Decker of the Society of Hospital Epidemiologists of America testified:

> Speaking of labels, generally, we support to biohazard label and if there is to be a label, that would I think be the preferred label. Why have conflicting labels? Others are going to require us to biohazard label a lot of the same things you're going to require. The last thing we want is two different labels, one for each agency on it. * * * [Tr. 10/18/89, pp 353-354]

Both CDC/NIOSH and the American Biological Safety Association support labeling/color-coding, but they stated that the biohazard symbol should be reserved to designate known sources of etiologic agents and should not be used on regulated waste containers (Ex. 20-634; Tr. 9/21/89, p. 101). However, under universal precautions, it is assumed that bloodborne pathogens are present in all blood and other potentially infectious materials. In fact, CDC adopted this stance in its recent notice of proposed rulemaking for interstate shipment of etiologic agents. Specifically, the CDC proposal states:

> * * * Because all health care workers are encouraged to handle all patient's clinical specimens as though they are infectious, the proposed regulations are intended to apply to all clinical specimens. * * * The new label for clinical specimens and biological products has the same biohazard symbol as does the label for etiologic agents. However, instead of white and red, this label will be fluorescent orange and black, as recommended by the Occupational Safety and Health Administration requirements for labeling biological hazards. [Federal Register, Vol. 56, No. 42, pp. 7878-7882, Ex. 286K citing 29 CFR 1910.145]

The Agency agrees with the Society of Hospital Epidemiologists of America in that requiring use of a new symbol could prove confusing and burdensome. Keeping with the intent of universal precautions and considering the above information, the Agency has concluded that use of the biohazard symbol is appropriate in the labeling of regulated waste.

Some situations could result in the outside of a regulated waste container becoming contaminated with blood or other potentially infectious materials as would occur if potentially infectious materials were spilled on the exterior of the container while it was being filled. To address such situations, the proposal required that if outside contamination of the container or bag was likely to occur, the container was to be placed in a second container which was closable, color-coded or labeled, and closed to prevent leakage. The final standard retains this basic requirement, with minor revisions, to prevent an employee's handling of the contaminated exterior and to limit spread of contamination throughout the work area. More specifically, paragraph (d)(4)(iii)(B)(2) states that if outside contamination of the regulated waste container occurs, it shall be placed in a second container. The second container must be: (a) Closable; (b) constructed to contain all contents and prevent leakage of fluids during handling, storage, transport, or shipping; (c) labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and (d) closed prior to removal to prevent spillage or protrusion of contents during handling storage, transport, or shipping. The second container must fulfill the same requirements as the contaminated primary container (closable, proper construction, labeled/color-coded, closed) for the same reasons discussed above relative to regulated waste containers.

Several commenters agreed that there were situations in which outside contamination of a primary container occurred and placing it in a second container was appropriate (East Jefferson General Hospital, Ex. 20-599; Elizabeth M. Rettig, RN, Ex. 20-588; Susan J. Williams, RN, CIC, St. Joseph Hospital, Ex. 20-148). However, a number of participants misinterpreted the proposed provision believing it to require "double-bagging" of all regulated waste or stated that the phrase "if outside contamination of the container or bag is likely to occur" was too vague to give proper guidance to employers about when a second bag would be required (e.g., American Association of Blood Banks, Ex. 20-1059; St. Alexis Hospital, Ex. 20-958; St. Luke's Hospital, Ex. 20-1230; Boone Hospital Center, Ex. 20-658). It was not the Agency's intent to imply that all regulated waste was to be "double-bagged" or to propose a provision that, due to its vagueness, would necessitate such a practice. Therefore, the provision has been revised to clarify that a second container would be required when outside contamination of the first occurs. Examples of when double bagging would be required include: a waste container that has been splashed with blood during surgery or autopsy, a container that has been handled by an employee wearing blood-contaminated gloves, or a waste bag that is leaking blood or other potentially infectious materials onto an adjacent bag(s). It should be noted that the Agency's reasoning for requiring secondary containers is not as a general infection control measure or to ensure containment of a particularly heavy load of waste. They are being required to address employee exposure and work area contamination in those instances where outside contamination of the primary container has occurred. In such circumstances, the Agency has concluded that this requirement is justified and appropriate.

As stated in the proposal, it is not OSHA's intent to set rigid regulations regarding regulated waste handling and disposal, but simply to put forth minimum requirements for containing waste which the Agency has determined warrants special handling in order to protect employees against exposure to bloodborne pathogens. The Agency maintains this intent and recognizes that additional requirements may apply to this waste under the jurisdiction of other governing bodies. Similar to the proposal, therefore, paragraph (d)(4)(iii)(C) requires that disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories. Relative to this, some commenters stated that OSHA's proposed packaging regulations for waste were inconsistent with those of EPA (Connecticut Hospital Association, Ex. 20-275; William W. Backus Hospital Ex. 20-911). EPA's comment contained the following statement on this issue:

> EPA's regulations are more stringent than the proposed OSHA requirement for packaging: EPA requires medical waste packaging to meet a set of performance-based standards. One of the EPA performance standards requires packaging to be rigid; EPA believes that single- or double-bagging wastes is insufficient to protect medical waste handlers when wastes are transported off-site. * * * [Ex. 20-991]

In addition, EPA commented that they require the words "Medical Waste," "Infectious Waste," or the universal biohazard symbol on the outside of packaging of untreated medical waste (Ex. 20-991). Upon reviewing this information, OSHA sees no unresolvable conflict. No particular requirement is stipulated in this standard for rigid or non-rigid containers for shipping wastes off-site. Therefore, a facility may initially collect waste in rigid containers or place waste contained in plastic bags into rigid containers for off-site shipping. Either method appears to satisfy both OSHA and EPA regulations relative to rigidity of containers. With respect to labeling, OSHA's required label contains the universal biohazard symbol, one of the three labeling choices offered by EPA's

regulations. Hence, the Agency concludes that the label required by this standard would satisfy EPA's regulations also.

Laundry

The final standard, in paragraph (d)(4)(iv)(A), requires that contaminated laundry shall be handled as little as possible with a minimum of agitation. In addition, contaminated laundry is to be:

(1) Bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use;

(2) Placed and transported in bags or containers that are labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard (When a facility utilizes universal precautions in the handling of all laundry and all employees are trained to follow universal precautions with laundry until it has been laundered, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with universal precautions); and

(3) Placed and transported in bags or containers which prevent soak-through and/or leakage of fluids to the exterior if the laundry is wet and presents a reasonable likelihood of soak-through or leakage from the bag or container.

By requiring bagging or containerization of contaminated laundry at the location of use and prohibiting sorting or rinsing in these areas, the amount of manual handling of the laundry by staff, other than laundry personnel, is limited to that which is necessary for removal and bagging or containerization. Contamination of additional surfaces such as sinks and floors is also reduced from that which may occur if sorting and rinsing were permitted in areas other than the laundry. This provision was adopted directly from CDC's recommendation for routine handling of soiled linen contained in their Guideline for Handwashing and Hospital Environmental Control, 1985 and later reiterated in Recommendations for Prevention of HIV Transmission in Health-Care Settings (Exs. 6-188; 6-153). In addition, the 1988 Guidelines for Healthcare Linen Service by the Joint Committee in Healthcare Laundry Guidelines support handling soiled linen as little as possible and with a minimum of agitation (Ex. 113a). This provision was also specifically supported, in whole or in part, by several commenters (e.g., AFSCME, Ex. 297; Glendale Memorial Hospital, Ex. 20-169; RWDSU, Ex. 20-1505; G.S. Naylor, M.D. and K.A. Yates, R.N., Ex. 20-555).

Placing and transporting contaminated laundry in bags or containers that are color-coded or labeled in accordance with paragraph (g)(1)(i) is required to inform employees who may handle the bags or containers of their contaminated contents and that special handling procedures are in order. Labeling or color-coding of contaminated laundry was supported by several commenters, such as the Service Employees International Union, the American Federation of State, County, and Municipal Employees, the Food and Allied Service Trades, and the American Association of Critical-Care Nurses (Exs. 299; 297; 20-888; 20-1162). However, SEIU went on to say:

> * * * SEIU recognizes that OSHA may want to reconsider its red-bagging and labelling requirements if *all* laundry is to be treated as potentially infectious. . Additionally, if *all* laundry is considered potentially infectious, labelling and bagging of laundry that is handled by outside contractors may need separate consideration. (Emphasis in original)(Ex. 299)

A large number of commenters felt that labeling or color-coding laundry bags was unnecessary. However, this statement was generally qualified with the comment that use of consistent handling or Universal Precautions in the handling of *all* laundry obviates the use of labels or color-coding (e.g., SHEA, Tr. 10/18/89, p. 356, 377; Casa Colina Hospital, Ex. 20-284; Dakota Hospital, Ex. 20-632; Frick Community Health Center, Ex. 20-292; Lakeland Regional Medical Center, Ex. 20-37). Harrisburg Medical Center discussed use of alternative labeling or color-coding (Ex. 20-738). Reviewing the record, it appears that a number of associations and facilities support and/or have adopted the policy of using universal precautions in the handling of *all* soiled laundry (e.g., Joint Committee on Healthcare Laundry Guidelines, Tr. 10/20/89, pp. 794,803; Textile Rental Services Association of America, Ex. 20-383; AAOHN, Ex. 20-357; APIC—Kansas City, Ex. 20-689; AFSCME, Ex. 297; SEIU, Ex. 299; Standard Textile Company, Tr. 9/28/89, p. 27; Society of Hospital Epidemiologists of America, Tr. 10/18/89, pp. 356, 377; Kaiser Permanente—Panorama City, Ex. 20-60; Greater Houston Hospital Council, Ex. 20-1252). Just as with the views expressed regarding specimen labeling, commenters following this policy felt that labeling/color-coding was unnecessary. The Agency has considered these comments and has reached a conclusion similar to that reached with specimen labeling. That is, when a facility utilizes universal precautions in the handling of all laundry and all employees are trained to follow universal precautions with laundry until it has been laundered, alternative labeling or color-coding is sufficient provided all employees who may come into contact with these bags or containers are able to recognize them as requiring compliance with universal precautions and the bags or containers remain within the facility. Labeling or color-coding of contaminated laundry shipped off-site is discussed below under paragraph (d)(4)(iv)(C). This addition to the provision increases the flexibility afforded to employers in the handling of contaminated laundry. They may either: (1) Separate contaminated laundry from other soiled laundry and place it into bags or containers labeled or color-coded in accordance with paragraph (g)(1)(i); or (2) they may utilize universal precautions and alternatively labeled or color-coded bags or containers in the handling of all soiled laundry, eliminating segregation of contaminated laundry and the need for two different types of bags or containers (i.e., contaminated versus non-contaminated) to contain soiled laundry.

In some circumstances, laundry may contain enough blood or other potentially infectious materials that soak-through and/or leakage from the bag or container could occur. Therefore, paragraph (d)(4)(iv)(A)(3) states that whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through of or leakage from the bag or container, the laundry shall be placed and transported in bags or containers which prevent soak-through and/or leakage of fluids to the exterior. This will not only minimize environmental migration of contaminants but will also reduce employee exposure which would occur during handling of wet or leaking bags or containers. Again, this provision has essentially been adopted from CDC's 1985 hospital environmental control document and their Recommendations for Prevention of HIV Transmission in Health-Care Settings (Exs. 6-188; 6-153).

The American Hospital Association urged that the proposed requirement for "leakproof" bags be changed to "leak-resistant" (Ex. 20-352). The comment of CDC/NIOSH stated that rather than "leakproof," bags or containers should prevent leakage and be of sufficient quality to contain wet laundry without outside contamination (Ex. 20-634). The 1988 Guidelines for Healthcare Linen Service specify:

> The collection bags or containers should be of sufficient quality to functionally contain wet/soiled linen to prevent contamination of

the environment during collection, transportation, and storage prior to processing. (Ex. 113a)

The Agency has modified the provision to make it more performance-oriented and thereby permit more flexibility by eliminating the term "leakproof" and simply requiring that the container chosen must prevent soak-through and/or leakage of fluids to the exterior. The bag or container is not required to be made of any particular material (e.g., plastic versus cloth), merely that it satisfies the above performance criteria. It should also be noted that all contaminated laundry is not required to be placed in such bags or containers, only wet contaminated linen which presents a reasonable likelihood of soak-through and/or leakage to the exterior. The use of bags or containers which prevent soak-through and/or leakage of fluids contained in wet contaminated laundry was supported by a number of other commenters (e.g., American Biological Safety Association, Ex. 241; Textile Rental Services Association of America, Ex. 20-383; SEIU, Exs. 20-979, 299; AFSCME, Ex. 297; California APIC Coordinating Council, Tr. 1/10/90, p. 191).

Paragraph (d)(4)(iv)(B) requires that the employer shall ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment. Gloves will reduce contact exposure to blood or other potentially infectious materials that are found in contaminated laundry. In addition, other appropriate personal protective equipment such as gowns, aprons, and possibly eyewear, may be necessary to prevent employee exposure. Use of gloves and other appropriate personal protective equipment during contact with contaminated laundry is supported by a number of participants in the rulemaking (e.g., CDC/NIOSH, Ex. 20-834; AHA, Ex. 20-352; Society of Hospital Epidemiologists of America, Tr. 10/18/89, p.377; Joint Committee on Healthcare Laundry Guidelines, Ex. 113a, Tr. 10/20/89, pp.800-801; Textile Rental Services Association of America, Ex. 20-383, Tr. 9/25/89, p.79; Angelica Corporation, Tr. 1/12/90, pp.528-527; SEIU, Exs. 20-979, 299).

Not all soiled laundry is processed on-site. Consequently, bags or containers of soiled laundry from a facility which utilizes universal precautions in the handling of all laundry and which have been labeled or color-coded using an alternative method recognized by all affected employees of the generating facility, may not be recognized as containing contaminated laundry by the employees of the off-site laundering facility. This problem is compounded in a laundry processing linen for a number of facilities, all of which may be utilizing different marking systems for their laundry containers. Employees of laundries which utilize universal precautions in handling all soiled laundry would not be affected by the differing markings since they would be uniformly treating all soiled laundry as potentially infectious regardless of its container markings. However, employees of laundries which did not adhere to universal precautions with all soiled laundry need to be informed as to which bags or containers hold contaminated laundry so that proper precautions can be taken. The situation of off-site laundering was brought up not only by SEIU as discussed in the labeling section above, but also was addressed by the RWDSU who commented that when institutions contract with a commercial laundry service to process soiled linens, it is necessary to inform the service's employees of the potential for infection from soiled linens (Exs. 298; 20-1505). Therefore, paragraph (d)(4)(iv)(C) has been added to the final standard to address this circumstance. This provision states that when a facility ships contaminated laundry off-site to a second facility which does not utilize universal precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded in accordance with paragraph (g)(1)(i). In order to be effective and minimize confusion among employees, the hazard warning used should be one that is standardized and universally recognized. Since the biohazard symbol and the color red are generally recognized as warning of potentially infectious material, OSHA concludes that this label or color-coding system is the most appropriate to employ to warn off-site employees of the hazard of contaminated laundry.

An additional issue was raised relative to labeling or color-coding. The proposal required that bags of contaminated laundry be labeled with the biohazard label or colored red. Jill Witter of Angelica Corporation testified that linen shortages in many of Angelica's client hospitals were found to be the result of red-bagged soiled linen being mistaken for bagged infectious wastes and consequently incinerated (Tr. 1/12/90, pp.533-534). Ms. Witter also stated that using red plastic bags for packaging soiled linen was causing a problem in that since they cannot be washed they must be disposed of and landfills were either refusing red and yellow bags or were charging increased prices for their disposal (presumably since they are associated with containment of infectious waste) (Tr. 10/20/89, p.812). A similar comment was made by Carmen C. Birk, a registered nurse and infection control practitioner (Ex. 20-106). Since alternative labeling or color-coding in facilities which utilize universal precautions in the handling of all soiled laundry is permitted by the final standard, this problem can be eliminated if both the generating facility and the off-site laundering facility utilize universal precautions.

Comment was received by a number of participants expressing that it was unnecessary for OSHA to regulate handling of laundry (e.g., Abington Memorial Hospital, Ex. 20-557; American Association of Blood Banks, Ex. 20-1058; Tri-County Area Hospital District, Ex. 20-63; Bingham Memorial Hospitals, Ex. 20-143). The most often cited rationale for this view was that laundry has not been implicated in the transmission of HBV or HIV; therefore, no special handling practices were indicated. During the hearings, Keith Mestrich, Director of Health and Safety for the Food and Allied Services Trades Union, questioned Dr. Stephen Hadler of CDC about the possibility of hepatitis B contraction among laundry workers, particularly in view of the virus's ability to survive even in a dried state (Tr. 9/14/89, p.73). Dr. Hadler responded:

> I can comment that data shows the virus can survive a week, if it were to be—if parenteral exposure were to occur, then it could cause infection * * * [O]ne would say if laundry is visibly blood-contaminated, then it is something that should be of concern. (Tr. 9/14/89, p.74)

Dr. Hadler testified further that it was theoretically possible for exposure to occur through contact of dried blood with non-intact skin (Tr. 9/14/89, p.74).

Information provided by laundry workers demonstrates that exposure to blood and other potentially infectious materials does occur during processing of contaminated laundry. Ms. Georgia Davenport, when asked if laundry workers in the facility where she worked handled blood-soaked laundry that was still wet, stated:

> Yes they do. Like some of the surgery, we get a lot of congealed blood, we get a lot of different parts of the body comes out. You also get some, like, from labor and delivery, you get different congealed blood come down in sheets and in blankets and different things. They have to handle all of this * * *
>
> You have to sort the linen. You put bath blankets in one place and you put sheets in

another, you put towels in another. You sort it. That means you have to handle it * * * (Tr. 1/16/90, pp.780–781)

Other participants also presented testimony regarding exposure including splashes to face, hands, arms or body and contact with wet blood and other potentially infectious materials such as body parts and human placentas in soiled laundry (Tr. 10/18/89, p.167; Tr. 11/14/89, pp.444–445; Tr. 1/16/90, pp.781–782; Tr. 10/17/89, pp.46–47). In addition, contaminated sharps are also generally recognized to be a potential hazard contained in soiled laundry.

In view of this information, along with the recommendations for specific laundry handling practices put forth by organizations such as CDC, the Joint Committee for Healthcare Laundry Guidelines, and the Textile Rental Services Association of America, the Agency has concluded that the likelihood of exposure does exist in the handling of contaminated laundry and that the regulations contained in this final standard are warranted and justified.

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

This paragraph addresses additional requirements that must be met by research laboratories and production facilities engaged in the culture, production, concentration, and manipulation of HIV and HBV. The risks associated with direct and routine work with pathogens have long been recognized:

> Microbiology laboratories are special, often unique, work environments that may pose special infectious disease risks to persons in or near them. Personnel have contracted infections in the laboratory throughout the history of microbiology (Ex. 6–338).

HIV and HBV research laboratories and production facilities are no exception, and the risks associated with work in such facilities warrant additional protective measures.

Prior to 1984, no single code of practice, standards, guidelines or other publication providing detailed descriptions of techniques or equipment for laboratory activities involving pathogens was available. In that year, the Centers for Disease Control (CDC) and the National Institutes of Health (NIH) published guidelines entitled "Biosafety in Microbiological and Biomedical Laboratories" (Ex. 6–338). These biosafety guidelines were based on combinations of standard and special practices, equipment, and facilities recommended for use when working with various infectious agents in laboratory settings. These guidelines were revised in 1988.

These biosafety guidelines are not limited to the bloodborne pathogens which are the subject of this standard. They are applicable to work with any infectious agent. The basic format for the biosafety guidelines categorizes infectious agents and laboratory activities into four classes or levels denoted as biosafety levels 1 through 4. These biosafety levels (BSL) are comprised of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities appropriate for the operations performed and the hazard posed. The Guidelines indicate the BSL to be used when working with various infectious agents and infected animals. Recommended BSL for working with HIV were not included in the original biosafety guidelines.

In 1988, CDC issued an "Agent Summary Statement for Human Immunodeficiency Virus" (Ex. 6–312) which outlined biosafety levels for various activities involving HIV. Activities performed in clinical laboratories were categorized at BSL 2 which covers standards and practices for handling all clinical specimens. For HIV research laboratories and production facilities, the Agent Summary states:

> Activities such as producing research-laboratory-scale amounts of HIV, manipulating concentrated virus preparations, and conducting procedures that may produce aerosols or droplets should be performed in a BSL 2 facility with the additional practices and containment equipment recommended for BSL 3.
>
> Activities involving industrial-scale, large-volume production or high concentration and manipulation of concentrated HIV should be conducted in a BSL 3 facility using BSL 3 practices and equipment (Ex. 6–312).

These recommendations with some modifications were adopted by OSHA to cover HIV/HBV research laboratories and production facilities. Accordingly, the Guideline's BSL 3 text for standard microbiological practices, special practices, and containment equipment was converted to regulatory language and comprises paragraph (e)(2) of the standard. Requirements for the facilities for research laboratories [paragraph (e)(3)] were derived from the text for BSL 2, while those for production facilities [paragraph (e)(4)] were derived from the text for BSL 3.

While general training requirements for employees working with pathogens are given in paragraph (g), OSHA feels that additional specialized training should be provided for employees of the research laboratories and production facilities covered by paragraph (e). HIV infection of a worker in an HIV production facility as a result of "undetected skin contact with virus culture supernatant" was attributed to inexperience coupled with "on-the-job training in a setting in which episodes of contamination may have occurred frequently" (Ex. 6–312). Therefore, the training recommendations of the NIH committee convened to investigate the incident were incorporated into paragraph (g)(2)(vii) of this standard as special training requirements.

OSHA recognizes the valuable contribution that is being made by research laboratories that are studying the human immuno-deficiency virus and the hepatitis B virus. The Agency also understands the need to produce extremely high concentrations of these viruses to prepare reagents and other products needed for research, diagnosis and, if an HIV vaccine is developed, prevention. The Agency has no desire to impede these efforts. However, there is clearly documented risk to individuals working with blood and other potentially infectious materials containing HIV and HBV. When the concentration of these viruses is increased as the result of growing virus in cell culture or artificial concentration, then the risk to employees increases. The two cases of HIV infection that occurred in HIV production facilities are discussed in the Health Effects section of this preamble.

The final standard for occupational exposure to bloodborne pathogens requires the employer to implement a number of provisions that are identical to those found in the Guidelines. The provisions in paragraph (e) are a minimal program, and OSHA anticipates that these employers will continue to follow the appropriate portions of the guideline in addition to those in the final standard.

The requirements in paragraph (e) are derived primarily from the CDC/NIH recommendations found in "Biosafety in Microbiological and Biomedical Laboratories" (Ex. 6–338). Only those provisions that relate to the health and safety of the employee are required by the standard. Since the employer is responsible for following the entire standard, requirements stated elsewhere in the standard (e.g. the prohibition of mouth pipetting) are not repeated. The special training requirements in paragraph (g)(2)(vii) are based on the conclusions and recommendations of an expert team convened by the Director of the National Institutes of Health.

This section applies to two types of facilities that we have designated

"research laboratories" and "production facilities." For the purpose of this standard, "research laboratories" means a laboratory producing or using research-laboratory scale amounts. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in the production facilities. Although attempts to grow HBV in this manner have not been successful in the past, researchers are attempting to culture HBV and the *in vitro* culture of HBV may soon be possible. This standard does not require research laboratories such as laboratories using unconcentrated blood or blood components as the source of HIV or HBV to follow the requirements in paragraph (e) if this is the only source of virus used in the laboratory. However, they must follow the other provisions of the standard and avoid the production of aerosols.

David Silberman, the Manager for Safety and Health Programs for the Stanford University School of Medicine, in his testimony raised some concerns about applying the OSHA standard to academic research facilities (Tr. 1/10/90, pp. 212–235). Rather than following the requirements of the paragraph (e) he urged that the academic community collaborate on safety issues in research laboratories with NIH and CDC. While such collaboration has undoubtedly resulted in hazard identification and communication among research laboratories, even the guidelines developed by NIH and CDC do not always result in successful communication of hazards. Mr. Silberman testified he was not familiar with the "1988 Agent Summary Statement for Human Immunodeficiency Virus * * *", recommendations issued by CDC for handling HIV. To avoid gaps in crucial information, OSHA has concluded academic research laboratories must be covered by this standard.

For purposes of the standard, facilities that are engaged in industrial-scale, large volume or high concentration production of HBV or HIV are called "production facilities." These facilities reduce many liters of plasma or culture fluid into a concentrate of a few milliliters. These concentrated preparations are used for a number of purposes including use as testing reagents and, in the past for HBV and perhaps in the future for HIV, for vaccines. In many cases, the production of concentrated virus is a byproduct of the process and not the goal, for example, in the production of HBsAg.

The provisions in paragraph (e) remain essentially unchanged as initially proposed. OSHA's expert witnesses, (Tr. 9/12/89, p. 35; Tr. 9/13/89, pp. 100–101) and NIOSH (Tr. 9/14/89, p. 34) strongly supported the provisions. Ms. J. Janczewski, the President of Consolidated Safety Service, Inc., who had already an opportunity to implement similar provisions in a production facility, testified that OSHA proposed standard "* * * is feasible, reasonable, cost-effective, and more importantly, provides these employees with a workplace free from recognized hazards" (Tr. 9/12/89 p. 35). Ms. J.G. Gordon, President of Gordon Resources Consultants, Inc., testified that OSHA requirements for HIV and HBV research laboratories and production facilities "* * * correspond to the CDC recommendation * * *" (Tr. 9/13/89, pp.100–101). And Dr. B. Hardin of NIOSH testified that "OSHA is correct to require a combination of engineering and work practice control, along with personal protective equipment, to manage the risks of occupational exposure to bloodborne pathogens." (Tr. 9/14/89, p. 26). In response to a few comments received in the record, several minor changes were made in the final standard. These changes only clarify or augment the requirements in this paragraph, and do not detract from the initial intent of the proposed provisions.

Paragraph (e)(2)(i) describes the requirement for the decontamination of regulated waste. The purpose is to prevent the accidental exposure of other employees to the concentrated virus. In the final standard the methods for decontamination of regulated waste were expanded to give specific examples including incineration and autoclaving. This change and reflects comments from CDC/NIOSH's (Ex. 20–634) and the State of Connecticut (Ex. 20–796).

Paragraph (e)(2)(ii) describes special practices to be followed and paragraph (e)(2)(ii)(A) (C) and (D) serve to further limit access to the laboratory and would warn of the hazards associated with bloodborne pathogens. These paragraphs ensure that unauthorized individuals are not placed at risk, and that they do not distract or otherwise interfere with the activity of the authorized employees. This works in concert with the requirement for signs in paragraph (g)(1)(ii). This ensures that only those individuals who meet special requirements, such as training, personal protective equipment and immunization, would enter the area. The requirement in paragraph (e)(2)(ii)(B) that contaminated material removed from the work area be placed in a durable, leakproof labeled or color-coded container that is closed before being removed from the work area is to assure there are no accidental spills or other contamination that may place other employees at risk. The requirement of this paragraph closely follows the provisions outlined in the CDC–NIH Publication "Biosafety in Microbiological and Biomedical Laboratories."

The requirement in paragraph (e)(2)(ii)(E) that all activities involving potentially infectious materials be conducted in a biological safety cabinet or equivalent containment is to ensure that material containing virus will be contained and away from the worker's mucous membranes, unprotected skin, and breathing zone (in the case of aerosols).

Paragraphs (e)(2)(ii)(F) and (G) specify personal protective clothing to be worn to prevent contact of the infectious materials with the employee's skin.

The requirements for decontamination of animal wastes, paragraph (e)(2)(ii)(H) and the use of traps on vacuum lines and HEPA or other filters of equivalent or superior efficiency, in paragraph (e)(2)(ii)(I), are to prevent the spread of contamination to other work areas. In response to NIOSH's suggestion, paragraph (e)(2)(ii)(H) was modified to include incineration and autoclaving as additional means of deactivating waste before disposal (Ex. 20–634). These methods are known to destroy bloodborne pathogens. During the hearings, Mr. M. Vincent, President of Arbor Technologies, Inc., testified that HEPA filters are ineffective in humid atmosphere and suggested that vacuum lines be protected with "hydrophobic safety filters" (Tr. 10/17/89, pp. 127–134; Ex. 92). Pharmaceutical Manufacturers Association citing Mr. Vincent's article also suggested the use of HEPA filters or "equivalent filtration systems" for vacuum lines (Ex. 20–729). In response to these comments, OSHA decided to supplement the HEPA filters requirement, recommended in the 1988 CDC–NIH biosafety guidelines, by allowing also the use of filters of equivalent or superior efficiency. The requirement for maintenance and replacement of filters and traps was added to paragraph (e)(2)(ii)(I) to ensure "* * * the efficacy of [these] engineering controls" (Ex. 20–847). OSHA considers engineering controls as the primary method of reducing exposure to toxic and harmful agents. Therefore, filters and traps should be regulatory checked, maintained, and changed if necessary to assure that the

capacity of these devices to filter or trap virus has not been exhausted.

Since needlestick injury is one of the most efficient methods of accidental infection, therefore, extreme caution should be used when handling needles and syringes. Paragraph (e)(2)(ii)(J) requires that the use of needles and other sharp objects be kept to a minimum, the sharps handled carefully and disposed of in containers that prevent accidental injury. Containers of used sharps are required to be incinerated, decontaminated or autoclave before being discarded or reused.

Paragraph (e)(2)(ii)(K) requires that all spills must be immediately contained and cleaned up by appropriate professional staff or other employees properly trained and equipped to work with concentrated amounts of potentially infectious materials.

Exposure incidents must be reported (paragraph (e)(2)(ii)(L)) so that post exposure follow-up required by paragraph (f)(3) can be initiated and the circumstances surrounding the exposure incidents can be investigated.

The requirement for a biosafety manual, paragraph (e)(2)(ii)(M), ensures that any necessary additional procedures are developed to address situations that are unique to a particular facility and to provide appropriate protection to potentially exposed employees. The manual should be periodically reviewed and updated annually or more often if necessary.

Paragraph (e)(2)(iii) specifies that specific containment equipment (engineering controls) are required to minimize or eliminate exposure to the viruses. Biological safety cabinets must be certified to ensure that they will provide the proper protection. The American College of Pathologists (Ex. 20-552) and Roche Biomedical Laboratories (Ex. 20-1157) recommended that OSHA adopt the National Sanitation Foundation's (NSF) Standard #49 for certifying biological safety cabinets (BSC). The NSF Standard 49 describes design, construction, and performance criteria for Class II cabinetry. It appears that the NSF Standard 49 specifications are good guidelines for the manufacturers of the Class II BSCs. OSHA standard allows also the use of Class I and Class III BSCs.

Moreover, NSF Standard 49 is subject to the periodic review by the Foundation in order to keep their requirements consistent with new technology. OSHA agrees with this objective, however, incorporating current NSF Standard 49 specifications into the OSHA standard might impede the potential development of different but equally effective products in the future. Some the NSF Standard 49 recommendations are similar to OSHA provisions. For example, the Standard 49 states * * * "that each cabinet be tested and performance evaluated on site, assuring that all physical containment criteria are met at the time of installation, prior to use, and periodically therefore." NSF Standard 49 also calls for recertification of Class II cabinets at least annually, and when HEPA filters are changed, after maintenance repairs, or relocation of a cabinet. In the OSHA standard, the paragraphs (e)(2)(iii)(A) and (B) have almost identical requirements.

The Agency has decided to retain the provisions for certification as initially proposed without specific reference to the NSF Standard 49. The Agency believes cabinets that are certified by the manufacturer as Class I, II, or III will provide adequate protection to employees.

Paragraph (e)(3) contains requirements specific for HIV and HBV research facilities. This paragraph requires a facility for hand and eye washing, and an autoclave. Handwashing reduces both the likelihood of infection and the contamination of environmental surfaces, and the availability of a handwashing facility near the work area is essential. In response to NIOSH comments, OSHA also added the requirement to the final standard for suitable eye washing facility for quick flushing of the eyes accidentally exposed to the viruses or other materials (Ex. 20-634). Such facility should be provided within the work area. The availability of an autoclave is required for inactivating or destroying HIV or HBV in or on a variety of media, including culture fluids, plastic ware, and equipment.

The specific requirements for HIV and HBV production facilities are found in paragraph (e)(4). Paragraph (e)(4)(i) requires that in production facilities work areas be separated from other areas by two sets of doors. This reduces the likelihood of accidental entry into the work area and means that entry into the area is a deliberate action. This further reduces the likelihood that untrained individuals will enter the work area as does the requirement that the doors be self-closing [paragraph (e)(4)(iv)].

The requirement for easy cleaning and decontamination of the work area [paragraph (e)(4)(ii)] is necessary because of the high concentration of the virus that may be present and the need to decontaminate the work area to reduce the possibility of infection.

The requirement for a handwashing sink [paragraph (e)(4)(iii)] is to allow for handwashing prior to exiting the work area and to keep environmental contamination to a minimum by requiring that the sink be foot, elbow and automatically operated. Similarly, as in paragraph (e)(3), OSHA added the requirement for suitable eye washing facility for HIV and HBV production facilities.

The requirement for an autoclave in or very near the work area [paragraph (e)(4)(v)] is necessitated because of the very high concentration of virus in these facilities. Transporting contaminated fluids, plastic ware and other equipment would result in a high potential for accidental exposure to other employees.

The requirement that production facilities have a directional airflow into the work area [paragraph (e)(4)(vi)] is to ensure air is drawn into the work area in order to maintain the containment of the facility.

Paragraph (e)(5) alerts the employees to the special, additional training requirements found in paragraph (g)(2)(ix) for employees in research laboratories and production facilities.

Paragraph (f) HBV Vaccination and Post-Exposure Follow-up

(1) General

This paragraph of the standard is designed to protect employees from infection caused by bloodborne pathogens by requiring the employer to (1) make Hepatitis B vaccination available to employees to prevent HBV infection and subsequent illness and death and (2) ensure that the employee receives appropriate medical follow-up after an exposure incident. Early intervention, including testing, counseling, and appropriate prophylaxis can reduce the risk of infection, and prevent further transmission should infection occur.

Paragraph (f)(1)(i) calls for hepatitis B vaccination (defined as both the Hepatitis B vaccine and vaccination series) to be made available to all employees who have occupational exposure, and post-exposure evaluation and follow-up to be made available to all employees who have had an exposure incident. Since a single exposure may result in an infection, OSHA believes that pre-exposure Hepatitis B vaccination of all occupationally-exposed employees and post-exposure evaluation and follow-up after each exposure incident helps prevent infection, benefits the health of employees, and is both technologically and economically feasible.

Paragraph (f)(1)(ii)(A) states that the employer shall ensure that all medical evaluations and procedures, including the Hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are made available at no cost to the employee. Numerous testimony and comment on the proposed rule stated the necessity that Hepatitis B vaccination and post-exposure evaluation and follow-up be made available by the employer at no cost to the employee (NIOSH, Ex. 20–634; Ms. Clark of Halstead Hospital, Ex. 20–145; Ms. Ahern of Phoenix Camelback Hospital, Ex. 20–311). This is consistent with OSHA policy, as stated in the Occupational Safety and Health Act of 1970 (OSH Act) which defines the employer's duty to furnish "employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees." 29 U.S.C. 644(a)(1). The American Nurses' Association remarked that the rule "must state that the vaccine shall be furnished to fully informed, consenting employees at no cost to them" (Tr. 9/20/89, p. 78). In addition, some commenters noted that an important factor in successful vaccination programs was providing the vaccination at no cost to the employee (Ms. Clark of Halstead Hospital, Ex. 20–145). The wording in this paragraph was changed from "provided" in the proposed rule to "made available" in the final rule to emphasize the employee's optional choice to participate in the programs. To those employees who consent to participate, the employer will provide Hepatitis B vaccination and post-exposure evaluation and follow-up at no cost to the employee.

Paragraph (f)(1)(ii)(B) requires that all evaluations and procedures, including Hepatitis B vaccine and vaccination series, post-exposure evaluation and follow-up, including prophylaxis, be made available at a reasonable time and place. In order to increase the likelihood that employees will receive the full benefits provided by the standard, evaluations must be convenient to employees. Children's Hospital of San Francisco commented that "providing the vaccine free at a convenient time and place will definitely increase compliance" (Ex. 20–845). OSHA recognizes the need for this provision and has included it in other standards (e.g., EtO, 49 FR 25798 (1984); and Asbestos, 51 FR 22737 (1986)).

Paragraph (f)(1)(ii)(C) states that all medical evaluations and procedures are required to be performed by or under the supervision of a licensed physician or by or under the supervision of another appropriately trained and licensed healthcare professional. Although other OSHA standards require medical evaluations and procedures to be accomplished by or under the supervision of a licensed physician, numerous commenters felt that other trained and licensed healthcare professionals could adequately perform or supervise the requirements of this section. The American Association of Occupational Health Nurses (AAOHN) pointed out that "expert evaluation and follow-up can be and, in fact, is now provided by registered professional nurses in occupational settings", and suggested that evaluations and procedures may be "performed by or under the supervision of a qualified occupational health professional, registered nurse, or physician" (Tr. 9/20/89, pp. 29, 31). The Guthrie Clinic Ltd. urged "that consideration be given to the involvement of other qualified healthcare professionals participating in the post-HBV exposure process" and suggested "a more liberal provision for use of trained healthcare professionals acting under the supervision of a licensed physician" (Ex. 20–1222). Other commenters stated that "physician evaluation of all exposed employees is resource-intensive; once the counseling and testing protocols have been developed, they should be administered by registered nurses with physician backup when needed", and recommended that "a provision for qualified personnel other than physicians be included in this regulation" (Mr. Polheber of Tucson Medical Center, Ex. 20–141; Mr. Hedrick of the University of Missouri Hospital and Clinics, Ex. 20–1117).

OSHA believes that those evaluations and procedures required by this section can be accomplished by or under the supervision of a physician or other healthcare professional licensed to perform or supervise others who perform the procedures specified in paragraph (f). In those states where nurse practitioners are licensed to perform or supervise the evaluations and procedures required by this section, such requirements of this standard can be accomplished by nurse practitioners. Throughout the rest of paragraph (f), the term healthcare professional refers to the physician or other licensed healthcare provider authorized to accomplish or supervise the accomplishment of the evaluations and procedures required by this section.

Paragraph (f)(1)(ii)(D) requires that evaluations and procedures be provided according to recommendations of the U.S. Public Health Service (USPHS), current at the time these evaluations and procedures take place, except as specified by this paragraph (f). The CDC, an agency of the USPHS, follows the epidemiology of bloodborne pathogens, and periodically revises and updates its guidelines and recommendations. At the time of publication of this rule, CDC is the USPHS agency responsible for issuing guidelines and making recommendations regarding infectious agents referred to in this standard as bloodborne pathogens. The proposed rule had specified that evaluations and procedures be done according to standard recommendations for medical practice. The Visiting Nurse Corporation stated that the "provision of effective post-exposure prophylaxis according to standard recommendations for medical practice is too vague" and advised OSHA to "adopt the recommendations of the U.S. Public Health Service" (Ex. 20–1268). The American Medical Association (AMA) noted that OSHA should "defer to the federal scientific agency with the most expertise" and "believes that the best strategy for reducing the risk of occupational transmission of bloodborne disease is implementation of the recommendations of the CDC for prevention of HIV transmission in healthcare settings" (Tr. 12/19/89, p. 982; Ex. 160). The American Association of Critical-Care Nurses commented that "The USPHS recommendations would provide consistency" (Ex. 20–1162).

As noted above, paragraph (f)(1)(ii)(D) specifies that the USPHS recommendations "current" at the time of the evaluation or procedure are to be followed. OSHA recognizes the dynamic nature of medical knowledge relating to bloodborne pathogens, and notes, from a retrospective compliance standpoint, that USPHS recommendations current at the time the standard is published may differ from recommendations current at the time of the evaluation. The AAOHN commented that "current CDC-USPHS recommendations that Hepatitis B vaccination and post-exposure follow-up and HIV post-exposure follow-up and HIV vaccination, should it become available, should be used as the standard of practice" (Tr. 9/20/89, pp. 32, 33). The AMA stated that "the constant new information that is added to our knowledge about HIV and the evolution of the medical response to AIDS requires periodic reassessment and revision of infection control practices. This revision is more readily achievable if the CDC guidelines are

incorporated by reference than if the OSHA standard must be modified through the administrative process" (Tr. 12/19/89, p. 982; Ex. 160).

OSHA thus defers specific details of medical practice to the USPHS recommendations, except as specified by paragraph (f). The exception implies that the standard, in certain areas such as employer responsibility and requiring a healthcare professional's written opinion, has set some more specific procedures and requirements than the USPHS recommendations.

Paragraph (f)(1)(iii) requires that all laboratory tests be performed by an accredited laboratory at no cost to the employee. Accreditation by a national accrediting body or its state equivalent means that the laboratory has participated in a recognized quality assurance program. This accreditation process is required to ensure a measure of quality control so that employees receive accurate information concerning their laboratory tests and tends to assure long-term stability and consistency among laboratory test procedures and interpretations of results. OSHA recognizes the need for this requirement and has included it in other standards [e.g., Benzene, 52 FR 34565 (1987)].

(2) Hepatitis B Vaccination

Paragraph (f)(2)(i) requires that Hepatitis B vaccination be made available after the employee has received the training required in paragraph (g)(2)(vii)(I) and within 10 working days of initial assignment to all employees who have occupational exposure. It is the goal of this standard to minimize or eliminate significant risk using vaccination, engineering and work practice controls and personal protective equipment. Because equipment may fail or be defective, employees may be fatigued or distracted by other demands resulting in an exposure incident, or the employee may have unsuspected cuts or dermatitis, infection may follow exposure. OSHA believes that the risk of infection is sufficient to require that the employer make Hepatitis B vaccination available to all employees who have occupational exposure. The information in paragraph (g)(2)(vii)(I) includes the efficacy and safety of the vaccine and benefits of being vaccinated. Therefore, OSHA concludes that it is necessary that such training be accomplished before the employee makes a decision regarding acceptance of the hepatitis B vaccine. Hepatitis B vaccination, defined in this section as both the hepatitis B vaccine and vaccination series, per requirements of section (f)(1)(ii), will be: (A) made available at no cost to the employee, (B) made available at a reasonable time and place, (C) performed by or under the supervision of a licensed physician or another appropriately trained and licensed healthcare professional, and (D) provided according to USPHS recommendations current at the time of evaluation.

Hepatitis B vaccination has been recommended by CDC and NIOSH (Exs. 286G; 20–634). The American Dental Association (ADA) has recommended that all dental healthcare workers with possible exposure to blood or direct patient contact obtain Hepatitis B vaccination, and the American College of Obstetricians and Gynecologists has recommended that healthcare workers be vaccinated against HBV (Exs. 11–43; 11–158). The American Association of Critical-Care Nurses (AACN) has endorsed provision of Hepatitis B vaccination by the employer, and the AHA supports "employer-sponsored vaccination of employees for hepatitis B" (Exs. 11–117; 302). The American Nurses' Association (ANA) has recommended that Hepatitis B vaccination be offered at no cost to employees, and SEIU "strongly supports provision of hepatitis B vaccine free of charge to all employees at risk who want to be vaccinated, not just direct patient care workers (Exs. 11–43; 299). AFSCME also "strongly supports OSHA's proposal to vaccinate at-risk employees at management's expense" and stated "for our members who barely earn more than minimum wage, the cost of the vaccine represents a week's wages. Therefore, employees will often refuse the vaccine if they are expected to bear the cost" (Ex. 297).

Extensive testimony and comment emphasized the importance of occupational HBV infection and prevention contrasted to the much higher publicized yet lower risk of occupationally acquired HIV infection. Many commenters noted statistics similar to the CDC estimates of annual HBV infection of 8,700 healthcare workers with occupational exposure, with 2,175 clinical illnesses, 435 hospitalizations, and approximately 194 deaths each year (Exs. 298; 6–392). Groups as diverse as the AMA, who stated "the loss of healthcare workers to hepatitis B virus infection overshadows the risk of AIDS and is almost entirely preventible", to ACTUP who "encourages OSHA to continue to educate workers of their excessive risk of contracting hepatitis B as opposed to their extremely small risk of contracting HIV or AIDS through work place exposure" concur that occupationally acquired Hepatitis B infection affects a far greater number of workers than does occupationally-acquired HIV infection (Tr. 12/19/89, p. 982; Ex. 160; Tr. 11/16/89, p. 767).

OSHA considered whether to require mandatory vaccination of employees, rather than requiring employers to make the vaccine available after providing information about its benefits. This issue was specifically raised and preliminarily addressed in Question 40 of the proposal (54 FR 23045). In that particular question, OSHA stated that although mandatory medical surveillance had never been the Agency's approach, the concept had been explored and rejected in the Lead Standard (43 FR 54450). In the preamble to that standard, the Agency considered such an approach and then abandoned it, concluding that mandating worker participation in such a sensitive area would present an array of religious and privacy concerns. OSHA stated in specific that:

> • • • Attempting to compel workers to subject themselves to detailed medical examinations presents the possibility of clashes with legitimate privacy and religious concerns. Health in general is an intensely personal matter. (54 FR 23045).

As in the lead standard, OSHA's aim in the proposed standard was to encourage rather than to coerce employee cooperation in the vaccination program for Hepatitis B. However, the Agency solicited comments with respect to this question.

A voluntary vaccination program for employees was supported by numerous witnesses and commenters. NIOSH/CDC stated emphatically that a vaccination program should be voluntary for all eligible employees because of the invasive nature of such a procedure. NIOSH/CDC went on to say that a mandatory vaccination program would be inappropriate and objectionable to some persons on religious grounds and that any person who declines vaccination should do so only with full knowledge of the risks of disease, disability, and death that are thereby incurred. "Workers who decline vaccination should also understand that they can reverse that decision at any time and participate in the immunization program at no cost to themselves." (Ex. 20–634).

NIOSH/CDC also commented on the efficacy of the vaccine:

> Vaccination is the single most effective means of preventing occupational hepatitis B virus (HBV) transmission. However, approximately 5% of individuals given vaccination do not develop an antibody response to the vaccine and remain susceptible to HBV. Even if 100% of workers

received the vaccination, this group of nonresponders alone would constitute a large enough group to justify enforcement of mandatory universal precautions (Ex. 29).

Donna Richardson, RN, JD., representing the American Nurses Association, the largest professional organization of registered nurses, stated:

• • • We wholeheartedly endorse OSHA's requirement that employers provide hepatitis B vaccine to employees. However, we believe OSHA needs to be much more explicit in its mandate. It must state that the *vaccine shall be furnished to fully informed, consenting employees* at no cost to them. Reports indicate that employees who are thoroughly educated about the vaccine accept it more readily. (Tr. 9/20/89, p.78) (emphasis added).

The Association of Operating Room Nurses also supported a voluntary hepatitis B vaccination program that included informed consent and to further strengthen the program, a requirement that healthcare workers who decline the vaccine do so in writing. (Tr. 9/20/89, p.89). Another commenter who shared the view of a voluntary vaccination program was the Service Employees International Union. It stated that:

Privacy and religious concerns make forced vaccination both illegal and unfair. OSHA should follow its longstanding practice of not forcing invasive medical procedures on workers and should not mandate the hepatitis B vaccine. Of course, as OSHA has recognized in the standard, workers who initially refuse the vaccine but later change their minds should be given the vaccine at a later date. (Ex. 299).

T. E. Kobrick of the Bethlehem Steel Corporation, stated:

HBV vaccination (or any other vaccination or medical surveillance requirement) should *never* be made mandatory, as such action would violate legal, medical, and ethical standards and be impossible to enforce. In this matter, OSHA should be consistent with its position in previous standards, which is that employers will "make available" to the employee protective measures, including vaccination. (Ex. 20-110) (emphasis in original).

Along the same line, The Food and Allied Services Trades set forth the following:

We feel that the voluntary approach is the right one to take. Requiring that employees be vaccinated undoubtedly impedes several constitutional protections. Vaccination procedures are inherently intrusive and may be accompanied by civil libertarian and religious concerns associated with requiring any medical procedure • • •. The best way to minimize the deterrence to vaccination is not to force employees to accept the vaccination, but to encourage education programs, at employer expense, that are designed to allay worker fears and to describe the benefits of the procedure. *The ultimate choice concerning vaccination should rest with the individual.* (Ex. 20-888) (emphasis in original).

Other interested participants in the rulemaking urged OSHA to keep the vaccination program a voluntary one for any exposed employees (e.g., AFSCME, Ex. 20-985; ServiceMaster Company, Ex. 20-21; Retail, Wholesale and Department Store Union:AFL-CIO, L20-1505; Lutheran General Hospital, Ex. 20-655; Mr. Koch et. al., Sharp Memorial Hospital, Ex. 20-660; The American Board of Orthodontists, Tr. 11/14/89, p. 502; The Florida Nurses Association, Tr. 12/21/89, p. 1395; Ms. Mary Quinn, Tr. 9/18/89, p. 74; The American Nurses Association, Tr. 9/20/89, p. 89).

Few commenters stated that the vaccine should be mandatory for all or some healthcare workers (The American Association of Orthodontists, Tr. 9/22/89, p. 50; Dr. Eugene Blair, Orthodontist, Tr. 10/19/89, p. 582). The American Dental Association considered the issue and specifically stated:

We do not believe that this should be voluntary but rather that it should be a prerequisite for entry into the dental field. The only acceptable reason for not being vaccinated would be a medical condition(s) contraindicating its use. (Ex. 20-665).

The ADA also commented that they did not believe "that the employer should have to pay for the cost of the vaccine for his employees • • •" (Ex. 20-665).

After reviewing the record, and considering all the above comments OSHA concludes that a voluntary vaccination program is the best approach to foster greater employee cooperation and trust in the system. While the Agency may have the legal authority to require vaccinations as part of the standard, it recognizes that voluntary participation by employees enhances compliance while respecting individuals' beliefs and rights to privacy. Accordingly, OSHA has chosen to require employers to offer Hepatitis B vaccination, but to make participation in the program voluntary.

Many commenters disagreed with the proposed rule's stipulation that Hepatitis B vaccination be based on an average monthly exposure. NIOSH stated that "HBV immunization should be offered to all workers whose jobs involve participation in tasks or activities with exposure to blood or other body fluids in which universal precautions apply. A time-dependent criterion, such as once per month exposure as proposed, invites disputes over actual frequency of exposure" (Tr. 9/14/89, p. 32). AFSCME felt "this arbitrary cut-off would allow too many workers to fall through the cracks" (Ex. 297). The National Association of Children's Hospitals and Related Institutions, Inc., commented that "HBV vaccination might be offered to all hospital employees with the potential for exposure, without linking it to a number of projected exposures" (Ex. 20-1003). The National Foundation for Infectious Diseases agreed that the employer should "make available Hepatitis B vaccine to all employees who have occupational exposure" and that the once per month criterion should be omitted (Tr. 12/19/89, p. 929). Local 1199, the Drug, Hospital and Health Care Employees Union, stated that the "vaccine should be offered to all employees who risk occupational exposure to blood and body fluids, not just those exposed once a month or more" and SEIU stated that the rule should "require free hepatitis B vaccination for all workers with potential exposure, not just workers with monthly exposure" (Tr. 11/14/89, p. 378; Ex. 299). In concurrence with these comments, the final rule deletes references to specific numbers of exposures and requires that Hepatitis B vaccination be made available to all employees who have occupational exposure.

The issue of non-standard routes of Hepatitis B vaccination administration was discussed by some commenters. AFSCME stated that "any non-standard administration of the vaccine to employees should be prohibited by OSHA" (Ex. 297). In their comments, CDC/NIOSH restated the current guidelines that recommend that the vaccine be administered in the deltoid muscle at the specified doses and schedule (Ex. 298). CDC guidelines dated February 9, 1990 state:

The immunogenicity of a series of three low doses (.1 standard dose) of plasma-derived hepatitis B vaccine administered by the intradermal route has been assessed in several studies. The largest studies of adults show lower rates of developing adequate antibody (80%-90%) and twofold to fourfold lower antibody titers than with intramuscular vaccination with recommended doses. Data on immunogenicity of low doses of recombinant vaccines given intradermally are limited. At this time, intradermal vaccination of adults using low doses of vaccine should be done only under research protocol, with appropriate informed consent and with postvaccination testing to identify persons with inadequate response who would be eligible for revaccination. Intradermal vaccination is not recommended for infants or children (Ex. 286G, MMWR. 1990;39[No. RR-2]:12).

Thus the above USPHS guidelines, which are current at the time of publication of this standard, state that

the intradermal inoculation of 0.1 of the normal dose of the Hepatitis B vaccine can be done only as a research protocol with informed consent and postvaccination testing. Employees therefore cannot be compelled to participate in a low dose intradermal program in order to receive the vaccine, and OSHA requires employers to make available Hepatitis B vaccination through the standard routes of administration as recommended in USPHS guidelines.

The second part of paragraph (f)(2)(i) indicates that Hepatitis B vaccination need not be made available to employees who have previously received the complete Hepatitis B vaccination series, who have antibody testing revealing immunity, or who have medical contraindications for the vaccine. Decisions on postvaccination testing are to be made in accordance with CDC guidelines current at the time of evaluation. Current CDC guidelines, at the time of this rule publication, do not routinely recommend testing for Hepatitis B immunity after vaccination, but do consider postvaccination testing for persons at occupational risk who may have needle-stick exposures necessitating post-exposure prophylaxis (Ex. 286G).

Paragraph (f)(2)(ii) states that the employer shall not make participation in a prescreening program a prerequisite for receiving Hepatitis B vaccination. OSHA had proposed that Hepatitis B prescreening, that is, prescreening of an individual's antibody status to determine whether there had been previous exposure to either the hepatitis vaccine or virus, be made available to an employee who desired such testing prior to deciding whether to receive Hepatitis B vaccination. Dr. Klees, of the Albert Einstein Medical Center, stated that "mandating prescreening prior to vaccination, allowing employee choice, is admirable" (Ex. 20–838). However, most commenters felt that there should be no requirement for such prescreening programs. The Greater Omaha Area Association for Practitioners in Infection Control stated that "the need for HBV antibody testing, if requested by the employee (prior to Hepatitis B vaccination), is questionable. This could be very costly with no efficacy to support it" (Ex. 20–943). The American Association of Dental Schools suggested "that OSHA eliminate this proposed requirement. This would not prevent employers from offering this service as they see fit" (Ex. 20–876). Stanford University Hospital stated that "offering HBV antibody testing on a routine basis to employees prior to receiving the vaccine is costly. It may be advantageous to offer the antibody testing to employees with a history of hepatitis or from high risk groups as defined by Centers for Disease Control" (Ex. 20–984). The final rule contains no requirement for Hepatitis B vaccination prescreening. However, OSHA acknowledges the merit of many of the comments concerning the possible usefulness of a pre-screening program in certain situations and will not prohibit employers from offering pre-screening programs if they so desire.

CDC has stated that prevaccination screening is usually only cost-effective if both the cost of the vaccine and the Hepatitis B immune prevalence is high (Ex. 286G). If an employer feels that employee prescreening is cost-effective, prevaccination testing may be made available to employees, on a voluntary basis, at no cost to the employee. However, the prescreening program shall not be a prerequisite for receiving Hepatitis B vaccination, so that an employee has the option to decline prevaccination testing and yet accept Hepatitis B vaccination. This provision is also consistent with OSHA's desire to encourage a high percentage of voluntary employee vaccination by making the vaccination process as simple as is medically possible.

The prescreening program in section (f)(2)(ii) is not a screen for medical indications or contraindications to receiving the Hepatitis B vaccine. A determination by a healthcare professional regarding indications and contraindications before receiving Hepatitis B vaccination is an absolute prerequisite for Hepatitis B vaccination, and a healthcare professional's written opinion on indications and contraindications for Hepatitis B vaccination is required per section (f)(5)(i).

Paragraph (f)(2)(iii) requires an employer to make the Hepatitis B vaccination available to an employee who initially declines vaccination, but later decides to accept the vaccination. In this case, the vaccination is still provided by the employer at no cost to the employee and according to the other conditions of paragraph (f)(1)(ii). This provision assures that employees who are initially reluctant to accept vaccination but who later change their minds as the result of information or experience are accorded the opportunity to receive vaccination. The signing of a waiver by the employee does not relieve the employer of the requirement to provide Hepatitis B vaccination at a later date and at no cost if the employee requests vaccination. This is consistent with OSHA's goal of encouraging employees to be vaccinated.

Paragraph (f)(2)(iv) states that the employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the statement in appendix A. The statement is as follows:

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

The purpose of requiring employees to sign a declination is to encourage greater participation in the vaccination program by reiterating that an employee declining the hepatitis B vaccination remains at risk of acquiring hepatitis B. To augment employee understanding of the declination they are signing, OSHA requires per paragraph (f)(2)(i) that employees receive the training specified in paragraph (g)(2)(vii)(I) before being offered the hepatitis B vaccine. The employer will benefit from signed declinations by being able to easily determine who is not vaccinated so that resources can be directed toward improving the acceptance rate of the vaccination program. Moreover, having signed declinations should enable compliance officers to more easily enforce the standard requirements regarding training and vaccination. Such written declination of the hepatitis B vaccine has been recommended by the Association of Operating Room Nurses and the American Nurses' Association, who stated, "If health care workers decline the vaccine, it should be in writing" (Tr. 9/20/89, p. 89).

In accordance with section 4(b)(4) of the OSH Act, the statement of declination of hepatitis B vaccination is not intended to supersede or in any manner affect any workmen's compensation law or to enlarge or diminish or affect in any other manner the common law or statutory rights, duties, or liabilities of employers and employees under any law with respect to injuries, diseases, or death of employees arising out of, or in the course of, employment.

Future hepatitis B vaccination routine booster doses are discussed in paragraph (f)(2)(v) and shall be made

available if recommended by USPHS at a future date. Since the plasma-derived Hepatitis B vaccine has been available in the United States only since 1982, with recombinant DNA Hepatitis B vaccines licensed in 1986, future follow-up of vaccinees may demonstrate that Hepatitis B antibody levels fall to a level at which they are no longer protective. If a routine booster dose or doses is recommended in the future to help elevate Hepatitis B antibody levels, it shall be provided per the requirements of paragraph (f)(1)(ii). USPHS recommendations current at publication of this rule state "that up to 50% of adult vaccinees who respond adequately to vaccine may have low or undetectable antibody levels by 7 years after vaccination", "for adults and children with normal immune status, booster doses are not routinely recommended within 7 years after vaccination", and that "the possible need for booster doses after longer intervals will be assessed as additional information becomes available" (Ex. 286G). If future USPHS recommendations advise routine prophylactic Hepatitis B vaccination booster doses in previously vaccinated employees who, after time, have low or undetectable antibody levels, the employer will be responsible for providing those booster doses. In accordance with the February 9, 1990, USPHS guidelines, for exposure incidents where the previously vaccinated employee's post-exposure evaluation shows no detectable Hepatitis B antibodies and the source individual is found to be infected with Hepatitis B, a Hepatitis B vaccine booster dose is recommended (Ex. 286G). Responsibility for the latter case of booster dose revaccination is delegated to the employer under the post-exposure prophylaxis reference in (f)(3)(iv).

(3) Post-Exposure Evaluation and Follow-up

Paragraph (f)(3) states that the employer, following a report of an exposure incident, shall make immediately available to the exposed employee a confidential medical evaluation and follow-up. Per paragraph (f)(1)(ii), post-exposure evaluation and follow-up will be: (A) Made available at no cost to the employee, (B) made available at a reasonable time and place, (C) performed by or under the supervision of a licensed physician or another appropriately trained and licensed healthcare professional, and (D) provided according to USPHS recommendations current at the time of evaluation. Post-exposure medical evaluations have been recommended by NIH/CDC, NIOSH, the National Committee for Clinical Laboratory Standards (NCCLS), the American Hospital Association (AHA), AAOHN, and AFSCME. The American Dental Association (ADA) has stated in their ANPR comment that CDC guidelines should be followed (Exs. 11–187; 11–159; 6–75; 6–153; 11–358; 11–157; 11–43).

The adverb "immediately" is used in this paragraph to re-emphasize the importance of prompt medical evaluation and prophylaxis. Some post-exposure Hepatitis B prophylactic measures should be given as soon as possible after exposure as their value beyond seven days after exposure is unclear, and HIV prophylaxis, if recommended in the future, may need to be accomplished within the first few hours after an incident (Ex. 286G, MMWR. 1990; 39[No. RR–2]:19). Timeliness is therefore an important factor in effective medical prophylaxis and treatment of bloodborne pathogens.

The word "confidential" is included in this paragraph as numerous commenters discussed the importance of confidentiality during post-exposure evaluation and follow-up. AFSCME stated that "it is very important to protect confidentiality, because it is important to encourage workers to report all exposure incidents." The American Association of Forensic Dentists noted that records of "treatment have a high probability of not being kept confidential because of access by non-medical office personnel", and the ADA commented that "the fear of breaching confidentiality in the dental office will be a real disincentive to the reporting of exposure incidents" (Exs. 20–985; 20–109; 20–655). The American Psychiatric Association (APA) stated that they view "the maintenance of strict confidentiality as the cornerstone to viable procedures for workplace exposures", that employees should be told of "the exact limits of confidentiality", and that "it is critical that employees have some guarantee that confidentiality limits cannot be changed at a later date" (Tr. 1/9/90, p. 24). The ANA stated that "reporting procedures must be convenient and afford privacy and confidentiality so that employees are not discouraged from reporting such exposures" and Local 1199 commented that "protection of anonymity would encourage employees to seek testing" (Trs. 9/20/89, pp. 78, 79; 11/14/89, p. 37). OSHA believes that all medical evaluations and follow-up, including the maintenance of required medical records, must be done in a manner that protects the confidentiality of the employee's identity and test results.

As a minimum, paragraph (f)(3) requires a post-exposure evaluation and follow-up to include the following elements:

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

(ii) Identification and documentation of the source individual;

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

(iv) Post-exposure prophylaxis when medically indicated, as recommended by USPHS;

(v) Counseling; and

(vi) Evaluation of reported illnesses.

Paragraph (f)(3)(i) requires the route(s) of exposure and the circumstances under which an exposure incident occurred to be documented. This documentation allows the employer to receive feedback regarding the circumstances of employee exposures, and the information collected can then be used to focus efforts on decreasing or eliminating specific circumstances or routes of exposures (e.g., exposure incident documentation may show that protective equipment is not being used because it is uncomfortable and the employer could then provide protective equipment that is more acceptable to and more likely to be used by employees, or training efforts could be increased on certain procedures which seem to be associated with exposure incidents). Both NIH/CDC and NCCLS recommended that institutions develop and maintain post-exposure documentation (Exs. 11–159; 6–312). Such determination and documentation of exposure incidents and circumstances has also been recommended by the American Blood Resources Association (ABRA) (Ex. 11–71), among others.

Identification and documentation of the source individual involved in an exposure incident is required by paragraph (f)(3)(ii), unless the employer can establish that identification is infeasible or prohibited by state or local law. Incidents involving unmarked sharps, or blood samples which may not have been properly labeled may make identification and documentation of the source individual infeasible or even impossible. It is the responsibility of the employer to establish the identification of the source individual or that such identification is infeasible or prohibited by state or local law.

Paragraph (f)(3)(ii)(A) states that the source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. Testing for a source

individual's infectious status provides exposed employees with information that will assist them in decisions regarding testing of their own blood, complying with other elements of post-exposure management, and using precautions to prevent transmission to their sexual partners or, in the case of pregnancy, to their fetuses. In addition, such testing assists the healthcare professional in deciding on appropriate follow-up. The American Red Cross has recommended that "every attempt must be made to evaluate the infectivity of the implicated material by appropriate serologic testing" (Ex. 11-280). The Service Employees International Union (SEIU) stated that it is the right of workers to know the HBV and HIV status of individuals if exposed to their blood or body fluids (Ex. 11-161).

The statement that the source individual's blood will be tested "as soon as feasible" is used instead of "as soon as possible", which connotes extreme immediacy in medical environments. While OSHA does not expect life-threatening procedures to be stopped or delayed in order to obtain testing of a source individual, to be effective the tests must be done in a timely fashion and, therefore, testing "as soon as feasible" is required. The need to obtain the consent of the source individual prior to testing has been recognized. Numerous organizations and associations, including CDC, NIOSH, AAOHN, NCCLS, and AHA support testing of source individuals only after obtaining consent of such individuals (Exs. 8-153; 11-187, 11-358; 11-159; 8-75). Many commenters concurred with the proposed rule's requirement for obtaining the source individual's consent. Dr. McBeath of the American Public Health Association "supports OSHA's position in obtaining the patient's consent before collection and testing of source patient's blood" (Ex. 20-1248). NIOSH stated that "any testing program must have effective provisions to address the necessity of informed consent and confidentiality" (Ex. 11-187). Consistent with the opinion expressed by the CDC and the majority of commenters, OSHA believes that testing of source individuals following an employee exposure incident should be accomplished after consent is obtained from the source individual.

It is to be expected that some individuals will not consent to testing, and OSHA does not expect the employer to test source individuals against their wishes. OSHA recognizes that it is the employer's responsibility to arrange for testing of the source individual, and that employers must make good faith efforts to both identify and obtain consent from the source individual. Paragraph (f)(3)(ii)(A) further states that if consent is not obtained from the source individual, the employer shall establish that legally required consent cannot be obtained. In those states where the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented. The condition, "if available", applies to blood samples that have been drawn from source individuals for other testing, and OSHA does not expect post-exposure re-drawing of the source individual's blood specifically for HBV and HIV infectivity testing to be performed without obtaining the source individual's consent.

Paragraph (f)(3)(ii)(B) states that when the source individual is already known to be infected with HBV or HIV, testing for the source individual's known infectious status need not be repeated. If, for example, the source individual is known by previous or current medical evaluations to already be infected with HIV, and is therefore considered to be infectious, there is no need to repeat testing for HIV infectiousness. OSHA acknowledges that there are various routinely accepted antibody and antigen tests for HBV, and antibody tests for HIV, with the possibility of routinely accepted HIV antigen tests being available in the future. The specific requirements for source individual testing shall be determined by the employee's healthcare professional, in accordance with USPHS guidelines. If the employee's healthcare professional determines that adequate medical information about the source individual's infectious status is already known, testing for the source individual's known infectious status need not be repeated.

The first half of paragraph (f)(3)(ii)(C) states that results of the source individual's testing shall be made available to the exposed employee. Although the healthcare professional acts as an agent of the employer, the employer does not have a right to know the results of source individual or exposed employee testing. Paragraph (f)(3) states that the employer shall make available to the exposed employee a confidential medical evaluation and [reference paragraph (f)(3)(ii)(C)] results of the source individual's testing shall be made available to the exposed employee. This paragraph does not give the employer authority to be informed of the results of source individual's or exposed employee's testing. OSHA realizes that the boundaries of employer and healthcare professional may be blurred in a medical setting where, for example, a physician is both the employer and evaluating healthcare professional, and that issues of consent and confidentiality are extremely important in encouraging employee participation in post-exposure incident evaluations.

The second half of paragraph (f)(3)(ii)(C) states that exposed employees shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual. Dr. Kantor of San Francisco General Hospital commented that "the standard should recommend a procedure to protect the confidentiality" of the source patient's HIV status, and that "this group of sero-positive people have regularly suffered negative consequences as a result of lack of privacy of this information" (Ex. 20-1029). Dr. Woodard agreed that the source individual "has the right to expect that the results of the test shall remain confidential" (Ex. 20-909). OSHA concurs with this concern related to medical information, but defers guidance to applicable state and federal laws and regulations that specifically cover medical privacy and confidentiality.

Paragraph (f)(3)(iii) states that it is the employer's responsibility, following an exposure incident, to make available to an exposed employee collection and testing of blood for HBV and HIV serological status. Blood from an exposed employee is to be collected as soon as feasible after the exposure incident and tested after consent is obtained for determination of HBV and HIV status. By offering serological testing after an exposure incident, the employer assures that the employee has the opportunity to have baseline testing which can be compared to future test results in order to determine if an infection resulted from an occupational exposure. The offering to exposed employees of voluntary blood collection and testing has been recommended by NIOSH, the Hospital Association of Greater Des Moines, AAOHN, NCCLS, ABRA, and SEIU (Exs. 11-187; 11-23; 11-358; 11-159; 11-71; 11-161). Since post-exposure testing and prophylaxis is a rapidly changing and developing field, it must be, per paragraph (f)(1)(ii)(D), provided according to recommendations of the U.S. Public Health Service current at the time post-exposure testing and prophylaxis take place.

Paragraph (f)(3)(iii)(A) states that the exposed employee's blood shall be

collected as soon as feasible and after consent is obtained and tested for HBV and HIV serological status as soon as feasible and after consent is obtained. As with consent and source individual testing, commenters also felt consent was necessary before testing the exposed employee. The APA stated that "testing should require the informed consent of the employee. Informed consent should include at least the following information: (1) the nature of the test to be performed, (2) the benefits and risks of testing, (3) alternatives including the benefits and risks of such alternatives and, (4) the exact limits of confidentiality" (Tr. 1/9/90, pp. 22, 23).

Paragraph (f)(3)(iii)(B) states that if an exposed employee consents to baseline blood collection after an exposure incident, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. In some cases, baseline HBV testing may be indicated and drawn without problem, but the exposed employee, secondary to concerns about confidentiality, employment, prejudice, or lack of medical information, may worry about consenting to baseline HIV testing. If, possibly after counseling, education, or further discussion, and within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing will be done as soon as feasible. Mr. Schmidt, of the Service Master Company, commented that "permitting the employee the option of having blood tested at a later date should increase the likelihood that they will be willing to participate in the post-exposure follow-up program. By giving the employee additional time, if desired, to make a decision, there is an opportunity for the employee to receive counseling and information with which to make an informed decision" (Ex. 20-21). OSHA believes that it is of great importance for employees to have the opportunity to obtain knowledge about baseline serologic testing after exposure incidents, and that this provision of opportunity for future testing rather than a demand for an immediate decision by the employee will encourage employees to consent to blood collection at the time of exposure.

The proposed rule indicated that actual blood testing could be done at a later date, but set no time limits on blood storage. The American Red Cross has recommended in an ANPR comment that employee blood samples be held until the employee requests testing and that samples not tested be held for at least 5 years (Ex. 11-280). Many commenters believed that an unlimited time period for blood storage would burden their institutions. The Gettysburg Hospital commented that "the collection and holding of an employee blood sample for an unstated period of time poses a very real storage problem for most hospitals" and the Association for Practitioners in Infection Control—Virginia stated that "an unspecified time for holding blood sample from exposed employees is logistically difficult from both space-keeping and record-keeping perspectives" (Exs. 20-182; 20-750). The University of Virginia Health Sciences Center commented that "because of space limitations", employee blood samples should "be held for one month" (Ex. 20-877). CDC has stated, "The worker should be advised to report and seek medical evaluation for any acute febrile illness that occurs within 12 weeks after the exposure. Such an illness, particularly one characterized by fever, rash, or lymphadenopathy, may be indicative of recent HIV infection." CDC has further stated that the first 6-12 weeks are "when most infected persons are expected to seroconvert" (Ex. 15, MMWR 1989; 38[No. S-6]:13). The final rule sets a minimum time limitation of 90 days for holding untested baseline blood samples, which includes this 12 week post-exposure period when an acute retroviral illness may develop and affords the employee the opportunity to know immediate post-exposure HIV status even if consent for HIV testing was initially withheld.

Paragraph (f)(3)(iv) states that it is the employer's responsibility, following an exposure incident, to make immediately available to the exposed employee post-exposure prophylaxis, when medically indicated, as recommended by the USPHS. Post-exposure prophylaxis has been recommended by CDC and NIOSH, and a number of other organizations have concurred with CDC recommendations (Exs. 6-153; 20-634; 11-280; 11-358; 11-161; 6-75; 11-71; 11-163; 11-159; 11-157). Since post-exposure prophylactic measures must often be accomplished quickly to increase effectiveness, it is imperative that such measures be accomplished as soon as possible.

Paragraph (f)(3)(v) stipulates that the employer, following an exposure incident, shall make counseling immediately available to the exposed employee. OSHA believes that counseling of exposed employees is a vital component of post-exposure follow-up procedures and that counseling concerning infection status, including results of and interpretation of all tests, will assist the employee in understanding the potential risk of infection and in making decisions regarding the protection of personal contacts. Post-exposure counseling has been recommended by CDC, NIOSH, and other organizations such as ARC, AAOHN, SEIU, AHA, ABRA, AMA, NCCLS, and AFSCME have either directly recommended post-exposure counseling or concurred with CDC recommendations (Exs. 6-153; 20-634; 11-280; 11-358; 11-161; 6-75; 11-71; 11-163; 11-159; 11-157). The APA stated that counseling should "be performed by adequately-trained professionals, including psychiatrists" and that "psychiatric follow-up should be made available" (Ex. 20-65).

Paragraph (f)(3)(vi) requires the employer, following an exposure incident, to make available evaluation of reported illnesses. This provision assures that exposed employees will have the benefit of early medical evaluation of such illnesses and can accept in a timely manner any currently recommended treatment and prophylaxis. Illness reporting provisions have been recommended by CDC and ABRA, and other organizations including NIH, AMA, AAOHN, and NCCLS support these CDC recommendations (Ex. 6-153; 11-71; 6-312; 11-163; 11-358; 11-159).

(4) Information Provided to the Healthcare Professional

OSHA believes it is the employer's responsibility to ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination and post-exposure follow-up is informed of the requirements of this standard. This will help assure that the healthcare professional implements the requirements. This provision is included in other OSHA standards [e.g., Benzene, 52 FR 34566, (1987)]. Therefore, paragraph (4)(i) requires the employer to ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

Paragraph (4)(ii) requires the employer to ensure that the healthcare professional evaluating an employee after an exposure incident is provided; (A) a copy of this regulation, (B) a description of the exposed employee's duties as they relate to the exposure incident, (C) documentation of the route or routes of exposure and circumstances under which the exposure occurred, (D) results of the source individual's blood testing, and (E) all medical records relevant to the appropriate treatment of the employee, including vaccination status, which are the employer's responsibility to maintain. The purpose of providing this information is to inform

the healthcare professional of the requirements of this standard. This information, which represents the minimum necessary for proper followup care, enables the healthcare professional to understand the employee's duties, the circumstances of the exposure incident, the source individual's infectious status, the employee's Hepatitis B vaccination status and other employee medical information. The information provided to the healthcare professional is essential to followup evaluation, so that a determination can be made regarding whether prophylaxis or medical treatment is indicated. The information required in paragraph (f)(4)(ii)(A-C and E) must be provided for each exposure incident. The information required in paragraph (f)(4)(ii)(D), results of the source individual's blood testing, must be provided, obviously, only if it is available. The employer does not have a specific right to know the actual results of the source individual's blood testing, but the employer is responsible for ensuring that the evaluating healthcare professional is provided the results of the testing.

(5) Healthcare Professional's Written Opinion

Paragraph (f)(5) has been changed from "Physician's Written Opinion" in the proposed rule to "Healthcare Professional's Written Opinion" in the final rule in accordance with the change discussed in this summary and explanation under paragraph (f)(1)(ii)(C) relating to the requirement for medical evaluations to be performed by or under the supervision of a licensed physician or another appropriately trained and licensed healthcare professional.

Paragraph (f)(5) states that the employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation. The employer does have a right to know the information contained in the written opinion and may retain the original written opinion, but must provide the employee with a copy. The 15 day provision assures that the employee is informed in a timely manner regarding information received by the employer and is consistent with other OSHA standards [e.g., Formaldehyde, 52 FR 46295, (1987); and Benzene, 52 FR 34566, (1987)].

The purpose of requiring the employer to obtain a written opinion from the evaluating healthcare professional is (1) to ensure that the employer is provided with documentation that a medical assessment of the employee's ability and indication to receive Hepatitis B vaccination was completed; and (2) to inform the employer regarding the employee's Hepatitis B vaccination status. For post-exposure evaluations, the purpose of requiring a written opinion is to ensure that the employer is provided with documentation that a post-exposure evaluation has been performed, and that the exposed employee has been informed of the results. Some commenters noted that requiring a physician's written opinion "will create a paper work burden for employee health physicians", and that a "written evaluation could prove to be very time consuming" (Ms. Salisbury of Akron General Medical Center, Ex. 20-81; Ms. Borton of Albert Einstein Medical Center, Ex. 20-945). However, OSHA believes that it is important for employers to know if their employees have had evaluations for Hepatitis B vaccination or exposure incidents, and that healthcare professionals, acting as agents for the employer, should provide the employer with written documentation that these evaluations have occurred. This provision requiring a written opinion after a medical evaluation has been included in other OSHA standards [e.g., Occupational Exposures to Hazardous Chemicals in Laboratories, 55 FR 3330, (1990); and Formaldehyde, 52 FR 46295, (1987)].

Paragraph (f)(5)(i) states that the healthcare professional's written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated, and if the employee has received such vaccination. The purpose of limiting the information the employer receives is to encourage employees to participate in the medical evaluation by removing concern that the employer will obtain information about their physical condition and specific medical findings or diagnoses. The American Public Health Association stated that "the worker's right to confidentiality is better protected if the physician's report simply stated whether the worker could receive the vaccine" (Ex. 20-1361). Appropriate written opinions may be as simple as "HBV vaccination indicated for this employee, vaccination not received", "HBV vaccination not indicated for this employee, vaccination not received", or "HBV vaccination indicated for this employee, vaccination received". Since Hepatitis B vaccination is a vaccination series, employers should work directly with the evaluating healthcare professional to develop a method to track and ensure completion of the vaccination series.

Paragraph (f)(5)(ii) states that the healthcare professional's written opinion for post-exposure evaluation of an exposure incident shall be limited to specific information. Paragraph (f)(5)(ii)(A) requires the written opinion to state that the employee has been informed of the evaluation results, while paragraph (f)(5)(ii)(B) requires a statement 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.

Paragraph (f)(5)(iii) states that all other findings or diagnoses shall remain confidential and shall not be included in the written report. The APA stated they view "the maintenance of strict confidentiality as the cornerstone to viable procedures for workplace exposure" (Tr. 1/9/90, pp. 23, 24). OSHA believes that the evaluating healthcare professional has an obligation to view medical information gathered or learned during Hepatitis B vaccination or post-exposure evaluation as confidential medical information, and that successful post-exposure programs must guarantee this confidentiality.

(6) Medical Recordkeeping

Paragraph (f)(6) states that medical records required by this standard shall be maintained in accordance with paragraph (h) of this section. This paragraph is included so that employers, physicians, and other healthcare professionals are made aware that there are requirements for medical recordkeeping elsewhere in this standard. These medical records must be kept confidential.

Paragraph (g) Communication of Hazards to Employees

Paragraph (g), Communication of Hazards to Employees, addresses the issue of transmitting information to employees about the hazards of bloodborne pathogens through the use of labels, signs, and information and training. These provisions apply to all operations where there is occupational exposure to blood and other potentially infectious materials. OSHA's intent here is to ensure that employees will receive adequate warning through labels and signs and training to eliminate or minimize their exposure to bloodborne pathogens.

(1) Labels and Signs.

Paragraph (g)(1) of the Bloodborne Pathogens Standard provides the specific labeling and sign requirements that are required to be used to warn employees of the hazards to which they are exposed. The requirements for

labels and signs are consistent with section 6(b)(7) of the OSH Act, which prescribes the use of labels or other appropriate forms of warning to apprise employees of occupational hazards.

Paragraph (g)(1)(i)(A) requires that labels or other appropriate forms of warning be provided on containers of regulated waste; on refrigerators or freezers that are used to store blood or other potentially infectious materials and on other containers used to store, dispose of, transport or ship either blood or other potentially infectious materials. The purpose of this requirement is to alert employees to possible exposure since the nature of the material or contents will not always be readily identified as blood or other potentially infectious materials under these circumstances. For example, if a refrigerator used to store blood or other potentially infectious materials is not labeled, then employees may be unaware that universal precautions must be observed upon handling the contents in the refrigerator, or that the refrigerator must not be used to store items such as food. Another example would be, if an unlabeled container of blood or potentially infectious material is leaking while being transported, then employees responsible for handling such a container may not be aware that they need to be implementing universal precautions.

Concurring with OSHA's labeling requirement, NIOSH (Ex. 31) states that, "OSHA is correct to require that workers be informed when handling materials or containers of materials that require observation of universal or barrier precautions * * * the labels required are only for the purpose of advising the workers that barriers precautions are required for the contents of the labeled container."

A number of commenters were opposed to such labeling since universal precautions were in place at their facilities. For instance, Saint Michael's Hospital commented that, "With universal precautions, all laboratory specimens are handled with the same precautions and therefore, specific biohazard labels are unnecessary (Ex. 20-1142)." Harborview Medical Center stated that such labeling would be "* * * redundant within hospitals and laboratories where universal precautions are practiced for all specimens (Ex. 20-346)." Likewise, Georgetown University Hospital commented that, "Specimen labeling requirements are redundant and inconsistent with CDC recommendations (Ex. 20-833)."

OSHA agrees that in work situations in which containers of blood and other potentially infectious materials can be identified by trained employees, then there is no need to label such containers. For instance, when blood is being drawn or laboratory procedures are being performed on blood samples, then the containers housing the blood or other potentially infectious materials would not have to be labeled. Paragraph (d)(2)(xiii)(A) above addresses labelling in facilities where Universal Precautions are observed with respect to all specimen. Under certain circumstances such as transport or shipment, employees may come into contact with these unlabeled substances and not be aware that universal precautions are required (for example, a maintenance worker who is required to clean up an unidentified spill.) In these instances, labels are required.

Several commenters felt that using warning labels on specimens would breach patient confidentiality, and infringe upon the source individual's right to privacy. (See for example, American Health Care Association; Ex. 20-287; Primary Children's Medical Center, Ex. 20-1094; The National Association of Children's Hospitals and Related Institutions, Inc., Ex. 20-1003.) OSHA recognizes that under Universal Precautions, blood and other potentially infectious materials from all source individuals are treated as if they contain HBV or HIV and there is no need for a label that states whether or not the specimen was collected from an individual known to be infected with these viruses. Therefore, OSHA is not requiring that the infection status of source individuals or specimens be identified. The Agency is requiring only that the outermost containers used to store, transport, ship or dispose of blood or other potentially infectious materials from any source individual bear a warning labeling signaling that appropriate barrier precautions must be used if there is occupational exposure. Thus, under this requirement, the source individual's rights to confidentiality and privacy are not violated.

Additionally, OSHA feels that using labels to designate the bloodborne infection status of some individuals and not others sets up a dual system in which employees may take fewer precautions with unlabeled specimens than with those labeled "HIV" or "HBV." There were a number of comments supporting the prohibition of warning labels and signs indicating on individual's bloodborne disease status. For example, CDC/NIOSH stated, "We recommend against using labels to differentiate samples that are known or suspected of being infectious from those not believed to be infectious (Ex. 31)." Likewise, AFSCME stated that, "* * * we are concerned that differential labeling will encourage employees to become lax with samples that are not explicitly marked but that may also be infectious (Ex. 297)." SEIU commented that, "* * * some hospitals follow universal precautions but then use door signs for patients already diagnosed with AIDS or hepatitis B. This inconsistent approach to infection control confuses healthcare workers and discourages compliance with any infection control guidelines (Ex. 299)." However, there were some commenters who felt that employees have the right to know the infection status of specimens and that such labeling should be permitted. For example, The College of American Pathologists commented that, "The College recommends a modification of the strict observance of universal precautions to permit special biohazard labeling of known infectious specimens * * * there are certain situations where additional precautions should be added (Tr. 11/13/89 pp. 191 & 206)." Dr. Jared Schwartz of Presbyterian Hospital in Charlotte, NC stated that it is:

> * * * common sense that if you know of a risk you are obligated to warn others. If you know a lot of ice cream bars are contaminated with Listeria you expect the manufacturer to warn the public which lot is bad. This does not guarantee that the other lots are safe and the public needs to be careful of all bars, but at least you are sure that they are aware of the bars that pose a danger (Ex. 20-641).

Finally, there was support in the record for OSHA's not addressing the issue of the use of labels or signs identifying an individual's infectious status (see, for example, Frankford Hospital, Tr. 12/20/89, pp. 1364; Westmoreland Hospital, Ex. 20-1102; The Bowman Gray School of Medicine, Wake Forest University, Ex. 20-637; and Lutheran General Hospital, Ex. 20-655.)

OSHA is not requiring the use of warning signs or labels indicating an individual's bloodborne infectious status. The Agency strongly agrees with the recommendations of CDC/NIOSH against using warning signs indicating such a status. The Agency feels that universal precautions should be implemented which requires that all blood and other potentially infectious materials are treated as if they contain certain bloodborne pathogens. The labeling requirements of paragraph (g)(1)(i)(A) are for the purpose of warning employees only that certain containers are housing blood and other potentially infectious materials. Such warning labels also would inform

employees that appropriate barrier precautions would need to be used if occupational exposure occurs. The final Standard includes "containers used to * * * *ship* blood * * *" in addition to containers used to transport blood in order to emphasize that containers in transit by various means either within or between facilities are covered by the labeling requirements.

Paragraph (g)(1)(i)(B) requires that the warning label includes the universal biohazard symbol followed by the term "BIOHAZARD." Any additional appropriate designation or major message, e.g., the term "Regulated Waste", may be included on the label. The provision ensures that appropriate and universally recognized warning is given to employees. The standard does not prevent the inclusion of any other appropriate designation or major message provided that such inclusions do not detract from the impact or visibility of the word "BIOHAZARD", the biohazard symbol or any required information or major message.

The specific requirement to use the word "BIOHAZARD" and the universal biohazard symbol is considered appropriate because epidemiological evidence indicates that HIV and HBV have been transmitted to workers occupationally exposed to blood and other potentially infectious materials. The word "BIOHAZARD" and the universal biohazard symbol indicate the nature of the hazard in a manner readily recognized by many employees exposed to bloodborne pathogens. They warn the employee that universal precautions have to be used when handling the contents of the labeled container. The symbol is placed after the word to reinforce the meaning of the word "BIOHAZARD" and to ensure that the warning of the presence of the hazard is conveyed. Although CDC/NIOSH supported the use of certain warning labels, they recommended that the biohazard symbol not be used (Ex. 298). Rather, they suggested substituting a gloved hand and a graphic representation of spilled liquid. They suggested the label also bear the legend "Universal Precautions." OSHA feels this symbol would be inappropriate for a number of reasons: First of all, the biohazard symbol has been used for a number of years and is effective in warning employees of the presence of biohazards. Secondly, the suggested symbol of a gloved hand and spilled liquid is remarkably similar to three symbols found in ANSI Z129.1–1988 that are used to designate the presence of corrosive chemical. Finally, the Agency has no evidence that such a symbol has ever been tested to determine whether it would convey the appropriate message to workers including those who are illiterate or who cannot read English.

Paragraph (g)(1)(i)(C) requires labels to be fluorescent orange, orange-red or predominantly so with lettering or symbols in a contrasting color. This requirement would ensure that the label attracts the attention of the employee and that the letters and symbols are easily seen. The color requirement is identical to that contained in appendix A of OSHA's standard for accident prevention tags (29 CFR 1910.145(f)). Although there were very few comments in the record that addressed this issue of color, at least one company supported standardizing the color of labels (Baxter Health Care Corporation, Tr., 10/20/89, pp. 872). There was no substantial evidence in the record that challenged the color requirements.

Paragraph (g)(1)(i)(D) requires that labels be either an integral part of the container or be affixed as close as feasible to the container by string, wire, adhesive or other methods that prevent their loss or unintentional removal. This ensures that the warning label will not be separated from the container used to store, ship, transport or dispose of the biohazard, so that employees coming in contact with the container will be aware of the hazard. Containers are available that have biohazard labels as an integral part of their structure, but the standard only requires that a label to be affixed to the container. This flexibility is particularly important since objects, such as refrigerators or freezers, will have to be labeled if they house containers of blood or other potentially infectious materials.

There are three exemptions to the labeling requirement of paragraph (g)(1)(i). The first exemption, paragraph (g)(1)(i)(E), allows the substitution of red bags for labels on bags or containers of regulated waste. OSHA believes that employees will be protected where red bags are used because employers will have to comply with paragraph (g)(2)(iv)(M) of the standard which requires that employees be trained to understand the meaning of all color coding used to comply with paragraph (g)(1). This would include information on the meaning of red bags, thus assuring that OSHA's intent, to inform employees of hazards present at their worksite, would be achieved by red bagging.

Paragraph (g)(1)(i)(F) exempts containers of blood, blood components, and blood products labeled as to their contents and released for transfusion or other clinical uses from the labeling provision of this standard. The wording in the final standard has been changed from the proposed standard to clarify the meaning of this provision as suggested by CDC/NIOSH (Ex. 20–634). OSHA's intent is to exempt blood, blood components, and blood products (bearing an identifying label as specified by the FDA) that have been screened for HBV and HIV antibodies and released for clinical use. This exemption is justified because containers having a specific label which identifies blood, blood components, or blood products would provide sufficient information to ensure that additional labeling would be unnecessary. Additional comments in the record supporting this exemption were provided by the American Red Cross, Ex. 20–215; the Department of Defense, the Armed Services Blood Program Office, Ex. 20–161.

Finally, the standard would exempt from the labeling requirement individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal. OSHA is not requiring that containers used for collecting or processing blood or other potentially infectious materials be labeled with the biohazard sign during such procedures. Labeling is required only for containers used to store, transport, ship or dispose of blood or other potentially infectious materials. During such times the contents of the containers may not be readily identifiable and employees who come in contact with these substances need to be apprised of the potential for exposure to bloodborne pathogens. For example, during transport a container holding test tubes of blood or other potentially infectious materials would need to be labeled. Also, the potential for breakage or puncture of such containers is of concern especially during shipping and transport and employees who are responsible for clean up procedures need to be warned of the presence of biohazards. Addressing this issue CDC/NIOSH (Ex. 31) states, "The purpose of the label * * * is to advise the worker that the contents of the container require observance of universal precautions; for example, if the container leaks, is torn or broken, or must be opened for any reason." OSHA has concluded that sufficient warning is provided by labelling the outer container.

Labels required for contaminated equipment (paragraph (g)(1)(i)(H)) that is to be serviced or repaired shall contain the additional information stating which parts of the equipment are contaminated. This will assure that employees who repair, service or

otherwise handle this equipment will be warned to take appropriate protective measures.

Paragraph (g)(1)(i)(I) states that regulated waste that has been decontaminated need not be labelled or color-coded. In the proposed standard, OSHA posed the question that if regulated waste (infectious waste) is decontaminated prior to disposal, should the Agency allow the label to be removed from the container? There was strong support in the record for allowing the removal of warning labels from decontaminated regulated waste. (For example, see CDC/NIOSH, Ex. 20-634; American Academy of Family Physicians, Ex. 20-1107; Society of Hospital Epidemiologists of America, Ex. 20-1002, Tr., 10/18/89, pp. 353-354; EPA, Ex. 20-991; American Association of Forensic Dentists, Ex. 20-109; APIC, San Francisco, Ex. 20-654; American Association of Critical Care Nurses, Ex. 20-1162; American Society for Microbiology, Ex. 20-1188; ADA, Ex. 20-665; and Baxter Health Care Corporation, Ex. 20-914.) The American Academy of Family Physicians stated that, "* * * effective decontamination should allow for removal of the label * * *" (Ex. 20-1107). The Society of Hospital Epidemiologist requested that OSHA allow the removal of the biohazard label "* * * from anything that has been adequately decontaminated * * *" (Tr., 11/18/89, pp. 353-354). On the other hand, several commenters felt that OSHA should not allow labels to be removed after the decontamination process as there was no way to ensure that the waste had been decontaminated. Expressing this viewpoint, AFSCME stated that, "Biohazard or other warning labels should remain on infectious waste containers even after decontamination, since studies show that incineration and autoclaving are not guaranteed methods of disinfection" (Tr., 9/15/90, pp. 106). The Visiting Nurses Corporation commented that OSHA should not allow hazard labels to be removed from waste containers even though such waste has been decontaminated before disposal because "this might create confusion, thereby increasing the risk of exposure" (Ex. 20-1268). The Food and Allied Services Trades (Ex. 20-868) stressed that there is not justification for removing the warning label on infectious waste as it cannot be ensured the waste is decontaminated. There were also a number of commenters who felt that additional labels could be placed on the regulated waste indicating that the waste had been decontaminated. Addressing this issue the Veterans Administration stated, "* * * the removal of the label, especially if the waste is red bagged would complicate disposal—suggest that an additional label be attached signifying that decontamination has been performed and that indicates date, time, location and certifying official" (Ex. 20-548d). The American Society of Clinical Pathologists similarly commented, "A label indicating decontamination should be added rather than the original label removed" (Ex. 20-351). The EPA (Ex. 20-991) indicated that although it supports the removing of the warning label once the regulated waste has been "treated," it none the less requires identification of the contents as medical waste using an identification tag.

OSHA recognizes that it is possible to decontaminate regulated waste by a number of methods including incineration, autoclaving or by chemical means. However, in order to ensure that the decontamination process is successful, it must be monitored carefully each time the decontamination process is used. There are several factors which may interfere with or require altering the decontamination process. For example, the denser the load of waste, the more difficult it would be to decontaminate the center of the load. Depending on the configuration of the load, different portions of the load may require variations in the decontamination process for example, greater heating or pressure. Additionally, variation in content or volume of the load may affect the efficacy of the decontamination process. For instance, the greater the organic content of the load, the more difficult it is to decontaminate. Thus, a load of bulk blood or of blood soaked gauzes, may require very different decontamination procedures or conditions than a load of extracted teeth or other body parts.

OSHA has considered all the evidence in the record and has decided not to prohibit the removal of the warning label required by paragraph (g)(1)(i) from decontaminated regulated waste. Of course, the employer who removes the label, covers the red bag or in some other way indicates that regulated waste has been decontaminated must assure that the waste is decontaminated which means that bloodborne pathogens are removed, inactivated, or destroyed to the point where they are no longer capable of producing disease and the surface of an item is rendered safe for handling, use or disposal as defined above in paragraph (b) Definitions.

Paragraph (g)(1)(ii)(A) requires that the entrance to research laboratories or production facilities be posted with signs specifically stating "BIOHAZARD" and showing the universal biohazard symbol. The sign also has to identify the infectious agent and specify any special requirements for entering the area. For example, if personal protective equipment is required, this information would have to be included on the sign. In addition, the name and telephone number of the laboratory director or other responsible person is required to be displayed. Such warning signs would have to be posted at the entrance to a research laboratory or a production facility as defined by paragraph (b) of this standard.

The Agency intends that the posting of these signs will serve as a warning to employees who may otherwise not know they are entering a restricted area. Signs would warn employees not to enter the area unless there is a need, unless the employee has been properly trained, and unless the employee also meets all other appropriate entrance requirements listed on the sign. The standard requires certain wording on the warning signs for regulated areas to assure that appropriate and universally recognized warning is given to employees. The specific requirement to use the word "BIOHAZARD" and the universal biohazard symbol is considered appropriate because epidemiological evidence indicates that HIV and HBV have been occupationally transmitted to laboratory workers in circumstances where these hazards existed. The universal biohazard symbol indicates the nature of the hazard in a manner readily recognized by laboratory workers, and it emphasizes the importance of the message that follows. The requirement that the name of the infectious agent and any special requirements for entering the area be listed on the sign would assure that employees are aware of the specific biohazard involved and of any special measures that need to be taken before entering the restricted area. The provisions for signs in paragraph (g)(1)(i) are virtually identical to the recommendations for signs found in Special Practices for Biosafety Levels 2 and 3 in "Biosafety in Microbiological and Biomedical Laboratories" (Ex. 6-338). The only exceptions are the color requirements and the requirement that the word "BIOHAZARD" be used. OSHA has added the requirement for the word "BIOHAZARD" because some individuals who are present in the general work area may be unfamiliar with the meaning of the biohazard

symbol. These individuals may not be covered by the standard and may not have received training required by the standard. Supporting this provision, The Food and Allied Services Trades (Ex. 20–888) commented that OSHA has no way of ensuring the success of a training program to convey this information.

There were commenters who questioned the need for specifying on signs any special requirements for entering a restricted area. Abbot Laboratories and the Pharmaceutical Manufacturers Association stated that these requirements may be rather extensive and not easily transferred to a sign (Exs. 20–1227; 20–729). OSHA believes the biohazard symbol alone does not provide sufficient warning to employees who may enter the regulated area. The requirement that the name and telephone number of the laboratory director or other responsible individual be posted on the sign will ensure that, in the event of an emergency or other unforeseen event, the employee will know how to reach a trained and knowledgeable individual who can provide guidance and ensure that procedures are followed to eliminate or minimize exposure.

The proposed standard posed the question of whether it is necessary to require the use of "Danger" or other additional words on biohazard signs in order to warn individuals who may not understand the meaning of "BIOHAZARD". This question generated a substantial response. The majority of those who commented on this issue felt that the word "Danger" should not be added to signs. A number of commenters suggested that posting the word "BIOHAZARD" along with the biohazard symbol would convey appropriate warning provided employees were adequately trained on the meaning of the word "BIOHAZARD." For example, CDC/NIOSH stated, "The word 'Danger' or other cautionary words are not necessary. Training required under this regulation should result in employees understanding the significance of the biohazard symbol" (Ex. 20–634). The American Academy of Family Physicians commented that, " 'Danger is certainly more widely used in the U.S. than 'Biohazard' * * * if OSHA feels that the training of employees will be effective, the term biohazard will be sufficient since all concerned persons will have received education in the meaning." (Ex. 20–1107). The Service Master Company commented that:

> The use of the term "Biohazard" in combination with the universal biohazard symbol should be sufficient to warn employees of the hazard. It should not be necessary to use the word "danger" * * * training should properly address the meaning and significance of both the term 'Biohazard' and the biohazard symbol. (Ex. 20–21)

The American Biological Safety Association stated:

> The use of the word "Danger" is redundant. The biohazard sign or universal biohazard symbol is indicative of warning of actual or potential hazard. Training of employees to adhere strictly to good laboratory practices and barrier protection is far more effective than posting of inappropriate warning signs which may be ignored if overused. (Ex. 20–241)

Several commenters felt that "Danger" should be added to signs in order to reinforce the meaning of the term "BIOHAZARD" and the biohazard symbol. For example, the American Public Health Association (Ex. 20–1361) suggested that the word "Danger" be added to signs as it is more instructive than "Biohazard". AFSCME (Ex. 20–985) stated, "* * * the word 'Danger' should be on signs for people who may not understand the meaning of 'Biohazard'." The Communications Workers of America, AFL–CIO, District 1, (Ex. 20–273) felt that the term "Biohazard" was not a clear enough indicator. Support for including the word "danger" on signs was also provided by Local 1199, Drug, Hospital and Healthcare Union (Tr., 11/14/89, p. 380).

Other commenters felt that the word "Danger" is inappropriate since it connotes areas that people should not enter and suggested the word "Caution" be used instead. (Abbott Laboratories, Ex. 20–1227; Pharmaceutical Manufacturers, Ex. 20–729; Health Industry Manufacturers, Ex. 20–795.)

OSHA has considered all these comments and has concluded that this final standard should not require use of the word "Danger." However, the employer may use the word "Danger" or "Caution" as long as including the word does not detract from the impact or visibility of the word "BIOHAZARD," the biohazard symbol or any required information or major message.

Consistent with the requirements for labels, signs shall be fluorescent orange-red or predominantly so, with lettering or symbols in a contrasting color.

The hazard warning signs are intended to supplement the training which employees are to receive under the other provisions of paragraph (g)(2), since even trained employees need to be reminded of the location of regulated areas and of the precautions to be taken before entering these hazardous areas.

(2) Employee Information and Training

Paragraph (g)(2) requires the employer to provide all employees with occupational exposure to bloodborne pathogens with training about the hazards associated with blood and other potentially infectious materials and the protective measures to be taken to minimize the risk of occupational exposure. Effective training is a critical element of any overall exposure control program. It will ensure that employees understand hazards associated with bloodborne pathogens, the modes of transmission, the exposure control plan, and the use of engineering controls, work practices, and personal protective clothing. Employees are also required to be trained in the appropriate actions to take in an emergency involving exposure to blood and other potentially infectious materials, and they are to be informed of the reasons that they should participate in hepatitis B vaccination and post-exposure evaluation and follow-up.

This training will help reduce the risk of occupational exposure, consequently reducing exposure-related infection, illness, and death. The more than 3,000 comments OSHA received comprise a record that strongly supports the need for employee training programs and endorses the conclusion that employee training should be mandated as an integral part of OSHA's standard on bloodborne pathogens. The comments also provided many suggestions regarding the types of information that should be included in a specific requirement for training, and OSHA relied heavily on these comments in developing the training requirements listed below. (See, for example, CDC/NIOSH, Ex. 11–187; AHA, Ex. 11–233; ANA, Ex. 11–86; AAOHN, Ex. 11–111; ARC, Ex. 11–156, 11–280; SEIU, Ex. 11–161, AFSCME, Tr., 9/15/89, pp. 84; Local 1199—Drug, Hospital and Healthcare Employees Union, Tr., 11/14/89, pp. 380–3.)

Typical of the comments received is that of the American Federation of State, County and Municipal Employees (AFSCME) (Ex. 11–157) which addressed the need for training as follows:

> A critically important part of preventing injuries or illnesses in the workplace is training workers about potential hazards and safe working conditions. Workers shall have the same right to know about communicable disease hazards to their health that they now have for chemical hazards (Ex. 11–157).
>
> All who are potentially exposed must be trained (Tr., 9/15/89, pp. 84).

Mr. Shirikian, Forensic Scientist, N.Y. State Police, testifying for the SEIU

stated that, "Employers and employees alike will be better prepared to protect themselves at the worksite if they have the proper education." (Tr. 11/13/89, pp. 170)

The American Dental Association (ADA) noted that such training is already received as part of a dental education. "Dental professionals are trained and educated in the delivery of quality dental care. Training and education include infection control practices" (Ex. 11-43).

Mr. Paul Maniscalco, Vice President of the National Association of Emergency Medical Technicians stated:

> Education is the linchpin in this process of protecting EMS workers. Without appropriately delineated training requirements, the necessary behavior modification from the EMT will not be realized and thus, will have no major impact on reducing the potential for illness or injury. It is imperative that corrective measures be taken immediately to address the inclusion of infection control in all EMS training programs." (Tr. 9/14/89, pp. 122-123)

The training is required to be conducted during working hours, at no cost to the employee and at a reasonable location. These provisions are required implicitly in all OSHA standards that require training so that the employee is not penalized in order to participate in a training program that is required to ensure as far as possible the employee's occupational safety and health. However, the Agency chose to state each provision explicitly in the final standard for Occupational Exposure to Bloodborne Pathogens in order that employers and employees are clearly aware that these requirements exist.

The provisions for employee training are performance oriented, listing categories of information that must be provided to employees. This ensures that important information is communicated to employees while allowing employers the most flexible approach to providing training. The Standard also requires that training records be established and maintained according to section (h)(2). In the proposed standard, OSHA asked whether it is appropriate to substitute some measure of competency in lieu of training for certain individuals. For example, some asserted that infection control practitioners, would be expected to be thoroughly familiar with some of the material in the training program. A number of commenters felt that there would be very few if any employees who would be knowledgeable or have sufficient background in all of the elements of the required training program and therefore there should be no employees exempted from the training requirements. Addressing this issue AFSCME commented that:

> Training is critical to the implementation of this standard and *no one* should be exempted from this requirement * * * it should not be assumed * * * that simply because someone has a medical or scientific degree that they are well-versed in infection control techniques, personal protective equipment, emergency procedures, this OSHA standard or other essentials. (Ex. 20-297)

CDC/NIOSH stated that, "* * * no employees should be exempt from training that pertains to the specific hazards and engineering controls, work practices and PPE associated with their job duties." (Ex. 20-634). Similarly, The Service Master commented that,

> Some employees will be thoroughly familiar with some material in the training program. However, they will not be thoroughly familiar with other materials in the program. There should not be a complete exemption from training. Tailoring of the training program * * * will allow for consideration of professional or technical competency. (Ex. 20-21)

On the other hand, SEIU suggests it is appropriate to "exclude diagnosing personnel from the training requirement. Physicians and dentists do not need to be trained in infection control procedures because of their professional education." (Ex. 299)

OSHA recognizes that having a professional degree or other credentials does not necessarily ensure that the individual is adequately familiar with all of the provisions of the Bloodborne Pathogens Standard. The Agency realizes also, that depending on one's background, an employee may be somewhat familiar with various elements of the required training program. Therefore, paragraph (g)(2)(i) requires that all employees with occupational exposure participate in a training program; however, the standard allows the employer flexibility in tailoring the program to the employee's background and responsibilities.

In keeping with the proposed standard, OSHA is requiring in paragraph (g)(2)(ii) that 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. In support of this provision, AFSCME pointed out that, "It is also important for training to be provided annually, to reinforce and update information that was provided previously" (Ex. 20-297). The New York Committee for Occupational Safety and Health commented that, "We support the provisions for education and training, in particular the requirements for such at the time of initial employment and then again at least annually" (Tr. 11/13/89, pp. 17).

Bloodborne pathogens constitute a serious hazard which can lead to very serious illness and death after only one exposure. It is extremely important that employees are trained to protect themselves from this hazard before occupational exposure occurs. It is equally important that those employees who have already incurred occupational exposure be trained as soon as possible to eliminate or minimize such exposure in the future. Therefore, the Agency is requiring that the training provisions be among the first requirements implemented after the effective date of the standard.

OSHA has concluded that it is essential for employees to understand the nature of the hazards they may face in the course of their employment and the procedures to follow to minimize or eliminate the risks associated with their exposure to these hazards. Because of the severity of the diseases and the potential to contract them from a single event, it is also important to retrain workers exposed to bloodborne pathogens on an annual basis. Annual retraining reinforces initial training and provides an opportunity to present new information that had not been available at the time of initial training.

The record also indicated that many employees who have occupational exposure have received training and training updates on infection control procedures. In order to avoid duplicating the previous training efforts of employers, the Agency has added a "grandfather" clause to the provision. Paragraph (g)(2)(iii) states that "for employees who have received training on bloodborne pathogens in the year preceding the effective date of the standard, only training on provisions of the standard which were not included need be provided within the 90 days." The annual training for these employees shall be provided within one year of their original training. This allows employers the option of supplementing prior employee training rather than repeating it initially.

There was strong support in the record for such a grandfather clause. For example, the American Hospital Association commented that OSHA should "recognize training in universal precautions that occurred within one year prior to the final publication of the rule as fulfilling the rule's initial training requirements, as long as the employer provides supplemental information to employees about the new rules" (Ex. 20-352). The American Association of Dental Schools stated, "We suggest a

training waiver for an employee who has taken a continuing education infection control course within one year prior to the effective date of the final rule—such individual would not need to take the training course until the next year after the rule takes effect." (Ex. 20–651) Mr. Graman, of the University of Rochester School of Medicine commented that, "Many aspects of the required initial training have been covered in recent in-service training on UP and infection control during the past year—duplication of effort should be avoided." (Ex. 20–1053) The SEIU (Ex. 20–979) felt that OSHA should allow for grandfathering of employees who have gone through training programs.

It is important that employees are trained not only initially and annually but whenever there is a change in an employee's responsibilities, procedures or work situation such that an employee's occupational exposure is affected. Therefore, paragraph (g)(2)(v) includes the following additional provision in the final standard:

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

Regarding the need for such additional training, AFSCME stated that, "Additional training should be provided annually and whenever a change of working conditions increases potential exposure" (Ex. 38). The American Nurses' Association commented that, "The employer should routinely assess the employee's need for training and provide [it] then and not just on the anniversary date" (Ex. 20–953). The Retail, Wholesale and Department Store Union, AFL–CIO stressed that in addition to annual training all employees must receive training as new scientific information becomes available (Tr. 11/14/89, pp. 431).

OSHA is concerned that the training information presented must be understood by the employee; otherwise the training will not be effective. Therefore, paragraph (g)(2)(vi) requires that employers must include training material that is appropriate in content and vocabulary to the educational, literacy and language background of employees. This will ensure that all employees, regardless of their cultural or education background will receive adequate training on how to eliminate or minimize their occupational exposure.

Many commenters suggested such a provision. For example:

> Education must be appropriate to education level, literacy and cultural or language background * * * clarify materials to workers at all levels with varying cultural, ethnic and literary backgrounds (American Association of Occupational Health Nurses, Ex. 11–111).
>
> * * * educational training must be designed and presented according to the employee's educational, language and English proficiency * * * it may be necessary to supplement with bilingual resources." (American Nurses Association, Tr., 9/20/89, pp. 91.)
>
> Program depth, content and frequency might vary widely depending on audience characteristics (such as prior training, educational background, job duties, nature and degree of risk) (American Hospital Association, Ex. 11–233).

The Service Employees International Union (SEIU) provided similar suggestions in recommending that the following factors be taken into consideration for training employees exposed to bloodborne pathogens:

> [Employee] attitudes and knowledge about these diseases; educational level of workers and potential barriers to training (i.e., language difficulties of non-English speaking workers, limited literacy on the part of some workers * * *) (Ex. 11–161).

The final standard requires that employers provide a training program that contains certain minimum information. The first element in paragraph (g)(2)(vii)(A) is a copy of the regulatory text of the final standard and an explanation of the contents. This ensures the employee will know the standard exists and will be familiar with its provisions. OSHA agrees with several commenters who stated that providing a complete copy of the final standard including the preamble as well as the regulatory text to each employee would be unreasonable and burdensome. For example, the State of Connecticut commented that, "Providing an overview of the standard and making a copy available upon request at a central point in the workplace such as a medical library should be permitted. Providing every employee their own personal copy of the standard does not seem productive or necessary" (Ex. 20–796). However, although providing a copy of the entire standard to each employee is not required, the Agency has concluded that each employee needs a copy of the regulatory text so that he or she will know exactly what its requirements are.

The second and third elements, (paragraph (g)(2)(vii) (B) and (C)) require that the training program include a general discussion of bloodborne diseases with specific emphasis on the epidemiology, symptomatology and modes of transmission of HBV and HIV. Discussion of the epidemiology, symptomatology and modes of transmission of HIV and HBV is an appropriate component of training for a number of reasons. First, this provision will ensure a basic understanding of the diseases caused by these viruses and the need to observe precautions to prevent disease transmission. There is general agreement in the record that such information would be needed in a training program for bloodborne pathogens. For example, the SEIU envisioned a training program where "[T]here will be sessions on the general epidemiology of diseases as well as a clinical explanation of the disease" (Ex. 11–161). As a more general statement of the same principle, CDC/NIOSH commented that "[w]orkers require complete understanding of the modes of transmission of HBV and HIV to observe properly the protective measures required of them" (Ex. 11–187). Similarly, the State of Maryland (Ex. 11–283), AFSCME (Ex. 11–157), California Nurses Association (Tr., 9/13/89, pp. 68.) and the American Red Cross (ARC) (Ex. 11–280) endorsed the need for training workers to understand the diseases that could be transmitted by exposure.

Second, employees need to be able to recognize the symptoms associated with these diseases. There may be an exposure incident where an employee may not realize that occupational exposure has occurred. For example, an employee may not realize that there was a small perforation in a glove worn while performing a surgical procedure. The employee must understand that if certain symptoms develop, e.g., abdominal pain and jaundice, then these symptoms may be related to hepatitis B.

It is not the Agency's intention in most cases for training programs to provide in depth information or to focus intensely on bloodborne diseases other than HIV and HBV and the other hepatitis viruses. However, it is appropriate to inform employees that there are bloodborne pathogens in addition to HIV and HBV.

OSHA believes that it is important for each worker to recognize how he or she specifically might be occupationally exposed to bloodborne pathogens and under which circumstances infection control precautions will be necessary. Therefore, the fourth element of the training program (paragraph (g)(2)(vii)(D)) requires an explanation of the exposure control plan and of the appropriate methods for recognizing tasks that may involve exposure to blood, and other potentially infectious materials.

Paragraph (g)(2)(vii)(E) of the training program requires the employer to

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

Several groups who have commented to OSHA's record on bloodborne pathogens supported this provision and stressed the need for workers to be able to recognize when they may be at risk of exposure. For example, the American Red Cross commented:

> Descriptions of staff duties must indicate whether duties routinely involve potential for exposure to infectious agents * * * whether such exposure might occasionally occur due to extra-ordinary circumstances * * * or whether duties do not include potential for exposure (Ex.11–280).

Likewise, AFSCME pointed out that "[t]raining should ensure that all workers * * * can identify tasks that may involve exposure to blood or other potentially infectious body fluids" (Ex. 11–157). In suggesting a specific training program, the SEIU proposed that "* * * workers will learn the exposure associated with specific occupations and tasks in health care facilities" (Ex. 11–161).

To ensure that employees will be able to identify and implement methods of reducing or preventing occupational exposure to bloodborne pathogens, paragraph (g)(2)(viii)(F) requires an explanation of the use and limitations of appropriate engineering controls, work practice controls, and personal protective equipment. In support of this provision, the State of Maryland commented that no worker should engage in a task involving occupational exposure before receiving training pertaining to standard operating procedures, work practices and PPE for that particular task (Tr., 9/15/89, pp. 173).

Paragraph (g)(2)(vii) (G) and (H) require that employees be provided information on the types, proper use, location, removal, handling, decontamination and/or disposal of personal protective equipment as well as an explanation of the basis for selection and limitations of protective equipment including protective clothing. This will ensure that employees are knowledgeable about the personal protective equipment available to achieve appropriate barrier protection.

Comments in the record support inclusion of information on personal protective equipment and clothing in the training program for employees. For example, AFSCME suggested the following:

> Training should ensure that all workers * * * know where all protective equipment is kept, how to remove, handle, decontaminate, maintain and dispose of contaminated equipment (Ex. 11–157).

The American Red Cross noted that:

> Staff must understand * * * protective clothing and equipment (is) available and their proper use * * * all proper practices and pertinent Standard Operating Procedures, including handling, decontamination, and disposal of contaminated clothing and equipment (Ex.11–280).

CDC/NIOSH (Ex. 11–187) stressed the need for employee training on measures to control exposure to bloodborne pathogens, recommending that "[a]ll workers * * * receive detailed training on engineering controls, personal protective clothing and equipment and work practices required for their duties." According to CDC/NIOSH, this training would have to cover not only the proper use of protective devices, but also the inherent limitations of those devices.

The Joint Committee on Health Care Laundry Guidelines stated:

> Training should include appropriate pi techniques and the use of PPE related to the risk involved (Tr., 10/20/89, pp. 798).

Paragraph (g)(2)(vii)(I) requires that employees be provided with information on the hepatitis B vaccine to ensure that they are aware of its efficacy and safety as well as its benefits and to ensure that employees are aware that the vaccine and vaccination will be offered to them free of charge. OSHA believes informing employees about the HBV vaccine is a critical component of any training program.

The vaccine is the best available means of preventing HBV in the vast majority of workers. Some employees at risk remain unvaccinated; many because of a lack of knowledge about the vaccine including an unfounded fear of contracting HBV or HIV from the vaccine. According to one vaccine manufacturer, Merck, Sharp and Dohme, a number of studies on worker acceptance attribute the "under utilization of the vaccine" to a "lack of information about the disease and the vaccine safety and effectiveness" (Ex. 11–165). In fact, a study conducted at three teaching hospitals found that "the amount of information received concerning the need for and safety of the vaccine correlated significantly with the level of vaccination among employees. Approximately 50% of employees who reported receiving adequate information were vaccinated, whereas fewer than 20% who indicated they did not receive adequate information requested the vaccine (Ex. 11–165)." Merck, Sharp and Dohme concluded that successful vaccination programs combined "proper education about the disease and the vaccine, [with] * * * active support for employee vaccinations from the managerial staff, and * * * vaccine(s) without cost to the employees" (Ex.11–165). Among the other supporters of this provision are the American Dental Hygienists Association (Tr., 1/16/90, pp. 569), the International Association of Fire Fighters (Tr., 9/18/89, pp. 138) and Local 1199 Drug, Hospital and Healthcare Union (Tr., 11/14/89, pp. 380–3).

The clause, "to ensure that employees are aware that the vaccine and vaccination will be offered to them free of charge" was added to the final provision to ensure that employees will know that they are in no way responsible for any portion of the cost of the HBV vaccine or vaccination series. Emphasizing this issue, the American Nurses' Association commented that, "* * * we believe OSHA needs to be much more explicit in its mandate. It must state that the vaccine shall be furnished to fully informed, consenting employees at no cost to them. Reports indicate that employees that are thoroughly educated about the vaccine accept it more readily." (Tr. 9/20/89, p. 78).

Paragraph (g)(2)(vii)(J) requires that employees be provided information on appropriate actions to take and persons to contact in an emergency involving exposure to blood or other potentially infectious materials. This ensures that workers will be prepared for unusual or extraordinary circumstances that include the potential for exposure to bloodborne pathogens. Typical of the support in the record for this provision is the following comment from the American Red Cross:

> Staff must understand * * * actions to be taken when confronted with a situation of potential exposure that had not been anticipated by the employee. Such training might include knowledge of the existence of safety procedures applicable to the situation and the availability of assistance (Ex. 11–280).

It is important that employees understand the actions to be taken if an occupational exposure does occur as well as what medical follow-up is available for exposed individuals to ensure that they seek appropriate medical treatment, prophylaxis and/or post exposure follow-up. Therefore, paragraph (g)(2)(vii) (K) and (L) require an explanation of the procedure to follow if an occupational exposure to bloodborne pathogens occurs, including the method of reporting the incident and a description of the medical follow-up

including counseling that would be made available.

Support for including training about exposure reporting and post-exposure follow-up after an exposure incident was given by several commenters to the record, such as the American Nurses Association stressed that:

> Employees must be educated about the necessity for reporting occupational exposures to blood and body fluids. Employees must be confident the reporting does not bring reprisal (Tr. 9/20/90, p. 77).

The American Red Cross stated that "[s]taff must understand * * * proper procedures to be followed in case of an accident or exposure (Ex. 11-280)." Elaborating on this position, AFSCME stated:

> Training should ensure that all workes * * * know the corrective actions to take in the event of * * * personal exposure to fluids or tissues, the appropriate reporting procedures and the medical monitoring recommended *in cases of suspected* parenteral exposure. (Ex. 11-157)

The AAOHN took an even more explicit position regarding training on the need for follow-up medical care in stating that:

> All health care workers should receive *education about the counseling of* occupationally exposed individuals, monitoring and surveillance activities, current management of the disease process and legal, ethical issues. (Ex.11-111)

Paragraph (g)(2)(vii)(M) requires an explanation of the required signs and labels, including color codings and "red bagging", to ensure that employees understand the warning messages presented and the need for appropriate infection control procedures.

Paragraph (g)(2)(vii)(N) requires that there be an opportunity for interactive questions and answers with the person *conducting the training session.* This will ensure that employees have an opportunity to clarify any issues of concern regarding occupational exposure. Supporting this provision, Helen Miramantes, an occupational health nurse who served as OSHA's expert witness on training, (Ex. 29) emphasized that:

> Trainers must allocate sufficient time to not only present the information but also to allow for questions and review of materials as needed. The trainer needs to provide an environment in which participants feel sufficiently comfortable in order to ask questions and make comments. Asking questions and discussing various aspect of a training program can clarify information and reinforce important learning objectives (Ex. 29).

Paragraph (g)(2)(viii) requires that the person conducting the training be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address. There was strong support in the record for requiring that training be conducted by a "qualified trainer." The American Nurses' Association commented that educators must be familiar with occupational health programs as well as bloodborne pathogens and that instructors must be competent (Ex. 20-953). Similarly, the American Association of Occupational Health Nurses stated that, "Because of the complex nature of the subject matter and the content of training required, trainers must be qualified; at a minimum, trainers should have knowledge of disease transmission and measures to prevent transmission, . . health surveillance and follow-up * * * *" (Ex. 20-357). Marquette Dental School suggested that, "It is appropriate that the training and/or a measure of competency is required from individuals who are training others in infection control procedures" (Tr., 10/19/89, pp. 589).

Other commenters stressed the need for allowing flexibility regarding what instructor qualifications should be. For example, NIOSH stated that, "Qualifications of the trainer should be specified in general terms; the trainer should have expertise in the subject area, as documented by objective evidence such as satisfactory completion of relevant training courses or degree programs" (Ex. 20-634).

Finally, the record indicated the need for instructors to be knowledgeable regarding how the elements in the training program relate to the workplace that the training will address. Regarding this issue, the Health Industry Manufacturers' Association requested that the final rule emphasize competency-based education and training, utilizing qualified instructors and that educational programs be tailored to individual facilities (Ex. 20-795). Based on these and other comments in the record, OSHA is requiring that the person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.

Employees in HIV/HBV research laboratories and HIV/HBV production facilities may be at especially high risk of infection following occupational exposure because they handle concentrated preparations of these viruses. OSHA has concluded that the risk is sufficiently high to warrant a requirement for additional initial training in the handling of HIV/HBV. Paragraph (g)(2)(ix)(A) of the standard, therefore, requires that employees in such facilities who have occupational exposures 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/HBV. OSHA understands that many of the employees who would be covered by this provision are highly skilled and experienced laboratorians who have been working with these viruses and carefully following the biosafety guidelines. For this reason, OSHA is specifying that proficiency be demonstrated rather than requiring that all employees be retrained.

Paragraph (g)(2)(ix)(B) requires employees in HIV/HBV research laboratories and HIV/HBV production facilities to be experienced in the handling of human pathogens or tissue cultures *prior to working with HIV or* HBV. Finally, Paragraph (g)(2)(ix)(C) requires that employees with no prior experience in handling human pathogens have to participate in an on-the-job training program where initial work activities do not include the handling of infectious agents. A progression of work activities is permitted as techniques are learned and proficiency is developed. An employee is permitted to participate in work activities involving infectious agents only after proficiency has been demonstrated to ensure that the worker is able to handle HIV or HBV as safely as possible, thereby minimizing the risk of occupationally related infection and illness.

OSHA's provisions requiring additional training for employees in HIV/HBV research laboratories and HIV/HBV production facilities are patterned after the recommendations made by an expert team convened by the Director of the National Institute of Health (Ex.6-312). This expert team made the following recommendations to help assure a safe and healthful work environment for employees who handle concentrated preparations of HIV:

> A. Strictly adhere to standard microbiologic practices and techniques:
>
> The most important recommendation is to adhere strictly to standard microbiologic practices and techniques. Persons working with HIV must be aware of potential hazards and must be trained and proficient in practice and techniques necessary for self-protection. Employees must be informed that parenteral exposure is the most serious potential hazard for causing a laboratory-acquired infection.
>
> They must be able to recognize how such exposures occur and how they can be prevented. Although on-the-job training is an

acceptable approach for learning techniques and practices, it is imperative that proficiency be obtained before virus is actually handled. Initial work activities should not include the handling of virus. A progression of work activities should be assigned as techniques are learned and proficiency is developed.

B. Assure that workers are proficient in virus-handling techniques:

Selection criteria for employees who will work in production operations or with concentrated preparations of HIV should require experience in the handling of human pathogens or tissue cultures. If an employee has not had such experience, she/he should participate in carefully structured, well supervised on-the-job training programs.

The director or person in charge of the laboratory or production facility must ensure that personnel are appropriately trained and are proficient in practices and techniques necessary for self protection. Initial work activities should not include the handling of virus. A progression of work activities should be assigned as techniques are learned and proficiency is developed. Virus should only be introduced into the work activities after the supervisor is confident it can be handled safely (Ex.6-312).

The employer must assure that the employee is proficient in the standard microbiological practices and special practices required by this standard that are applicable to the employee's job, and that the employee can perform his or her tasks in a safe manner. Proficiency is achieved by experience and training. The employer is responsible for evaluating the employee's proficiency and for documenting the mechanism used to determine proficiency. For example, the employee's proficiency may be demonstrated by passing a written test and by having his or her techniques observed by the laboratory director or the director's designated representative. The results of the written tests and observations must be documented. OSHA also recognizes that some employees will be scientists who have extensive experience in these practices. Therefore, proficiency may also be demonstrated by a graduate degree in the study of HIV or HBV or another closely related subject area with a period of related laboratory research experience.

OSHA concludes that the requirements for labelling, signs, and employee training are necessary elements in the effort to eliminate or minimize exposure to bloodborne pathogens.

Paragraph (h) Recordkeeping

The final standard requires that employers maintain records related to bloodborne pathogens including exposure incidents, post exposure follow-up, hepatitis B vaccination status and training for all employees with occupational exposure. These recordkeeping requirements are in accordance with the Occupational Safety and Health Act of 1970 (OSH Act). Section 8(c) of the OSH Act authorizes the promulgation of regulations which require an employer to keep necessary and appropriate records. OSHA has determined that, in this context, medical and training records are necessary to assure that employees receive appropriate information on the hazards and effective prevention and treatment measures, as well as to aid in the general development of information on the causes of occupational illnesses and injuries involving bloodborne pathogens. Specifically, OSHA believes that maintenance of medical records is essential because documentation is necessary to insure proper evaluation of the employee's immune status and for proper healthcare management following an exposure incident.

As proposed, paragraph (h)(1) of the final standard requires employers to maintain employee medical records which include:

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

(2) A copy of the employee's hepatitis B vaccination status;

(3) A copy of all results of examinations, medical testing, and follow-up procedures related to post-exposure evaluation;

(4) The employer's copy of the responsible healthcare professional's written opinion; and

(5) A copy of the information given to the healthcare provider as required by paragraph (f) of this standard.

The American Federation of State, County and Municipal Employees, AFL-CIO (AFSCME) petitioned OSHA to promulgate a permanent standard, "requir[ing] the employer to keep records on all occupationally related infectious diseases contracted by employees." (Ex. 2A, p. 4). Many commenters supported AFSCME's petition for a recordkeeping provision. Retail, Wholesale and Department Store Union (RWDSU) commented, "[w]e concur with the recordkeeping requirements of the proposed standard * * *" (Ex. 20-1505, p. 6). Monsour Medical Center agreed that such records should be maintained and kept confidential (Ex. 20-158). Providence Hospital and Clearfield Hospital commented that they had no argument or problem with the recordkeeping provision and have already instituted changes in recordkeeping practices (Exs. 20-343; 20-585). Children's Hospital of the King's Daughters stated that "[i]t is appropriate that the employer establish and maintain an accurate health record for each employee in their institution." (Ex. 20-574, p. 5). Finally, Verdugo Hills Hospital and Northwest Center for Occupational Health and Safety agreed that accurate and unified records are important and should be maintained on employees with risks of exposure to bloodborne pathogens (Exs. 20-525; 20-526). However, the overwhelming majority of commenters did not address this paragraph in their comments. OSHA believes that the lack of comment is due, in part at least, to the common understanding that the establishment and maintenance of employee medical records are an integral part of an occupational health program.

Although the majority of the commenters agreed that records must be maintained, some commenters disagreed about who should maintain the record; how long the record should be retained; and how confidentiality of records should be maintained.

Three commenters suggested that the maintenance of medical records should be the responsibility of the employee's treating healthcare professional and not the employer (Exs. 20-350; 20-1004; 20-665). Other commenters believe that the responsibility for maintaining employee medical records on occupational illnesses properly lies with the employer (Exs. 2A; 20-574). OSHA agrees with the latter and this standard, like other OSHA standards, confers the responsibility for recordkeeping upon the employer. However, this standard does not require the employer to maintain possession of the records. For example, an employer may wish to have the records kept in the office of the physician or other licensed healthcare professional with whom he or she has a contract to provide healthcare to his or her employees. On the other hand, many employers, particularly healthcare providers, already maintain employee medical records (i.e. TB tests, vaccinations, physical examinations, etc.). In these instances, the information from this paragraph would simply be added to existing confidential medical files. This standard does not require an additional record, so long as the existing record is considered confidential. Regardless of where the records are kept, the employer bears the responsibility for their creation and maintenance.

Other commenters suggested that state agencies or OSHA should be responsible for maintaining the medical records. (Exs. 20-665; 20-1205; Tr. 9/21/

89, p. 165). Reasons for this suggestion ranged from a belief that confidentiality would be increased to a suggestion that errors and losses would be decreased. OSHA believes that the day to day maintenance of individual employee medical records by state agencies or OSHA would be inconsistent with the OSH Act. First, in Section (2)(b)(7) of the OSH Act, Congress intended for OSHA to be responsible for "provid[ing] medical criteria which will assure insofar as practicable that no employee will suffer diminished health, functional capacity, or life expectancy as a result of his work experience." Second, in section (6)(b)(7) of the Act, Congress intended that OSHA prescribe appropriate controls, including such controls as medical examinations, as may be necessary, for the protection of employees. Finally, section 8(c) of the Act states clearly who is responsible for recordkeeping: "* * * each employer shall make, keep and preserve and make available * * * such records regarding his activities relating to [the OSH] Act." OSHA has concluded that medical recordkeeping on vaccination and occupational exposure incidents is an appropriate and necessary control for the protection of employees against bloodborne pathogens. Specifically, OSHA concludes that in order for records to be useful in, for example, assessing post exposure follow-up or instituting and directing an HBV vaccine program, they need to be readily available and this is best accomplished when the employer is responsible for the records. Additionally, OSHA believes that it is the employer, as the individual most familiar with his or her workplace, who is in the best position to institute appropriate recordkeeping provisions and to insure compliance, maintenance and confidentiality.

How records of exposure incidents could be maintained in a manner that would provide useful information to the employer, the employees and compliance officers without compromising employees' confidentiality was of concern to a number of commenters. Local 1199, The American Association of Occupational Health Nurses (AAOHN), APSCME, and The National Institute for Occupational Safety and Health (NIOSH) commented that *all* needle sticks should be reportable on the OSHA 200 Log (Tr. 11/14/89, p. 379; Exs. 20-357; 297; and 634). OSHA has responded to these concerns by amending 29 CFR 1904.7 to require that when a log or a supplementary record contains information related to bloodborne pathogens the employer must assure that personal identifiers are removed prior to granting access to the record. (For a more thorough discussion of the amendment, see Amendment to Part 1904, above).

There was little public comment on what was required to be kept in the medical records, paragraph (h)(1)(ii)(A), (B), (C), (D) and (E). This was not surprising since the information is entirely related to the goal of preventing occupational illnesses caused by exposures to bloodborne pathogens and it is limited to that which is necessary for the employer to administer an effective HBV vaccination program and medical follow-up after an exposure incident, the employee and his or her healthcare provider to render adequate care, and OSHA to enforce the medical provisions of this standard.

Paragraph (h)(1)(iii) of the final standard states that the employer shall assure that the employee's medical record is kept confidential. Jeanette Wilke, R.N., President of the Association for Practitioners in Infection Control (APIC) of Northwestern Wisconsin and others agree that confidentiality of medical records is a universal standard of ethical conduct within the healthcare professions. (APIC, Ex. 20-108; St. John's Riverside Hospital, Ex. 20-783; American Nurses Association, Inc., Ex. 20-953; American Association of Critical Care Nurses, Ex. 20-1162). In addition, Monongahela Valley Hospital, Indiana Hospital, and Allegheny Valley Hospital pointed out that confidentiality of medical records is codified in state and federal regulations. (Exs. 20-270; 20-656; 20-966). This standard does not abridge, enlarge, or alter any existing ethical or statutory code, rather it is a reiteration of existing standards of conduct.

However, despite existing laws and ethical codes, there are many privacy concerns. OSHA has attempted to reduce concerns which may lead to barriers in exposure reporting by requiring that medical records, including all test results, be kept confidential except as otherwise required by law. Fear that co-workers or others may see test results may discourage the reporting of exposure incidents and the seeking of follow-up care. OSHA recognizes the sensitive nature of HIV testing and the possible repercussions should that test be positive.

The American Dental Association (ADA) expressed concern that any medical recordkeeping requirement could lead to breaches in confidentiality, especially in small dental offices. (Exs. 295; 20-665). This concern is based on an assumption that the dentist will physically maintain the complete medical record in his or her office. However, the dentist, like many other employers affected by this standard, would not be expected to be the primary healthcare provider to his or her employees. These employers will likely contract with a healthcare provider for vaccination and follow-up care, including the generation and maintenance of the employee's medical records. Thus, the employer's office files will include only the information required by paragraph (f)(5) above which is limited to a determination of whether an employee can receive the Hepatitis B vaccine; and, following an exposure incident, a statement that the employee has been told of any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment; and a determination of whether the employee can return to work after an exposure incident.

The College of American Pathologists and The Cleveland Clinic Foundation suggested that the confidentiality requirement is unrealistic where the employer is also the employee's healthcare provider, i.e. a physician or hospital. (Exs. 20-552; 20-563). OSHA believes the mere fact that the patient is an employee does not remove, lessen or make it unreasonable to expect the employer to keep the employee's medical records confidential. The American Society for Medical Technology concurs with OSHA's reasoning, stating that "[e]mployee medical records should be treated with the same respect and assurance of confidentiality as any other medical record." (Ex. 20-990, p. 14) They added that "* * * all medical records should be handled with the same assurance of confidentiality." (emphasis added) (Ex. 20-990, p. 14). OSHA concludes, and APIC of Northwestern Wisconsin and the Veterans Administration Hospital of Hines, Illinois agree that the approach taken by the final standard and existing ethical, legal and accreditation requirements adequately address the issue of confidentiality in the healthcare setting. (Exs. 20-108; 20-961).

NIOSH recommended that an additional paragraph be added which would require employers to develop a written confidentiality plan detailing, among other things, where records would be stored, how records would be secured, and who would have access. (Ex. 20-634). OSHA has considered this recommendation and has declined to adopt it because the Agency believes that this is an area where, because of the great variety of work-places, flexibility in methods of complying with

the confidentiality requirement is needed. However, OSHA recognizes that voluntary development of such a plan can provide guidance to an employer; therefore, OSHA encourages employers to create and institute such plans in order to assist them with the confidentiality requirement of this standard.

Paragraph (h)(1)(iv) requires the employer to retain medical records for the duration of the employment plus thirty years. This time period is consistent with Access to Employee Exposure and Medical Records, 29 CFR 1910.20 (d)(i)(1990). Retaining medical records for the period of employment plus thirty years is necessary because hepatocellular carcinoma, which can occur as a result of hepatitis B infection can, and indeed commonly does, take twenty to thirty years to develop. Individuals who become HBV carriers or develop chronic hepatitis are often ill and infected for the rest of their lives. Moreover, OSHA believes this is an appropriate time period, in light of the fact, that 5% of those exposed to HIV infected blood do not seroconvert within six (6) months. Finally, the time period for retention of records is consistent with other OSHA standards requiring retention of occupational medical records.

The comments received in opposition to the retention provision primarily objected to the length of time. The American Red Cross and The Academy of General Dentistry were among those who expressed objections citing that the time period was excessive, impractical and burdensome. (Exs. 20–207; 20–350). OSHA concludes that this provision is neither excessive nor impractical when viewed from the perspective of the employee. Vaccination records are an essential part of an employee's medical history. OSHA believes that retention of these records and exposure incident records is necessary to assist current and future healthcare professionals in assessing an employee's medical history and prescribing medical treatment. Additionally, OSHA believes that this requirement is not unduly burdensome, especially for an industry that is known for its long-term recordkeeping. Dr. David Eggleston, of the California Dental Association testified that the maintenance of the medical records would not be inconvenient for dentists because dental records of patients are literally being kept forever. (Tr. 1/11/90, pp. 329–330). Matilda Babbitz, RN of AAOHN testified in support of the provision, stating that it was also usual and customary for medical records covered by other OSHA standards to be kept for thirty (30) years. (Tr. 9/20/89, p. 47).

Home Health Service and Staffing Association, representing healthcare temporary service employers, suggested that the medical recordkeeping requirement be limited to two types of employees: all occupationally exposed employees who have worked more than 1200 hours per year for the same employer and all exposed employees who have incurred an exposure incident (Ex. 20–878). OSHA has considered these requests and decided not to incorporate them in the final standard because to distinguish between temporary and permanent employees would have defeated the purpose of preventing occupational illnesses among all healthcare workers who may reasonably be exposed to potentially infectious materials. Bloodborne pathogens do not discriminate among temporary, permanent or even full time and part time workers. In effect, this suggestion would allow employers to wait until an employee has worked seven and a half months (1200 hours/40 hours per week) before offering the HBV vaccine and establishing a medical record, unless there was a reported exposure incident. This could leave a substantial number of employees unprotected from potential occupational exposure. In addition, the HBV vaccination status of a substantial number of employees would likely remain unknown to the employer as well as the employee for approximately the first 7.5 months of employment. In effect, an employee's HBV vaccination status could potentially remain unknown for a significantly longer length of time if the employee changes jobs frequently. Finally, if the employee had an exposure incident during the initial 1200 hours of employment, the healthcare provider would be giving follow-up care without first receiving any pre-exposure information. For the aforementioned reasons, OSHA concludes that medical records are necessary for the protection of all employees occupationally exposed, regardless of the length of their employment. Therefore, the final standard requires that the employer maintain an accurate record for each employee with occupational exposure to bloodborne pathogens.

Paragraph (h)(2) of the final standard requires employers to maintain training records which include: (1) The dates of the training sessions, (2) the contents or a summary of the training session, (3) the names and qualifications of the persons conducting the training sessions, and (4) the names and titles of all persons attending the training sessions.

The American Association of Dental Schools (AADS) commented that: "AADS supports this [paragraph (h)(2)] requirement." (Ex. 20–651, p. 8). Monsour Medical Center agreed that "records of training should be kept—date, time, attendance, educator and evaluation of session." (Ex. 20–158, p. 2). Two commenters alluded to the fact that they already keep training records which would comply with this standard. (Frick Community Health Center, Ex. 20–292; High Point Regional Hospital, Ex. 20–1312). One of them, Frick Community Health Center, commented that accredited hospitals are already maintaining records of training sessions, summaries and attendance as required by the Joint Commission for Accreditation of Healthcare Organizations (JCAHO). (Ex. 20–292). Bernard Grothaus, DDS, testified that his practice conducts in-house training and he keeps records of who attended, and a summary of what was presented for three to four years (Tr. 10/19/89, pp. 534–535). The CDC commented that, "* * * training records, indicating dates of training sessions, the content of those training sessions along with the names of all persons conducting the training, and the names of all those receiving training * * *" should be maintained by the employer (Ex. 15, p. 7).

As indicated earlier, the overwhelming majority of the commenters did not address this portion of paragraph (h) in their comments or testimony. Again, OSHA believes that the lack of comment is due, in part, to the common understanding that instituting, maintaining and using training records are essential elements of any exposure control training program. However, a few commenters, although they agreed that training records were necessary, disagreed on the information the record should contain and the length of time the records should be retained.

Two commenters argued that the amount of information requested in the training record was excessive (Exs. 20–680; 20–11). One of the commenters, Laboratory Administrative Scientific Assembly of Northwestern Washington (LASSA NW), suggested that the record be limited to the name of the employee, nature of the training, and the date of training. (Ex. 20–680). This suggestion omits the job titles of the attending employees, and the name and qualifications of the trainer.

OSHA recognizes that employees may perform different tasks and are therefore exposed to risks of occupational

illnesses in different ways. In these situations, the level of training will likely need to vary depending on the job. Helen Merie Miramontes, B.A., training consultant, testified that, in order

> [t]o be effective, educational and training programs must address the specific needs of the different categories of healthcare workers. As an example, infection control educational needs of registered nurses would be different than the infection control educational needs of housekeepers. (emphasis added) (Tr. 9/13/89, p. 72)

OSHA concurs with Ms. Miramontes and maintains that accurate recordkeeping of the training session, including title of the employees who attended, is necessary to assist the employer and OSHA in determining whether the training program adequately addresses the risks involved in each job. Additionally, OSHA has concluded that requiring employers to list job titles of the employee will enable the employer to easily determine that employees with occupational exposure have received the proper level of training. Moreover, the employer is likely to find this information very useful in tracking the exposure incidents among various jobs with the level of training.

The ADA requested that minimum qualifications for the trainer not be specified in order to allow for training by video or commercial workbooks. (Ex. 20-665). Obviously, if there is no "live" trainer, the name of the trainer cannot be recorded. On the other hand, RWDSU commented that, "[a]udiovisual presentations should not be substituted for "live" training presentations. There must be a knowledgeable trainer available to answer questions and explain area-and-task specific protocols." (emphasis in original) (Ex. 20-1505, p. 7). Although OSHA agrees with the ADA that information can be presented in a variety of ways, including a video tape, the Agency has concluded that the presence of a knowledgeable person who can respond to employee concerns and questions at the training session is essential to the effectiveness of the training program. (See paragraph (g)(2)(vii) above for the criterion for the knowledgeable person). Ms. Miramontes testified, and OSHA agrees, that a qualified trainer is not only needed to disseminate the most current and accurate information, but the trainer is needed to receive feedback, answer questions, and evaluate the adequacy of the training program. (Tr. 9/13/89, pp. 71-72). Jordan Barab, Health and Safety Coordinator for AFSCME, adds that the trainer should also be familiar with the working conditions of the employees attending the training session. (Tr. 9/15/89, p. 85). He also testified that receiving no training is dangerous, but that receiving inaccurate training from an unqualified trainer may be worse because employees will lose trust in the training program. (Tr. 9/15/89, pp. 85-86). OSHA considered requests to specify minimum qualifications for the trainer, but decided instead to put the provision in performance language thereby requiring only that the trainer be knowledgeable in the subject matter. (For a fuller discussion of the trainer, see the explanation to paragraph (g)(2)(vii), above). Requiring the employer to keep a record of the name and qualifications of the knowledgeable person who was available to respond to employees at the training sessions will help ensure that the trainer actually conducted the sessions and will aid the employer in evaluating his or her training program.

Some dentists testified that many small private dental offices conduct informal training. They noted that this training often consists of on-the-job spontaneous discussions. (Tr. 10/19/89, p. 533, 536). While the performance approach of the training requirements allows a great deal of latitude in how and when information is presented to employees, more than informal discussions while work is being done is necessary to ensure workers are properly trained. Each employer will have to see that all the components of the program required by paragraph (g)(2)(vi) are covered in order to ensure that the employee training is complete. Moreover, a critical additional component of training is the maintenance of records which would be difficult, if not impossible to accomplish when informal discussions during work are substituted for a training program. As noted above, the creation and maintenance of records will enable the employer to assess the content and completeness of the training program in order to ensure that his or her employees have received the required training. High Point Regional Hospital addressed this reason for keeping records when they commented that they already keep training records, and they conduct a review of the attendance records to make sure that all applicable employees have been trained. (Ex. 20-1312).

The time period for retention of training records is three years. These records are not considered to be confidential and may be maintained in any file. AADS and RWDSU, among others, support this portion of the recordkeeping requirement for training records (Exs. 20-651, 20-1505).

A few commenters believed that requiring employers to retain training records for several years is excessive and of questionable utility. (Exs. 20-655; 20-525; 20-39; 20-141). Most of these commenters were under the impression that a special file had to be established for each employee. OSHA did not intend to imply that employers had to establish and maintain individual training files for each employee, although many employers will keep the training records in each employee's personnel file. So long as the records are created and maintained the employer may choose how to keep them, in the employee's file or in a single file. This paragraph only requires that training records be maintained for three years and that they contain the prescribed information.

Of those employers who testified that they currently keep training records or employment records, OSHA learned that they typically retain the records long after the employee leaves. For example, a dentist, Dr. Howard Stone, testified that he has kept employment records for his long term employees of twenty two and nineteen years. (Tr. 10/19/89, p. 532). Dr. Stone further testified that for those "employees that left * * * their records are still in * * * [the] files * * * [including] * * * [t]he last one that left * * * four years ago." (Tr. 10/19/89, p. 534). OSHA believes that three years is not a burdensome length of time given the fact that many employers already retain records for this period or longer. OSHA has concluded that training records need to be kept for three years to be of use to employer, the employee and OSHA in evaluating the effectiveness and adequacy of the training program.

Paragraph (h)(3) provides that employees shall be afforded unrestricted access to their medical records, in accordance with Access to Employee Exposure and Medical Records, 29 CFR 1910.20(e)(1990), and to their training records in accordance with the Occupational Safety and Health Act of 1970, section 8(c). This paragraph does not affect existing legal and ethical obligations concerning maintenance and confidentiality of employee medical records. An employer's access is governed by existing federal, state and local laws and regulations. A few commenters, including AAOHN, suggested that OSHA should include language in this portion of the paragraph expressly limiting employer access. (Abington Memorial Hospital, Ex. 20-557; St. Thomas Hospital, Ex. 20-890; Bethlehem Steel Corporation, 20-1105; Martin Lubin, AFSME, AFL-CIO, Tr. 11/14/89, p. 457). Other commenters believe

such language is unnecessary because of existing laws. (Monongahela Valley Hospital, Inc., Ex. 20–270, Indiana Hospital, 20–656, Allegheny Valley Hospital, 20–966, Westmoreland Hospital, 20–1102). OSHA believes that the standard, as written, sufficiently limits employer access to confidential information while allowing the employer access to the information needed to make appropriate decisions regarding the employer's hepatitis B vaccination program, medical follow-up, and training. Paragraph (f) limits the information that can be included in the record and paragraph (h) requires that this information be kept confidential. Finally, there exists no language in this standard that grants an employer access to the confidential information in an employee's medical file.

In paragraph (h)(3)(ii), OSHA retains access to medical records in accordance with 29 CFR 1910.20(e)(3). Monongahela Valley Hospital and San Antonio Community Hospital expressed concerns about the extent of OSHA's access to the employee medical records. (Exs. 20–270, 20–530). In clarification, OSHA's access to personally identifiable medical records is subject to regulations, published in the Rules of Agency Practice and Procedure Concerning OSHA Access to Employee Medical Records, 29 CFR 1913.10 (1990), will protect the privacy concerns of the employees.

As proposed and consistent with other standards, OSHA also retains access to training records as authorized by Section (8)(c) of the Occupational Safety and Health Act of 1970.

Paragraph (h)(4)(i) provides that the employer shall comply with the requirements of 29 CFR 1910.20(h) and Section 8 of the Act regarding the transfer of employee records. If an employer ceases to do business and there is no successor employer, paragraph (h)(4)(ii) requires the employer to notify NIOSH at least three months prior to the disposal of the records and to transmit them to the Director, upon request, for retention. AADS objected to the transfer of the medical records to NIOSH. Dr. John Green representing the AADS, testified that the transfer of records to NIOSH would present numerous problems in maintaining confidentiality. (Tr. 1/11/90, p. 291). AADS suggested that all confidential records on exposed employees should be transferred to the treating healthcare professional. OSHA believes that the goal of improving occupational safety and health will be better served if all occupational illness and training records are transferred to NIOSH, if requested. NIOSH has a vested interest in maintaining records of occupational injuries and illnesses and is in an excellent position to decide how the records can be best used to be of value to the exposed employee, subsequent employers in the field and OSHA. At NIOSH, the records remain confidential as required under 29 CFR 1910.20(e). Thus, only the employee or his or her representative (with the permission of the employee) retains access to the medical records transferred to NIOSH.

Paragraph (i) Dates

The dates for compliance have been adjusted from those listed in the proposed standard. The final rule would become effective ninety (90) days after its publication in the Federal Register. This increase in the effective date is the result of testimony from several commenters that the proposed thirty(30) days was too short to allow for public distribution and to give employers time to familiarize themselves with the standard (Tr. 11/14/89, p. 301; Exs. 20–1087; 20–1059, p.20). Although other commenters urged OSHA to implement a standard rapidly, it was felt that these concerns could be met by shortening the phase-in effective dates of the various provisions (Trs. 11/14/89, p. 460; 11/14/89,p. 272; 11/14/89, p. 382).

The first phase-in effective date concerns the Exposure Control Plan. The Exposure Control Plan required by paragraph (c) (2) shall be completed within sixty (60) days of the effective date of the final standard. The Exposure Control Plan includes the Exposure Determination. Because the Exposure Determination has been streamlined to require only job classifications or groups of tasks, it is felt that this requirement can be met within this timeframe.

Paragraph (g)(2) Information and Training and paragraph (h) Recordkeeping shall take effect within ninety (90) days of the effective date. Although many commenters testified that more time was required to implement a full training program, provisions have been made in the final standard to recognize training about bloodborne pathogens provided in the year preceding the effective date of the standard and to require only training with respect to the provisions of the standard which were not included (Tr. 1/9/90, p.54; Exs. 20–1092; 20–621; 20–655; 20–556). Subsequent training is required annually thereafter or when changes affect the employee's occupational exposure. Little comment was received regarding the effective dates for implementing the recordkeeping requirements of the standard.

One hundred, twenty days (120) days after the effective date of the standard, the paragraphs regarding Engineering and Work Practice Controls (d)(2), Personal Protective Equipment(d)(3), Housekeeping (d)(4), HIV and HBV Research Laboratories and Production Facilities (e), Hepatitis B vaccination and Post-Exposure Follow-up (f) and Label and Signs (g) (1) shall take effect. Much of the comment revolved around the issue of implementation of the HBV vaccination program. OSHA recognizes that this vaccination series requires six months to complete. The standard requires that the HBV vaccination program be in effect within these dates; although employees may not have completed their series within 120 days after the effective date for the standard.

There were also concerns documented in the record about the time required to complete proposed medical exams (Exs. 20–940 , p. 8; 20–217; 20–700, 20–199). These concerns were addressed by changes in the language of the standard regarding Hepatitis B vaccination (f) which allow for the vaccine program to be managed using appropriate healthcare providers. These changes will allow employers to implement this section using a wider variety of protocols and strategies.

A final concern about the effective dates for these sections was related to the availability of HBV vaccine. Although several commenters expressed concern about the vaccine availability, reassurances were received from the primary manufacturer that an adequate supply would be available within the time period (Exs. 20–847; 20–299; 20–154; 20–940).

Little further comment was received regarding the effective dates proposed for the other sections of the standard. It is useful to note that these dates all follow the effective dates for the final standard, which is ninety (90) days after the publication of the standard in the Federal Register. Planning for compliance, therefore, needs to be undertaken with these new dates in mind.

OSHA concludes that these dates provide sufficient time for the employer to become informed about the standard and to implement the provisions of this standard. At the same time, the dates are not excessively long and assure that all of the protection of the standard will be provided as soon as feasible.

Appendix

The final standard contains an appendix designed to assist employers

in implementing the provisions of this standard. Appendix A is incorporated as part of this standard and imposes additional mandatory obligations on employers covered by the standard. Paragraph (f)(2)(iv) of the standard requires the employer to assure that employees who initially decline to be vaccinated sign a statement declining the HB vaccination. Appendix A contains the mandatory language for the declination.

List of Subjects in 29 CFR Part 1910

AIDS, Hepatitis B, Human Immunodeficiency Virus, Hepatitis B Virus, Blood, Blood Diseases, Communicable Disease, Health, Healthcare, Health Professions, Hospitals, Protective Equipment, Immunization, Medical Research, Occupational Safety and Health.

X. Authority and Signature

This document was prepared under the direction of Gerard F. Scannell, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Ave., 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 parts 1904 and 1910 are amended as set forth below.

Signed at Washington, DC on this 26th day of November, 1991.

Gerard F. Scannell,

Assistant Secretary of Labor.

XI. The Standard

General Industry

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

PART 1910—[AMENDED]

Subpart Z—[Amended]

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

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

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

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

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

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

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

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

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

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

HBV means hepatitis B virus.

HIV means human immunodeficiency virus.

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

Other Potentially Infectious Materials means

(1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;

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

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

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

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

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

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

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

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

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

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

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

(c) *Exposure control*—(1) *Exposure Control Plan.* (i) Each employer having an employee(s) with occupational exposure as defined by paragraph (b) of this section shall establish a written Exposure Control Plan designed to

eliminate or minimize employee exposure.

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

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

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

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

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

(iv) The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure.

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

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

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

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

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

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

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

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

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

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

(iv) When provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible.

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

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

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

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

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

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

(A) Puncture resistant;

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

(C) Leakproof on the sides and bottom; and

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

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

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

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

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

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

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

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

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

(xiv) Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(*1*) Periodically reevaluate this policy;

(*2*) Make gloves available to all employees who wish to use them for phlebotomy;

(*3*) Not discourage the use of gloves for phlebotomy; and

(*4*) Require that gloves be used for phlebotomy in the following circumstances:

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

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

(*iii*) When the employee is receiving training in phlebotomy.

(x) Masks, Eye Protection, and Face Shields. Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

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

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

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

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

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

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

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

(D) Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means,

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

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

(iii) Regulated Waste.

(A) Contaminated Sharps Discarding and Containment. (*1*) Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:

(*i*) Closable;

(*ii*) Puncture resistant;

(*iii*) Leakproof on sides and bottom; and

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

(*2*) During use, containers for contaminated sharps shall be:

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

(*ii*) Maintained upright throughout use; and

(*iii*) Replaced routinely and not be allowed to overfill.

(*3*) When moving containers of contaminated sharps from the area of use, the containers shall be:

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

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

(*A*) Closable;

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

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

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

(B) Other Regulated Waste Containment.(*1*) Regulated waste shall be placed in containers which are:

(*i*) Closable;

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

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

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

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

(*i*) Closable;

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

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

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

(C) Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.

(iv) Laundry.

(A) Contaminated laundry shall be handled as little as possible with a minimum of agitation. (1) Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.

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

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

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

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

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

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

(i) Standard microbiological practices. All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

(ii) Special practices.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) The surfaces of doors, walls, floors and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.

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

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

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

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

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

(f) *Hepatitis B vaccination and post-exposure evaluation and follow-up—(1) General.* (i) The employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident.

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

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

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

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

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

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

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

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

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

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

(v) If a routine booster dose(s) of hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii).

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

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

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

(A) The source individual's blood shall be tested as soon as feasible and

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

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

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

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

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

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

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

(v) Counseling; and

(vi) Evaluation of reported illnesses.

(4) *Information Provided to the Healthcare Professional.* (i) The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

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

(A) A copy of this regulation;

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

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

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

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

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

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

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

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

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

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

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

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

BIOHAZARD

BIOHAZARD

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

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

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

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

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

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

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

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

BIOHAZARD

BIOHAZARD

(Name of the Infectious Agent)
(Special requirements for entering the area)
(Name, telephone number of the laboratory director or other responsible person.)

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

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

(ii) Training shall be provided as follows:

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

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

(C) At least annually thereafter.

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

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

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

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

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

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

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

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

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

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

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

(G) Information on the types, proper use, location, removal, handling, decontamination and 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, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;

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

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

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

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

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

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

(ix) **Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities.** Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements.

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

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

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

(h) *Recordkeeping—(1) Medical Records.* (i) The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.20.

(ii) This record shall include:

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

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

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

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

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

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

(A) Kept confidential; and

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

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

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

(A) The dates of the training sessions;

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

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

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

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

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

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

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

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

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

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

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

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

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

Appendix A to Section 1910.1030—Hepatitis B Vaccine Declination (Mandatory)

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

[FR Doc. 91-28886 Filed 12-2-91; 8:45 am]
BILLING CODE 4510-26-M