State of Alaska

Department of Labor and Workforce Development
Division of Labor Standards and Safety

Effective April 14, 2026
AKOSH PD #26-02

To: **All AKOSH Staff**

From: **Tanya Keith, Director of LSS** DocuSigned by: AFD59BBF720C48C...

Subject: Enforcement Procedures for the Occupational Exposure to the Bloodborne Pathogens Standard.

AKOSH (Alaska Occupational Safety & Health) Program Directive (PD) formally adopts the OSHA's most current CPL regarding Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens which is attached. This program directive cancels the previous PD #92-05. This instruction establishes policies and provides clarification to ensure uniform inspection procedures are followed when conducting inspections to enforce OSHA's Occupational Exposure to the Bloodborne Pathogens Standard.

This program directive is effective immediately. Please ensure that all members of your staff receive a copy of this program directive and understand how to implement it.

cc: James Wulff, Regional Administrator, OSHA, San Francisco Region Abby Lopez, Assistant Regional Administrator, OSHA, San Francisco Region Eric Christensen, State Programs Manager, OSHA, San Francisco Region Brenda Smith, Team Leader for Cooperative and State Programs, OSHA, San Francisco Region

OSHA INSTRUCTION

U.S. DEPARTMENT OF LABOR

Occupational Safety and Health Administration

DIRECTIVE NUMBER: CPL 02-02-069	EFFECTIVE DATE: November 27, 2001
SUBJECT: Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens	

****NOTE: Minor changes {in brackets} were made to this directive on March 1, 2017, to update coding instructions for the OSHA Information System (OIS), and to update referenced Web site addresses throughout. These changes do not impact this directive's enforcement policy.**

ABSTRACT

Purpose: This instruction establishes policies and provides clarification to ensure uniform inspection procedures are followed when conducting inspections to enforce the Occupational Exposure to Bloodborne Pathogens Standard.

Scope: This instruction applies OSHA-wide.

References: 29 CFR 1910.1030, Occupational Exposure to Bloodborne Pathogens
OSHA Instruction CPL 2.103, Field Inspection Reference Manual

Cancellations: This instruction cancels CPL 2-2.44D

State Impact: This instruction describes a Federal Program Change for which State adoption is not required (See Paragraph VI).

Action Offices: National, Regional and Area Offices

Originating Office: Directorate of Compliance Programs

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By and Under the Authority of
John L. Henshaw
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TABLE OF CONTENTS

I. Purpose....1

II. Scope....1

III. Cancellation....1

IV. References....1

V. Action....2

VI. Federal Program Change....2

VII. Background....3

VIII. Inspection Scheduling, and Scope....5

IX. General Inspection Procedures....5

X. Recording of Exposure Incidents....6

XI. Multi-Employer and Related Worksites....6
- A. Employment Agencies....6
- B. Personnel Services....6
- C. Home Health Services....7
- D. Physicians and Healthcare professionals....8
- E. Independent Contractors....8

XII. Federal Agency Facilities....8

XIII. Clarification of the Standard on Occupational Exposure to Bloodborne Pathogens,....9
- A. Scope and Application....9
- B. Definitions....11
- C. Exposure Control Plan....13
- D. Methods of Compliance....17
- E. HIV and HBV Research Laboratories and Production Facilities....45
- F. Hepatitis B Vaccination and Post Exposure Evaluation and Follow-up....48
- G. Employee Information and Training....59
- H. Recordkeeping....63

XIV. Interface With Other Standards....66

{ XV. Coding in the OIS....67 }

APPENDIX A - TYPICAL COMMITTEES IN HEALTH CARE FACILITIES A-1

APPENDIX B - ENGINEERING CONTROL EVALUATION FORMS B-1

APPENDIX C - WEB SITE RESOURCE LIST C-1

APPENDIX D - MODEL EXPOSURE CONTROL PLAN D-1

APPENDIX E E-1

INDEX

I. Purpose. This instruction establishes policies and provides clarifications to ensure uniform inspection procedures are followed when conducting inspections to enforce the Occupational Exposure to Bloodborne Pathogens Standard.

II. Scope. This instruction applies OSHA-wide.

III. Cancellation. This instruction cancels OSHA Instruction CPL 2-2.44D, Nov. 5, 1999.

IV. References

A. OSHA Instruction, CPL 2.103, September 26, 1994, Field Inspection Reference Manual (FIRM).
B. OSHA Instruction CPL 2.111, November 27, 1995, Citation Policy for Paperwork and Written Program Violations.
C. OSHA Instruction, CPL 2-2.30, November 14, 1980, Authorization of Review of Medical Opinions.
D. OSHA Instruction, CPL 2-2.32, January 19, 1981, Authorization of Review of Specific Medical Information.
E. OSHA Instruction, CPL 2-2.33, February 8, 1982, Rules of Agency Practice and Procedure Concerning OSHA Access to Employee Medical Records-Procedures Governing Enforcement Activities.
F. OSHA Instruction, CPL 2-2.46, January 5, 1989, Authorization and Procedures for Reviewing Medical Records.
G. OSHA Instruction, PER 8-2.4, March 31, 1989, CSHO Pre-Employment Medical Examinations.
H. Centers for Disease Control *Morbidity and Mortality Weekly Report*: "Public Health Service Guidelines for the Management of Health-Care Worker Exposures to HIV and Recommendations for Postexposure Prophylaxis." May 15, 1998; Vol. 47, No. RR-7.
I. Centers for Disease Control *Morbidity and Mortality Weekly Report*: "Recommendations for Follow-Up of Health-Care Workers After Occupational Exposure to Hepatitis C Virus". July 4, 1997; Vol. 46, No. 26.
J. Record Summary of the Request for Information (RFI) on Occupational Exposure to Bloodborne Pathogens due to Percutaneous Injury. May 20, 1999.
K. Safer Needle Devices: Protecting Health Care Workers , Directorate of Technical Support, Office of Occupational Health Nursing, October 1997.
L. Needlestick Injuries Among Health Care Workers: A Literature Review, Directorate of Technical Support, Office of Occupational Health Nursing, July, 1998.
M. International HealthCare Worker Safety Center, #407, Health Sciences Center, University of Virginia, Charlottesville, VA 22908, EPINet, Exposure Prevention Information Network, E-mail: *epinet@virginia.edu*.
N. DHHS, Public Health Service, "FDA Safety Alert: Needlestick and Other Risks from Hypodermic Needles on Secondary IV Administration Sets - Piggyback and Intermittent IV", April 16, 1992.
O. Glass Capillary Tubes: Joint Safety Advisory About Potential Risks,

OSHA/NIOSH/FDA, February, 1999 and Memorandum dated February 18, 1999, from Steve Witt to the Regional Administrators.

P. NIOSH, "Selecting, Evaluating, and Using Sharps Disposal Containers", DHHS (NIOSH) Publication No. 97-111, January 1998.

Q. Centers for Disease Control, *MMWR*, October 16, 1998/Vol.47/No. RR-19 "Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease."

R. Centers for Disease Control, *American Journal of Infection Control*, June 1998, Vol. 26, "Guideline for Infection Control in Health Care Personnel, 1998." {http://www.cdc.gov/hicpac/pdf/InfectControl98.pdf}

S. Centers for Disease Control, *MMWR*, December 26, 1997, Vol.46, No.RR-18, Immunization of Health-Care Workers: Recommendations

T. 29 CFR Part 1910.1030, Occupational Exposure to Bloodborne Pathogens; Final Rule, Federal Register/Vol.56, No.235/ December 6, 1991.

U. Training for Development of Innovative Control Technology Project, "Safety Feature Evaluation Forms".

V. 29 CFR Part 1910.1030, Occupational Exposure to Bloodborne Pathogens; Needlesticks and Other Sharps Injuries; Final Rule, Federal Register/Vol.66, No. 12/ January 18, 2001.

W. Centers for Disease Control, *MMWR*, June 29, 2001, Vol.50, No.RR-11, Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis.

V. **Action**. OSHA Regional Administrators and Area Directors should use the guidelines in this instruction to ensure uniform enforcement of the Bloodborne Pathogens Standard. The Directorate of Compliance Programs will provide support necessary to assist the Regional Administrators and Area Directors in enforcing the Bloodborne Pathogens Standard.

VI. **Federal Program Change:** This instruction describes a federal program change for which State adoption is not required. On April 19, 2001, OSHA notified the state plan states of the requirement to adopt revisions to the Bloodborne Pathogens Standard by October 18, 2001. In order to effectively enforce safety and health standards, guidance to compliance staff is necessary. Therefore, although adoption of this instruction is not required, states are expected to have standards, enforcement policies and procedures which are at least as effective as those of Federal OSHA.

A. **Preemption.** A number of states have enacted state "needlestick" laws which apply to the public sector, the private sector or both. The issuance of OSHA's revised Bloodborne Pathogens Standard has raised questions as to the status of those State laws. Section 18 of the OSH Act expresses Congress' intent, as reaffirmed by the U.S. Supreme Court in *Gade v. National Solid Wastes Management Assoc.* [505 U.S. 19, 107 (1992)], to preempt state laws relating to issues in the private sector on which Federal OSHA has promulgated occupational safety and health standards, such as the Bloodborne Pathogens Standard,

regardless of whether the requirements are more or less stringent. Preemption is a complex legal matter which can only be finally resolved by the courts when raised by an affected party. OSHA does not take any formal legal or other action with regard to preemption of state activities. However, in general, the following principles apply:

1. **State Plan States**. All OSHA-approved state plans are required to incorporate "at least as effective" needlestick protection for private sector and public sector (state and local government) employment, either through a standard or a state needlestick prevention law administered under the plan. To avoid the preemptive effect of Section 18 of the OSH Act, state needlestick prevention laws applicable to the private sector must be administered under the state plan, and in accordance with the enforcement provisions of the state OSH Act.

2. **States Without State Plans**. State "needlestick" laws and/or regulations in these states would not be affected by the preemptive effect of the federal Bloodborne Pathogens Standard to the extent to which they regulate the occupational safety and health conditions of public sector (state and local government) employment. (See: Section 3(5) of the OSH Act; 29 CFR Parts 1952 and 1956; 66 FR 5323.) However, state laws or programs which regulate private sector activities addressed by the federal Bloodborne Pathogens Standard, absent an OSHA-approved state plan, would be subject to challenge as preempted.

VII. Background. In September 1986, OSHA was petitioned by various unions representing healthcare employees to develop an emergency temporary standard to protect employees from occupational exposure to bloodborne diseases. The agency decided to pursue the development of a Section 6(b) standard and published a proposed rule on May 30, 1989.

A. The agency also concluded that the risk of contracting the hepatitis B virus (HBV) and human immunodeficiency virus (HIV) among members of various occupations within the healthcare sector required an immediate response and therefore issued OSHA Instruction CPL 2-2.44, January 19, 1988. That

instruction was superseded by CPL 2-2.44A, August 15, 1988; subsequently, CPL 2-2.44B was issued February 27, 1990.

B. On December 6, 1991, the agency issued its final regulation on occupational exposure to bloodborne pathogens (29 CFR 1910.1030). Based on a review of the information in the rulemaking record, OSHA determined that employees face a significant health risk as the result of occupational exposure to blood and other potentially infectious materials (OPIM) because they may contain bloodborne pathogens. These pathogens include but are not limited to HBV, which causes hepatitis B; HIV, which causes acquired immunodeficiency syndrome (AIDS); hepatitis C virus; human T-lymphotrophic virus Type 1; and pathogens causing malaria, syphilis, babesiosis, brucellosis, leptospirosis, arboviral infections, relapsing fever, Creutzfeldt-Jakob disease, and viral hemorrhagic fever. The agency further concludes that these hazards can be minimized or eliminated by 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. Both the standard and CPL 2-2.44C became effective on March 6, 1992.

C. On September 9, 1998 OSHA published a Request for Information (RFI) on engineering and work practice controls used to eliminate or minimize the risk of occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps. The responses indicated that safer medical devices along with training are the most effective means of reducing injury rates. A Summary of the comments received on response to the RFI was published in March 1999. On November 5, 1999 CPL 2-2.44D was issued. It incorporated information from the RFI, past interpretations and several CDC guidelines on vaccination and post-exposure prophylaxis.

D. On November 6, 2000 the Needlestick Safety and Prevention Act was signed into law (Public Law 106-430). It directed OSHA to revise the Bloodborne Pathogens standard to include new examples in the definition of engineering controls; to require that exposure control plans reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; to require employers to document annually in the exposure control plans consideration and implementation of safer medical devices; to require employers to solicit input from non-managerial employees responsible for direct patient care in the identification, evaluation, and selection of engineering and work practice controls; to document this input in the exposure control plan; and to require certain employers to establish and maintain a log of percutaneous injuries from contaminated sharps. OSHA published these revisions on January 18, 2001 with an effective date of April 18, 2001.

VIII. Inspection Scheduling, and Scope.

A. Inspection scheduling should be conducted in accordance with the procedures outlined in the FIRM (CPL 2.103), Chapter II, Inspection Procedures.

B. All inspections, programmed or unprogrammed, should include, if appropriate, a review of the employer's exposure control plan and employee interviews to assess compliance with the standard.

C. Expansion of an inspection to areas involving the hazard of occupational exposure to blood or other potentially infectious materials (including on site healthcare units and emergency response or first aid personnel) should be performed when:

1. The exposure control plan or employee interviews indicate deficiencies in complying with OSHA requirements, as set forth in 29 CFR 1910.1030 or this instruction.

2. Relevant formal employee complaints are received which are specifically related to occupational exposure to blood or OPIM.

3. A fatality/catastrophe inspection is conducted as the result of occupational exposure to blood or OPIM.

IX. General Inspection Procedures.

The procedures given in the FIRM, Chapter II, should be followed except as modified in the following sections:

A. Where appropriate, the facility administrator, as well as the directors of infection control, employee (occupational) health, training and education, and environmental services (housekeeping) will be included in the opening conference or interviewed early in the inspection.

B. The facility's sharps injury log and any other file of "incident reports" that document the circumstances of exposure incidents in accordance with the provisions in the exposure control plan, and any first aid log of injuries, should be reviewed. The compliance officer should ask for any other additional records that track bloodborne incidents. The compliance officer should review the most recent Part 1904 - Recording and Reporting Occupational Injuries and Illnesses regulations prior to citing recordkeeping violations. See Paragraph X below.

C. Compliance officers should take necessary precautions to avoid direct contact with blood or OPIM and should not participate in activities that will require them to come into contact with blood or OPIM. The CSHO should avoid direct contact with needles or other sharp instruments potentially contaminated with blood or OPIM. To evaluate such activities, compliance officers normally should establish the existence of hazards and adequacy of work practices through employee interviews and should observe them at a safe distance.

D. On occasions when entry into potentially hazardous areas is judged necessary, the compliance officer should be properly equipped as required by the facility as well as by his/her own professional judgment, after consultation with the supervisor, who should refer to OSHA's exposure control plan for further guidance.

E. Compliance officers should use appropriate caution when entering patient care areas of the facility. When such visits are judged necessary for determining actual conditions in the facility, the privacy of patients must be respected. Photos or videos are normally not necessary and in no event should identifiable photos be taken without the patient's consent.

X. Recording of Exposure Incidents. The new recordkeeping rule effective January 1, 2002 requires at 29 CFR 1904.8 that all employers, whether or not they are covered by the bloodborne pathogens standard, record all work-related needlesticks and cuts from sharp objects that are contaminated with another person's blood or OPIM on the 300 Log as an injury. The employee's name must not be entered on the 300 Log. [See the requirements for privacy cases in paragraphs **1904.29(b)(6)** through **(b)(9)**.] If the employee is later diagnosed with an infectious bloodborne disease, the identity of the disease must be entered and the classification must be changed to an illness. If an employee is splashed or exposed to blood or OPIM without being cut or punctured, the incident must be recorded on the OSHA 300, if it results in the diagnosis of a bloodborne illness or it meets one or more of the recording criteria of **1904.7**.

XI. Multi-Employer and Related Worksites. There are a number of different types of multi-employer worksites. This paragraph addresses a few typical situations but does not address all the circumstances that occur. In addition, this paragraph deals with situations in which employees are sent out to sites that are not multi-employer worksites. Where these guidelines do not address a particular question, see CPL 2-0.124, Multi-Employer Citation Policy.

A. **Employment Agencies.** An employment agency refers job applicants to potential employers but does not put these workers on the payroll or otherwise establish an employment relationship with them; thus, the employment agency is not the employer of these workers. These agencies shall not be cited for violations affecting the workers they refer. The company that uses these workers, *e.g.*, a hospital, is the employer of these workers and shall be cited for all violations affecting them.

B. **Personnel Services.** Personnel services firms employ medical care staff and service employees who are assigned to work at hospitals and other healthcare facilities that contract with the firm. Typically, the employees are on the payroll of the personnel services firm, but the healthcare facility exercises day-to-day supervision over them. In these circumstances, due to the concerns expressed by the court in **American Dental Association v. Martin**, 984 F.2d 823, 829-30 (7th Cir. 1993) (dictum about medical personnel services) the personnel services firm

should be cited for violations of the bloodborne pathogens standard only in the following categories: (1) hepatitis B vaccinations; (2) post-exposure evaluation and follow-up; (3) recordkeeping under paragraph (h) of the standard; (4) generic training; (5) violations occurring at the healthcare facility about which the personnel services firm actually knew and where the firm failed to take reasonable steps to have the host employer (the employer using the workers, *e.g.*, a hospital) correct the violation (see FIRM multi-employer worksite guidelines); and (6) pervasive serious violations occurring at the healthcare facility about which the personnel service firm could have known with the exercise of reasonable diligence.

When the host employer exercises day-to-day supervision over the personnel service workers, they are the employees of the host employer, as well as of the personnel service, and thus the host employer must comply with all provisions of the standard with respect to these workers. With respect to Hepatitis B vaccination, post-exposure evaluation and follow-up, recordkeeping, and generic training, the host employer's obligation is to take reasonable measures to assure that the personnel service firm has complied with these provisions.

C. **Home Health Services.** The **American Dental Association v. Martin** decision upheld the bloodborne pathogens standard but restricted its application in the home health services industry. These are companies whose employees provide home health services in private homes. The court held that OSHA had not adequately considered feasibility problems for such employers, where employees work at sites that the employer does not control. As a result, OSHA may not cite those employers for site-dependent provisions of the standard when the hazard is site-specific.

In implementing this decision, OSHA determined that the employer will not be held responsible for the following site-specific violations: housekeeping requirements, such as the maintenance of a clean and sanitary worksite and the handling and disposal of regulated waste; ensuring the use of personal protective equipment; and ensuring that specific work practices are followed (e.g., handwashing with running water) and ensuring the use of engineering controls.

The employer will be held responsible for all non-site-specific requirements of the standard, including the non-site specific requirements of the exposure control plan, hepatitis B vaccinations, post exposure evaluation and follow-up, recordkeeping, and the generic training requirements. OSHA will also cite employers for failure to supply appropriate personal protective equipment to employees.

D. **Physicians and Healthcare professionals who have established an independent practice.** In applying the provisions of the standard in situations involving physicians, the status of the physician is important. Physicians may be

employers or employees. Physicians who are unincorporated sole proprietors or partners in a bona fide partnership are employers for purposes of the OSH Act and may be cited if they employ at least one employee (such as a technician or secretary). Such physician-employers may be cited if they create or control bloodborne pathogens hazards that expose employees at hospitals or other sites where they have staff privileges in accordance with the multi-employer worksite guidelines of CPL 2-0.124, Multi-Employer Citation Policy. Because physicians in these situations are not themselves employees, citations may not be based on the exposure of such physicians to the hazards of bloodborne diseases.

Physicians may be employed by a hospital or other healthcare facility or may be members of a professional corporation and conduct some of their activities at host employer sites where they have staff privileges. In general, professional corporations are the employers of their physician-members and must comply with the hepatitis B vaccination, post-exposure-evaluation and follow up, recordkeeping, and generic training provisions with respect to these physicians when they work at host employer sites. The host employer is not responsible for these provisions with respect to physicians with staff privileges, but in appropriate circumstances, may be cited under other provisions of the standard in accordance with the multi-employer worksite guidelines of CPL 2-0.124, Multi-Employer Citation Policy. The professional corporation may also be cited under other provisions of the standard for the exposure of its physicians and other workers at a host employer site in accordance with the multi-employer worksite guidelines of CPL 2-0.124, Multi-Employer Citation Policy.

E. **Independent Contractors.** These are companies that provide a service, such as radiology or housekeeping, to host employers. They provide supervisory personnel, as well as rank-and-file workers, to carry out the service. These companies and the host employers are responsible for complying with all provisions of the standard in accordance with the multi-employer worksite guidelines of CPL 2-0.124, Multi-Employer Citation Policy.

XII. Federal Agency Facilities. Agencies of the Federal Government are covered by this instruction.

XIII. Clarification of the Standard on Occupational Exposure to Bloodborne Pathogens, 29 CFR 1910.1030. The guidance that follows relates to specific provisions of **29 CFR 1910.1030** and is provided to assist compliance officers in conducting inspections where the standard may be applicable:

A. **Scope and Application - 29 CFR 1910.1030(a)**. This paragraph defines the range of employees covered by the standard.

1. Since there is no population that is risk free for HIV, HBV or other bloodborne disease infection, any employee who has occupational exposure to blood or other potentially infectious material will be included within the scope of this standard.

2. Although a list is included below of a number of job classifications that may be associated with tasks that have occupational exposure to blood and other potentially infectious materials, **the scope of this standard is not limited to employees in these jobs**. The hazard of exposure to infectious materials affects employees in many types of employment and is not restricted to the healthcare industry. At the same time, **employees in the following jobs are not automatically covered unless they have the potential for occupational exposure**:

Physicians, physician's assistants, nurses, nurse practitioners, and other healthcare employees in clinics and physicians' offices; employees of clinical and diagnostic laboratories; housekeepers in healthcare and other facilities; personnel in hospital laundries or commercial laundries that service healthcare or public safety institutions; tissue bank personnel; employees in blood banks and plasma centers who collect, transport, and test blood; freestanding clinic employees (e.g., hemodialysis clinics, urgent care clinics, health maintenance organization (HMO) clinics, and family planning clinics); employees in clinics in industrial, educational, and correctional facilities (e.g., those who collect blood, and clean and dress wounds); employees designated to provide emergency first aid; dentists, dental hygienists, dental assistants and dental laboratory technicians; staff of institutions for the developmentally disabled; hospice employees; home healthcare workers; staff of nursing homes and long-term care facilities; employees of funeral homes and mortuaries; HIV and HBV research laboratory and production facility workers; employees handling regulated waste; custodial workers required to clean up contaminated sharps or spills of blood or OPIM; medical equipment service and repair personnel; emergency medical technicians, paramedics, and other emergency medical service providers; fire fighters, law enforcement personnel, and correctional officers (employees in the private sector, or the Federal Government, or a state or local government in a state that has an OSHA-approved state plan); maintenance workers, such as plumbers, in healthcare facilities and employees of substance abuse

clinics.

3. **INSPECTION GUIDELINES**. The scope paragraph of this standard states that it "applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b)." The compliance officer must take careful note of the definition of "occupational exposure" in paragraph (b) in determining if an employee is covered by this standard.

   a. Part-time, temporary, and healthcare workers known as "per diem" employees are covered by this standard.

   b. OSHA jurisdiction extends only to employees in the workplace. It does not extend to students if they are not also considered employees; to state, county, or municipal employees; to health care professionals who are sole practitioners or partners, or to the self-employed. However, the 26 OSHA-approved state plans must protect state and local government workers under an "at least as effective" state standard.

   c. If an employee is trained in first aid and identified by the employer as responsible for rendering medical assistance **as part of his/her job duties**, that employee is covered by the standard. See the citation policy for paragraph **(f)(2)** of the standard below regarding designated first aid providers, who administer first aid as a **collateral duty** to their routine work assignments. An employee who routinely provides first aid to fellow employees with the knowledge of the employer may also fall, *de facto*, under this designation even if the employer has not officially designated this employee as a first aid provider.

   d. Exposure to bloodborne pathogens in **shipyard operations** is covered under 29 CFR 1915.1030, which states that its requirements are identical to those in 29 CFR 1910.1030.

   e. **Other Industries:** The bloodborne pathogens standard **does not** apply to the construction, agriculture, marine terminal and longshoring industries. OSHA has not, however, stated that these industries are free from the hazards of bloodborne pathogens. For industries not covered by the bloodborne pathogens standard, Section 5(a)(1) of the OSH Act provides that "each employer shall furnish to each of his employees employment and a place of employment which is free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees." The General Duty Clause should not be used to cite for violations of the bloodborne pathogens rule, but may be used to

cite for failure to provide a workplace free from exposure to bloodborne pathogens. Section 5(a)(1) citations must meet the requirements outlined in the FIRM, OSHA Instruction CPL 2.103, Chapter III. Failure to implement all or any part of **29 CFR 1910.1030** should not be, in itself, the basis for a citation. Accordingly, **29 CFR 1910.1030** should not be specifically referenced in a citation.

B. **Definitions - 29 CFR 1910.1030(b)**. The following provides further clarifications of some definitions found in this paragraph:

1. **"Blood"**: The term "human blood components" includes plasma, platelets, and serosanguineous fluids (e.g., exudates from wounds). Also included are medications derived from blood, such as immune globulins, albumin, and factors 8 and 9.

2. **"Bloodborne Pathogens"**: While HBV and HIV are specifically identified in the standard, **the term includes any pathogenic microorganism** that is present in human blood or OPIM and can infect and cause disease in persons who are exposed to blood containing the pathogen. **Pathogenic microorganisms can also cause diseases such as hepatitis C, malaria, syphilis, babesiosis, brucellosis, leptospirosis, arboviral infections, relapsing fever, Creutzfeldt-Jakob disease, adult T-cell leukemia/lymphoma (caused by HTLV-I), HTLV-I associated myelopathy, diseases associated with HTLV-II, and viral hemorrhagic fever.**

   NOTE: According to the Centers for Disease Control and Prevention (CDC), hepatitis C virus (HCV) infection is the most common chronic bloodborne infection in the United States. (*MMWR: Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease, October 16, 1998/Vol.47/No. RR-19.)*

   HCV is a viral infection of the liver that is transmitted primarily by exposure to blood. Currently there is no vaccine effective against HCV. See discussion of paragraph **(f)(3)** below.

3. **"Exposure Incident"**: In this definition, "non-intact skin" includes skin with dermatitis, hangnails, cuts, abrasions, chafing, acne, etc

4. **"Engineering controls"** means controls that isolate or remove the bloodborne pathogens hazard from the workplace. Examples include safer medical devices, such as sharps with engineered sharp injury protection (SESIPs) and needleless systems. These two terms were further defined in the revision to 1910.1030 mandated by the Needlestick Safety and Prevention Act.

5. **‘‘Needleless Systems’’** means a device that does not use needles for: (1) the collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (2) the administration of medication or fluids; or (3) any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps. ‘‘Needleless Systems’’ provide an alternative to needles for the specified procedures, thereby reducing the risk of percutaneous injury involving contaminated sharps. Examples of needleless systems include, but are not limited to, intravenous medication delivery systems that administer medication or fluids through a catheter port or connector site using a blunt cannula or other non-needle connection, and jet injection systems that deliver subcutaneous or intramuscular injections of liquid medication through the skin without use of a needle.

6. **"Occupational Exposure**": The term "reasonably anticipated contact" includes the potential for contact as well as actual contact with blood or OPIM. Lack of history of blood exposures among designated first aid personnel of a particular manufacturing site, for instance, does not preclude coverage. "Reasonably anticipated contact" includes, among others, contact with blood or OPIM (including regulated waste) as well as incidents of needlesticks. For example, a compliance officer may document incidents in which an employee observes a contaminated needle on a bed or contacts other regulated waste in order to substantiate "occupational exposure."

   NOTE: This definition does not cover "Good Samaritan" acts (i.e. voluntarily aiding someone in one’s place of employment) that result in exposure to blood or other potentially infectious materials from voluntarily assisting a fellow employee, although OSHA encourages employers to offer follow-up procedures to these employees in such cases.

7. **"Other Potentially Infectious Materials" (OPIM)**: Coverage under this definition also extends to blood and tissues of experimental animals that are infected with HIV or HBV.

8. **"Parenteral"**: This definition includes human bites that break the skin, which are most likely to occur in violent situations such as may be encountered by prison and law enforcement personnel and in emergency rooms or psychiatric wards.

9. **‘‘Sharps with Engineered Sharps Injury Protections (SESIPs)’’** are defined as ‘‘a nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.’’ This term encompasses a broad array of devices that make injury involving a contaminated sharp less likely. They include, but are not limited to: syringes with guards or sliding sheaths that shield the attached needle after use; needles that retract into a syringe after use; shielded or retracting catheters used to access the bloodstream for intravenous administration of medication or fluids; intravenous medication delivery systems that administer medication or fluids through a catheter port or connector site using a needle that is housed in a protective covering, blunt suture needles; and plastic (instead of glass) capillary tubes.

C. **Exposure Control Plan - 29 CFR 1910.1030(c)**. This paragraph requires the employer to identify those tasks and procedures in which occupational exposure may occur and to identify the positions whose duties include those tasks and procedures identified as having occupational exposure. 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 protections of the standard.

1. **INSPECTION AND CITATION GUIDELINES**. The Compliance Officer should review the facility's written exposure control plan. While the plan may be part of a larger document, such as one addressing all health and safety hazards in the workplace, in order for the plan to be accessible to employees, it must be a cohesive entity by itself or there must be a guiding document which states the overall policy goals and references the elements of existing separate policies that comprise the plan.

   The Compliance Officer should determine whether the plan is reviewed annually and updated to reflect significant modifications in tasks or

procedures which may result in occupational exposure as required in paragraph **(c)(1)(iv)**.

The location of the plan may be adapted to the circumstances of a particular workplace, provided that the employee can access a copy at the workplace, during the workshift (e.g., if the plan is maintained solely on computer, employees must be trained to operate the computer). In accordance with 29 CFR 1910.1020, a hard copy of the exposure control plan must be made available to the employee within 15 working days of the employee's request.

If a facility is lacking an exposure control plan and the other requirements of the standard have not been implemented, the other relevant paragraphs of the standard should be cited in addition to **paragraph (c)**. These should normally be classified as serious violations.

2. **Paragraphs (c)(1)(ii)(A) and (c)(2)(i)**. The exposure determination requires employers to identify and document:

   a. Those job classifications in which all employees have occupational exposure, and/or

   b. Those job classifications in which **some** employees have occupational exposure.

      1) In the latter case, the specific tasks and procedures, or groups of closely related tasks and procedures, which are associated with occupational exposure must be delineated. For example, only **some** of the employees in a hospital laundry room might be assigned the task of handling contaminated laundry.

      2) The tasks and procedures that are grouped must be related; i.e., they must share a common activity such as "vascular access procedures," "handling of contaminated sharps," or "handling of deceased persons," etc.
      NOTE: If a job classification, task, or procedure involving occupational exposure is omitted from the list, but all employees in the job or performing the task or procedure have been included in all other aspects of the plan (e.g., vaccinations, training, etc.), it is to be considered an other-than-serious violation.

c. The exposure determination must have been made without taking into consideration the use of personal protective clothing or equipment.

3. **Paragraph (c)(1)(ii)(B)**. While the primary purpose of the exposure control plan is to identify those employees who have occupational exposure and to commit the employer to a timetable for implementation of the standard's requirements, paragraphs **(d)-(h)** of the standard must also be addressed in a manner appropriate to the circumstances of the particular workplace. An annotated copy of the final standard may be adequate for small facilities. Larger facilities could develop a broad facility-wide program incorporating provisions from the standard that apply to their establishments.

4. **Paragraph (c)(1)(ii)(C)**. The exposure control plan must include the procedure for evaluating the circumstances surrounding exposure incidents, in accordance with paragraph **(f)(3)(i)**.

CITATION GUIDELINES: If the employer failed to include procedures for the documentation of exposure incidents in the exposure control plan, a citation for paragraph **(c)(1)(ii)(C),** should be issued. If procedures are included in the plan but not implemented, then **paragraph (f)(3)(i)** should be cited.

5. **Paragraph (c)(1)(iv)** requires the employer to review and update the exposure control plan at least annually (every 12 months) 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. As stated in the preamble to the standard, the review and update must reflect innovations in procedure and technological developments that eliminate or reduce exposure to bloodborne pathogens. [56 Fed. Reg. 64109-10 (1991).] This includes, but is not limited to, newly available medical devices designed to reduce the risk of percutaneous exposure to bloodborne pathogens. A periodic review ensures that the exposure control plan remains current with the latest information and scientific knowledge pertaining to bloodborne pathogens. A review of the sharps log required in paragraph **(h)(5)** can identify problem areas and/or ineffective devices which may need replacement. The exposure control plan must document consideration and implementation of appropriate commercially available and effective engineering controls designed to eliminate or minimize exposure. The Exposure Control Plan must also include the procedure for evaluation of

circumstances surrounding exposure incidents. See discussion of paragraph **(f)(3)(i)**.

NOTE: While the exact number of injuries sustained annually in the United States is unknown, current estimates vary between 590,000 and 800,000 injuries annually. The implementation of effective engineering controls can reduce needlesticks and other sharps injuries. Effective engineering controls include safer medical devices used to prevent percutaneous injuries before, during, or after use through safer design features. When the Final Rule was published in December 1991, the variety of engineering controls was limited although some were available. At that time adequate data and information on effective engineering controls and their effectiveness were not available. The preamble to the Final Rule in 1991 stated that "with regard to percutaneous incidents, such as needlestick injuries, evidence indicated that most injuries were preventable . . . 75 percent of all exposure incidents are caused by disposable syringes . . . and could be prevented by using syringes which incorporate resheathing or retracting designs." [56 Fed. Reg./64057(1991)] Since publication of the standard, there has been a substantial increase in the number and assortment of effective engineering controls available to employers. There is now a large body of research and data available to OSHA and to the public concerning the effectiveness of these engineering controls.

CITATION GUIDELINES: The employer must review and update the plan, as necessary, to reflect changes in technology, such as the use of effective engineering controls, that can eliminate or minimize exposures. If the employer did not review and update its exposure control plan at least annually, paragraph **(c)(1)(iv)** should be cited. See Appendix D for a Sample Exposure Control Program.

6. **Paragraph (c)(1)(v)** requires the employer to solicit input from non-managerial employees responsible for direct patient care in the identification, selection and evaluation of effective engineering and work practice controls and document the solicitation in the Exposure Control Plan. The employer must solicit employee input in a manner appropriate to the circumstances in the workplace. Methods for soliciting employee input may include joint labor-management safety committees; involvement in informal problem-solving groups; participation in safety meetings and audits, employee surveys, worksite inspections, or exposure incident investigations; using a suggestion box or other effective methods for obtaining written employee comments; and participation in the evaluation of devices through pilot testing. The opportunities for

employee input shall be effectively communicated to employees. Input from employees covered by a collective bargaining agreement may also be requested through their bargaining agent. Employers are not required to request input from **each and every** exposed employee; however, the employees selected must represent the range of exposure situations encountered in the workplace (e.g., emergency department, pediatrics, nuclear medicine). The employer must document the process by which the input was requested and identify the employees or the positions of those employees who were involved.

INSPECTION GUIDELINES: Compliance Officers should determine how the devices used in the facility were selected and review the employers' documentation of their employees' input. Many departments require different features in a safer device and have different concerns for both employee and patient safety. Employees in various departments and situations should be interviewed to determine the extent to which the employer solicited employee input. The fact that some employees have not provided input does not automatically mean the employer has not solicited input, but should prompt the compliance officer to thoroughly investigate whether input was solicited.

CITATION GUIDELINES: This section should only be cited if input was not solicited from non-managerial employees involved in administering treatment or performing any procedure in the presence of an individual receiving care. Any employee who, for example, collects blood from patients in a nursing home; administers flu vaccinations in a factory employee health unit, or collects blood from other employees for research purposes would be performing "patient care." Laboratory workers, on the other hand, who do not have patient contact, would not be included in this provision.

D. **Methods of Compliance - 29 CFR 1910.1030(d)**. Paragraph **(d)** sets forth the method by which employers must protect their employees from the hazards of bloodborne pathogens and comply with this standard through the use of universal precautions, engineering controls, work practice controls, personal protective equipment, proper housekeeping and handling of regulated waste.

1. **Universal Precautions - Paragraph (d)(1)**. Universal precautions are OSHA's required methods of control to protect employees from exposure to all human blood and OPIM. The term "universal precautions" refers to a concept of bloodborne disease control which requires that all human

blood and OPIM be treated as if known to be infectious for HIV, HBV, HCV or other bloodborne pathogens, regardless of the perceived "low risk" status of a patient or patient population.

Alternative concepts in infection control are called Body Substance Isolation (BSI) and Standard Precautions. These methods define **all** body fluids and substances as infectious. These methods incorporate not only the fluids and materials covered by this standard but expands coverage to include all body fluids and substances.

These concepts are acceptable alternatives to universal precautions, provided that facilities utilizing them adhere to all other provisions of this standard.

CITATION GUIDELINES. If the employer has a policy of treating the blood or OPIM of some patients as potentially infectious and the blood or OPIM of others (e.g., the elderly or children) as not infectious, a violation of this provision exists.

2. **Engineering Controls and Work Practices - Paragraph (d)(2)(i).** This paragraph requires the employer to institute engineering and work practice controls as the primary means of eliminating or minimizing employee exposure. It conforms to OSHA's traditional adherence to a hierarchy of controls [See 56 Fed. Reg. 64114-15 (1991)]. OSHA has always required employers to use engineering and work practice controls. Thus the employer must use engineering and work practice controls that eliminate occupational exposure or reduce it to the lowest feasible extent. Preventing exposures requires a comprehensive program, including the use of engineering controls (e.g., needleless devices, shielded needle devices, and plastic capillary tubes) and proper work practices (e.g., no-hands procedures in handling contaminated sharps, eliminating hand-to-hand instrument passing in the operating room). Paragraph XIII.B provides definitions of engineering controls, safer medical devices, needleless systems, and sharps with engineered sharps injury protection. If engineering and work practice controls do not eliminate exposure, the use of personal protective equipment (e.g., eye protection) is required. The use of sharps containers is not an acceptable means of complying with **(d)(2)(i)**. The specific provisions of **(d)(4)(iii)(A)** covers sharps containers and thus preempts this section, pursuant to 29 CFR 1905 (specific standard preempts general standard).

Note: Needles that will not become contaminated by blood during use (such as those used only to draw medication from vials) are not required to

have engineering controls under this standard. The needle used for the actual injection, however, must incorporate engineering controls.

The employer must also make changes to its Exposure Control Plan to include the selection and use of these engineering controls. [**See discussion of paragraph (c)(1)(iv)** above.] Safer medical devices are generally of two types: needleless systems (e.g., needleless IV connectors) and sharps with engineered sharps injury protection (e.g., self-sheathing needles on syringes). Substitution methods such as the use of plastic (instead of glass) capillary tubes are also available. Appendix B (Safety Evaluation Forms) and Appendix C (Web Site Resource List) have been provided to assist in the evaluation of these devices. Paragraph **(c)(1)(v)** requires employers to involve employees in the selection of effective engineering controls to improve employee acceptance of the newer devices and to improve the quality of the selection process.

Where engineering controls will reduce employee exposure either by removing, eliminating or isolating the hazard, they **must** be used. Significant improvements in technology are most evident in the growing market of safer medical devices that minimize, control or prevent exposure incidents.

Ideally, the most effective way of removing the hazard of a contaminated needle is to eliminate the needle completely by converting to needleless systems. When this is not possible, removal of the hazard as soon as possible after contamination is required. This is best accomplished by using a sharp with engineered sharps injury protection, which shields the sharp from exposure as soon as it is withdrawn from the patient.

No one medical device is appropriate in all circumstances of use. Employers must implement the safer medical devices that are appropriate, commercially available, and effective.

The FDA is responsible for clearing medical devices for marketing, although this “clearance” alone is not enough to guarantee the device will be effective in the workplace. The employer must rely on further evidence to ensure its effectiveness in the situations it will be used . There are specific design features for recessed needle systems that the Food and Drug Administration (FDA Safety Alert, April 16, 1992 and Draft Supplementary Guidance on the Content of Premarket Notification 510(K) Submissions for Medical Devices with Sharps Injury Prevention Features, March 1995) has published and agrees are important in preventing percutaneous injury. These design features have the following characteristics:

a. A fixed safety feature provides a barrier between the hands and the

needle after use; the safety feature should allow or require the worker's hands to remain behind the needle at all times;

b. The safety feature is an integral part of the device and not an accessory;

c. The safety feature is in effect before disassembly and remains in effect after disposal to protect users and trash handlers, and for environmental safety;

d. The safety feature is as simple as possible, and requiring little or no training to use effectively.

INSPECTION GUIDELINES. The Compliance Officer should determine through interviews or observation of work involving exposure to blood or OPIM whether sufficient engineering controls and work practices are used. While it is generally accepted that an exposure incident can occur at any time or place, a review of the facility records can better direct the Compliance Officer to areas that are more likely to be sites of exposure incidents. Data from The Uniform Needlestick and Sharp Object Injury Report, 77 Hospitals, 1993-1995 (Exposure Prevention Information Network EPINet at {https://www.medicalcenter.virginia.edu/epinet}) show that injuries occurred, in order of frequency, in patient rooms, operating rooms, emergency departments, and intensive/critical care units. The report indicates that nurses (RN's and LPN's) were injured more often than any other type of healthcare worker. Furthermore, the report finds that an overwhelming majority (93%) of the injuries were caused by items that were not a "safe design with a shielded, recessed, or retractable needle." The Compliance Officer should determine if there were occasions where injuries were incurred during the same procedure, using the same equipment, in the same location or among similar employees (e.g., housekeepers), and determine whether effective engineering or work practices have been or can be implemented to prevent or minimize future injuries. The Compliance Officer should investigate whether the employer has instituted alternative engineering controls and work practices to eliminate or minimize employee exposure in areas where exposure incidents have been documented.

CITATION GUIDELINES. Paragraph **(d)(2)(i)** should be cited for failure to use engineering/work practice controls as discussed above. The lack of recorded injuries on the sharps injury log or OSHA 200 (through the end of 2001) or OSHA 300 (effective January 1, 2002) does not exempt the employer from this provision. The Compliance Officer should carefully evaluate the exposure control measures, such as effective engineering controls, that are in use at the facility. Part of this evaluation

should include whether other devices that are commercially available were reviewed or considered by the employer and whether there is evidence that other engineering controls would reduce exposures. Such evidence might include CDC studies of efficacy, pilot tests by the employer, or data available in published studies. The Record Summary indicated that over 87% of the respondents who provided information on device usage were already using needleless or shielded needle IV line access in 1998. Other popular devices include blunt suture needles, safer syringes, and safer phlebotomy devices. This is not an exhaustive list of effective engineering controls that are available. Appendix B provides some examples of forms an employer might use for evaluation of engineering controls.

Compliance with this paragraph should take into consideration that the availability or use of an engineering control is not enough to guarantee that an employee cannot be injured. Employee acceptance and employee training are necessary for an engineering control to be effective. The Compliance Officer should evaluate the training in accordance with paragraph **(g)(2)(vii)**. A citation for the appropriate paragraph of **(g)(2)(vii)** should be grouped with paragraph **(d)(2)(i)**, if the Compliance Officer determines that inadequate training caused the failure to use such controls. Examples of effective engineering controls can be found in several resources linked on OSHA's Needlestick Injuries page, {https://www.osha.gov/SLTC/bloodbornepathogens/evaluation.html}.

Citations for paragraph **(d)(2)(i)** should be issued when these criteria are met:

> If no engineering controls are being used to eliminate or minimize exposure, a citation should be issued.
>
> If a combination of engineering and work practice controls used by the employer does not eliminate or minimize exposure, the employer shall be cited for failing to use engineering and work practice controls.
>
> When the compliance officer finds that an employer is using an engineering control, but believes another device would be clearly more effective than the one in use, the compliance officer should document how the device was being used and how it was selected. The compliance officer should consult with the Regional Bloodborne Pathogens Coordinator to determine if a violation of **(d)(2)(i)** exists.

The citation should state that the employer failed to use engineering controls or work practices that would "eliminate or minimize exposures"

and identify particular engineering controls, such as self-sheathing needles, and particular work practice controls, such as no-hand procedures in handling contaminated sharps, which should have been used. After each particular control mentioned in the citation, the words "among other controls" should be added unless it is clear that there are no other controls.

Paragraph **(d)(2)(i)** should not be cited where another provision of the standard mandates a specific engineering or work practice control (e.g., paragraph **(d)(4)(iii)(A)** for sharps containers and paragraph **(d)(2)(vii)** for the prohibition of recapping).

3. **Paragraph (d)(2)(ii)**. This paragraph requires that engineering controls be examined and maintained or replaced on a regular schedule to ensure their effectiveness. Regularly scheduled inspections are required to confirm, for instance, that engineering controls such as safer devices continue to function effectively, that protective shields have not been removed or broken, and that physical, mechanical or replacement-dependent controls are functioning as intended.

CITATION GUIDELINES. It is the employer's responsibility to regularly examine and repair and/or replace engineering controls as often as necessary to ensure that each control is maintained and that it provides the protection intended. If the Compliance Officer finds that there is no system for regular checking of the engineering controls or that regular checking is not done, paragraph **(d)(2)(ii)** should be cited.

4. **Paragraphs (d)(2)(iii) through (d)(2)(vi)**. These paragraphs require employers to provide handwashing facilities which are readily accessible to employees. Handwashing with soap and at least tepid running water must be performed as soon as feasible, particularly in cases of gross contamination, to adequately flush contaminated material from the skin.

   b. **Paragraph (d)(2)(iv).** This paragraph allows the use of alternative handwashing methods as an interim measure when soap and water are not a feasible means of washing the hands or other parts of the body. In such cases, the employer must provide either antiseptic hand cleaner and clean cloth/paper towels, or antiseptic towelettes. When these types of alternatives are used, employees must wash their hands (or other affected area) with soap and running water as soon as feasible thereafter.

   The Compliance Officer may see these types of alternative washing methods used by ambulance-based paramedics and emergency medical technicians (EMT's), fire fighters, police, and mobile blood collection personnel who are exposed to blood or OPIM but have no means of washing up with running water at the

site of the exposure (e.g., a crime scene, traffic accident, fire).

c. **Paragraph (d)(2)(v).** This paragraph requires employers to ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other PPE. There is no requirement for handwashing upon leaving the work area unless contact with blood or OPIM has occurred or gloves/PPE have been removed.

CITATION GUIDELINES. If the compliance officer finds that required handwashing facilities are not being provided, paragraph **(d)(2)(iii)** should be cited unless the employer demonstrates that handwashing facilities are not feasible. If infeasibility is demonstrated, paragraph **(d)(2)(iv)** should be cited when the required alternatives are not used. If handwashing is not performed by the employees immediately or as soon as feasible after exposures or removal of gloves, paragraphs **(d)(2)(iv), (v), or (vi)** should be cited. A citation for one or more of these paragraphs may be grouped with the pertinent training paragraphs of **(g)(2)** if employees have not been adequately trained in handwashing procedures.

At a fixed establishment, if handwashing facilities are not readily accessible, i.e., within a reasonable distance from the area where the employee is exposed, **(d)(2)(iii)** should be cited. For example, if an employee must leave the work area and thread his/her way through doorways and/or stairs to wash, there is a reasonable chance of resultant environmental surface contamination. This situation is a violation.

5. **Paragraph (d)(2)(vii**). Shearing or breaking of contaminated sharps is completely prohibited by this paragraph. Bending, recapping, or removing contaminated needles is prohibited as a general practice. The practice of removing the needle from a used blood-drawing/phlebotomy device is rarely, if ever, required by a medical procedure. Because such devices involve the use of a double-ended needle, such removal clearly exposes employees to additional risk. Devices with needles must be used and immediately discarded after use, un-recapped, into accessible sharps containers. Certain circumstances may exist, however, in which

recapping, bending, or removing needles is necessary (e.g., administering incremental doses of a medication such as an anesthetic to the same patient).

b. In these procedures, if the employer can demonstrate that such action is required by a specific medical procedure, or that no alternative is feasible, recapping must be performed by some method other than the traditional two-handed procedure, e.g., by means of a mechanical device or forceps.

c. The use of the properly performed one-hand scoop method (in which the hand holding the sharp is used to scoop up the cap from a flat surface) for recapping is a recognized and acceptable method; however, the scoop method must be performed in a safe manner and must also be limited to situations in which recapping is necessary.

d. If the employer claims that no alternative to bending, recapping, or removing contaminated needles is feasible or that such action is required by a specific medical procedure, the compliance officer should review the exposure control plan for a written justification supported by reliable evidence. This justification must state the basis for the employer's determination that no alternative is feasible or must specify that a particular medical procedure requires, for example, the bending of the needle and the use of forceps to accomplish this.

6. **Paragraph (d)(2)(viii)**. Since reusable sharps, such as large bore needles, scalpels, and saws, pose the same percutaneous exposure hazard as disposable sharps, they must be contained in a manner that eliminates or minimizes the hazard until they are reprocessed. Therefore, the containers for reusable sharps must meet the same requirements as containers for disposable sharps, with the exception that they are not required to be closable since it is anticipated that containers used for collecting and holding reusable sharps will, themselves, be reused.

7. **Paragraphs (d)(2)(ix) and (x)**. These paragraphs are intended primarily to eliminate or minimize indirect transmission of bloodborne pathogens from contaminated environmental surfaces.

Hand cream is not considered a "cosmetic" and is permitted. It should be noted that some petroleum-based hand creams can adversely affect glove integrity, and the hand washing requirements of paragraph **(d)(2)(v)** and **(d)(2)(vi)** must be followed.

NOTE: The term "work area" means the area where work involving exposure or potential exposure to blood or OPIM exists, along with the potential contamination of surfaces. Employees are permitted to eat and drink in an ambulance cab, for example, as long as the employer has implemented procedures to permit employees to wash up and change contaminated clothing prior to entering the ambulance cab, and to ensure that patients and contaminated material remain behind the separating partition.

INSPECTION GUIDELINES. In addition to direct contamination of food or drink by blood or OPIM, the Compliance Officer must keep in mind that containers of food and beverage may also become contaminated, resulting in unsuspected contamination of the hands. The purpose of this paragraph is to prevent food and drink from being contaminated by the leakage/spilling of specimen containers, contact with contaminated items, or the performance of activities (e.g., laboratory analysis) that could generate splashes, sprays, or droplets of blood or OPIM.

CITATION GUIDELINES. Deficiencies of paragraphs **(d)(2)(iv)** through **(x)** should be cited in conjunction with the appropriate paragraph of **(g)(2)** if inadequate training exists.

8. **Paragraph (d)(2)(xi).** The intent of this paragraph is not only to decrease the chances of direct employee exposure through spraying or splashing of infectious materials onto employees, but also to reduce contamination of surfaces in the general work area.

Surgical power tools, lasers, and electrocautery devices may generate aerosols as well as be a source for splashing and spattering. Some of these devices include labeling recommendations such as local exhaust ventilation. The employer is responsible for appropriate operation of these devices, including controls recommended by the manufacturer.

Typically, reasonably anticipated spattering or generation of droplets would necessitate use of eye protection and mask or a face shield to prevent contamination of the mucous membranes of the eyes, nose, and mouth.

CITATION GUIDELINES. The use of sprays, brushes, and high pressure in equipment lines is particularly hazardous. A citation should normally be issued for paragraph **(d)(2)(xi)** if cleaning procedures cause unnecessary splashing, spraying, spattering, or generation of droplets of blood or OPIM.

9. **Paragraph (d)(2)(xii)**. While this paragraph prohibits mouth pipetting/suctioning, the agency allows a recognized emergency care method of clearing an infant's airways called "DeLee suctioning" in the following situation: in an emergency; when no other method is available, and a trap which prevents suctioned fluid from reaching the employee's mouth is inserted in-line between the infant and the employee.

10. **Paragraphs (d)(2)(xiii)-(d)(2)(xiii)(C)**. These paragraphs deal with the containerization and labeling of specimens with the intent to eliminate or minimize the possibility of inadvertent employee contact with blood or OPIM which have leaked out of the container, contaminated exterior surfaces of the container, and/or surrounding surfaces. The labeling requirement warns employees that these substances are present so that proper handling precautions can be taken.

    The labeling exemption listed in paragraph **(d)(2)(xiii)(A)** applies to facilities which handle **all** specimens (not just those specimens which contain blood or OPIM) with universal precautions. This exemption applies only while these specimens remain within the facility. All employees who will have contact with the specimens must be trained to handle all specimens with universal precautions. If the specimens leave the facility (e.g., during transport, shipment, or disposal) a label or red color-coding is required.

    Extracted teeth which are being discarded or used as specimens are subject to the containerization and labeling provisions of the standard. However, OSHA does not issue citations to dentists and doctors for non-employee exposures. Extracted teeth, gall stones and kidney stones may be given to the patients. In these situations, the teeth and stones are not subject to the containerization and labeling provisions of the standard.

    The use of **pneumatic tube** systems for transport of small materials in hospitals now includes transmittal of laboratory specimens and other more fragile items. The primary concern in the transportation of clinical specimens in a pneumatic tube system is leakage of the specimen into the carrier and potentially into the system tubing. Some systems have virtually eliminated breakage as a cause of leakage by means of padded inserts for carriers and soft delivery of the carrier. Leakage generally results from improper packaging and/or the use of primary containers that do not prevent leakage during transport.

    All employees who might potentially open a carrier must be trained to regard the contents as biohazardous in nature. Employees who open

biohazard carriers must wear gloves in accordance with paragraph **(d)(3)** when removing specimens from the tube system carrier, because it may be contaminated with leakage. They must be trained in decontamination of the carrier and, if need be, the tube system in accordance with paragraph **(g)(2)**.

All precautions and standards for manual transport of specimens also apply to the automated transport of specimens (e.g., containerization and tagging/labeling).

INSPECTION GUIDELINES. The Compliance Officer must observe or document work practices to determine whether a secondary container is being used when necessary. If a bloody glove contaminates the outside of a primary container while the employee is placing a specimen, the employee would need to use a secondary container. Also, primary containers which may be punctured by their contents, including such items as pointed bone slivers, must be placed in a puncture-resistant secondary container.

11. **Paragraph (d)(2)(xiv)**. When it is not possible to decontaminate equipment prior to servicing or shipping (e.g., highly technical or sensitive equipment and/or limited access to contaminated parts), at least partial decontamination, such as flushing lines and wiping the exterior, must be accomplished.

INSPECTION AND CITATION GUIDELINES. The Compliance Officer should ensure that the employer's program makes provision for the required equipment labels. A label must be attached to equipment stating which portions of the equipment remain contaminated in order to inform downstream servicing/repair employees of the hazard and precautions they need to take.

Before citing paragraph **(d)(2)(xiv)**, the Compliance Officer should document that equipment is being shipped and/or serviced. Compliance Officers should observe or document work practices used when employees are decontaminating equipment. When decontaminating reusable equipment that is heavily soiled, the employee will have to perform some prewashing before proceeding with decontamination because most disinfectants/sterilants cannot sufficiently penetrate the organic material that may remain on such heavily soiled equipment.

12. **Personal Protective Equipment - Paragraph (d)(3).** When there is occupational exposure, PPE must be provided at no cost to the employee

to prevent blood or OPIM from passing through to, or contacting, the employees' work or street clothes, undergarments, skin, eyes, mouth, or other mucous membranes.

13. **Paragraph (d)(3)(i).** The type and amount of PPE must be chosen to protect against contact with blood or OPIM based upon the type of exposure and quantity of these substances reasonably anticipated to be encountered during the performance of a task or procedure.

INSPECTION AND CITATION GUIDELINES. The financial responsibility for purchasing and providing PPE rests with the employer. The employer is not obligated under this standard to provide general work clothes to employees, but is responsible for providing PPE. If laboratory coats or uniforms are intended to protect the employee's body from contamination, they are to be provided by the employer at no cost to the employee.

Laboratory coats, uniforms and the like that are used as PPE must be laundered by the employer and not sent home with the employee for cleaning.

Scrubs are usually worn in a manner similar to street clothing, and normally should be covered by appropriate gowns, aprons or laboratory coats when splashes to skin or clothes are reasonably anticipated.

If a pullover scrub (as opposed to scrubs with snap closures) becomes minimally contaminated, employees should be trained in accordance with paragraph **(g)(2)(vii)(G)** to remove the pullover scrub in such a way as to avoid contact with the outer surface, e.g., rolling up the garment as it is pulled toward the head for removal.

However, if the amount of blood exposure is such that the blood penetrates the scrub and contaminates the inner surface, not only is it impossible to remove the scrub without exposure to blood, but the penetration itself would constitute skin exposure. Even though wearing scrubs for protection against exposures of this magnitude is inappropriate, it may also be prudent to train employees on the proper methods to remove grossly contaminated scrubs and prevent exposure to the face.

A gown which is frequently ripped or falls apart under normal use would not be considered "appropriate PPE."

Resuscitator devices are to be readily available and accessible to employees who can reasonably be expected to perform resuscitation procedures. Emergency ventilation devices also fall under the scope of PPE and hence must be provided by the employer for use in resuscitation

(e.g., masks, mouthpieces, resuscitation bags, shields/overlay barriers). Improper use of these devices should be cited as a violation of paragraph **(d)(3)(ii)**. In addition, paragraph **(g)(2)(vii)(G),** which requires employees to be trained in the types, proper use, location, etc., of the PPE should be cited if inadequate training exists. Improper use includes failure to follow the manufacturer's instructions and/or accepted medical practice.

NOTE: The American Society for Testing and Materials (ASTM) has several complete testing and evaluation methods which can be used for assessing the resistance of materials used for PPE for medical use. (ASTM-F1819-98, ASTM-F-1671-97b, and ASTM-F1670-97)

14. **Paragraph (d)(3)(ii).** This paragraph requires the use of PPE. It also provides for a limited exemption from the use of PPE, based on situations in which use of PPE would prevent the proper delivery of healthcare or public safety services, or would pose an increased hazard to the personal safety of the worker or coworker. The following represent examples of when such a situation could occur:

    b. A sudden change in patient status occurs such as when an apparently stable patient unexpectedly begins to hemorrhage profusely, putting the patient's life in immediate jeopardy;

    c. A fire fighter 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;

    d. A bleeding suspect unexpectedly attacks a police officer with a knife, threatening the safety of the officer and/or coworkers.

    NOTE: An employee's decision not to use PPE is to be made on a case-by-case basis and must have been prompted by legitimate and truly extenuating circumstances. In such cases, no citation should be issued when the employee temporarily and briefly abandons use of PPE. This does not relieve the employer of the responsibility to ensure that PPE is readily accessible at all times. The employer must investigate and document why PPE was not used in each case and evaluate the circumstances surrounding the incident to reduce the likelihood of a future (unprotected) incident.

CITATION GUIDELINES. Paragraph **(d)(3)(ii)** should be cited if PPE is not being used properly. Improper use would include wearing the wrong PPE (e.g., wearing a laboratory coat when a rubber apron is needed) or wearing the wrong size glove.

In addition, paragraph **(g)(2)(vii)(G)** should also be cited if the employees have not been adequately trained.

Unless all elements of the exemption, including the documentation requirement, are met, the employer should not receive the benefit of this exemption and paragraph **(d)(3) (ii)** should be cited.

15. **Paragraph (d)(3)(iii)**. This paragraph requires that the employer provide PPE in appropriate sizes and accessible locations. In addition, "hypoallergenic" gloves (see Note below), glove liners, powderless gloves, or other similar alternatives must be readily available and accessible at no cost to those employees who are allergic to the gloves normally provided. Similar alternatives must supply appropriate barrier protection and must be approved by the FDA for use as a medical glove. The compliance officer should review the employer's program and, through employee interviews and inspection of places where PPE is kept, ensure that these provisions have been met.

NOTE: In accordance with a notice published in the Federal Register, Volume 62, No. 189, effective September 30, 1998, the FDA now requires labeling statements for medical devices which contain natural rubber and prohibits the use of the word "hypoallergenic" to describe such products. Additional information on the incidence of hypersensitivity reactions to natural rubber latex can be found in the following documents: NIOSH Alert, *Preventing Allergic Reactions to Natural Rubber Latex in the Workplace* (Publication No. 97-135) published in June 1997; Directorate of Technical Support, Technical Information Bulletin: *Potential for Allergy to Natural Rubber Latex Gloves and other Natural Rubber Products*, http://www.osha.gov/dts/shib/shib012808.html.

CITATION GUIDELINES. If PPE is not provided at no cost to the employee, the Compliance Officer should cite paragraph **(d)(3)(i)**. If PPE is not being used properly or the wrong PPE is used (e.g., wearing a laboratory coat when a rubber apron is needed) or wearing the wrong size PPE, paragraph **(d)(3)(ii)** should be cited. If PPE is not available in appropriate sizes or readily accessible, the Compliance Officer should cite paragraph **(d)(3)(iii)**. For example, the clothing of paramedics out on an emergency call may become blood soaked. If they are unable to change

before the next emergency call because a second set of clothing is located at the ambulance's home base, and the ambulance does not return to base for prolonged periods, a violation of paragraph **(d)(3)(iii)** would exist.

If it is common practice that PPE is not utilized during certain situations or procedures where exposure to blood or OPIM is anticipated, then a violation of paragraph **(d)(3)(ii)** would exist. If inaccessibility of PPE exists, paragraph **(d)(3)(iii)** should also be cited.

16. **Paragraph (d)(3)(iv).** It is the employer's responsibility not only to provide PPE, but to clean, maintain, and/or dispose of it. Home laundering is not permitted since the employer cannot guarantee that proper handling or laundering procedures are being followed.

While many employees have traditionally provided and laundered their own uniforms or laboratory coats or the like, if the item's intended function is to act as PPE, then it is the employer's responsibility to provide, clean, repair, replace, and/or dispose of it.

Home laundering by employees is not permitted since the standard requires that the laundering be performed by the employer at no cost to the employee. Home laundering is unacceptable because the employer cannot ensure that proper handling or laundering procedures are being followed and because contamination could migrate to the homes of employees.

If the employee wishes to choose, wear, and maintain his/her own uniform or laboratory coat, then he/she would need to don additional employer-handled and employer-controlled PPE when performing tasks where it is reasonable to anticipate exposure to blood or OPIM.

CITATION GUIDELINES. If PPE is not cleaned, laundered, and disposed of by the employer, or if the employer cleans the PPE but there is a charge to the employee, then paragraph **(d)(3)(iv)** should be cited. If PPE is not repaired and/or replaced by the employer at no cost to the employee, then paragraph **(d)(3)(v)** should be cited.

If a garment is not removed as soon as possible when penetrated by blood or OPIM, the Compliance Officer should cite paragraph **(d)(3)(vi)**.

If the PPE is not changed, and additional PPE was available, paragraph **(g)(2)(vii)(G)** may also be cited if employees have not been adequately trained.

17. **Paragraph (d)(3)(vii)**. To minimize migration of contamination beyond the work area, employees must remove any contaminated clothing before leaving a work area (i.e. before they may enter designated lunchrooms or break rooms). Failure to wash up would be cited under **(d)(2)(iv), (v)** or **(vi).**

INSPECTION AND CITATION GUIDELINES. While "work areas" must be determined on a case-by-case basis, a work area is generally considered to be an area where work involving occupational exposure occurs or where the contamination of surfaces may occur. The standard would not require employees to change PPE when traveling, for example, from one hospital laboratory area to another, provided the connecting hallway is also considered to be a work area. The Compliance Officer should evaluate on a case-by-case basis whether the employee received adequate training in accordance with paragraph **(g)(2)(vii)(F)** to ensure that no surface contamination occurs during the employee's movement. A violation would exist for the following:

An employee wearing contaminated gloves exits from a pathology laboratory to use a public telephone located in a public hallway of the hospital. Under such circumstances, it can be reasonably anticipated that another employee, without benefit of gloves or knowledge of the potential surface contamination, could use the phone and unwittingly become contaminated.

18. **Paragraph (d)(3)(ix)(A)-(C)**. These paragraphs discuss the use of gloves. Gloves of appropriate sizes must be made available in accordance with paragraph **(d)(3)(iii)**. Studies have shown that gloves provide a barrier, but that neither vinyl nor latex procedure gloves are completely impermeable. Thus, hand washing after glove removal is required. Disposable gloves must be replaced as soon as practical or as soon as feasible when contaminated.

While disposable gloves must be replaced as soon as practical when contaminated, obviously some critical procedures (i.e., surgery, delivery) cannot be interrupted to change gloves. The key words to evaluate are "practical" and "feasible."

Disinfecting agents may cause deterioration of the glove material; washing with surfactants could result in "wicking" or enhanced penetration of liquids into the glove via undetected pores, thereby transporting blood or other potentially infectious materials into contact with the hand. For this reason, disposable (single use) gloves may not be washed and reused.

The Compliance Officer should note that certain solutions, such as iodine, may cause discoloration of gloves without affecting their integrity and function.

At a minimum, gloves must be used where there is reasonable anticipation of employee hand contact with blood, OPIM, mucous membranes, or non-intact skin; when performing vascular access procedures; or when handling or touching contaminated surfaces or items.

Gloves are usually not necessary when administering intramuscular or subcutaneous injections as long as bleeding that could result in hand contact with blood or OPIM is not anticipated.

Plastic film food handling gloves ("cafeteria" or "baggie" gloves) are not considered to be appropriate for use in exposure-related tasks. They would not fit the employee as required by paragraph **(d)(3)(iii)** of the standard.

19. **Paragraph (d)(3)(ix)(D)**. The exemption regarding the use of gloves during phlebotomy procedures applies only to employees of volunteer donor blood collection centers, and does not apply to phlebotomy conducted in other settings such as plasmapheresis centers or hospitals.

INSPECTION GUIDELINES. Where an employer in a volunteer donor blood collection center does not require routine gloving for all phlebotomies, the Compliance Officer should document that the employer has fulfilled the requirements of paragraphs **(d)(3)(ix)(D)(1)** through **(d)(3) (ix)(D)(4)(iii)**, and that employees have received the training necessary to make an informed decision on the wearing of gloves.

CITATION GUIDELINES. Paragraph **(d)(3)(ix)(D)** should not be cited. Rather, the other paragraphs of **(d)(3)** should be cited if such an employer violates them and if the employer has not demonstrated fulfillment of all the requirements of the exemptions.

20. **Paragraph (d)(3)(x)**. This paragraph requires protection for the mucous membranes of the face and upper respiratory tract from exposure. Depending on the degree and type of anticipated exposure, protection for the face would consist of a surgical mask in conjunction with goggles or eye glasses with solid side shields or, alternatively, a chin length face shield.

The employer would not necessarily have to provide prescription eyewear for employees. He/she could provide and mandate the use of side shields, goggles, and/or protective face shields, and provide proper training in decontamination procedures.

During microsurgery, when it is not reasonably anticipated that there would be any splattering, a surgeon would not be required to wear eye protection while observing surgery through the microscope.

21. **Paragraphs (d)(3)(xi)-(xii)**. Requirements for the use of protective body clothing, such as gowns, aprons, laboratory coats, clinic jackets, surgical caps, or shoe covers, and the degree to which such PPE must resist penetration, are performance based. The employer must evaluate the task and the type of exposure expected and, based on the determination, select the "appropriate" personal protective clothing in accordance with paragraph **(d)(3)(i)**. For example, laboratory coats or gowns with long sleeves must be used for procedures in which exposure of the forearm to blood or OPIM is reasonably anticipated to occur.

INSPECTION GUIDELINES. The Compliance Officer will need to evaluate the task being performed and the degree of anticipated exposure by direct observation, employee interview, or review of written standard operating procedures.

22. **Housekeeping (d)(4)**. The term "worksite" in this paragraph refers not only to permanent fixed facilities such as hospitals, dental/medical offices, clinics, etc., 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 OPIM.

Paragraph (d)(4)(i). Cleaning schedules and methods will vary according to the factors outlined in this paragraph. While extraordinary attempts to disinfect or sterilize environmental surfaces such as walls or floors are rarely indicated, routine cleaning and removal of soil are required.

The employer must determine and implement an 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 splattering), and tasks and

procedures being performed (e.g., laboratory analyses versus routine patient care).

The particular disinfectant used, as well as the frequency with which it is used, will depend upon the circumstances in which the housekeeping task occurs.

23. **Paragraph (d)(4)(ii)**. Since environmental contamination is an effective method of disease transmission for HBV (the CDC states that HBV can survive for at least one week in dried blood on environmental surfaces or contaminated needles and instruments), paragraph **(d)(4)(ii)** provides the minimum requirements for the cleaning and decontamination of equipment and environmental and working surfaces that come into contact with blood or OPIM.

Under paragraph **(d)(4)(ii)(A)**, cleaning of contaminated work surfaces after completion of procedures is required to ensure that employees are not unwittingly exposed to blood or OPIM remaining on a surface from previous procedures. This paragraph requires contaminated work surfaces to be cleaned with an **"appropriate disinfectant**." Appropriate disinfectants include a diluted bleach solution and EPA-registered tuberculocides (List B), sterilants registered by EPA (List A), products registered against HIV/HBV (List D) or Sterilants/High Level Disinfectants cleared by the FDA. The lists of the EPA Registered Products are available from the National Antimicrobial Information Network on its web site at http://nain.orst.edu/ or at (800) 447-6349. The sterilants and high level disinfectants cleared by FDA can be found at http://www.fda.gov/cdrh/ode/germlab.html. Any of the above products are considered effective when used according to the manufacturer's instructions, provided the surfaces have not become contaminated with agents or volumes of or concentrations of agents for which higher level disinfection is recommended.

NOTE: The EPA lists contain the primary registrants' products only. The same formulation is frequently repackaged and renamed and distributed by other companies. These renamed products will not appear on the list, but their EPA Registration number must appear on the label. Products cleared solely by the FDA will not have an EPA number.

INSPECTION GUIDELINES. Compliance Officers should check the product label for EPA registration and/or consult the Environmental Protection Agency (EPA) lists of registered sterilants (representing the highest level of antimicrobial activity that destroys all viruses),

tuberculocidal disinfectants (effective against tuberculosis bacteria and the specific viruses named on the product label as well as the hepatitis B virus), and antimicrobials with HIV/HBV efficacy claims for verification that the disinfectant used is appropriate. The employer must follow the label instructions regarding the amount of disinfectant and the length of time it must remain wet on the surface. Since the effectiveness of a disinfectant is governed by strict adherence to the instructions on the label, Compliance Officers should also interview employees to ensure that the disinfectants are being used according to the manufacturer's instructions. If employees have not been trained in the proper use of the disinfectant, a violation of the appropriate paragraph in **(g)(2)(vii)** should be cited.

NOTE: Fresh solutions of diluted household bleach made up daily (every 24 hours) are also considered appropriate for disinfection of environmental surfaces and for decontamination of sites following initial cleanup (i.e., wiping up) of spills of blood or other potentially infectious materials. Contact time for bleach is generally considered to be the time it takes the product to air dry. Solutions of bleach should not be stored in glass containers, but in material such as the plastic in which the bleach, the consumer product, is packaged in. Household bleach (5.25% sodium hypochlorite) diluted to the appropriate strength for the clean up job at hand is also an effective disinfectant, although bleach may cause damage to some medical instruments and therefore cannot be used in all cases. In addition, gross contamination must be cleaned up first with a soap and water solution, to ensure the disinfectant is completely effective.

. Where procedures are performed on a continual basis throughout a shift or a day, as may be the case with a clinical laboratory 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; rather the intention is for contaminated work surfaces to be decontaminated after the procedures are completed which, in the above example, would include a set of analyses. The completion of procedures might also occur when the employee is going to leave the work area for a period of time.

Decontamination is not automatically required after each patient care procedure, but is required only after procedures resulting in surface contamination.

There may be some instances in which "immediate" decontamination of overt contamination and spills may not be practical as in, for example, an operating table during surgery.

The work surface decontamination is to be performed at the end of the work shift **if** the work surface may have become contaminated since the last cleaning by, for example, setting down contaminated instruments or specimens on the work surface. This requirement is based upon the existence of a contaminated work surface rather than a particular worksite location. It does not, for example, encompass desks, countertops, and so forth that remain uncontaminated.

The use of protective coverings described in paragraph **(d)(4)(ii)(B)** is an acceptable alternative for protecting items and surfaces against contamination and is particularly useful in situations in which a piece of equipment would be difficult to decontaminate but could be protected by a cover.

If this option is chosen, the covering must be removed and replaced at the stated minimum intervals, i.e., as soon as feasible following overt contamination or at the end of a workshift if it may have become contaminated during the shift.

More stringent decontamination rules, such as cleaning equipment or changing coverings between patients, may be prudent infection control policy but do not fall under OSHA's mandate to safeguard employee (not patient) health.

24. **Paragraph (d)(4)(ii)(C)** requires both the inspection and decontamination, on a regularly scheduled basis, of cans, bins, pails, and so forth which are intended for reuse.

Since these containers may be used in a manner which presents the potential for their becoming contaminated with blood or OPIM, they must be cleaned immediately or as soon as feasible upon visible contamination. For example, a reusable metal trash can could have been lined with a disposable plastic regulated waste bag which leaks and contaminates the can. In addition, regular decontamination will prevent the can from leaking, spilling, or contaminating the outside of successive bags. Disinfection of these containers is not necessary to ensure their safety for their intended use; it may be possible to achieve their proper decontamination by means of a soap and water wash.

Since contaminated broken glass (e.g., glass capillary tubes, lab specimen dishes, phlebotomy tubes) is capable of inflicting percutaneous injury and direct inoculation of bloodborne pathogens into the bloodstream, paragraph **(d)(4)(ii)(D)** stipulates that broken glassware which may be contaminated must not be picked up directly with the hands. The tools

which are used in cleanup (e.g., forceps) must be properly decontaminated or discarded after use and the broken glass placed in a sharps container, and employees must be given specific information and training with respect to this task in accordance with the requirements of paragraph **(g)(2)**. Vacuum cleaners are not appropriate for cleanup of contaminated broken glass.

25. **Paragraph (d)(4)(ii)(E)** prohibits employers from allowing employees to place their hands into containers whose contents include reusable sharps contaminated with blood or OPIM. The intent is to prevent conditions of use in which the contents cannot be seen and safely handled. For example, employees must not reach into sinks filled with soapy water into which sharp instruments have been placed; appropriate controls in such a circumstance would include the use of strainer type baskets to hold the instruments and forceps to remove the items.

    The final standard recognizes that proper decontamination of reusable equipment, such as glassware or hand instruments, cannot be achieved in the presence of organic debris (e.g., blood) because it interferes with the efficacy of the disinfecting/sterilizing process, and the number of products which can successfully penetrate a heavy bioburden is limited.

    Violations of paragraphs **(d)(4)(ii)** and **(d)(4)(ii)(A)-(E)** may result from a failure to adequately train employees in proper housekeeping procedures. If the Compliance Officer determines this is the case, violations should be grouped with the appropriate paragraph(s) of paragraph **(g)(2)**.

26. **Regulated Waste (d)(4)(iii)**. This paragraph requires regulated waste to be properly contained and disposed of, so as not to become a source of transmission of disease to employees.

    To eliminate the implication that OSHA has determined the "infectivity" of certain medical wastes, the bloodborne pathogens standard uses the term "regulated waste" to refer to the following categories of waste which require special handling, at a minimum: liquid or semi-liquid blood or OPIM; items contaminated with blood or OPIM and which would release these substances in a liquid or semi-liquid state if compressed; items that are caked with dried blood or OPIM and are capable of releasing these materials during handling; contaminated sharps; pathological and microbiological wastes containing blood or OPIM.

    INSPECTION AND CITATION GUIDELINES. The compliance officer should not use the actual volume of blood to determine whether or

not a particular material is to be considered regulated waste, since 10 ml of blood on a disposable bed sheet would appear as a spot (not regulated waste) while the same amount of blood on a cotton ball would likely cause saturation and dripping (regulated waste). Similarly, an item may adequately contain these materials when in a static state yet liberate them when compacted in the waste container. Instead, the compliance officer should consider the potential for generation of bulk blood (i.e through dripping or flaking off of material that may contain either blood or OPIM). Under no circumstances should a bag of waste be squeezed or shaken to determine this. The compliance officer should exercise professional judgment to make a determination based on visual factors such as a pool of liquid in the bottom of the container or dried blood flaking or falling off during handling, or based on employee interviews.

NOTE: The Compliance Officer should keep in mind that, while OSHA specifies certain features of the regulated waste containers, including appropriate tagging, the ultimate disposal method (landfilling, incinerating, and so forth) for medical waste falls under the purview of the EPA and possibly State and local regulations.

Lacking information to the contrary, the Compliance Officer should consider a used needle to be contaminated.

27. **Paragraph (d)(4)(iii)(A)(1)**. This provision should be cited if contaminated sharps are not discarded in containers immediately or as soon as feasible. If containers are located too far away from the point of use, then **(d)(4)(iii)(A)(2)(i)** should be cited. See below.

28. **Paragraph (d)(4)(iii)(A)(1)(i)-(iv)** The construction of the sharps containers must meet at least four criteria, two of which will be easily discernible. The Compliance Officer should examine a container, preferably empty, to check that it is closable and color-coded or labeled. Sharps containers are made from a variety of products, from cardboard to plastic. As long as they meet the criteria for a sharps container, the Compliance Officer should consider them to be acceptable no matter what the composition. If questions arise, the Compliance Officer should consult the manufacturer's literature or contact the manufacturer directly to determine if the container is leakproof on the sides and bottom, as well as puncture resistant. The NIOSH publication, “Selecting, Evaluating and Using Sharps Disposal Containers” is also a good resource.

If the container is considered puncture resistant by the manufacturer, but there is evidence, through observation or employee statements, that sharps

have been protruding through a container, paragraph **(d)(4)(iii)(A)(1)(ii)** should be cited.

The sharps container should not create additional hazards. Some sharps containers have unwinders that are used to separate needles from reusable syringes or from reusable blood tube holders. The use of these are generally prohibited. However, if a medical procedure requires needle removal, the design of the sharps container and the location of the unwinder must allow the needle removal to be accomplished in a safe, one-handed manner. If this situation is encountered, the Compliance Officer should determine if the circumstances warrant needle removal. If they do not, paragraph **(d)(2)(vii)(A),** which prohibits needle removal unless no alternative is feasible or it is required by a specific medical procedure, should be cited. If needle removal must be accomplished, the employee must be trained in the correct procedure as required by paragraph **(g)(2)(vii)(F)**.

The needle sheath on a self-sheathing needle is **not** to be considered a "waste container" because it is viewed as a temporary measure. Self-sheathing needle products and other SESIPs, even after activation, must be disposed of in a sharps container which conforms to the requirements of paragraph **(d)(4)(iii)(A)(1)**.

Duct tape may be used to secure a sharps container lid, but tape is not acceptable if it serves as the lid itself.

29. **Paragraph (d)(4)(iii)(A)(2)(i)**. The Compliance Officer should ensure that the sharps container is as close as feasible to where sharps are used or can be reasonably anticipated to be found.

If an employee must travel to a remote location to discard a sharp, it will increase the possibility of an accidental needlestick and increase the chances that needles and sharps will be improperly discarded and create potential hazards for other staff members.

Areas such as correctional facilities, psychiatric units, pediatric units, or residential homes may have difficulty placing containers in the immediate use area. Alternatives include using containers which are lockable or which are designed to prevent removal of syringes while maintaining easy accessibility for discarding. Containers may also be locked onto a mobile cart if one is used by healthcare workers in these units, or they may be brought to the site and removed by the employee upon leaving.

The determination of whether or not the container is as close as feasible should be made on a case-by-case basis. After interviewing employees, if the Compliance Officer believes there is a better location for the container, management should be given the opportunity to explain the reasons for the present location of the container. The acceptability of the new site should also be discussed. The Compliance Officer should then decide if a violation of this paragraph exists.

Laundries must also have sharps containers easily accessible because of the high incidence of needles being mixed with laundry. Facilities that handle shipments of waste which may contain contaminated sharps must also have sharps containers available in the event a package accidentally opens and releases sharps.

30. **Paragraph (d)(4)(iii)(A)(2)(iii)**. The Compliance Officer should ensure that sharps containers are being replaced routinely to prevent overfilling. The Record Summary states that overfilling of sharps containers is an often reported problem. Overfilling is often associated with containers that were too small to accommodate the volume of sharps, limited ability to see the contents in order to determine the remaining capacity, and lax procedures for container maintenance. Examples of methods by which sharps containers can be examined to determine a need for replacement, are the use of sharps containers which have a transparent window or are placed at a height which allows employees to see if the container needs to be replaced. Overfilling of sharps containers should be cited under paragraph **(d)(4)(iii)(A)(2)(iii)**. A citation for inadequate training on work practices, paragraph **(g)(2)(vii)(F)**, should be grouped with the citation for this paragraph if the overfilled containers are present because of lack of training.

NOTE: The Exposure Prevention Information Network (EPINet) study Uniform Needlestick and Sharp Object Injury Report (77 Hospitals, 1993-1995) reports that 717 injuries occurred in this time period when an employee was putting an item into a disposal container. The Compliance Officer should closely inspect sharps disposal containers at the site to ensure containers are not overfilled. Additional information on sharps disposal containers is available in the NIOSH publication, Selecting, Evaluating and Using Sharps Disposal Containers, January 1998, DHHS (NIOSH) Publication No. 97-111.

31. **Paragraphs (d)(4)(iii)(A)(3)(i) and (ii)**. If work practice violations of these paragraphs exist (e.g., not closing the container prior to movement or not placing the container in a secondary container if leakage is possible),

the citations should be grouped with paragraph **(g)(2)(vii)(F)** if employees have not received adequate training.

32. **Paragraph (d)(4)(iii)(A)(3)(ii)(B)**. It is reasonable to presume that some sharps containers will contain residual liquids. If the container cannot be sealed to prevent leakage, it must be placed in a secondary container.

33. **Paragraph (d)(4)(iii)(A)(4)**. A reusable sharps container system for disposable sharps will be acceptable if it does not expose employees to the risk of percutaneous injury. No system involving the manual opening, emptying, or cleaning of the containers will be allowed. The only acceptable system is a fully automated container cleaning system that eliminates employee exposure to sharps.

34. **Paragraph (d)(4)(iii)(B)**. While this paragraph requires that regulated waste containers be closable, simply being closed does not ensure that waste will be contained. Waste-containing bags may break and spill their contents, including liquid blood, while, for example, being loaded onto incinerator hoppers, thus contaminating both the employees and the work area. Also, small medical offices which generate only a small volume of regulated waste may place that waste in a large holding container until the container is filled. In such a case, the design of the container must be such that it is able to retain the waste over an extended period of time between pickups by a specialized waste service. The Compliance Officer should, therefore, check for visual signs of leakage of fluids during handling, storage, transport, or shipping.

    Any failures to comply with the container construction requirements would be cited under this paragraph. If the compliance officer determines that the employee was not properly trained to recognize the problem or use the containers correctly, a citation for the appropriate paragraph of paragraph **(g)(2)** should be grouped with violations of paragraph **(d)**.

35. **Paragraphs (d)(4)(iii)(B)(1)(iii) and (2)(iii)**. Regulated waste containers are required to be labeled with the biohazard symbol or color-coded to warn employees who may have contact with the containers of the potential hazard posed by their contents.

    Even if a facility considers all of its waste to be regulated waste, the waste containers must still bear the required label or color-coding in order to protect new employees, employees who would not normally come into contact with wastes, and employees from outside the facility. This

requirement is in contrast to the labeling alternative allowed when laundries use universal precautions for the handling of all soiled laundry.

Regulated waste that has been decontaminated need not be labeled or color-coded. The compliance officer in such a case should verify that the employer's exposure control plan states the decontamination procedures to be followed. In order to ensure that the decontamination process is successful, the employer must monitor factors such as the content, volume, density, configuration, and organic content of the load of waste. The temperature needed for incineration is sufficient to decontaminate regulated waste. Autoclave efficiency can be verified by means of biological or chemical indicators. While most disposal bags used will contain an indicative color strip, if this is not the case a review may be made of the documentation kept for the sterilizer. Such documentation should include (1) date, time, and operator of each run, (2) type and approximate amount of waste tracked, (3) post-treatment reading of temperature-sensitive tape, (4) dates and results of calibration of the sterilizer, and (5) results of routine spore testing. Although these paragraphs contain label requirements, failure to label can also be cited under paragraph **(g)(1)(i)**.

36. **Paragraph (d)(4)(iii)(B)(2).** A second container is required to be used when outside contamination of the first waste container occurs. This provision does not require routine double-bagging but rather requires double-bagging in such circumstances as a waste container being splashed with blood during surgery or autopsy, when a container has been handled by an employee with bloody gloves, or when a waste bag leaks blood or OPIM onto an adjacent bag.

37. **Paragraph (d)(4)(iv)**. This paragraph reduces employee exposure to bloodborne pathogens by reducing the amount of manual handling of contaminated laundry. Restricting the sorting to the laundry area will also reduce contamination of additional surfaces.

INSPECTION AND CITATION GUIDELINES. Paragraphs (d)(4)(iv)(A) and (A)(1) limit the handling of laundry to removal and bagging or containerization. The compliance officer should check the laundry collection program as well as the training of the employees assigned to these tasks.

38. **Paragraph (d)(4)(iv)(A)(2)**. The employer has been given the choice, by this paragraph, to either: label or color-code according to paragraph

(g)(1)(i), or to utilize universal precautions in the handling of all soiled (i.e., used) laundry.

If universal precautions are used for handling all soiled laundry, the employer may use an alternative color or label for the bags/containers, as long as all employees are trained to recognize them as containing soiled laundry which requires the use of universal precautions.

Training violations would be cited under the appropriate paragraph of **(g)(2)(vii)**.

39. **Paragraph (d)(4)(iv)(A)(3)**. The material for the bags or containers used in laundry collection must prevent soak-through or leakage of fluids to the exterior, if the contaminated laundry is wet and presents a reasonable likelihood of soak-through or leakage. Not all contaminated laundry must be placed in such bags or containers; only laundry wet enough to leak or soak through and expose workers handling the bags/containers to blood or OPIM, or contaminate other surfaces should be considered contaminated laundry.

40. **Paragraph (d)(4)(iv)(B)**. Employees having direct contact with contaminated laundry must wear protective gloves (e.g., utility gloves) and any other appropriate personal protective equipment, in order to prevent or reduce contact exposure to blood or OPIM. Any other personal protective equipment required must be determined on a case-by-case basis. Gowns, aprons, eyewear, and masks may be necessary to prevent employee exposure.

41. **Paragraph (d)(4)(iv)(C)**. The employer generating the laundry must have determined if the facility to which it is shipped utilizes universal precautions in the handling of all laundry. If not, all bags or containers of contaminated laundry must be labeled or color-coded in accordance with paragraph **(g)(1)(i)**. In this instance, if the employer generating the laundry chooses to color-code rather than label, the color of the bag must be red.

INSPECTION AND CITATION GUIDELINES. The compliance officer should check the employer's program to determine if laundry is shipped to another facility for cleaning and should evaluate the methods used to ship contaminated laundry (CL) to a facility that does not utilize universal precautions in the handling of all soiled laundry.

The following are unacceptable shipment methods and constitute violations of this paragraph:

The CL is not shipped labeled or in a red bag, paragraph **(d)(4)(iv)(C)** would be cited and grouped with the applicable subparagraph of paragraph (**g)(1)(i**);

The CL is shipped with an improper label, paragraph **(d)(4)(iv)(C)** would be cited and grouped with the applicable subparagraphs of paragraphs **(g)(1)(i) (B), (C) and/or (D)**;

The CL is shipped in a bag color-coded for in-house use (in a color other than red), paragraph **(d)(4)(iv)(C)** would be cited and grouped with citations for paragraph **(g)(1)(i)(E)**.

CDC has published "Guidelines for Laundry in Health Care Facilities." Current recommendations for the laundering of contaminated linen stipulate only that normal laundering methods be used according to the manufacturer's recommendations.

E. **HIV and HBV Research Laboratories and Production Facilities - 29 CFR 1910.1030(e).** This paragraph includes additional requirements that must be met by research laboratories and production facilities engaged in the culture, production, concentration, and manipulation of HIV and HBV.

"Research laboratory" means a laboratory which produces or uses research laboratory scale amounts of HIV or HBV. Although research laboratories may not have the volume found in production facilities, they deal with solutions containing higher viral titers than those normally found in patients' blood. Academic research laboratories are included in this definition. Laboratories that conduct research on blood and other body fluids unrelated to HIV or HBV, or that use unconcentrated blood or blood components as the source of HIV or HBV, are not considered research laboratories for the purpose of this paragraph.

"Production facilities" are those engaged in industrial scale, large volume, or high concentration production of HIV or HBV.

NOTE: Employers in such facilities remain responsible for complying with the entire standard. Requirements stated elsewhere in the standard are not repeated here. These requirements are based largely on information from published guidelines of the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH). (Resource: "Biosafety in Microbiological and Biomedical Laboratories.")

INSPECTION AND CITATION GUIDELINES. The compliance officer should review the covered facility's plan, interview a sufficient number of employees, and observe work practices as necessary to determine if the requirements of this paragraph are met. Care should be taken to ensure the compliance officer understands the special practices and precautions in place at the facility so that the compliance officer is not placed at risk. Specific requirements include:

1. **Paragraph (e)(2)(i)**. The term "regulated waste" refers to the OSHA definition as found in paragraph **(b)** of this standard. The purpose of decontaminating regulated waste is to prevent the accidental exposure of other employees to the concentrated virus.

2. **Paragraphs (e)(2)(ii)(A) through (M)**. Paragraphs **(A), (C), and (D)** require employers to limit access to the laboratory and warn of the hazards associated with bloodborne pathogens. They must review the written policies and procedures to determine if they are adequate to ensure that access to the work areas and animal rooms is limited to authorized persons. Interviews with employees should be used to determine if the policies are followed.

3. **Paragraph (e)(2)(ii)(E)**. The "other physical containment device" must be sufficient to ensure that virus containing material will be kept away from the worker's mucous membranes, unprotected skin, and breathing zone.

4. **Paragraphs (e)(2)(ii)(H) and (I)**. These paragraphs are designed to prevent the spread of contamination to other work areas. Paragraph **(I)** allows for an alternative to a HEPA filter as long as it is of equivalent or superior efficiency. HEPA filters may be ineffective in humid atmospheres.

   The employer must also have made provisions for routine maintenance and/or replacement of all filters and traps.

   If the compliance officer suspects that the engineering controls are failing to prevent the spread of the virus, the manufacturer should be contacted to establish the limits and required maintenance of the filters and traps.

5. **Paragraph (e)(2)(ii)(J)**. The compliance officer should determine if the use of needles and syringes is kept to a minimum and that they are properly handled as required, paying particular attention to establishing if

the puncture-resistant containers are properly autoclaved or decontaminated before being discarded, reused, or incinerated.

6. **Paragraph (e)(2)(ii)(M)**. This paragraph ensures that any necessary additional procedures are developed to protect employees in situations unique to a research/production facility. The biosafety manual required by this paragraph must be reviewed and updated annually or more often if necessary. The facility will thus be required to review its procedures and determine if they are adequate to protect workers.

7. **Paragraph (e)(2)(iii)**. Specific containment equipment is required by this paragraph to minimize or eliminate exposure to the viruses.

   If the compliance officer determines that biological safety cabinets (BSC) have been chosen as the means of containment, they must be certified (Class I, Class II, or Class III, as appropriate) when installed or moved, and at least annually.

   The compliance officer should check that a dated tag is affixed to the BSC indicating who performed the certification. Alternatively, a certification report attesting to a minimum inward face velocity of at least 75 linear feet per minute and the integrity of the HEPA filters should be reviewed by the compliance officer. The report must be dated and signed by the trained technician performing the measurements and integrity tests.

   In the alternative, appropriate combinations of PPE or physical containment devices (examples listed in the standard) will be accepted.

8. **Paragraphs (e)(3)(i) and (e)(4)(iii)**. The hand washing facility must be supplied with at least tepid water, soap, and hand towels. The eyewash must supply a sufficient quantity of water to completely flush the eyes. A 15-minute supply of continuous free-flowing water is acceptable. The hands must be free to hold the eyelids open to aid in the complete flushing of the eyes. Portable facilities are acceptable only if they meet these requirements.

9. **Paragraph (e)(4)** covers additional requirements for production facilities only. The requirement in paragraph **(e)(4)(v)** minimizes the potential for accidental exposure of other employees from the transport of culture fluids, plastic ware, and other contaminated equipment.

10. **Paragraph (e)(5)**. The additional training requirements for employees in HIV/HBV research laboratories are specified in paragraph **(g)(2)(ix)**. Any violations found should be cited under that paragraph of the standard.

F. **Hepatitis B Vaccination and Post Exposure Evaluation and Follow-up - 29 CFR 1910.1030(f).** This paragraph provides a means to protect employees from infection caused by the hepatitis B virus by requiring employers to make the hepatitis B vaccination available to employees with occupational exposure to blood or OPIM. It also ensures that employees receive appropriate medical follow-up after each specific exposure incident.

1. **General - Paragraph (f)(1).** This paragraph refers to the hepatitis B vaccination as both the hepatitis B vaccine and vaccination series. These are to be made available to all occupationally exposed employees. In addition, a post-exposure evaluation and follow-up procedures are to be made available to all employees who experience an exposure incident. While it is OSHA's intent to have the employer remove, as much as possible, obstacles to the employee's acceptance of the vaccine, the term "made available" emphasizes that the employee has the option to decline participation in the vaccination and follow-up programs.

   INSPECTION GUIDELINES. The compliance officer should examine the employer's program to determine if the vaccination series and post-exposure follow-up procedures meet the requirements of paragraph **(f)(1)(ii)**.

2. **Paragraph (f)(1)(ii)(A)**. The term "no cost to the employee" means, among other things, no "out of pocket" expense to the employee.

   The employer may not permit the employee to use his/her healthcare insurance to pay for the series unless the employer pays all of the cost of the health insurance and unless there is no cost to the employee in the form of deductibles, copayments, or other expenses. Even partial employee contribution to the insurance premium means the employee could be affected by a rise in the total premium caused by insurance company reaction to widespread hepatitis B vaccinations and is therefore unacceptable. Likewise, any use of a spouse or other family member's insurance plan to provide vaccination would not be considered "at no cost" to the employee.

   The employer may not institute a program in which the employee pays the original cost of the vaccine and is reimbursed by the employer if she/he remains employed for a specified period of time.

An "amortization contract" which requires employees to reimburse the employer for the cost of the vaccination should they leave his/her employ prior to a specified period of time is similarly prohibited.

A waiver of liability for any harm caused by the vaccine is also prohibited.

3. **Paragraph (f)(1)(ii)(B)**. The term "reasonable time and place" requires the medical procedures and evaluations to be convenient to the employee. They must normally be offered during employees' scheduled work hours. If participation requires travel away from the worksite, the employer must bear the cost.

4. **Paragraph (f)(1)(ii)(C)**. The Compliance Officer can contact the National Council of State Boards of Nursing, Inc. at the Board of Nursing Contact Information web site at http://www.ncsbn.org to obtain the most current lists of addresses and phone numbers for each State Board of Nursing, to determine if the State Board of Nursing allows licensed healthcare professionals other than physicians to carry out the procedures and evaluations required by paragraph **(f)**. The National Commission on Certification of Physicians' Assistants can clarify the role of physician assistants in these procedures. They can be reached at (770) 399-9971.

5. **Paragraph (f)(1)(ii)(D)**. This paragraph takes into consideration the changing nature of medical treatment relating to Hepatitis B. The CDC is the U.S. Public Health Service (USPHS) agency responsible for issuing guidelines and making recommendations regarding infectious agents. OSHA requires employers to follow the CDC guidelines current at the time of the evaluation or procedure. Copies of the current guidelines and other CDC documents can be obtained on CDC's web site, http://www.cdc.gov. The hepatitis B vaccination must be given in the standard dose and through the standard route of administration as recommended in the USPHS/CDC guidelines. The most current CDC guideline regarding Hepatitis B is Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis published in Morbidity and Mortality Weekly Report Vol 50, No. RR-11, June 29, 2001. (Attached as Appendix E) It states that employees who have ongoing contact with patients or blood and are at ongoing risk for percutaneous injuries are to be tested for antibody to Hepatitis B surface antigen, one to two months after the completion of the three-dose vaccination series. Employees who do not respond to the primary vaccination series must be revaccinated with a second three-dose vaccine series and retested, unless they are HbsAg-positive (infected). Non-responders must be medically evaluated.

INSPECTION GUIDELINES: It is important that the compliance officer investigate thoroughly whether the employer knows of the contents of the CDC guidelines. Evidence may include statements from supervisors or managers that they were aware of the guidelines; an interview with the employer, employer's attendance at conferences or seminars where in-service training about the CDC guidelines was provided; knowledge of interactive webpages associated with the CDC guidelines; or actual copies of the MMWR.

CITATION GUIDELINES: Paragraph **(f)(1)(ii)(D)** should be cited if the employer failed to provide vaccinations, evaluations, or follow-up procedures for **Hepatitis B** in accordance with the CDC recommendations that were current at the time these procedures took place. Any additional requirements (such as obtaining a written healthcare professional's opinion) specified in paragraph **(f)** must also be met.

6. **Paragraph (f)(1)(iii)** requires that all laboratory tests be conducted by an accredited laboratory. The Compliance Officer must determine by means of employer documentation (e.g., certificate) that the laboratory is accredited by a national accrediting body (e.g., American Association of Blood Labs, College of American Pathologists, Joint Commission on Accreditation of Healthcare Organizations, etc.) or equivalent State agency which participates in a recognized quality assurance program.

7. **Hepatitis B Vaccination - Paragraph (f)(2)**. The Compliance Officer should determine whether or not all occupationally exposed employees have had the hepatitis B vaccination series made available to them after the training required by paragraph **(g)(2)(vii)(I)** and within 10 working days of their initial assignment. The term "made available" includes the healthcare professional's evaluation and arranging for the administration of the first dose of the hepatitis B vaccination series to begin within the 10 days. This includes all employees with occupational exposure, regardless of how often the exposure may occur. Part-time and temporary employees are included in this coverage. The vaccine does not have to be made available if the employer documents the exemption(s) set forth in paragraph **(f)(2)**. It does not have to be administered if the employer can produce the signature of the employee on the mandatory declination form (See **Appendix A** of **29 CFR 1910.1030**.)

8. **Paragraph (f)(2)(i)** states the circumstances under which an employer is exempted from making the vaccination available. If, (a) the complete hepatitis B vaccination series was previously received (three vaccine shots or in the case of a non-responder, six), or (b) antibody testing shows the

employee to be immune, or (c) the vaccine cannot be given for medical reasons, the series does not have to be made available. If the employer claims one of these exemptions, it must be documented in the employee's medical record in accordance with paragraph **(h)(1)(ii)(B)**.

Current USPHS guidelines recommend post-vaccination screening for antibody to HBsAg (anti-HBs) for certain healthcare workers. See discussion of **(f)(1)(ii)(D)**. Periodic antibody tests thereafter are not currently recommended.

CITATION POLICY FOR FIRST AID PROVIDERS. Citations should be issued when designated first aid providers, who have occupational exposure, are not offered the hepatitis B vaccine before they are exposed unless the following conditions are in place:

a. The primary job assignment of such a designated first aid provider is not the rendering of first aid or other medical assistance, and

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

   NOTE: This exception does **not** apply to designated first aid providers who render assistance on a regular basis, for example, at a first aid station, clinic, dispensary or other location where injured employees routinely go for assistance; nor does it apply to any healthcare, emergency, or public safety personnel who are expected to render first aid in the course of their work. These employees must be offered the vaccine prior to exposure.

c. The employer's exposure control plan must specifically address the provision of the hepatitis B vaccine to all unvaccinated first aid providers who render assistance in any situation involving the presence of blood or OPIM (regardless of whether an actual "exposure incident" as defined by the standard occurred) and the provision of appropriate post-exposure evaluation, prophylaxis, and follow-up for those employees who experience an "exposure incident." The plan must include:

   1) Provision for a reporting procedure that ensures that **all** first aid incidents involving the presence of blood or OPIM will

be reported to the employer before the end of the work shift during which the incident occurred. The report must include the names of all first aid providers who rendered assistance, regardless of whether personal protective equipment was used and must describe the first aid incident, including time and date. The description must include a determination of whether or not, in addition to the presence of blood or other potentially infectious materials, an "exposure incident," as defined by the standard, occurred. This determination is necessary in order to ensure that the proper post-exposure evaluation, prophylaxis, and follow-up procedures required by paragraph **(f)(3)** of the standard are made available immediately, whenever there has been an "exposure incident" as defined by the standard.

2) A report that lists all such first aid incidents, that is readily available, upon request, to all employees and to the Assistant Secretary.

3) Provision for the bloodborne pathogens training program for designated first aiders to include the specifics of this reporting procedure.

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

5) Unless all the requirements of this de minimis policy are met, paragraph **(f)(2)(i)** should be cited for failure to provide the hepatitis B vaccine.

NOTE: For industries not covered by 1910.1030 or 1915.1030, failure to provide appropriate evaluation of first aid incidents (including the determination of whether an exposure incident occurred) and adequate follow-up of exposure incidents (including the provision of the hepatitis B vaccine series free of charge) should be considered for a possible 5(a)(1) citation.

9. **Paragraph (f)(2)(ii)**. Prevaccination screening for antibody status cannot be required of an employee, although if an employer wishes, he/she can make it available at no cost to employees. An employee may decline the prescreening, and the employer must still make the vaccination series available to the employee.

10. **Paragraph (f)(2)(iii)**. The signing of the hepatitis B vaccine declination form by the employee, at the time the vaccination is made available, does not relieve the employer from the requirement to provide the vaccine at a later date if the employee so chooses.

11. **Paragraph (f)(2)(iv)**. Employers must ensure that employees who decline the vaccine sign a declination form. The language in the declination form is set forth in 29 CFR 1910.1030, Appendix A. An employer's form which conveys the same information as Appendix A, although in different words, should be considered a de minimis violation. However, any additions to that language should be made for the sole purpose of improving employee comprehension. Forms must not add language that would discourage employee acceptance of the vaccine or add liability concerns.

    If the employer has added information that requires the employee to provide confidential medical information, regardless of whether it is physically on the declination form or on a separate form, a citation of **(h)(1)(iii)** should be considered

    The standard does not make reference to consent forms for employees accepting the vaccine. Medical informed consent forms are acceptable. However, any waiver of liability for any harm caused by the vaccine violates paragraph **(f)(1)(ii)(A),** which requires that the vaccine be provided at no cost. Consent forms which require the employee to release his or her test results to the employer violate the confidentiality requirements in paragraph **(f)(5)(iii)**. Consent forms on which the hazards of the vaccine are clearly exaggerated violate paragraph **(g)(2)(vii)(I)**.

12. **Paragraph (f)(2)(v)**. At the time of this publication, the provision of routine boosters of the hepatitis B vaccine is still being assessed. There is no requirement to provide boosters unless the USPHS recommends it at a later date.

13. **Post-Exposure Evaluation and Follow-up paragraph (f)(3)**. This paragraph requires the employer to make immediately available a

confidential medical evaluation and follow-up to an employee reporting an exposure incident.

Bloodborne pathogens are defined by the standard (see the Definitions paragraph of this Directive), to include more than just HIV and HBV. The standard applies to any pathogenic microorganism present in human blood that can cause disease in humans. **Paragraph (f)(3)** is not specific to HIV and HBV. This paragraph requires that the employer provide post-exposure evaluation and follow-up to employees for bloodborne pathogens, such as hepatitis C (HCV), as recommended by the CDC. The current CDC recommendations for HBV, HIV and HCV are found in the Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis in Vol 50, No. RR-11, published in the June 29, 2001 MMWR (Attached as Appendix E).

NOTE: Employees who do not fall within the scope of this standard may still experience a specific exposure incident at work that is unrelated to the performance of their job duties. An example is "Good Samaritan" assistance, voluntarily performed, to an injured co-worker or a member of the public. In such a case, OSHA strongly encourages employers of these employees to offer them the follow-up procedures set forth in this paragraph.

INSPECTION GUIDELINES. The compliance officer should determine if the employer's plan ensures immediate and confidential post-exposure and follow-up procedures in accordance with the current CDC guidelines. As advised in paragraph **(f)(1)(ii)(D)**, the compliance officer should document the employer's awareness of CDC guidelines. At sites where an exposure incident has occurred it should be determined if the procedures were properly followed through interviews, incident report reviews, and, if necessary, medical records reviews.

CITATION GUIDELINES: The word **"immediately"** is used in the standard to emphasize the importance of prompt medical evaluation and prophylaxis. An exact time was not given in the standard because the time limit on the effectiveness of post-exposure prophylactic measures can vary depending on the infection of concern. OSHA requires the post-exposure evaluation and follow-up to be given as soon as possible after exposure. Where medical practice is an issue, and the compliance officer believes that access to care was delayed or denied or the employer was not following accepted post-exposure procedures, the Regional Bloodborne Pathogens Coordinator shall be contacted. A health care professional in

the Directorate of Technical Support will be consulted if necessary. The employer must have established a system that maintains the confidentiality of the employee's identity and test results. If the employer has contracted with a clinic or other healthcare facility to provide the follow-up programs, the confidentiality requirements must be part of the contract.

The boundary between employer and healthcare professional may be blurred in a medical setting in which, for example, the physician is both the employer and the evaluating healthcare professional or where the employer's certified medical laboratory analyzes the serological samples. In such cases, the compliance officer should ensure that requirements for consent and confidentiality have been followed. The medical information is to be confined to the medical department and not to be discussed with or revealed to others (e.g., the personnel department, supervisors, or other healthcare professionals who do not need the information to comply with the standard).

The employer should be cited for violating paragraph **(f)(3)** provisions (except **(iv)**) for not providing a confidential medical evaluation and follow-up, e.g., testing. Failure to provide post-exposure prophylaxis should be cited under **(f)(3)(iv)**.

14. **Paragraph (f)(3)(i)**. Documentation of the circumstances surrounding an exposure incident will help the employer and the Compliance Officer determine, for example, if PPE is being used or if training is lacking. Percutaneous injuries are primarily associated with the following activities: disposing of needles; administering injections; drawing blood, including use of capillary tubes; recapping needles; and handling trash and dirty linens.

Following an exposure incident, such as a needlestick or other sharps injury, employers are required to document, at a minimum, "the route(s) of exposure, and the circumstances under which the exposure incident occurred," as per **paragraph (f)(3)(i)**. The documentation of circumstances surrounding an incident by the employer allows identification and correction of hazards. To be useful, the documentation must contain sufficient detail about the incident. There should be information about the following: engineering controls in use at the time, work practices followed, a description of the device in use, protective equipment or clothing that was used at the time of the exposure incident, location, procedure being performed when the incident occurred, and the employee's training. Additional information might also include a

comparison of similar occurrences and recommendations to avoid future incidents, although this information is not mandatory. The Compliance Officer should request copies of the employer's documentation on exposure incidents to determine if they are in compliance with **paragraphs (c)(1)(ii)(C)** and **(f)(3)(i).**

INSPECTION AND CITATION GUIDELINES. The goal of the employer should be to implement a method or device that prevents exposure incidents from recurring. Evaluating the circumstances around an exposure incident as required by paragraph **(f)(3)(i)** provides the employer with data necessary to make effective decisions about engineering controls and work practices that will reduce the risk of exposure. The compliance officer should review the documentation of incidents available in the facility. The compliance officer should request the Exposure Control Plan and review the procedures for evaluating the circumstances surrounding exposure incidents.

15. **Paragraph (f)(3)(ii)**. This paragraph requires the employer to identify the source individual in an exposure incident, unless this is infeasible. The employer must document in writing the identity of, or infeasibility of identifying, the source individual. Examples of when it may not be feasible to identify the source individual include: incidents of needlesticks caused by unmarked syringes left in laundry, or those involving blood samples which are not properly labeled, as well as incidents occurring where State or local laws prohibit such identification.

16. **Paragraph (f)(3)(ii)(A)**. This paragraph requires testing of the source individual's blood after consent is obtained. The employer must ask for consent from the source individual or anyone legally authorized to give consent on his/her behalf. If legally-required consent is not obtained, the employer must establish this. This fact should be documented in writing, unless there is other clear evidence that consent could not be obtained. The compliance officer should ensure that the employer's plan includes this provision.

    For those jurisdictions that do not require consent of the individual, available blood may be used for testing rather than redrawing a specimen. The term "if available" applies to blood samples that have already been drawn from the source individual. OSHA does not require redrawing of blood specifically for HBV and HIV testing without the consent of the source individual.

17. **Paragraph (f)(3)(ii)(C)**. This paragraph does not authorize the employer to be informed of the results of source individual or exposed employee testing. However, the results of the source individual's testing must be made available to the exposed employee in accordance with applicable State and Federal laws and regulations concerning medical privacy and confidentiality.

18. **Paragraph (f)(3)(iii)**. The Compliance Officer must determine if the employer's program offers covered employees all of the listed requirements in the event of an exposure incident. Counseling and evaluation of reported illnesses are not dependent on the employee's electing to have baseline HBV and HIV serological testing.

19. **Paragraph (f)(3)(iii)(A)**. The consent of the employee must be obtained before the collection and testing of his or her blood.

20. **Paragraph (f)(3)(iii)(B).** This paragraph allows employees the opportunity for future testing without the need for an immediate decision. Employees involved in an exposure incident have at least 90 days following baseline blood collection to decide if they wish to have their blood tested for HIV.

    To the employee, HIV testing may present adverse ramifications, e.g., confidentiality, employment, prejudice, or lack of medical information. Therefore, the 90-day time frame allows for the opportunity to obtain knowledge about baseline serologic testing after exposure incidents, and to participate in further discussion, education or counseling. This opportunity will, instead of placing a demand on the employee to make an immediate decision, encourage employees to consent to blood collection at the time of exposure.

    Employers are required to preserve the blood the employee consented to have drawn, if it was not tested for HIV initially, for at least the 90-day period. Compliance officers should check that if the employer contracts for post-exposure follow-up, the contractor has been informed of the 90-day requirement.

21. **Paragraph (f)(3)(iv)**. Employers must follow the current guidelines at the time of exposure to determine if post-exposure prophylaxis is medically indicated. See paragraph **(f)(3)** above.

    CITATION GUIDELINES: Failure to offer post-exposure HIV prophylaxis where indicated under the current CDC guidelines should be

cited as a violation of paragraph **(f)(3)(iv)**. The guidelines leave decisions about prophylaxis up to the healthcare professional. However, in unusual circumstances involving gross misapplication of the CDC guidelines by the healthcare professional, the employer may be cited. In such cases consultation with the National office is appropriate.

22. **Information Provided to the Healthcare Professional - Paragraph (f)(4).** This paragraph requires the employer to provide information to the healthcare professional responsible for the employee's hepatitis B vaccination and post-exposure incident follow-up.

INSPECTION GUIDELINES. The Compliance officer must determine if the employer's plan includes providing a copy of this standard to the healthcare professional responsible for the employee's hepatitis B vaccination. In the case of an exposure incident, the plan must provide for the transmission of the information required by paragraphs **(f)(4)(ii)(A)-(C) and (E)** to the healthcare professional. The information required by paragraph **(f)(4)(ii)(D)** must be provided only if available. The employer does not have a specific right to know the actual results of the source individual's blood testing, but must ensure that the information is provided to the evaluating healthcare professional. If the evaluating healthcare professional is also the employer, the information must still be in the employee's record and be made available at the time of a post-exposure incident. All applicable laws and standards of confidentiality apply in this situation.

23. **Healthcare Professional's Written Opinion - Paragraph (f)(5)**. The employer is required to obtain a written opinion and provide it to the employee within 15 working days of completion of the original evaluation. The standard specifies the information which is to be included in the written opinion:

(i) for hepatitis B vaccination: whether hepatitis B vaccination is indicated for the employee, and if the employee received the vaccination;

(ii) for post-exposure evaluation and follow-up: that the employee has been informed of the results of the evaluation and told about any medical conditions resulting from exposure to blood or OPIMs requiring further evaluation or treatment.

(iii) All other findings or diagnoses shall remain confidential and shall not be included in the written report. The employer is afforded access to the limited information stated above. Any information regarding the results of

the employee's evaluation or medical conditions must be conveyed by the health care professional to the employee alone and not as part of the written opinion that goes to the employer.

24. **Paragraph (f)(5)(i)** limits the healthcare professional's written opinion to very specific information regarding the employee's hepatitis B vaccine status, including indication for vaccine and whether such vaccination was initiated (i.e., the first shot had been given.)

25. **Paragraph (f)(5)(ii)** requires documentation that a post-exposure evaluation was performed and that the exposed employee was informed of the results as well as any medical conditions resulting from exposure which require further evaluation and treatment.

G. **Employee Information and Training - Paragraph (g)**. Paragraph **(g)** ensures that employees receive sufficient warning through labels, signs, and training to eliminate or minimize their exposure to bloodborne pathogens.

1. **Labels, paragraph (g)(1)**. Labels must be provided on containers of regulated waste, on refrigerators and freezers that are used to store blood or OPIM, and on containers used to store, transport, or ship blood or OPIM. This requirement alerts employees to possible exposure since the nature of the material or contents will not always be readily identifiable as blood or OPIM.

NOTE: The labeling requirements do not preempt either the U.S. Postal Service labeling requirements (39 CFR Part III) or the Department of Transportation's Hazardous Materials Regulations (49 CFR Parts 171, 180).

DOT labeling is required on some transport containers (i.e., those containing "known infectious substances"). It is not required on all containers for which 29 CFR 1910.1030 requires the biohazard label. Where there is an overlap between the OSHA-mandated label and the DOT-required label, the DOT label will be considered acceptable on the outside of the transport container, provided that the OSHA-mandated label appears on any internal containers which may be present. Containers serving as collection receptacles within a facility must bear the OSHA label since these are not covered by the DOT requirements.

INSPECTION AND CITATION GUIDELINES. The Compliance Officer should determine that the warning labels in the facility are used as

required by paragraphs **(g)(1)(i)(A) through (D)** and include the term "BIOHAZARD."

2. **Paragraphs (g)(1)(i)(E) through (G)**. These paragraphs list exemptions from the labeling requirements which are additional to those exemptions listed for specimens in paragraph **(d)(2)(xiii)(A)** and for laundry in paragraph **(d)(4)(iv)(A)(2)**.

   Blood and blood products bearing an identifying label as specified by the Food and Drug Administration, which have been screened for HBV and HIV antibodies and released for transfusion or other clinical uses, are exempted from the labeling requirements.

   When blood is being drawn or laboratory procedures are being performed on blood samples, then the individual containers housing the blood or OPIM do not have to be labeled, provided the larger container into which they are placed for storage, transport, shipment, or disposal (e.g., a test tube rack) is labeled.

3. **Paragraph (g)(1)(i)(I)**. Regulated waste that has been decontaminated by incineration, autoclaving, or chemical means, prior to disposal is not required to bear the BIOHAZARD warning label. Failure to ensure adequate decontamination procedures prior to removal of the hazard label should be cited under paragraph **(g)(1)(i)(A)**, since the material would still be regulated waste.

4. **Information and Training - Paragraph (g)(2)**. All employees with occupational exposure must receive initial and annual training on the hazards associated with blood and OPIM, and the protective measures to be taken to minimize the risk of occupational exposure. Retraining must take place when changes in procedures or tasks occur which affect occupational exposure. While the provisions for employee training are performance oriented, with flexibility allowed to tailor the program to, for example, the employee's background and responsibilities, the categories of information listed in paragraph **(g)(2)(vii)** must be covered, at a minimum. These requirements include some site-specific information.

   INSPECTION GUIDELINES. The Compliance Officer should verify that the training is provided at the time of initial employment and at least annually thereafter as well as whenever a change in an employee's responsibilities, procedures, or work situation is such that an employee's occupational exposure is affected. "At the time of initial assignment to tasks where occupational exposure may take place" means that employees

must be trained prior to being placed in positions where occupational exposure may occur. The annual retraining for these employees must be provided within one year of their original training. This refresher training must cover topics listed in the standard to the extent needed and must emphasize new information or procedures. It does need to be an exact repetition of the previous annual training.

Part-time and temporary employees, and healthcare employees, known as "per diem" employees, are covered and are also to be trained on company time.

The Compliance Officer should interview a representative number of employees from different work areas to determine that the training (including written material, oral presentations, films, videos, computer programs, or audiotapes) was presented in a manner that was appropriate to the employee's education, literacy level, and language. If an employee is only proficient in a foreign language, the trainer or an interpreter must convey the information in that foreign language.

5. **Paragraphs (g)(2)(vii)(B)** and **(C)**. These paragraphs require that HIV and HBV and other bloodborne diseases be described. The employer must convey the idea that a number of bloodborne diseases other than HIV and HBV exist, such as **hepatitis C** (HCV) and **syphilis**. At the same time, the employer need not cover such uncommon diseases as Creutzfeldt-Jakob disease unless it is appropriate, for example, for employees working in a research facility with that particular virus.

   HCV is the most common chronic bloodborne infection in the United States. Persons who are chronically infected with HCV may not be aware of their infection because they may not be clinically ill. The infection may lead to chronic liver disease that develops slowly, often taking two or more decades before it is recognized. It is important that training include information on the transmission and symptoms of HCV.

6. **Paragraph (g)(2)(vii)(F).** This paragraph requires that training include 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.

   This requirement is very important, because the development of safer engineering controls introduces a variety of new techniques and practices to the work environment. Manufacturers market passive safety features, active devices, integrated safety designs, and accessory safety devices. The Record Summary respondents “repeatedly” emphasized the necessity of effective training and education whenever new engineering controls are implemented. Training must include instruction in any new techniques

and practices. “Hands-on” training is particularly useful. Employee participation in the selection of new devices, which plays a major part in their acceptance and correct use, is also required. (See above discussion in paragraphs **(c)(1)(iv)**, **(c)(1)(v)** and **(d)(2)** on engineering and work practice controls.)

7. **Paragraph (g)(2)(vii)(J)**. The word "emergency" in this paragraph refers to blood or OPIM exposure outside the normal scope of work. This does not refer to hospital emergency rooms or emergency medical technicians' work.

8. **Paragraph (g)(2)(vii)(N)**. This paragraph requires that there be an opportunity for interactive questions and answers with the person conducting the training session. During training, it is critical that trainees have an opportunity to ask and receive answers to questions where material is unfamiliar to them. Frequently, a trainee may be unable to go further with the training or to understand related training content until a response is received.

   Training the employees solely by means of a film or video without the opportunity for a discussion period would constitute a violation of this paragraph.

   Similarly, a generic computer program, even an interactive one, is not considered appropriate unless the employer supplements such training with the site-specific information required (e.g., the location of the exposure control plan and the procedures to be followed if an exposure incident occurs) and a person is accessible for interaction.

   Trainees must have direct access to a qualified trainer during training. OSHA’s requirement can be met if trainees have direct access to a trainer by way of a telephone hot line. The use of an electronic mail system to answer employee questions is not considered direct access to a qualified trainer, unless the trainer is available to answer e-mailed questions at the time the questions arise.

9. **Paragraph (g)(2)(viii)**. The person conducting the training is required to 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. In addition to demonstrating expertise in the area of the occupational hazard of bloodborne pathogens, the trainer must be familiar

with the manner in which the elements in the training program relate to the particular workplace.

The Compliance Officer should verify the competency of the trainer based on the completion of specialized courses, degree programs, or work experience, if he/she determines that deficiencies in training exist.

Possible trainers include a variety of healthcare professionals such as infection control practitioners, nurse practitioners, registered nurses, occupational health professionals, physician's assistants, and emergency medical technicians.

Non-healthcare professionals, such as but not limited to, industrial hygienists, epidemiologists, or professional trainers, may conduct the training provided they are knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace. One way, but not the only way, knowledge can be demonstrated is the fact that the person received specialized training.

In some workplaces, such as dental or physicians' offices, the individual employer may conduct the training, provided he or she is familiar with bloodborne pathogen exposure control and the subject matter required by paragraphs **(g)(2)(vii)(A) through (N)**.

10. **Paragraphs (g)(2)(ix)(A)-(C)**. "Standard microbiological practices" as used in these paragraphs refer to procedures outlined in "Biosafety in Microbiological and Biomedical Laboratories." The requirement that "proficiency" be demonstrated means that employees who are experienced laboratory workers may not need to be retrained in accordance with these paragraphs. Education such as a graduate degree in the study of viral diseases, or another closely related subject area with a period of related laboratory research experience, would also constitute "proficiency." The employer is responsible for evaluating the employee's proficiency and for documenting the mechanism used to determine proficiency.

H. **Recordkeeping 29 CFR 1910.1030(h)**. Records are required to be kept for each employee covered by this standard for training, as well as for medical records.

1. Medical records required by paragraph **(h)(1)** will be of particular importance to the healthcare professional in determining vaccination status and recommendation for treatment in the event of an exposure incident. Although the employer is required to establish and maintain medical records, he/she may contract for the services of a healthcare professional located offsite and that person or company may retain the records.

The requirements of **29 CFR 1910.1020** apply. In particular, **29 CFR 1910.1020(d)(1)(i)(C)** provides that the medical records of employees who have worked for less than one (1) year need not be retained beyond the term of employment if they are provided to the employee upon termination of employment.

NOTE: While paragraph **(h)(1)(iii)** requires that medical records are to be kept confidential, paragraph **(h)(1)(iii)(B)** stipulates that disclosure is permitted when required by this standard or other Federal, State, or local law.

INSPECTION GUIDELINES. All medical records required to be kept by this standard are also required to be made available to OSHA. The Compliance Officer must protect the confidentiality of these records. If they are copied for the case file, the provisions of **29 CFR 1913.10** must be followed.

The Compliance Officer should review the employer's recordkeeping program to ensure that the required information is collected, and provision has been made to ensure the confidentiality of the medical records in accordance with 29 CFR 1910.1020. While 29 CFR **1910.1020(a)** makes allowances for its provisions being carried out on behalf of the employer, paragraph **1910.1020(b)(3)** states that "each employer must ensure that the preservation and access requirements are complied with regardless of the manner in which the records are made or maintained." If the employer has contracted with a responsible third party to maintain the required records, the employer should only be cited for deficiencies of which she/he knew or could have known with the exercise of reasonable diligence.

2. **Paragraph (h)(2)** requires accurate recordkeeping of training sessions, including titles of the employees who attend. The records are necessary to assist the employer and OSHA in determining whether the training program adequately addresses the risks involved in each job. Additionally, this information is helpful in tracking the relationship between exposure incidents (e.g., needlesticks) and various jobs and the corresponding level of training.

   Training records may be stored onsite where the actual documents will be easily accessible for review. In order to ensure that the employee training is complete, all the components of the program required by paragraph **(g)(2)(vii)** must be covered.

Training records are not considered to be confidential. Training records may be stored onsite where the actual documents are readily accessible. They must be retained for 3 years from the training date.

3. **Paragraph (h)(5)** requires employers to establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. This log is separate from the log of injuries and illnesses kept under Part 1904. Employers who are already partially exempt from Part 1904 recordkeeping requirements (See **29 CFR 1904.1** and **1904.2**) are not required to keep a sharps injury log, but are encouraged to do so. Federal agencies will be required to keep a sharps injury log by a revision to Part 1960 that is currently under review.

   The log must include the type and brand of device involved in the incident, the department or work area where the exposure incident occurred and an explanation of how the incident occurred so that the intended evaluation of risk and device effectiveness can be accomplished. More information may be included; however the confidentiality of the injured employee must be maintained throughout the process. If the nature of the incident is such that determining the type and brand of the device would increase the potential for additional exposure (e.g., housekeeper stuck through trash bag), the type/brand may be recorded as "Unknown".

   The purpose of the log is to aid in the evaluation of devices being used in the workplace and to quickly identify problem areas in the facility. Thus, it should be reviewed regularly and during the review and update of the Exposure Control Plan.

   If the data is made available to other parties (e.g., supervisors, safety committees, employees, employee representatives), any information that directly identifies an employee or any information that could reasonably be used to identify the employee must be withheld. Logs must be saved for at least five years following the end of the calendar year that they cover.

   INSPECTION GUIDELINES: The format of the sharps injury log is not specified. The employer is permitted to determine the format in which the log is maintained (e.g. paper or electronic) and may include information in addition to that required by the standard, so long as the privacy of the injured worker is protected. Many employers already compile reports of percutaneous injuries to comply with paragraph **(f)(3)**. Existing mechanisms for collecting these reports could be considered sufficient to meet the requirements for maintaining a log provided that the information meets the minimum requirements specified by the standard and the confidentiality of the injured employee is protected.

CITATION GUIDELINES: Employers partially exempt from recordkeeping requirements under **29 CFR1904** are exempt from the requirement of maintaining a sharps injury log, but are encouraged to do so. All employers, however, must still comply with the post-exposure documentation requirements of paragraphs **(f)(3)** and the annual review documentation requirements of **(c)(1)(iv)**, even when a physical log is not required.

XIV. Interface With Other Standards.

A. The current 1904 Recordkeeping rule requires recording of needlesticks and other exposure incidents on the OSHA 200 only if there is a seroconversion or the injury requires medical treatment. Medical treatment includes the administration of post-exposure prophylaxis.

A revision to the Recordkeeping Regulation was published January 19, 2001 and will become effective Jan. 1, 2002. Paragraph **1904.8** requires **all** work-related injuries from needlesticks and cuts, lacerations, punctures and scratches from sharp objects contaminated with another person's blood or OPIM to be recorded on the OSHA 300 as an injury. To protect the employee's privacy, the employees name may not be entered on the OSHA 300. Paragraphs **1904.29(b)(6)** thru **(b)(9)** discuss privacy concerns. Employers must keep a separate confidential list of the case numbers and employee names so they can update the cases or provide them if asked by the government. If the employee develops a bloodborne disease, the entry must be updated and recorded as an illness.

B. The hazard communication standard, **29 CFR 1910.1200**, applies only to the hazards of chemicals in the workplace and does not apply to biological hazards such as bloodborne diseases.

C. Records concerning employee exposure to bloodborne pathogens and records about HIV and/or HBV status are both considered employee medical records within the meaning of **29 CFR 1910.1020.** Under **29 CFR 1913.10 (b)(4)** the Compliance Officer may review these records onsite for verification of compliance with the medical surveillance requirements. If requested, this review shall be conducted under the observation of the medical record holder or other employer designated healthcare professional. The compliance officer should not record or take offsite any information from the medical record other than documentation of the fact of compliance or noncompliance. Generally, compliance/noncompliance verification requires no additional action (i.e., in-depth review, copying, and/or removal of confidential medical information from

the worksite) on behalf of the compliance officer. If additional or more detailed information is required for clarification, or to support a suspected violation, the compliance officer is advised to seek a medical access order (MAO) for obtaining the necessary information from the Director (Medical Records Officer), Office of Occupational Medicine. Also, when a compliance officer anticipates, or if it is known that there may be a problem in gaining access to confidential medical information/medical records, or the employer denies access during the course of the inspection, the compliance officer is advised to obtain an administrative subpoena (from the regional solicitor) in addition to the MAO before looking at any confidential medical information or medical records.

D. Generally, the respiratory protection standard, **29 CFR 1910.134**, does not apply. However, placing or storing respirators in areas where they could be contaminated by body fluids constitutes a violation of **29 CFR 1910 .134(h)(2)(i)** or **29 CFR 1910 .139(b)(6)**, if the respirator is used for protection against tuberculosis.

E. The Hazardous Waste Operations and Emergency Response (HAZWOPER) standard, **29 CFR 1910.120**, covers four groups of employees: workers at uncontrolled hazardous waste remediation sites; workers at Resource Conservation and Recovery Act (RCRA) permitted hazardous waste treatment, storage and disposal facilities; workers performing corrective actions involving cleanup operations at RCRA sites; and those workers expected to respond to emergencies caused by the uncontrolled release of a hazardous substance.

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

2. Employers of employees engaged in these types of 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 safety and health applies.

{ XV. Coding in the OIS.

Current instructions for completing the appropriate inspection classification fields in the OSHA Information System (OIS), as further explained in the OIS Enforcement User Guide, shall be applied when recording bloodborne pathogens inspections:

A. For any inspection which includes an evaluation of the hazards of bloodborne

pathogens, the inspection shall be coded as follows:

Additional Code / N-02-BLOOD.

B. Add any additional codes for related regional or local emphasis programs related to bloodborne pathogens for either Federal or State Plan enforcement activity. }

This directive provides guidance for enforcement of the Bloodborne Pathogens Standard. The agency's application of this policy in any particular matter will, however, depend upon all relevant circumstances. For purposes of providing information and guidance, this directive also restates, clarifies, or explains the provisions of the standard. OSHA's restatement, clarification or explanation of the requirements of the standard does not amend the standard or create new legal duties, obligations or defenses.

APPENDIX A - TYPICAL COMMITTEES IN HEALTH CARE FACILITIES

The Compliance Safety and Health Officer (CSHO) may find that a health care facility has a variety of committees involved in assuring compliance with the bloodborne pathogens standard. Although committees are rarely mandated by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the Health Care Financing Administration (HCFA), there are certain committees which are typically found in health care facilities. Although the minutes or reports from these committees may be "protected" (not available to the general public), discussions about the committees' functions may be useful in evaluating the facility's processes. Committee functions may vary and there is no prescribed form for their structure. However, listed below are some general functions and the committees which might be involved in those processes:

ASSURING IMPLEMENTATION OF THE EXPOSURE CONTROL PLAN:

Safety Committee/ Employee Health Committee
Typically composed of representatives from the occupational health unit, safety manager, human resources, and employees from the various departments. The duties of this committee usually include:

- Developing and reviewing policies and procedures for safe and healthy work conditions for employees.
- Developing and evaluating all safety and health programs, including implementation of the Exposure Control Plan for Bloodborne Pathogens.
- Establishing and implementing procedures for workplace safety inspections.
- Establishing procedures for investigating and recording all workplace accidents, illnesses, and fatalities.
- Assuring implementation of OSHA standards, including resource allocation.
- Making recommendations in response to exposure incidents.
- Reviewing screening and surveillance data.

Infection Control Committee
Typically composed of employee and management representatives from various departments, including the infection control practitioner and facility epidemiologist. The duties of this committee usually include:

- Analyzing and identifying infections among patients/residents.
- Developing and evaluating infection control plans to protect the patients/residents, including the use of universal precautions.
- Establishing policies and procedures regarding infection control, focusing on risks to patients/residents and the general public (e.g., visitors, volunteers, etc.).

HAZARD IDENTIFICATION (Including worksite inspections and tracking trends)

Safety Committee (see description above)

Facilities Maintenance /Hazardous Waste Committee
Typically composed of the facilities engineer and representatives from various departments. The duties of this committee usually include:

- Developing and reviewing policies and procedures related to environmental, facility, and hazardous waste issues.
- Coordinating with the Safety and Quality Assurance committees for investigation and recording all workplace accidents, illnesses, and fatalities which relate to environmental and hazardous waste issues
- Assuring compliance with applicable OSHA standards.
- Performing building inspections.

Quality Assurance/Utilization Review/Risk Management Committee
Typically composed of a Board of Directors representative, chief executive officer, director of quality care/assurance/utilization review/risk management, and representatives from various departments. The duties of this committee usually include:

- Ensuring the presence of overall acceptable standards of quality care for patients/residents.
- Complying with laws and regulations related to patient safety, specifically JCAHO and HCFA.
- Evaluating the utilization of health care services by patients/residents**.**

SELECTION, EVALUATION & RECOMMENDATIONS FOR PPE AND NEW DEVICES

Products Management Committee
Typically composed of the safety director, the purchasing agent and representatives from various departments. The duties of this committee typically include:

- Monitoring equipment currently in use.
- Evaluating new products being considered or already ordered.
- Providing information about equipment and products to involved employees**.**

Quality Care/Assurance/Utilization Review/Risk Management Committee (see description above)

Safety Committee (See description above)

EDUCATION/TRAINING/ORIENTATION

Education Committee
Typically composed of a Board of Directors representative and representatives from various departments. The duties of this committee usually include:

- Assuring delivery of education programs for both professional and non-professional employees within the health care facility and the community, such as training with new equipment**.**
- Ensuring that educational presentations meet professional standards.
- Evaluating new employee orientation and on-going continuing educational programs.

Products Management Committee (see description above)

RECORDKEEPING

Safety Committee (see description above)

Quality Assurance/Utilization Review/Risk Management Committee (see description above)

Infection Control Committee (see description above)

ASSURE COMPLIANCE BY PHYSICIAN STAFF

Medical Executive Committee
Typically composed of elected officers of the medical staff, the immediate past president of the medical staff, the chairpersons of the various medical departments, and physicians on the Board of Directors. The president of the hospital, vice president of medical affairs, director of nursing services and director of quality care/assurance/utilization review/risk management serve as nonvoting members. The duties of this committee usually include:

- Accounting to the Board of Directors for patient/resident care.
- Acting on reports and recommendations offered by other committees.
- Coordinating the activities of the medical staff.
- Making recommendations on medical issues.
- Recommending appointment, reappointment, and corrective action of medical staff.

OTHER COMMITTEES WHICH THE CSHO MAY ENCOUNTER

Budget/Finance and Audit Committee
Typically composed of representatives from the Board of Directors, chief executive officer, chief financial officer, and various departmental directors. The duties of this committee usually include:

- Monitoring the financial status of the health care facility.
- Advising the Board of Directors concerning financial policies.
- Reporting to the Board of Directors on the effectiveness of resource allocations.

Ethics Committee
Typically composed of facility staff such as nurses, physicians, attorneys, hospital

administrators, social workers and clergy. May also include community members. The duties of this committee usually include:

- Clarifying complex ethical issues that affect the care and treatment of patients/residents in the health care facility**.**

Information Systems Committee
Typically composed of the director of information systems and representatives from the various departments. The duties of this committee usually include:

- Evaluating and recommending clinical computer systems.
- Providing training on clinical computer systems.
- Responding to requests for assistance with computer applications**.**

Pharmacy and Therapeutics Committee
Typically composed of the director of pharmacy, a nursing representative, the infection control practitioner, a dietician, and a physician. The duties of this committee usually include:

- Developing policies and procedures concerning drugs used in the facility.
- Establishing standards concerning the use of investigational drugs.
- Recommending drugs to be made available at the facility ("formulary"), including vaccines.

APPENDIX B - ENGINEERING CONTROL EVALUATION FORMS

The following pages contain sample forms that may be used in evaluating safer engineering controls. These forms are only applicable to certain groups of devices. Safer engineering controls are not limited to the devices contained in the following pages. None of these forms are specifically required by the bloodborne pathogens standard, but they may be useful as guidance documents. Employers are responsible for setting the evaluation criteria for the devices used in their facilities in accordance with the standard.

Sample Forms:

NIOSH

Questionnaire for Evaluating Sharps Disposal Container Performance [PDF 20 KB]

ECRI©

ECRI's Needlestick-Prevention Device Evaluation Form [PDF 18 KB]

NPD Cost Calculation Worksheet [PDF 21 KB]

Training for Development of Innovative Control Technologies Project (TDICT)©

SAFETY FEATURE EVALUATION FORMS [PDF 21 KB]

SAFETY SYRINGES [PDF 24 KB]

I.V. ACCESS DEVICES [PDF 23 KB]

SHARPS DISPOSAL CONTAINERS [PDF 24 KB]

I.V. CONNECTORS [PDF 21 KB]

VACUUM TUBE BLOOD COLLECTION SYSTEMS [PDF 21 KB]

E. R. SHARPS DISPOSAL CONTAINERS [PDF 24 KB]

SAFETY DENTAL SYRINGES [PDF 24 KB]

HOME USE SHARPS DISPOSAL CONTAINER [PDF 24 KB]

APPENDIX C - WEB SITE RESOURCE LIST

{ **Corrected 3/1/2017** with updates to Web site addresses }

Effective Engineering Controls
CDC Guidelines and Recommendations
Vaccine Safety

NOTE: This appendix contains web sites that can be used for the purposes of information and research. The examples of effective engineering controls in this appendix do not include all those on the market, but are simply representative of the devices available. **OSHA does not approve, endorse, register, or certify any medical devices.** Inclusion in this list does not indicate OSHA approval, endorsement, registration, or certification. The final determination of compliance with OSHA's standards takes into account all factors pertaining to the use of such devices at a particular worksite.

EFFECTIVE ENGINEERING CONTROLS

ECRI
Available: http://www.ecri.org/
ECRI, designated as an Evidence-based Practice Center by the Agency for Health Care Policy and Research, is a nonprofit international health services research organization.

Food and Drug Administration (FDA) Safety Alerts
Available: http://www.fda.gov/medicaldevices/safety/default.htm
Link page for Safety Alerts and Advisories that warn of the risk of injuries from medical devices.

International Health Care Worker Safety Center, University of Virginia
Available: **{**https://www.medicalcenter.virginia.edu/epinet}
Features a list of safety devices with manufacturers and specific product names.

National Institute for Occupational Safety and Health (NIOSH) Sharps Disposal Containers
Available: **{**http://www.cdc.gov/niosh/docs/97-111/}
Features information on selecting, evaluating, and using sharps disposal containers.

Occupational Safety and Health Administration (OSHA) Glass Capillary Tubes: Joint Safety Advisory About Potential Risks
Available: /pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=22695
Describes safer alternatives to conventional glass capillary tubes.

Occupational Safety and Health Administration (OSHA) Needlestick Injuries
Available: **{**https://www.osha.gov/SLTC/bloodbornepathogens/index.html}
Features recent news, recognition, evaluation, controls, compliance, and links to information on effective engineering controls.

Safety Sharp Device Contracts
Available: **{**https://www.va.gov/oal/business/pps/scaInventory.asp}
Features safety sharp devices on contract with the US Department of Veterans Affairs (VA).

SHARPS Injury Control Program
Available: **{**http://www.cdph.ca.gov/programs/ohsep/Documents/CompletedProj-Sharps.pdf}
Established by Senate Bill 2005 to study sharps injuries in hospitals, skilled nursing facilities, and home health agencies in California. Features a Beta version of Safety Enhanced Device Database Listing by Manufacturer.

Training for Development of Innovative Control Technologies (TDICT) Project
Available: http://www.tdict.org/
Features "Safety Feature Evaluation Forms" for specific devices.

US DEPARTMENT OF HEALTH & HUMAN SERVICES (HHS): CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) GUIDELINES AND RECOMMENDATIONS

CDC Prevention Guidelines Database
Available: **{**http://www.cdc.gov/hicpac/pubs.html#a2}
Provides access to the CDC Prevention Guidelines Database, which is a compilation of all of the official guidelines and recommendations published by the CDC for the prevention of diseases, disabilities, and injuries. Information on how to find a specific CDC Prevention Guideline.

Morbidity and Mortality Weekly Report (MMWR)
Available: http://www.cdc.gov/mmwr/
Provides access to the MMWR, a series which is prepared by the CDC. Contains comprehensive information on policy statements for prevention and treatment that are within the CDC's scope of responsibility, for example, recommendations from the Advisory Committee on Immunization Practices (ACIP).

The following are CDC guidelines and recommendations on HIV, Hepatitis B, and Hepatitis C:

Guideline for Infection Control in Health Care Personnel, 1998.
Available: {http://www.cdc.gov/hicpac/pdf/InfectControl98.pdf}

Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease. *Publication date 10/16/1998.*
Available: www.cdc.gov/mmwr/preview/mmwrhtml/00055154.htm

Public Health Service Guidelines for the Management of Health-Care Worker Exposures to HIV and Recommendations for Postexposure Prophylaxis. *Publication date 05/15/1998.*
Available: http://wonder.cdc.gov/wonder/prevguid/m0052722/m0052722.asp

Appendix - First-Line Drugs for HIV Postexposure Prophylaxis (PEP). *Publication date*

05/15/1998.
Available: http://www.cdc.gov/mmwr/preview/mmwrhtml/00052801.htm

Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). *Publication date 12/26/1997.*
(Provides recommendations for Hepatitis B).
Available: {https://www.cdc.gov/mmwr/preview/mmwrhtml/00050577.htm}

Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis.
Publication date June 29, 2001
Available: http://www.cdc.gov/mmwr/PDF/rr/rr5011.pdf

VACCINE SAFETY

Centers for Disease Control and Prevention (CDC)
Available: {http://www.cdc.gov/vaccinesafety/index.html}
The National Immunization Program (NIP) of the CDC features information on vaccine safety.

Food and Drug Administration (FDA)
Available:
{http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm133806.htm} and
{http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/VaccineAdverseEvents/default.htm}
The first site features information on how the FDA ensures vaccine safety. The second site features information on the Vaccine Adverse Event Reporting System (VAERS), a cooperative program for vaccine safety of the FDA and CDC.

Immunization Action Coalition (IAC)
Available: http://www.immunize.org/
The IAC is a nonprofit organization working to increase immunization rates and prevent disease. Features Vaccine Information Statements, free print materials, and other hepatitis and immunization sites.

Infectious Diseases Society of America (IDSA)
Available: {http://www.idsociety.org/Immunization/}
The Vaccine Initiative is a project of the IDSA and the Pediatric Infectious Diseases Society. Features information on vaccination and vaccination-related issues.

Institute for Vaccine Safety, Johns Hopkins School of Public Health
Available: http://www.vaccinesafety.edu/
The purpose of the Institute is to obtain and distribute information on the safety of recommended immunizations.

National Institutes of Health (NIH)
Available: {https://wayback.archive-it.org/7761/20160822232544/https://www.niaid.nih.gov/topics/vaccines/documents/undvacc.pdf}
Features a 40-page brochure "Understanding Vaccines."

World Health Organization (WHO)
Available: {http://www.who.int/immunization/quality_safety/en/}
Features a vaccine safety home page which offers links to vaccine safety-related information.

APPENDIX D - MODEL EXPOSURE CONTROL PLAN

To see Appendix D Click here [PDF 59 KB]

APPENDIX E

Centers for Disease Control *Morbidity and Mortality Weekly Report*:
"Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis."
June 29, 2001, Vol.50, No.RR-11
http://www.cdc.gov/mmwr/PDF/rr/rr5011.pdf

INDEX

1904 ..... 5, 6, 65, 66, D-10, D-12
1910.1020 ..... 14, 64, 66, D-10
1910.1200 66
1910.134 67
aerosols 25
agriculture 10
annually 4, 13, 15, 16, 47, 60, D-2, D-3, D-11
antibody testing 51, D-7
ASTM 29
biohazard 27, 42, 59, 60, B-14, D-6
bleach 35, 36
bulk blood 39
capillary tubes 2, 13, 18, 19, 37, 55, C-1, D-3
CDC 2, 4, 11, 21, 35, 45, 49, 50, 54, 57, 58, C-1-3, E-1
closable 24, 39, 42, B-12, D-5
collateral duty 10, 51
color-coded 39, 42-45, D-5, D-6
construction 10, 39, 42, B-3
container 26, 27, 38-43, 59, 60, B-1-5, B-9, B-12, B-14
contaminated 4-6, 9, 12-14, 18, 19, 22-28, 32-39, 41, 43-45, 47, 65-67, D-4-6, D-8, D-10, D-12
correctional officers 9
custodial 9
declination 50, 53, D-7, D-13
decontamination 27, 34-38, 43, 60, B-2, D-4, D-9
dentists 9, 26
device 12, 13, 17, 19-21, 23, 24, 46, 55, 56, 65, B-1, B-4-8, B-10, B-11, B-13, C-2, D-8, D-10, D-12
disinfectants 27, 35, 36
disposable 16, 24, 32, 37, 39, 42, D-5
DOT 59
emergency 3, 5, 9, 13, 17, 20, 23, 26, 29-31, 51, 62, 63, 67, B-3, B-12, D-9
engineering controls 4, 7, 15-22, 46, 55, 56, 61, 62, C-1-3, D-8, D-9
environmental surfaces 24, 34-36
EPA 35, 39
Epinet 1, 20, 41, C-1
exposure control plan 4-7, 13-16, 19, 24, 43, 51, 56, 62, 65, D-1, D-3
exposure incident 12, 13, 16, 20, 48, 51, 52, 54-58, 62, 63, 65, D-1, D-7-10
eye protection 18, 25, 34, D-4, D-5
FDA 2, 19, 30, 35, C-1, C-3
federal agency 8
FIRM 1, 5, 7, 11, D-1
first aid 5, 9, 10, 12, 51, 52, D-7

follow-up 1, 7, 12, 48, 50-55, 57, 58, D-1, D-7-9
funeral homes 9
general duty clause 11
gloves 23, 27, 30, 32, 33, 43, 44, B-7, B-13, D-4, D-5, D-8
Good Samaritan 12
gowns 28, 34, 44
hand cream 24
handwashing 7, 22, 23
HBV 2-4, 9, 11, 13, 18, 35, 36, 45, 48, 49, 54, 56, 57, 60, 61, 66, C-3, D-7, D-13, E-1
hepatitis 1-4, 7, 8, 11, 36, 48-54, 58, 59, 61, C-2, C-3, D-1, D-6-9, D-13
HIV 1-4, 9, 11, 13, 18, 35, 36, 45, 48, 49, 54, 56, 57, 60, 61, 66, C-2, C-3, D-7, E-1
home health services 7
housekeepers 9, 20
housekeeping 5, 7, 8, 17, 34, 35, 38, D-1, D-5
human blood 11, 17, 18, 54
hypodermic 2
incident report 54
incineration 43, 60
IV 2, 14-16, 19, 21-23, 25, 31, 32, 39, 43-45, 53, 55, 57, 58, 60, 62, 66, B-2, B-4
kidney stones 26
labeling 25-27, 30, 43, 59, 60, B-2, D-6
laboratory 9, 17, 25, 26, 28, 30-32, 34-36, 45, 46, 50, 55, 60, 63
lasers 25
latex 30, 32
laundering 31, 45, D-4, D-6
laundries 9, 41, 43
laundry 14, 41, 43-45, 56, 60, D-6
longshoring 10
medical equipment 9
medical records 1, 54, 63, 64, 66, 67, D-8, D-10
medical waste 39
microsurgery 34
mucous membranes 25, 28, 33, 46
multi-employer 6-8
needle sheath 40
needleless 12, 18, 19, 21, D-3
needlestick 1-4, 12, 16, 20, 21, 40, 41, 55, B-1, B-2, B-4, C-1
NIOSH 2, 30, 39, 41, B-1, B-3, C-1, D-2
occupational exposure ..... Cover, 1-5, 9, 10, 12-15, 18, 27, 32, 48, 50, 51, 60, 61, D-1-3, D-9, D-10, D-13
OPIM 4-6, 9, 11-13, 17, 18, 20, 23, 25, 26, 28, 31, 33-35, 37-39, 43, 44, 48, 51, 52, 59, 60, 62, 66, D-2, D-4-6, D-9
OSHA 200 ..... 20, 66
per diem employees D-3
phlebotomy 21, 23, 33, 37

physicians 8, 9, 49, A-3, A-4
plasma centers 9
plasmapheresis 33
pneumatic tube 26
post-exposure 4, 7, 8, 48, 51-55, 57-59, 66, D-1, D-7-9
PPE 23, 27-32, 34, 47, 55, D-4-6, D-9
prescreening 53
prophylaxis 1, 2, 4, 49, 51, 52, 54, 55, 57, 58, 66, C-3, E-1
recapping 22-24, 55, B-7, B-13
Record Summary 1, 21, 41, 61
recordkeeping 5-8, 63-66, A-3, D-1, D-7, D-9, D-10
regulated waste 7, 9, 12, 17, 37-39, 42, 43, 46, 59, 60, D-3, D-5, D-6
research laboratories 45, 48
resuscitator devices 29
retraining 60, 61
reusable sharps 24, 38, 42
RFI 1, 4
safer medical devices 4, 12, 16, 18, 19
scrubs 28
SESIPs 12, 13, 40, D-3
sharps containers 18, 22, 23, 39-42, B-4, B-5, D-2
sharps injury log 5, 20, 65, 66, D-8, D-10, D-12
shipyard 10
solicit 4, 16
spattering 25
specimen 25-27, 37, 56
standard precautions 18
sterilize 34
surfaces 24-26, 32-37, 43, 44, B-2, B-9, D-5
syphilis 4, 11, 61
teeth 26
towelettes 22
training 2, 4, 5, 7, 8, 13, 14, 20, 21, 23, 25, 29, 32-34, 38, 41-44, 48, 50, 52, 55, 59-65, A-3, A-4, B-1, B-4, B-6-14, C-2, D-1-4, D-6-10
U.S. Public Health Service 2, 49, 54, C-3, E-1
vaccination 4, 7, 8, 13, 48-53, 58, 59, 63, C-3, D-1, D-6-8, D-13
vaccine 11, 48-53, 59, C-1, C-3, C-4, D-7, D-9, D-13
volunteer 33
wicking 32
work areas 32, 46, 61
work practices 6, 7, 18, 20, 21, 27, 41, 46, 55, 56, 61, D-2-4, D-8, D-9
written opinion 58, 59, D-7, D-8