OSHA INSTRUCTION

U.S. DEPARTMENT OF LABOR — Occupational Safety and Health Administration

DIRECTIVES NUMBER: CPL 2-2.69	**EFFECTIVE DATE:** November 27, 2001

SUBJECT: Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens

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

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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.

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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/ncidod/hip/Guide/guide.htm)

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 *http://www.med.virginia.edu/~epinet/ soio.html*) 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, http://www.osha-slc.gov/SLTC/needlestick/index.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.

   a. 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).

b. 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 where the area 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).

a. 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.

b. 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.

c. 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:

    a. 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;

    b. 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;

    c. 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-slc.gov/html/hotfoias/tib/TIB19990412.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://ace.orst.edu/info/nain/lists.htm* 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 not 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.

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

ECRI©

ECRI's Needlestick-Prevention Device Evaluation Form

NPD Cost Calculation Worksheet

Training for Development of Innovative Control Technologies Project (TDICT)©
SAFETY FEATURE EVALUATION FORMS

SAFETY SYRINGES

I.V. ACCESS DEVICES

SHARPS DISPOSAL CONTAINERS

I.V. CONNECTORS

VACUUM TUBE BLOOD COLLECTION SYSTEMS

E. R. SHARPS DISPOSAL CONTAINERS

SAFETY DENTAL SYRINGES

HOME USE SHARPS DISPOSAL CONTAINER

QUESTIONNAIRE FOR EVALUATING SHARPS DISPOSAL CONTAINER PERFORMANCE

INSTRUCTIONS: Product evaluators should inspect and operate containers to be evaluated in side-by-side comparisons. Representative sharps (syringes, IV sets, blades, biopsy needles, pipettes, etc.) should be used to test candidate products. Actual use conditions should be simulated, if possible. Prior to inserting test sharps, attempt to reopen sealed containers and attempt to spill or remove contents from unsealed containers if this is a functional requirement. Evaluation facilitators should provide product manufacturer literature and visual instructions and should demonstrate proper operation of each of the containers. Use of this guideline requires knowledge that the ideal product may not exist and that this evaluation tool was based on common product designs available at the time.

PLEASE CIRCLE YOUR RESPONSE

FUNCTIONALITY

	agree . . . . . disagree				
Container is stable when placed on horizontal surface and when used as described in the product labeling for use in trays, holders, or enclosures	1	2	3	4	5
Container provides for puncture, leak, and impact resistance	1	2	3	4	5
Container, labels, warning devices, and brackets are durable	1	2	3	4	5
Container is autoclavable, if necessary	1	2	3	4	5
Container is available in various sizes and capacities	1	2	3	4	5
Container is available with auxiliary safety features (e.g., restricted access to sharps in the container), if required	1	2	3	4	5
Closure mechanism will not allow needlestick injury	1	2	3	4	5
Closure mechanism provides secure seal	1	2	3	4	5
Design minimizes needle-tip flipback	1	2	3	4	5
Design promotes clinical performance (e.g., will not compromise sterile field or increase injury or infection control hazards)	1	2	3	4	5
Design resists easy reopening after sealing for final disposal or autoclaving	1	2	3	4	5
Inlet design defeats waste removal when open	1	2	3	4	5
Inlet design prevents spillage of contents (physical or liquid) while sharps disposal container is in use in the intended upright position	1	2	3	4	5
Containers designed to be reopenable have removable lids design with tight closure that facilitates ease of removal with grip safety and comfort	1	2	3	4	5
Mounting brackets are rugged and designed for ease of service and decontamination	1	2	3	4	5

ACCESSIBILITY

	agree . . . . . disagree				
Container available in various opening sizes and shapes	1	2	3	4	5
Containers are supplied in sufficient quantity	1	2	3	4	5
Container has an entanglement-free opening/access way	1	2	3	4	5
Container opening/access way and current fill status visible to user prior to placing sharps into container	1	2	3	4	5
Internal design/molding of container does not impede ease of use	1	2	3	4	5
Handles, if present, located above full-fill level	1	2	3	4	5
Handles, if present, facilitate safe vertical transport and are located away from opening/access way and potentially soiled surfaces	1	2	3	4	5
Fixed locations place container within arm's reach of point of waste generation	1	2	3	4	5
Fixed locations allow for installation of the container below horizontal vision level	1	2	3	4	5
If necessary, in high patient or visitor traffic areas, container should provide for security against tampering	1	2	3	4	5

VISIBILITY

	agree				disagree
Color or warning label implies danger.	1	2	3	4	5
A warning indicator (i.e., color or warning label) is readily visible to the user prior to user placing sharps into container	1	2	3	4	5
Overfill level provided and current fill status is readily visible to the user prior to use placing sharps into container	1	2	3	4	5
Sharps disposal container complies with OSHA requirements	1	2	3	4	5
Disposal opening/access way is visible prior to user placing sharps into container	1	2	3	4	5
Security, mounting, aesthetic, and safety features do not distort visibility of the opening/access way or fill status indicator	1	2	3	4	5

ACCOMMODATION

	agree				disagree
No sharp edges in construction or materials	1	2	3	4	5
Safety features do not impede free access	1	2	3	4	5
Promotes patient and user satisfaction (i.e., aesthetic to extent possible)	1	2	3	4	5
Is simple to operate	1	2	3	4	5
Any emissions from final disposal comply with pollution regulations	1	2	3	4	5
Easy to assemble, if required	1	2	3	4	5
Components of containers that require assembly are easy to store prior to use	1	2	3	4	5
Use allows onehanded disposal	1	2	3	4	5
Product available in special designs for environments with specific needs (e.g., laboratories, emergency rooms, emergency medical services, pediatrics, correctional facilities)	1	2	3	4	5
Mounting system durable, secure, safe, cleanable, and, where appropriate, lockable	1	2	3	4	5
Mounting systems allow height adjustments	1	2	3	4	5
Design promotes task confidence	1	2	3	4	5
Cost effectiveness	1	2	3	4	5

OTHER COMMENTS

What design or performance requirements are missing from the product you evaluated that are really needed to safely or more comfortably conduct your job or sharps related task?

Additional Evaluator Concerns and Comments:

This product selection questionnaire was developed by the Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health in conjunction with NIOSH Educational Resource Centers; The Johns Hopkins University, Baltimore; the University of Texas, Houston; the University of California, Berkeley; and the Mount Sinai School of Medicine, New York City.

ECRI's Needlestick-Prevention Device Evaluation Form

Device: _____

Supplies/Trade Name _____

Applications: _____

Reviewer: _____ Date: _____

For each question circle the appropriate response for the needlestick-prevention (NPD) device being evaluated.

Healthcare Worker Safety

1. A. Does the NPD prevent needlesticks during use (i.e., before disposal)? . . . . . Yes No

   B. Does it do so after use(i.e., does the safety mechanism remain activated through disposal of the NPD)? . . . . . Yes No

2. A. Does NPD provide protection one of the following ways: Either intrinsically or automatically? (Answer "No" if a specific action by the user is required to activate the safety mechanism.) . . . . . Yes No

   B. If "No," is the mechanism activated in one of the following ways: either by one-handed technique or by a two-handed technique accomplished as part of the usual procedure? . . . . . Yes No

3. During the use of NPD do user's hands remain behind the needle until activation of the safety mechanism is complete? . . . . . Yes No

4. Is the safety mechanism reliable when activated properly? . . . . . Yes No

5. Does the NPD minimize the risk of user exposure to the patient's blood? . . . . . Yes No

Patient Safety and Comfort

6. Does the NPD minimize the risk of infection to the patient (e.g., through cross-contamination)? . . . . . Yes No

7. Can the NPD be used without causing more patient discomfort than a conventional device? . . . . . Yes No

8. *For IV NPDs* : Does the NPD attach comfortably (i.e., without causing patient discomfort at the catheter port or IV tubing? . . . . . Yes No

Ease of use and Training

9. Is NPD Operation obvious? That is can the device be used properly without extensive training? . . . . . Yes No

10. Can the NPD be used by a left-handed person as easily as by a right handed person? . . . . . Yes No

11. Is the technique required for using the NPD the same as that for using a conventional device? . . . . . Yes No

12. Is it easy to identify the type and size of the product from the packaging? . . . . . Yes No

13. *For intravenous (IV) catheters and blood collection needle sets*: Does the NPD provide a visible blood flashback during initial insertion? . . . . . Yes No

14. Please rate the ease of using this NPD . . . . . Exc. Good Fair Poor

15. Please rate the quality of the in-service training . . . . . Exc. Good Fair Poor

Compatibility

16. Is the NPD compatible with devices (e.g., blood collection tubes) from a variety of suppliers? . . . . . Yes No

17. *For IV NPDs*:

   A. Is the NPD compatible with intralipid solutions? . . . . . Yes No

   B. Does the NPD attach securely at the catheter port? . . . . . Yes No

   C. Doe the NPD attach securely or lock at a Y-site (e.g. for piggybacking)? . . . . . Yes No

18. Is the NPD easy to dispose of in sharps containers of all sizes (if required)? . . . . . Yes No

19 Does using the NPD instead of a conventional device result in only a modest (if any) increase in sharps container waste volume? (Answer "No" if the NPD will increase waste volume significantly.) . . . . . Yes No

Overall

20 Would you recommend using this device? . . . . . Yes No

Comments (e.g., describe problems, list incompatibilities)

NPD Cost Calculation Worksheet*

WORKSHEET			SAMPLE DATA	
PROTECTIVE SYSTEM			**Protective blood collection tube holder**	
NPD (supplier/trade name)			XYZ Medical Pro Hold	
A. Price per device	A=	$	A=	$4.00
B. Uses per year	B=		B=	130,000
C. Uses per device	C=		C=	300
D. Quantity used per year (B ÷ C)	D=		D=	433
E. NPD cost per year (A × D)	E=	$	E=	$ 1,732
Additional component			XYZ Medical ProHold Companion 1 Qt Sharps Container	
F. Price per device	F=	$	F=	$3.50
G. Uses per year	G=		G=	Dispose of 130,000 needles
H. Uses per device	H=		H=	NA (see next entry)
I. Quantity used per year (G ÷ H)	I=		I=	32**
J. Additional component cost per year (F × I)	J=	$	J=	$112
K. Annual protective system cost (E ÷ J)	K=	$	K=	$1,844
CONVENTIONAL SYSTEM			**Blood collection tube holder**	
Conventional device			XYZ Medical Tube Holder	
L.. Price per device	L=	$	L=	$0.15
M. Uses per year	M=		M=	130,000
N. Uses per device	N=		N=	300
O. Quantity used per year (M ÷ N)	O=		O=	433
P. Conventional device cost per year (L × O)	P=	$	P=	$65
Additional component			**Conventional 1qt sharps container**	
Q. Price per device	Q=	$	Q=	$2.13
R. Uses per year	R=		R=	Dispose of 130,000 needles
S. Uses per device	S=		S=	NA (see next entry)
T. Quantity used per year ® ÷ S)	T=		T=	32**
U. Additional component cost per year (Q × T)	U=	$	U=	$68.16
V. Annual conventional system cost (P + U)	V=	$	V=	$133.16
RELATED DISPOSAL COSTS				
Additional sharps containers				
W. Disposal volume of each NPD	W=		W=	14 cm^3 (tube holder only)
X. Disposal volume of each conventional device	X=		X=	12 cm^3 (tube holder only)
Y. Sharps container volume	Y=		Y=	1 qt (= 943cm^3)
Z. Number of additional sharps containers per year ([{W ×			Z=	1 (assumes 100% packing efficiency)
AA. Price per sharps container	AA=	$	AA=	$3.50
AB. Annual additional sharps containers cost (Z ×AA)	AB=	$	AB=	$3.50
AC. Other additional disposal costs	AC=	$	AC=	None
AD. Total annual increase in disposal costs (AB + AC)	AD=	$	AD=	$3.50
NSI COST				
AE. Number of NSIs per year with conventional device	AE=		AE=	6
AF. Projected NSIs per year with NPD (50% × AE)	AF=		AF=	3
AG. Cost of each NSI	AG=	$	AG=	$540
AH. Annual NSI cost savings (AG × [AE - AF])	AH=	$	AH=	$1,620
AI. MISCELLANEOUS COSTS	AI=	$	AI=	None
AJ. NET PROTECTIVE SYSTEM COSTS (K+AD+AI -AH)	AJ=	$	AJ=	$227.50
AK. ANNUAL INCREASE IN EXPENDITURES (AJ - V)	AK=	$	**Annual increase in expenditures:** $94.34	

*The figures obtained by completing this worksheet should be used for comparison purposes only. These figures will not reflect the actual costs and cost savings- associated with implementing the alternative under consideration, and they cannot reflect the true value of using an NPD in terms of staff safety and the economic impact on NSIs that result in seroconversion.

**Calculated by multiplying the estimated volume of one needle (0.23 cm^3) by the number of needles per year (130,000) and then dividing by the volume of one sharps container (1 qt = 943 cm^3). Note that this analysis assume 100% packing efficiency.

GUIDELINES FOR THE USE OF SAFETY FEATURE EVALUATION SHEETS

Coordinators:

Determine which products are to be evaluated and provide at least four or more test samples for each individual evaluating the product. (Each evaluator should have enough samples to disassemble and examine the design thoroughly.)

Set up a testing station for each type of device which allows testers to evaluate products in a simulated patient procedure. Provide training dummies (injection pads, oranges, etc.) as necessary.

Provide visual instructions and demonstrate proper use of each device.

Review the instructions and rating system with each evaluator.

Encourage each evaluator to comment on the sheets and prioritize the questions at the end of the evaluation. This will provide a useful decision making tool and will help alert you to specific areas of concern which may not have been covered by the questionnaire.

Evaluators:

Re-enact all steps of intended or possible procedures performed with the device being tested.

Attempt to misuse the device and circumvent or disable the safety feature.

Answer each question, including the short answer section at the end. If you do not understand a question, please write comments directly on the sheets.

NOTE: The utility of these criteria is for initial screening of devices and **NOT** for clinical assessment/pilot testing. Certain assumptions have been made in the development of these forms based on information about currently available products. We recognize the likelihood that the ideal product may not exist. TDICT welcomes your comments on the use of these tools.

Source: Reprinted with permission of Training for Development of Innovative Control Technology Project
June Fisher, M.D.

Trauma Foundation, Bldg #1, Room #300
San Francisco General Hospital
1001 Potrero Avenue
San Francisco, CA 94110

SAFETY FEATURE EVALUATION FORM
SAFETY SYRINGES

Date: _____ Department: _____ Occupation:_____
Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

agree.....disagree

DURING USE:

1. The safety feature can be activated using a one-handed technique . . . . . 1 2 3 4 5 N/A
2. The safety feature **does not** obstruct vision of the tip of the sharp . . . . . 1 2 3 4 5 N/A
3. Use of this product requires you to use the safety feature . . . . . 1 2 3 4 5 N/A
4. This product does not require more time to use than a non-safety device . . . . . 1 2 3 4 5 N/A
5. The safety feature works well with a wide variety of hand sizes . . . . . 1 2 3 4 5 N/A
6. The device is easy to handle while wearing gloves . . . . . 1 2 3 4 5 N/A
7. This device **does not** interfere with uses that do not require a needle . . . . . 1 2 3 4 5 N/A
8. This device offers a good view of any aspirated fluid . . . . . 1 2 3 4 5 N/A
9. This device will work with all required syringe and needle sizes . . . . . 1 2 3 4 5 N/A
10. This device provides a better alternative to traditional recapping . . . . . 1 2 3 4 5 N/A

AFTER USE:

11. There is a clear and unmistakable change (audible or visible) that occurs when the safety feature is activated . . . . . 1 2 3 4 5 N/A
12. The safety feature operates reliably . . . . . 1 2 3 4 5 N/A
13. The exposed sharp is permanently blunted or covered after use and prior to disposal . 1 2 3 4 5 N/A
14. This device is no more difficult to process after use than non-safety devices . . . . . 1 2 3 4 5 N/A

TRAINING:

15. The user **does not** need extensive training for correct operation . . . . . 1 2 3 4 5 N/A
16. The design of the device suggests proper use . . . . . 1 2 3 4 5 N/A
17. It is **not** easy to skip a crucial step in proper use of the device . . . . . 1 2 3 4 5 N/A

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

SAFETY FEATURE EVALUATION FORM
I.V. ACCESS DEVICES

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

agree.....disagree

1. The safety feature can be activated using a one-handed technique . . . . . 1 2 3 4 5 N/A
2. The safety feature **does not** interfere with normal use of this product . . . . . 1 2 3 4 5 N/A
3. Use of this product requires you to use the safety feature . . . . . 1 2 3 4 5 N/A
4. This product **does not** require more time to use than a non-safety device . . . . . 1 2 3 4 5 N/A
5. The safety feature works well with a wide variety of hand sizes . . . . . 1 2 3 4 5 N/A
6. The device allows for rapid visualization of flashback in the catheter or chamber . . . 1 2 3 4 5 N/A
7. Use of this product **does not** increase the number of sticks to the patient . . . . . 1 2 3 4 5 N/A
8. The product stops the flow of blood after the needle is removed from the catheter (or after the butterfly is inserted) and just prior to line connections or hep-lock capping . . . . . 1 2 3 4 5 N/A
9. A clear and unmistakable change (either audible or visible) occurs when the safety feature is activated . . . . . 1 2 3 4 5 N/A
10. The safety feature operates reliably . . . . . 1 2 3 4 5 N/A
11. The exposed sharp is blunted or covered after use and prior to disposal . . . . . 1 2 3 4 5 N/A
12. The product **does not** need extensive training to be operated correctly . . . . . 1 2 3 4 5 N/A

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

SAFETY FEATURE EVALUATION FORM
SHARPS DISPOSAL CONTAINERS

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

agree.....disagree

1. The container's shape, its markings, or its color, imply danger . . . . . 1 2 3 4 5 N/A
2. The implied warning of danger can be seen from the angle at which people commonly view it (very short people, people in wheel chairs, children, etc) . . . . . 1 2 3 4 5 N/A
3. The implied warning can be universally understood by visitors, children, and patients . . 1 2 3 4 5 N/A
4. The container's purpose is self-explanatory and easily understood by a worker who may be pressed for time or unfamiliar with the hospital setting . . . . . 1 2 3 4 5 N/A
5. The container can accept sharps from any direction desired . . . . . 1 2 3 4 5 N/A
6. The container can accept all sizes and shapes of sharps . . . . . 1 2 3 4 5 N/A
7. The container allows single handed operation. (Only the hand holding the sharp should be near the container opening) . . . . . 1 2 3 4 5 N/A
8. It is difficult to reach in and remove a sharp . . . . . 1 2 3 4 5 N/A
9. Sharps can go into the container without getting caught on the opening . . . . . 1 2 3 4 5 N/A
10. Sharps can go into the container without getting caught on any molded shapes in the interior . . . . . 1 2 3 4 5 N/A
11. The container is puncture resistant . . . . . 1 2 3 4 5 N/A
12. When the container is dropped or turned upside down (even before it is permanently closed) sharps stay inside . . . . . 1 2 3 4 5 N/A
13. The user can determine easily, from various viewing angles, when the container is full . . . . . 1 2 3 4 5 N/A
14. When the container is to be used free-standing (no mounting bracket), it is stable and unlikely to tip over . . . . . 1 2 3 4 5 N/A
15. It is safe to close the container. (Sharps should not protrude into the path of hands attempting to close the container) . . . . . 1 2 3 4 5 N/A
16. The container closes securely. (e.g. if the closure requires glue, it may not work if the surfaces are soiled or wet.) . . . . . 1 2 3 4 5 N/A
17. The product has handles which allow you to safely transport a full container . . . . . 1 2 3 4 5 N/A
18. The product **does not** require extensive training to operate correctly . . . . . 1 2 3 4 5 N/A

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

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June Fisher, M.D.

SAFETY FEATURE EVALUATION FORM
I.V. CONNECTORS

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

---

agree.....disagree

1. Use of this connector eliminates the need for exposed needles in connections . . . . . 1 2 3 4 5 N/A
2. The safety feature **does not** interfere with normal use of this product . . . . . 1 2 3 4 5 N/A
3. Use of this product requires you to use the safety feature . . . . . 1 2 3 4 5 N/A
4. This product **does not** require more time to use than a non-safety device . . . . . 1 2 3 4 5 N/A
5. The safety feature works well with a wide variety of hand sizes . . . . . 1 2 3 4 5 N/A
6. The safety feature allows you to collect blood directly into a vacuum tube, eliminating the need for needles . . . . . 1 2 3 4 5 N/A
7. The connector can be secured (locked) to Y-sites, hep-locks, and central lines . . . . . 1 2 3 4 5 N/A
8. A clear and unmistakable change (either audible or visible) occurs when the safety feature is activated . . . . . 1 2 3 4 5 N/A
9. The safety feature operates reliably . . . . . 1 2 3 4 5 N/A
10. The exposed sharp is blunted or covered after use and prior to disposal . . . . . 1 2 3 4 5 N/A
11. The product **does not** need extensive training to be operated correctly . . . . . 1 2 3 4 5 N/A

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

SAFETY FEATURE EVALUATION FORM
VACUUM TUBE BLOOD COLLECTION SYSTEMS

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

agree.....disagree

1. The safety feature can be activated using a one-handed technique . . . . . 1 2 3 4 5 N/A
2. The safety feature **does not** interfere with normal use of this product . . . . . 1 2 3 4 5 N/A
3. Use of this product requires you to use the safety feature . . . . . 1 2 3 4 5 N/A
4. This product **does not** require more time to use than a non-safety device . . . . . 1 2 3 4 5 N/A
5. The safety feature works well with a wide variety of hand sizes . . . . . 1 2 3 4 5 N/A
6. The safety feature works with a butterfly . . . . . 1 2 3 4 5 N/A
7. A clear and unmistakable change (either audible or visible) occurs when the safety feature is activated . . . . . 1 2 3 4 5 N/A
8. The safety feature operates reliably . . . . . 1 2 3 4 5 N/A
9. The exposed sharp is blunted or covered after use and prior to disposal . . . . . 1 2 3 4 5 N/A
10. The inner vacuum tube needle (rubber sleeved needle) **does not** present a danger of exposure . . . . . 1 2 3 4 5 N/A
11. The **product does** not need extensive training to be operated correctly . . . . . 1 2 3 4 5 N/A

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

SAFETY FEATURE EVALUATION FORM
E. R. SHARPS DISPOSAL CONTAINERS

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

agree.....disagree

1. The container's shape, its markings, or its color, imply danger which can be understood by visitors, children, and patients . . . . . 1 2 3 4 5 N/A
2. The implied warning of danger can be seen from the angle at which people commonly view it. (very short people, people in wheel chairs, children, etc) . . . . . 1 2 3 4 5 N/A
3. The container can be placed in a location that is easily accessible during emergency procedures . . . . . 1 2 3 4 5 N/A
4. The container's purpose is self-explanatory and easily understood by a worker who may be pressed for time or unfamiliar with the hospital setting . . . . . 1 2 3 4 5 N/A
5. The container can accept sharps from any direction desired . . . . . 1 2 3 4 5 N/A
6. The container can accept all sizes and shapes of sharps . . . . . 1 2 3 4 5 N/A
7. The container is temporarily closable, and will not spill contents (even after being dropped down a flight of stairs) . . . . . 1 2 3 4 5 N/A
8. The container allows single handed operation. (Only the hand holding the sharp should be near the container opening) . . . . . 1 2 3 4 5 N/A
9. It is difficult to reach in and remove a sharp . . . . . 1 2 3 4 5 N/A
10. Sharps can go into the container without getting caught on the opening or any molded shapes in the interior . . . . . 1 2 3 4 5 N/A
11. The container can be placed within arm's reach . . . . . 1 2 3 4 5 N/A
12. The container is puncture resistant . . . . . 1 2 3 4 5 N/A
13. When the container is dropped or turned upside down (even before it is permanently closed) sharps stay inside . . . . . 1 2 3 4 5 N/A
14. The user can determine easily, from various viewing angles, when the container is full . 1 2 3 4 5 N/A
15. When the container is to be used free-standing (no mounting bracket), it is stable and unlikely to tip over . . . . . 1 2 3 4 5 N/A
16. The container is large enough to accept all sizes and shapes of sharps, including 50 ml preloaded syringes . . . . . 1 2 3 4 5 N/A
17. It is safe to close the container. (Sharps should not protrude into the path of hands attempting to close the container) . . . . . 1 2 3 4 5 N/A
18. The container closes securely under all circumstances . . . . . 1 2 3 4 5 N/A
19. The product has handles which allow you to safely transport a full container . . . . . 1 2 3 4 5 N/A
20. The product **does not** require extensive training to operate correctly . . . . . 1 2 3 4 5 N/A

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/ utility of this product?

SAFETY FEATURE EVALUATION FORM
SAFETY DENTAL SYRINGES

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

agree.....disagree

1. The safety feature can be activated using a one-handed technique . . . . . 1 2 3 4 5 N/A
2. The safety feature **does not** obstruct vision of the tip of the sharp and the intraoral injection site. . . . . 1 2 3 4 5 N/A
3. Use of this product requires you to use the safety feature . . . . . 1 2 3 4 5 N/A
4. This product **does not** require more time to use than a non-safety device . . . . . 1 2 3 4 5 N/A
5. The safety feature works well with a wide variety of hand sizes . . . . . 1 2 3 4 5 N/A
6. The device is easy to handle while wearing gloves . . . . . 1 2 3 4 5 N/A
7. The device is easy to handle when wet . . . . . 1 2 3 4 5 N/A
8. This device accepts standard anesthetic carpules and does not hinder carpule changing . . . . . 1 2 3 4 5 N/A
9. The safety feature **does not** restrict visibility of carpule contents intraorally . . . . . 1 2 3 4 5 N/A
10. This device accepts standard dental needles of all common lengths and gauges, and does not interfere with needle changing . . . . . 1 2 3 4 5 N/A
11. The device provides a better alternative to traditional recapping . . . . . 1 2 3 4 5 N/A
12. Sterilization of this device is as easy as a standard dental syringe . . . . . 1 2 3 4 5 N/A
13. For syringes with integral needles only: The needle on this syringe **will not** break while bending and repositioning in the tissue . . . . . 1 2 3 4 5 N/A
14. This device is no more difficult to break down after use for sterilization than a standard dental syringe . . . . . 1 2 3 4 5 N/A
15. The safety feature operates reliably . . . . . 1 2 3 4 5 N/A
16. The exposed sharp is permanently blunted or covered after use and prior to disposal . . . . . 1 2 3 4 5 N/A
17. There is a clear and unmistakable change (either visible or audible) that occurs when the safety feature is activated . . . . . 1 2 3 4 5 N/A
18. The user **does not** need extensive training to operate the product correctly . . . . . 1 2 3 4 5 N/A
19. The design of the device allows for easy removal of the needle from the syringe . . . . . 1 2 3 4 5 N/A
20. The design of the device allows for easy removal of the carpule from the syringe . . . . . 1 2 3 4 5 N/A

SAFETY FEATURE EVALUATION FORM
HOME USE SHARPS DISPOSAL CONTAINER

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

agree.....disagree

The container is puncture resistant . . . . . 1 2 3 4 5 N/A
The container is stable . . . . . 1 2 3 4 5 N/A
There is a handle which is robust, comfortable to carry, and compact . . . . . 1 2 3 4 5 N/A
The container allows single handed use . . . . . 1 2 3 4 5 N/A
The user can access the container from any direction . . . . . 1 2 3 4 5 N/A
It is possible to drop sharps into the container vertically . . . . . 1 2 3 4 5 N/A
Minimal or no force is required to put sharps into the container . . . . . 1 2 3 4 5 N/A
The container opens and closes easily . . . . . 1 2 3 4 5 N/A
Container closure maintains integrity after repeated use . . . . . 1 2 3 4 5 N/A
The box accommodates a range of sharps, including 12 cc syringe, butterfly, and lancet . . . . . 1 2 3 4 5 N/A
The size of the container is appropriate to its use . . . . . 1 2 3 4 5 N/A
No one (including a child) can access the contents of the container to retrieve a sharp . . . . . 1 2 3 4 5 N/A
Needles/tubing do not get caught on the opening or interior shape . . . . . 1 2 3 4 5 N/A
There is a temporary lock for transport which is secure but reversible . . . . . 1 2 3 4 5 N/A
There is a permanent lock for final disposal which is not reversible . . . . . 1 2 3 4 5 N/A
There is an absorbent lining to collect excess fluid . . . . . 1 2 3 4 5 N/A
The user can determine the fill level visually . . . . . 1 2 3 4 5 N/A
There is a signal when the box is 2/3 full . . . . . 1 2 3 4 5 N/A
The container is appropriately labeled . . . . . 1 2 3 4 5 N/A
Biohazard of container contents is apparent . . . . . 1 2 3 4 5 N/A
The box is not threatening to patients . . . . . 1 2 3 4 5 N/A
Use of this container in no way compromises infection control practices . . . . . 1 2 3 4 5 N/A

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/ utility of this product?

APPENDIX C
WEB SITE RESOURCE LIST

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://healthcare.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/cdrh/safety.html
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: http://www.people.virginia.edu/~epinet/products.html
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/sharps1.html
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: http://www.osha-slc.gov/OshDoc/Interp_data/I19990222.html
Describes safer alternatives to conventional glass capillary tubes.

Occupational Safety and Health Administration (OSHA) Needlestick Injuries
Available: http://www.osha-slc.gov/SLTC/needlestick/index.html
Features recent news, recognition, evaluation, controls, compliance, and links to information on effective engineering controls.

Safety Sharp Device Contracts
Available: http://www.va.gov/vasafety/osh-issues/needlesafety/safetysharpcontracts.htm
Features safety sharp devices on contract with the US Department of Veterans Affairs (VA).

SHARPS Injury Control Program
Available: http://www.dhs.ca.gov/ohb/sharps/default.htm
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/criteria.html
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://aepo-xdv-www.epo.cdc.gov/wonder/PrevGuid/PrevGuid.shtml
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://www2.cdc.gov/mmwr/mmwr.html
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/ncidod/hip/GUIDE/InfectControl98.pdf

Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease. Publication date 10/16/1998.
Available: http://www.cdc.gov/epo/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://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00052722.htm

Appendix - First-Line Drugs for HIV Postexposure Prophylaxis (PEP). Publication date 05/15/1998.
Available: http://www.cdc.gov/epo/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: http://www.cdc.gov/epo/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/nip/vacsafe/
The National Immunization Program (NIP) of the CDC features information on vaccine safety.

Food and Drug Administration (FDA)
Available: http://www.fda.gov/fdac/features/095_vacc.html and
http://www.fda.gov/cber/vaers/vaers.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/vaccine/index.html
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/

National Institutes of Health (NIH)
Available: http://www.niaid.nih.gov/publications/vaccine/undvacc.htm
Features a 40 page brochure "Understanding Vaccines."

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

APPENDIX D
MODEL EXPOSURE CONTROL PLAN

The Model Exposure Control Plan is intended to serve employers as an example exposure control plan which is required by the Bloodborne Pathogens Standard. A central component of the requirements of the standard is the development of an exposure control plan (ECP).

The intent of this model is to provide small employers with an easy-to-use format for developing a written exposure control plan. Each employer will need to adjust or adapt the model for their specific use.

The information contained in this publication is not considered a substitute for the OSH Act or any provisions of OSHA standards. It provides general guidance on a particular standard-related topic but should not be considered a definitive interpretation for compliance with OSHA requirements. The reader should consult the OSHA standard in its entirety for specific compliance requirements.

POLICY

The __(*Facility Name)*__ is committed to providing a safe and healthful work environment for our entire staff. In pursuit of this endeavor, the following exposure control plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with OSHA standard 29 CFR 1910.1030, "Occupational Exposure to Bloodborne Pathogens."

The ECP is a key document to assist our firm in implementing and ensuring compliance with the standard, thereby protecting our employees. This ECP includes:

* Determination of employee exposure
* Implementation of various methods of exposure control, including:
    - Universal precautions
    - Engineering and work practice controls
    - Personal protective equipment
    - Housekeeping
* Hepatitis B vaccination
* Post-exposure evaluation and follow-up
* Communication of hazards to employees and training
* Recordkeeping
* Procedures for evaluating circumstances surrounding an exposure incident

The methods of implementation of these elements of the standard are discussed in the subsequent pages of this ECP.

PROGRAM ADMINISTRATION

* _(*Name of responsible person or department)*_____ is (are) responsible for the implementation of the ECP. _(*Name of responsible person or department)*_____ will maintain, review, and update the ECP at least annually, and whenever necessary to include new or modified tasks and procedures. Contact location/phone number:_____

* Those employees who are determined to have occupational exposure to blood or other potentially infectious materials (OPIM) must comply with the procedures and work practices outlined in this ECP.

* ___(*Name of responsible person or department)*_____ will maintain and provide all necessary personal protective equipment (PPE), engineering controls (e.g., sharps containers), labels, and red bags as required by the standard. __(*Name of responsible person or department*_____ will ensure that adequate supplies of the aforementioned equipment are available in the appropriate sizes. Contact location/phone number:_____

* _(*Name of responsible person or department)*_____ will be responsible for ensuring that all medical actions required are performed and that appropriate employee health and OSHA records are maintained. Contact location/phone number:_____

* _(*Name of responsible person or department)*_____ will be responsible for training, documentation of training, and making the written ECP available to employees, OSHA, and NIOSH representatives.
Contact location/phone number:_____

EMPLOYEE EXPOSURE DETERMINATION

The following is a list of all job classifications at our establishment in which **all** employees have occupational exposure:

JOB TITLE	DEPARTMENT/LOCATION
(Example: Phlebotomists)	*(Clinical Lab)*

The following is a list of job classifications in which **some** employees at our establishment have occupational exposure. Included is a list of tasks and procedures, or groups of closely related tasks and procedures, in which occupational exposure may occur for these individuals:

JOB TITLE	DEPARTMENT/LOCATION	TASK/PROCEDURE
(Example: Housekeeper	*Environmental Services*	*Handling Regulated Waste)*
_____	_____	_____

Part-time, temporary, contract and per diem employees are covered by the standard. How the provisions of the standard will be met for these employees should be described in the ECP.

METHODS OF IMPLEMENTATION AND CONTROL

Universal Precautions

All employees will utilize universal precautions.

Exposure Control Plan

Employees covered by the bloodborne pathogens standard receive an explanation of this ECP during their initial training session. It will also be reviewed in their annual refresher training. All employees have an opportunity to review this plan at any time during their work shifts by contacting _(*Name of responsible person or department)*_____. If requested, we will provide an employee with a copy of the ECP free of charge and within 15 days of the request.

___(*Name of responsible person or department)*_____ is responsible for reviewing and updating the ECP annually or more frequently if necessary to reflect any new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure.

Engineering Controls and Work Practices

Engineering controls and work practice controls will be used to prevent or minimize exposure to bloodborne pathogens. The specific engineering controls and work practice controls used are listed below:

* *(For example: non-glass capillary tubes, SESIPs, needleless systems)*
* _____
* _____

Sharps disposal containers are inspected and maintained or replaced by ___(*Name of responsible person or department)* _____ every ___*(list frequency* _____ or whenever necessary to prevent overfilling.

This facility identifies the need for changes in engineering control and work practices through *(Examples: Review of OSHA records, employee interviews, committee activities, etc.)* _____

We evaluate new procedures or new products regularly by *(Describe the process, literature reviewed, supplier info, products considered)* _____
_____
_____ _____

Both front line workers and management officials are involved in this process: *(Describe how employees will be involved)* _____
_____

(Name of responsible person or department) _____ will ensure effective implementation of these recommendations.

Personal Protective Equipment (PPE)

PPE is provided to our employees at no cost to them. Training is provided by __(*Name of responsible person or department)* _____ in the use of the appropriate PPE for the tasks or procedures employees will perform.

The types of PPE available to employees are as follows:

__*(Ex., gloves, eye protection, etc.*) _____
_____

PPE is located ____*(List location)* _____ and may be obtained through *(Name of responsible person or department)* _____
(Specify how employees are to obtain PPE, and who is responsible for ensuring that it is available.)

All employees using PPE must observe the following precautions:

* Wash hands immediately or as soon as feasible after removal of gloves or other PPE.
* Remove PPE after it becomes contaminated, and before leaving the work area.
* Used PPE may be disposed of in _____(List appropriate containers for storage, laundering, decontamination, or disposal.)
* Wear appropriate gloves when it can be reasonably anticipated that there may be hand contact with blood or OPIM, and when handling or touching contaminated

items or surfaces; replace gloves if torn, punctured, contaminated, or if their ability to function as a barrier is compromised.

* Utility gloves may be decontaminated for reuse if their integrity is not compromised; discard utility gloves if they show signs of cracking, peeling, tearing, puncturing, or deterioration.
* Never wash or decontaminate disposable gloves for reuse.
* Wear appropriate face and eye protection when splashes, sprays, spatters, or droplets of blood or OPIM pose a hazard to the eye, nose, or mouth.
* Remove immediately or as soon as feasible any garment contaminated by blood or OPIM, in such a way as to avoid contact with the outer surface.

The procedure for handling used PPE is as follows: *(may refer to specific agency procedure by title or number and last date of review)*

_____

_____

(*For example, how and where to decontaminate face shields, eye protection, resuscitation equipment)*

Housekeeping

Regulated waste is placed in containers which are closable, constructed to contain all contents and prevent leakage, appropriately labeled or color-coded (see Labels), and closed prior to removal to prevent spillage or protrusion of contents during handling.

The procedure for handling **sharps disposal containers** is: *(may refer to specific agency procedure by title or number and last date of review)*

_____

_____

_____

The procedure for handling **other regulated waste** is: *(may refer to specific agency procedure by title or number and last date of review)*

_____

_____

_____

Contaminated sharps are discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leakproof on sides and bottoms, and labeled or color-coded appropriately. Sharps disposal containers are available at _____(*must be easily accessible and as close as feasible to the immediate area where sharps are used*).

Bins and pails (e.g., wash or emesis basins) are cleaned and decontaminated as soon as feasible after visible contamination.

Broken glassware which may be contaminated is picked up using mechanical means, such as a brush and dust pan.

Laundry

The following contaminated articles will be laundered by this company:

_____ _____

_____ _____

Laundering will be performed by *(Name of responsible person or department)* _____ at (*time and/or location*) .

The following laundering requirements must be met:

* handle contaminated laundry as little as possible, with minimal agitation
* place wet contaminated laundry in leak-proof, labeled or color-coded containers before transport. Use *(red bags or bags marked with biohazard symbol)* _____ for this purpose.
* wear the following PPE when handling and/or sorting contaminated laundry: (*List appropriate PPE*) _____

Labels

The following labeling method(s) is used in this facility:

EQUIPMENT TO BE LABELED *(e.g., specimens, contaminated laundry, etc.)*	LABEL TYPE (size, color, etc.) *(red bag, biohazard label, etc.)*
_____	_____
_____	_____

(Name of responsible person or department) _____ will ensure warning labels are affixed or red bags are used as required if regulated waste or contaminated equipment is brought into the facility. Employees are to notify _____ if they discover regulated waste containers, refrigerators containing blood or OPIM, contaminated equipment, etc. without proper labels.

HEPATITIS B VACCINATION

(Name of responsible person or department) _____ will provide training to employees on hepatitis B vaccinations, addressing the safety, benefits, efficacy, methods of administration, and availability.

The hepatitis B vaccination series is available at no cost after training and within 10 days of initial assignment to employees identified in the exposure determination section of this plan. Vaccination is encouraged unless: 1) documentation exists that the employee has previously received the series, 2) antibody testing reveals that the employee is immune, or 3) medical evaluation shows that vaccination is contraindicated.

However, if an employee chooses to decline vaccination, the employee must sign a declination form. Employees who decline may request and obtain the vaccination at a later date at no cost. Documentation of refusal of the vaccination is kept at _____*(List location or person responsible for this recordkeeping).*

Vaccination will be provided by _____ (List *Health care Professional who is responsible for this part of the plan*)_____ at _____(*location)*_____.

Following the medical evaluation, a copy of the health care professional's Written Opinion will be obtained and provided to the employee. It will be limited to whether the employee requires the hepatitis vaccine, and whether the vaccine was administered.

POST-EXPOSURE EVALUATION AND FOLLOW-UP

Should an exposure incident occur, contact ____*(Name of responsible person)* at the following number:_____.

An immediately available confidential medical evaluation and follow-up will be conducted by __*(Licenced health care professional)*__. Following the initial first aid (clean the wound, flush eyes or other mucous membrane, etc.), the following activities will be performed:

* Document the routes of exposure and how the exposure occurred.
* Identify and document the source individual (unless the employer can establish that identification is infeasible or prohibited by state or local law).
* Obtain consent and make arrangements to have the source individual tested as soon as possible to determine HIV, HCV, and HBV infectivity; document that the source individual's test results were conveyed to the employee's health care provider.
* If the source individual is already known to be HIV, HCV and/or HBV positive, new testing need not be performed.
* Assure that the exposed employee is provided with the source individual's test results and with information about applicable disclosure laws and regulations concerning the identity and infectious status of the source individual (e.g., laws protecting confidentiality).
* After obtaining consent, collect exposed employee's blood as soon as feasible after exposure incident, and test blood for HBV and HIV serological status
* If the employee does not give consent for HIV serological testing during collection of blood for baseline testing, preserve the baseline blood sample for at least 90

days; if the exposed employee elects to have the baseline sample tested during this waiting period, perform testing as soon as feasible.

ADMINISTRATION OF POST-EXPOSURE EVALUATION AND FOLLOW-UP

(*Name of responsible person or department)*_____ ensures that health care professional(s) responsible for employee's hepatitis B vaccination and post-exposure evaluation and follow-up are given a copy of OSHA's bloodborne pathogens standard.

*(Name of responsible person or department)*_____ ensures that the health care professional evaluating an employee after an exposure incident receives the following:

* a description of the employee's job duties relevant to the exposure incident
* route(s) of exposure
* circumstances of exposure
* if possible, results of the source individual's blood test
* relevant employee medical records, including vaccination status

*(Name of responsible person or department)*_____provides the employee with a copy of the evaluating health care professional's written opinion within 15 days after completion of the evaluation.

PROCEDURES FOR EVALUATING THE CIRCUMSTANCES SURROUNDING AN EXPOSURE INCIDENT

*(Name of responsible person or department)*_____ will review the circumstances of all exposure incidents to determine:

* engineering controls in use at the time
* work practices followed
* a description of the device being used (including type and brand)
* protective equipment or clothing that was used at the time of the exposure incident (*gloves, eye shields, etc.)*
* location of the incident (*O.R., E.R., patient room, etc.)*
* procedure being performed when the incident occurred
* employee's training

*(Name of Responsible Person)*_____ will record all percutaneous injuries from contaminated sharps in the Sharps Injury Log.

If it is determined that revisions need to be made, *(Responsible person or department)*_____ will ensure that appropriate changes are made to this ECP. *(Changes may include an evaluation of safer devices, adding employees to the exposure determination list, etc.)*

EMPLOYEE TRAINING

All employees who have occupational exposure to bloodborne pathogens receive training conducted by _____*(Name of responsible person or department)*_____. (*Attach a brief description of their qualifications.)*

All employees who have occupational exposure to bloodborne pathogens receive training on the epidemiology, symptoms, and transmission of bloodborne pathogen diseases. In addition, the training program covers, at a minimum, the following elements:

* a copy and explanation of the standard
* an explanation of our ECP and how to obtain a copy
* an explanation of methods to recognize tasks and other activities that may involve exposure to blood and OPIM, including what constitutes an exposure incident
* an explanation of the use and limitations of engineering controls, work practices, and PPE
* an explanation of the types, uses, location, removal, handling, decontamination, and disposal of PPE
* an explanation of the basis for PPE selection
* information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine will be offered free of charge
* information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM
* an explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available
* information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident
* an explanation of the signs and labels and/or color coding required by the standard and used at this facility
* an opportunity for interactive questions and answers with the person conducting the training session.

Training materials for this facility are available at _____.

RECORDKEEPING

Training Records

Training records are completed for each employee upon completion of training. These documents will be kept for at least **three years** at __*(Name of responsible person or location of records)*_____.

The training records include:

* the dates of the training sessions
* the contents or a summary of the training sessions
* the names and qualifications of persons conducting the training
* the names and job titles of all persons attending the training sessions

Employee training records are provided upon request to the employee or the employee's authorized representative within 15 working days. Such requests should be addressed to _____*(Name of Responsible person or department)*_____.

Medical Records

Medical records are maintained for each employee with occupational exposure in accordance with 29 CFR 1910.1020, "Access to Employee Exposure and Medical Records."

_____*(Name of Responsible person or department)*_____ is responsible for maintenance of the required medical records. These **confidential** records are kept at ____*(List location)*_____for at least the **duration of employment plus 30 years**.
Employee medical records are provided upon request of the employee or to anyone having written consent of the employee within 15 working days. Such requests should be sent to ____*(Name of responsible person or department and address)*_____

OSHA Recordkeeping

An exposure incident is evaluated to determine if the case meets OSHA's Recordkeeping Requirements (29 CFR 1904). This determination and the recording activities are done by _*(Name of responsible person or department)*_____.

Sharps Injury Log

In addition to the 1904 Recordkeeping Requirements, all percutaneous injuries from contaminated sharps are also recorded in the Sharps Injury Log. All incidences must include at least:
- the date of the injury
- the type and brand of the device involved
- the department or work area where the incident occurred
-an explanation of how the incident occurred.

This log is reviewed at least annually as part of the annual evaluation of the program and is maintained for at least five years following the end of the calendar year that they cover. If

a copy is requested by anyone, it must have any personal identifiers removed from the report.

Establishment/Facility Name: _____

Sample Sharps Injury Log Year 2____

Date	**Case/ Report No.**	**Type of Device** (e.g., syringe, suture needle)	**Brand Name of Device**	**Work Area where injury occurred** [e.g., Geriatrics, Lab]	**Brief description of how the incident occurred** [i.e., procedure being done, action being performed (disposal, injection, etc.), body part injured]

29 CFR 1910.1030, OSHA's Bloodborne Pathogens Standard, in paragraph (h)(5), requires an employer to establish and maintain a Sharps Injury Log for recording all percutaneous injuries in a facility occurring from *contaminated* sharps. The purpose of the Log is to aid in the evaluation of devices being used in healthcare and other facilities and to identify problem devices or procedures requiring additional attention or review. This log must be kept in addition to the injury and illness log required by 29 CFR 1904. The Sharps Injury Log should include all sharps injuries occurring in a calendar year. The log must be retained for five years following the end of the year to which it relates. The Log must be kept in a manner that preserves the confidentiality of the affected employee.

HEPATITIS B VACCINE DECLINATION (MANDATORY)

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

Signed:__(*Employee Name)*_____
Date:_____

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

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

June 29, 2001 / Vol. 50 / No. RR-11

MMWR™

MORBIDITY AND MORTALITY WEEKLY REPORT

Recommendations and Reports

Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention (CDC)
Atlanta, GA 30333

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Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis

Summary

This report updates and consolidates all previous U.S. Public Health Service recommendations for the management of health-care personnel (HCP) who have occupational exposure to blood and other body fluids that might contain hepatitis B virus (HBV), hepatitis C virus (HCV), or human immunodeficiency virus (HIV).

Recommendations for HBV postexposure management include initiation of the hepatitis B vaccine series to any susceptible, unvaccinated person who sustains an occupational blood or body fluid exposure. Postexposure prophylaxis (PEP) with hepatitis B immune globulin (HBIG) and/or hepatitis B vaccine series should be considered for occupational exposures after evaluation of the hepatitis B surface antigen status of the source and the vaccination and vaccine-response status of the exposed person. Guidance is provided to clinicians and exposed HCP for selecting the appropriate HBV PEP.

Immune globulin and antiviral agents (e.g., interferon with or without ribavirin) are not recommended for PEP of hepatitis C. For HCV postexposure management, the HCV status of the source and the exposed person should be determined, and for HCP exposed to an HCV positive source, follow-up HCV testing should be performed to determine if infection develops.

Recommendations for HIV PEP include a basic 4-week regimen of two drugs (zidovudine [ZDV] and lamivudine [3TC]; 3TC and stavudine [d4T]; or didanosine [ddI] and d4T) for most HIV exposures and an expanded regimen that includes the addition of a third drug for HIV exposures that pose an increased risk for transmission. When the source person's virus is known or suspected to be resistant to one or more of the drugs considered for the PEP regimen, the selection of drugs to which the source person's virus is unlikely to be resistant is recommended.

In addition, this report outlines several special circumstances (e.g., delayed exposure report, unknown source person, pregnancy in the exposed person, resistance of the source virus to antiretroviral agents, or toxicity of the PEP regimen) when consultation with local experts and/or the National Clinicians' Post-Exposure Prophylaxis Hotline ([PEPline] 1-888-448-4911) is advised.

Occupational exposures should be considered urgent medical concerns to ensure timely postexposure management and administration of HBIG, hepatitis B vaccine, and/or HIV PEP.

INTRODUCTION

Avoiding occupational blood exposures is the primary way to prevent transmission of hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in health-care settings (*1*). However, hepatitis B immunization and postexposure management are integral components of a complete program to prevent infection following bloodborne pathogen exposure and are important elements of workplace safety (*2*).

The U.S. Public Health Service (PHS) has published previous guidelines for the management of HIV exposures that included considerations for postexposure prophylaxis (PEP) (*3–5*). Since publication of the 1998 HIV exposure guidelines (*5*), several new antiretroviral agents have been approved by the Food and Drug Administration (FDA), and more information is available about the use and safety of HIV PEP (*6–11*). In addition, questions exist regarding considerations about PEP regimens when the source person's virus is known or suspected to be resistant to one or more of the antiretroviral agents that might be used for PEP. Concern also has arisen about the use of PEP when it is not warranted. Data indicate that some health-care personnel (HCP) take a full course of HIV PEP after exposures that do not confer an HIV transmission risk (*10,11*).

In September 1999, a meeting of a PHS interagency working group* and expert consultants was convened by CDC. The PHS working group decided to issue updated recommendations for the management of occupational exposure to HIV. In addition, the report was to include recommendations for the management of occupational HBV and HCV exposures so that a single document could comprehensively address the management of occupational exposures to bloodborne pathogens. This report updates and consolidates the previous PHS guidelines and recommendations for occupational HBV, HCV, and HIV exposure management for HCP. Specific practice recommendations for the management of occupational bloodborne pathogen exposures are outlined to assist health-care institutions with the implementation of these PHS guidelines (Appendices A and B). As relevant information becomes available, updates of these recommendations will be published. Recommendations for nonoccupational (e.g., sexual, pediatric, and perinatal) HBV, HCV, and HIV exposures are not addressed in these guidelines and can be found elsewhere (*12–15*).

Definition of Health-Care Personnel and Exposure

In this report, health-care personnel (HCP) are defined as persons (e.g., employees, students, contractors, attending clinicians, public-safety workers, or volunteers) whose activities involve contact with patients or with blood or other body fluids from patients in a health-care, laboratory, or public-safety setting. The potential exists for blood and body fluid exposure to other workers, and the same principles of exposure management could be applied to other settings.

*This interagency working group comprised representatives of CDC, the Food and Drug Administration (FDA), the Health Resources and Services Administration, and the National Institutes of Health. Information included in these recommendations may not represent FDA approval or approved labeling for the particular product or indications in question. Specifically, the terms "safe" and "effective" may not be synonymous with the FDA-defined legal standards for product approval.

An exposure that might place HCP at risk for HBV, HCV, or HIV infection is defined as a percutaneous injury (e.g., a needlestick or cut with a sharp object) or contact of mucous membrane or nonintact skin (e.g., exposed skin that is chapped, abraded, or afflicted with dermatitis) with blood, tissue, or other body fluids that are potentially infectious (*16,17*).

In addition to blood and body fluids containing visible blood, semen and vaginal secretions also are considered potentially infectious. Although semen and vaginal secretions have been implicated in the sexual transmission of HBV, HCV, and HIV, they have not been implicated in occupational transmission from patients to HCP. The following fluids also are considered potentially infectious: cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid. The risk for transmission of HBV, HCV, and HIV infection from these fluids is unknown; the potential risk to HCP from occupational exposures has not been assessed by epidemiologic studies in health-care settings. Feces, nasal secretions, saliva, sputum, sweat, tears, urine, and vomitus are not considered potentially infectious unless they contain blood. The risk for transmission of HBV, HCV, and HIV infection from these fluids and materials is extremely low.

Any direct contact (i.e., contact without barrier protection) to concentrated virus in a research laboratory or production facility is considered an exposure that requires clinical evaluation. For human bites, the clinical evaluation must include the possibility that both the person bitten and the person who inflicted the bite were exposed to bloodborne pathogens. Transmission of HBV or HIV infection only rarely has been reported by this route (*18–20*) (CDC, unpublished data, 1998).

BACKGROUND

This section provides the rationale for the postexposure management and prophylaxis recommendations presented in this report. Additional details concerning the risk for occupational bloodborne pathogen transmission to HCP and management of occupational bloodborne pathogen exposures are available elsewhere (*5,12,13,21-24*).

Occupational Transmission of HBV

Risk for Occupational Transmission of HBV

HBV infection is a well recognized occupational risk for HCP (*25*). The risk of HBV infection is primarily related to the degree of contact with blood in the work place and also to the hepatitis B e antigen (HBeAg) status of the source person. In studies of HCP who sustained injuries from needles contaminated with blood containing HBV, the risk of developing clinical hepatitis if the blood was both hepatitis B surface antigen (HBsAg)- and HBeAg-positive was 22%–31%; the risk of developing serologic evidence of HBV infection was 37%–62%. By comparison, the risk of developing clinical hepatitis from a needle contaminated with HBsAg-positive, HBeAg-negative blood was 1%–6%, and the risk of developing serologic evidence of HBV infection, 23%–37% (*26*).

Although percutaneous injuries are among the most efficient modes of HBV transmission, these exposures probably account for only a minority of HBV infections among HCP. In several investigations of nosocomial hepatitis B outbreaks, most infected HCP could not recall an overt percutaneous injury (*27,28*), although in some studies, up to one third of infected HCP recalled caring for a patient who was HBsAg-positive (*29,30*). In addition, HBV has been demonstrated to survive in dried blood at room temperature on

environmental surfaces for at least 1 week (*31*). Thus, HBV infections that occur in HCP with no history of nonoccupational exposure or occupational percutaneous injury might have resulted from direct or indirect blood or body fluid exposures that inoculated HBV into cutaneous scratches, abrasions, burns, other lesions, or on mucosal surfaces (*32–34*). The potential for HBV transmission through contact with environmental surfaces has been demonstrated in investigations of HBV outbreaks among patients and staff of hemodialysis units (*35–37*).

Blood contains the highest HBV titers of all body fluids and is the most important vehicle of transmission in the health-care setting. HBsAg is also found in several other body fluids, including breast milk, bile, cerebrospinal fluid, feces, nasopharyngeal washings, saliva, semen, sweat, and synovial fluid (*38*). However, the concentration of HBsAg in body fluids can be 100–1000—fold higher than the concentration of infectious HBV particles. Therefore, most body fluids are not efficient vehicles of transmission because they contain low quantities of infectious HBV, despite the presence of HBsAg.

In serologic studies conducted in the United States during the 1970s, HCP had a prevalence of HBV infection approximately 10 times higher than the general population (*39–42*). Because of the high risk of HBV infection among HCP, routine preexposure vaccination of HCP against hepatitis B and the use of standard precautions to prevent exposure to blood and other potentially infectious body fluids have been recommended since the early 1980s (*43*). Regulations issued by the Occupational Safety and Health Administration (OSHA) (*2*) have increased compliance with these recommendations. Since the implementation of these recommendations, a sharp decline has occurred in the incidence of HBV infection among HCP.

PEP for HBV

Efficacy of PEP for HBV. The effectiveness of hepatitis B immune globulin (HBIG) and/or hepatitis B vaccine in various postexposure settings has been evaluated by prospective studies. For perinatal exposure to an HBsAg-, HBeAg-positive mother, a regimen combining HBIG and initiation of the hepatitis B vaccine series at birth is 85%–95% effective in preventing HBV infection (*44,45*). Regimens involving either multiple doses of HBIG alone or the hepatitis B vaccine series alone are 70%–75% effective in preventing HBV infection (*46*). In the occupational setting, multiple doses of HBIG initiated within 1 week following percutaneous exposure to HBsAg-positive blood provides an estimated 75% protection from HBV infection (*47–49*). Although the postexposure efficacy of the combination of HBIG and the hepatitis B vaccine series has not been evaluated in the occupational setting, the increased efficacy of this regimen observed in the perinatal setting, compared with HBIG alone, is presumed to apply to the occupational setting as well. In addition, because persons requiring PEP in the occupational setting are generally at continued risk for HBV exposure, they should receive the hepatitis B vaccine series.

Safety of PEP for HBV. Hepatitis B vaccines have been found to be safe when administered to infants, children, or adults (*12,50*). Through the year 2000, approximately 100 million persons have received hepatitis B vaccine in the United States. The most common side effects from hepatitis B vaccination are pain at the injection site and mild to moderate fever (*50–55*). Studies indicate that these side effects are reported no more frequently among persons vaccinated than among those receiving placebo (*51,52*).

Approximately 45 reports have been received by the Vaccine Adverse Event Reporting System (VAERS) of alopecia (hair loss) in children and adults after administration of

plasma-derived and recombinant hepatitis B vaccine; four persons sustained hair loss following vaccination on more than one occasion (*56*). Hair loss was temporary for approximately two thirds of persons who experienced hair loss. An epidemiologic study conducted in the Vaccine Safety Datalink found no statistical association between alopecia and receipt of hepatitis B vaccine in children (CDC, unpublished data, 1998). A low rate of anaphylaxis has been observed in vaccine recipients based on reports to VAERS; the estimated incidence is 1 in 600,000 vaccine doses distributed. Although none of the persons who developed anaphylaxis died, anaphylactic reactions can be life-threatening; therefore, further vaccination with hepatitis B vaccine is contraindicated in persons with a history of anaphylaxis after a previous dose of vaccine.

Hepatitis B immunization programs conducted on a large scale in Taiwan, Alaska, and New Zealand have observed no association between vaccination and the occurrence of serious adverse events. Furthermore, in the United States, surveillance of adverse events following hepatitis B vaccination has demonstrated no association between hepatitis B vaccine and the occurrence of serious adverse events, including Guillain-Barré syndrome, transverse myelitis, multiple sclerosis, optic neuritis, and seizures (*57–59*) (CDC, unpublished data, 1991). However, several case reports and case series have claimed an association between hepatitis B vaccination and such syndromes and diseases as multiple sclerosis, optic neuritis, rheumatoid arthritis, and other autoimmune diseases (*57,60–66*). Most of these reported adverse events have occurred in adults, and no report has compared the frequency of the purported vaccine-associated syndrome/disease with the frequency in an unvaccinated population. In addition, recent case-control studies have demonstrated no association between hepatitis B vaccination and development or short-term risk of relapse of multiple sclerosis (*67,68*), and reviews by international panels of experts have concluded that available data do not demonstrate a causal association between hepatitis B vaccination and demyelinating diseases, including multiple sclerosis (*69*).

HBIG is prepared from human plasma known to contain a high titer of antibody to HBsAg (anti-HBs). The plasma from which HBIG is prepared is screened for HBsAg and antibodies to HIV and HCV. The process used to prepare HBIG inactivates and eliminates HIV from the final product. Since 1996, the final product has been free of HCV RNA as determined by the polymerase chain reaction (PCR), and, since 1999, all products available in the United States have been manufactured by methods that inactivate HCV and other viruses. No evidence exists that HBV, HCV, or HIV have ever been transmitted by HBIG commercially available in the United States (*70,71*).

Serious adverse effects from HBIG when administered as recommended have been rare. Local pain and tenderness at the injection site, urticaria and angioedema might occur; anaphylactic reactions, although rare, have been reported following the injection of human immune globulin (IG) preparations (*72*). Persons with a history of anaphylactic reaction to IG should not receive HBIG.

PEP for HBV During Pregnancy. No apparent risk exists for adverse effects to developing fetuses when hepatitis B vaccine is administered to pregnant women (CDC, unpublished data, 1990). The vaccine contains noninfectious HBsAg particles and should pose no risk to the fetus. HBV infection during pregnancy might result in severe disease for the mother and chronic infection for the newborn. Therefore, neither pregnancy nor lactation should be considered a contraindication to vaccination of women. HBIG is not contraindicated for pregnant or lactating women.

Occupational Transmission of HCV

Risk for Occupational Transmission of HCV

HCV is not transmitted efficiently through occupational exposures to blood. The average incidence of anti-HCV seroconversion after accidental percutaneous exposure from an HCV-positive source is 1.8% (range: 0%–7%) (*73–76*), with one study indicating that transmission occurred only from hollow-bore needles compared with other sharps (*75*). Transmission rarely occurs from mucous membrane exposures to blood, and no transmission in HCP has been documented from intact or nonintact skin exposures to blood (*77,78*). Data are limited on survival of HCV in the environment. In contrast to HBV, the epidemiologic data for HCV suggest that environmental contamination with blood containing HCV is not a significant risk for transmission in the health-care setting (*79,80*), with the possible exception of the hemodialysis setting where HCV transmission related to environmental contamination and poor infection-control practices have been implicated (*81–84*). The risk for transmission from exposure to fluids or tissues other than HCV-infected blood also has not been quantified but is expected to be low.

Postexposure Management for HCV

In several studies, researchers have attempted to assess the effectiveness of IG following possible exposure to non-A, non-B hepatitis. These studies have been difficult to interpret because they lack uniformity in diagnostic criteria and study design, and, in all but one study, the first dose of IG was administered before potential exposure (*48,85,86*). In an experiment designed to model HCV transmission by needlestick exposure in the health-care setting, high anti-HCV titer IG administered to chimpanzees 1 hour after exposure to HCV-positive blood did not prevent transmission of infection (*87*). In 1994, the Advisory Committee on Immunization Practices (ACIP) reviewed available data regarding the prevention of HCV infection with IG and concluded that using IG as PEP for hepatitis C was not supported (*88*). This conclusion was based on the following facts:

- No protective antibody response has been identified following HCV infection.
- Previous studies of IG use to prevent posttransfusion non-A, non-B hepatitis might not be relevant in making recommendations regarding PEP for hepatitis C.
- Experimental studies in chimpanzees with IG containing anti-HCV failed to prevent transmission of infection after exposure.

No clinical trials have been conducted to assess postexposure use of antiviral agents (e.g., interferon with or without ribavirin) to prevent HCV infection, and antivirals are not FDA-approved for this indication. Available data suggest that an established infection might need to be present before interferon can be an effective treatment. Kinetic studies suggest that the effect of interferon on chronic HCV infection occurs in two phases. During the first phase, interferon blocks the production or release of virus from infected cells. In the second phase, virus is eradicated from the infected cells (*89*); in this later phase, higher pretreatment alanine aminotransferase (ALT) levels correlate with an increasing decline in infected cells, and the rapidity of the decline correlates with viral clearance. In contrast, the effect of antiretrovirals when used for PEP after exposure to HIV is based on inhibition of HIV DNA synthesis early in the retroviral replicative cycle.

In the absence of PEP for HCV, recommendations for postexposure management are intended to achieve early identification of chronic disease and, if present, referral for evaluation of treatment options. However, a theoretical argument is that intervention with antivirals when HCV RNA first becomes detectable might prevent the development of chronic infection. Data from studies conducted outside the United States suggest that a short course of interferon started early in the course of acute hepatitis C is associated with a higher rate of resolved infection than that achieved when therapy is begun after chronic hepatitis C has been well established (*90–92*). These studies used various treatment regimens and included persons with acute disease whose peak ALT levels were 500–1,000 IU/L at the time therapy was initiated (2.6–4 months after exposure).

No studies have evaluated the treatment of acute infection in persons with no evidence of liver disease (i.e., HCV RNA-positive <6 months duration with normal ALT levels); among patients with chronic HCV infection, the efficacy of antivirals has been demonstrated only among patients who also had evidence of chronic liver disease (i.e., abnormal ALT levels). In addition, treatment started early in the course of chronic HCV infection (i.e., 6 months after onset of infection) might be as effective as treatment started during acute infection (*13*). Because 15%–25% of patients with acute HCV infection spontaneously resolve their infection (*93*), treatment of these patients during the acute phase could expose them unnecessarily to the discomfort and side effects of antiviral therapy.

Data upon which to base a recommendation for therapy of acute infection are insufficient because a) no data exist regarding the effect of treating patients with acute infection who have no evidence of disease, b) treatment started early in the course of chronic infection might be just as effective and would eliminate the need to treat persons who will spontaneously resolve their infection, and c) the appropriate regimen is unknown.

Occupational Transmission of HIV

Risk for Occupational Transmission of HIV

In prospective studies of HCP, the average risk of HIV transmission after a percutaneous exposure to HIV-infected blood has been estimated to be approximately 0.3% (95% confidence interval [CI] = 0.2%–0.5%) (*94*) and after a mucous membrane exposure, approximately 0.09% (95% CI = 0.006%–0.5%) (*95*). Although episodes of HIV transmission after nonintact skin exposure have been documented (*96*), the average risk for transmission by this route has not been precisely quantified but is estimated to be less than the risk for mucous membrane exposures (*97*). The risk for transmission after exposure to fluids or tissues other than HIV-infected blood also has not been quantified but is probably considerably lower than for blood exposures (*98*).

As of June 2000, CDC had received voluntary reports of 56 U.S. HCP with documented HIV seroconversion temporally associated with an occupational HIV exposure. An additional 138 episodes in HCP are considered possible occupational HIV transmissions. These workers had a history of occupational exposure to blood, other infectious body fluids, or laboratory solutions containing HIV, and no other risk for HIV infection was identified, but HIV seroconversion after a specific exposure was not documented (*99*).

Epidemiologic and laboratory studies suggest that several factors might affect the risk of HIV transmission after an occupational exposure. In a retrospective case-control study of HCP who had percutaneous exposure to HIV, the risk for HIV infection was found

to be increased with exposure to a larger quantity of blood from the source person as indicated by a) a device visibly contaminated with the patient's blood, b) a procedure that involved a needle being placed directly in a vein or artery, or c) a deep injury (*100*). The risk also was increased for exposure to blood from source persons with terminal illness, possibly reflecting either the higher titer of HIV in blood late in the course of AIDS or other factors (e.g., the presence of syncytia-inducing strains of HIV). A laboratory study that demonstrated that more blood is transferred by deeper injuries and hollow-bore needles lends further support for the observed variation in risk related to blood quantity (*101*).

The use of source person viral load as a surrogate measure of viral titer for assessing transmission risk has not yet been established. Plasma viral load (e.g., HIV RNA) reflects only the level of cell-free virus in the peripheral blood; latently infected cells might transmit infection in the absence of viremia. Although a lower viral load (e.g., <1,500 RNA copies/mL) or one that is below the limits of detection probably indicates a lower titer exposure, it does not rule out the possibility of transmission.

Some evidence exists regarding host defenses possibly influencing the risk for HIV infection. A study of HIV-exposed but uninfected HCP demonstrated an HIV-specific cytotoxic T-lymphocyte (CTL) response when peripheral blood mononuclear cells were stimulated in vitro with HIV-specific antigens (*102*). Similar CTL responses have been observed in other groups who experienced repeated HIV exposure without resulting infection (*103–108*). Among several possible explanations for this observation is that the host immune response sometimes might prevent establishment of HIV infection after a percutaneous exposure; another is that the CTL response simply might be a marker for exposure. In a study of 20 HCP with occupational exposure to HIV, a comparison was made of HCP treated with zidovudine (ZDV) PEP and those not treated. The findings from this study suggest that ZDV blunted the HIV-specific CTL response and that PEP might inhibit early HIV replication (*109*).

Rationale for HIV PEP

Considerations that influence the rationale and recommendations for PEP include

- the pathogenesis of HIV infection, particularly the time course of early infection;
- the biological plausibility that infection can be prevented or ameliorated by using antiretroviral drugs;
- direct or indirect evidence of the efficacy of specific agents used for prophylaxis; and
- the risk and benefit of PEP to exposed HCP.

The following discussion considers each of these concerns.

Role of Pathogenesis in Considering Antiretroviral Prophylaxis. Information about primary HIV infection indicates that systemic infection does not occur immediately, leaving a brief window of opportunity during which postexposure antiretroviral intervention might modify or prevent viral replication. In a primate model of simian immunodeficiency virus (SIV) infection, infection of dendritic-like cells occurred at the site of inoculation during the first 24 hours following mucosal exposure to cell-free virus. Over the subsequent 24–48 hours, migration of these cells to regional lymph nodes occurred, and virus was detectable in the peripheral blood within 5 days (*110*). Theoretically, initiation of antiretroviral PEP soon after exposure might prevent or inhibit systemic infection by limiting the proliferation of virus in the initial target cells or lymph nodes.

Efficacy of Antiretrovirals for PEP in Animal Studies. Data from animal studies have been difficult to interpret, in part, because of problems identifying an animal model that is comparable to humans. In early studies, differences in controlled variables (e.g., choice of viral strain [based on the animal model used], inoculum size, route of inoculation, time of prophylaxis initiation, and drug regimen) made extrapolation of the results to humans difficult. Recently, refinements in methodology have facilitated more relevant studies; in particular, the viral inocula used in animal studies have been reduced to levels more analogous to human exposures but sufficient to cause infection in control animals (*111–113*). These studies provide encouraging evidence of postexposure chemoprophylactic efficacy.

Studies among primates and in murine and feline animal models have demonstrated that larger viral inocula decrease prophylactic efficacy (*114–117*). In addition, delaying initiation, shortening the duration, or decreasing the antiretroviral dose of PEP, individually or in combination, decreased prophylactic efficacy (*113,118–124*). For example, when (R)-9-(2-phosphonylmethoxypropyl) adenine (tenofovir) was administered 48 hours before, 4 hours after, or 24 hours after intravenous SIV inoculation to long-tailed macaques, a 4-week regimen prevented infection in all treated animals (*122*). A subsequent study confirmed the efficacy of tenofovir PEP when administered 24 hours after intravenous inoculation of a dose of SIV that uniformly results in infection in untreated macaques. In the same study, protection was incomplete if the tenofovir administration was delayed to 48 or 72 hours postexposure or if the total duration of treatment was curtailed to 3 or 10 days (*123*).

Efficacy of Antiretrovirals for PEP in Human Studies. Little information exists from which the efficacy of PEP in humans can be assessed. Seroconversion is infrequent following an occupational exposure to HIV-infected blood; therefore, several thousands of exposed HCP would need to enroll in a prospective trial to achieve the statistical power necessary to directly demonstrate PEP efficacy (*125*).

In the retrospective case-control study of HCP, after controlling for other risk factors for HIV transmission, use of ZDV as PEP was associated with a reduction in the risk of HIV infection by approximately 81% (95% CI = 43%–94%) (*100*). Although the results of this study suggest PEP efficacy, its limitations include the small number of cases studied and the use of cases and controls from different cohorts.

In a multicenter trial in which ZDV was administered to HIV-infected pregnant women and their infants, the administration of ZDV during pregnancy, labor, and delivery and to the infant reduced transmission by 67% (*126*). Only part of the protective effect of ZDV was explained by reduction of the HIV viral load in the maternal blood, suggesting that ZDV prophylaxis, in part, involves a mechanism other than the reduction of maternal viral burden (*127,128*). Since 1998, studies have highlighted the importance of PEP for prevention of perinatal HIV transmission. In Africa, the use of ZDV in combination with lamivudine (3TC) decreased perinatal HIV transmission by 50% when administered during pregnancy, labor, and for 1 week postpartum, and by 37% when started at the onset of labor and continued for 1 week postpartum (*129*). Studies in the United States and Uganda also have demonstrated that rates of perinatal HIV transmission have been reduced with the use of abbreviated PEP regimens started intrapartum or during the first 48–72 hours of life (*130–132*).

The limitations of all of these studies with animals and humans must be considered when reviewing evidence of PEP efficacy. The extent to which data from animal studies

can be extrapolated to humans is largely unknown, and the exposure route for mother-to-infant HIV transmission is not similar to occupational exposures; therefore, these findings might not be directly applicable to PEP in HCP.

Reports of Failure of PEP. Failure of PEP to prevent HIV infection in HCP has been reported in at least 21 instances (*78,133–139*). In 16 of the cases, ZDV was used alone as a single agent; in two cases, ZDV and didanosine (ddI) were used in combination (*133,138*); and in three cases, ≥3 drugs were used for PEP (*137–139*). Thirteen of the source persons were known to have been treated with antiretroviral therapy before the exposure. Antiretroviral resistance testing of the virus from the source person was performed in seven instances, and in four, the HIV infection transmitted was found to have decreased sensitivity to ZDV and/or other drugs used for PEP. In addition to possible exposure to an antiretroviral-resistant strain of HIV, other factors that might have contributed to these apparent failures might include a high titer and/or large inoculum exposure, delayed initiation and/or short duration of PEP, and possible factors related to the host (e.g., cellular immune system responsiveness) and/or to the source person's virus (e.g., presence of syncytia-forming strains) (*133*). Details regarding the cases of PEP failure involving combinations of antiretroviral agents are included in this report (Table 1).

Antiretroviral Agents for PEP

Antiretroviral agents from three classes of drugs are available for the treatment of HIV infection. These agents include the nucleoside reverse transcriptase inhibitors (NRTIs), nonnucleoside reverse transcriptase inhibitors (NNRTIs), and protease inhibitors (PIs). Only antiretroviral agents that have been approved by FDA for treatment of HIV infection are discussed in these guidelines.

Determining which agents and how many to use or when to alter a PEP regimen is largely empiric. Guidelines for the treatment of HIV infection, a condition usually involving a high total body burden of HIV, include recommendations for the use of three drugs (*140*); however, the applicability of these recommendations to PEP remains unknown. In HIV-infected patients, combination regimens have proved superior to monotherapy regimens in reducing HIV viral load, reducing the incidence of opportunistic infections and death, and delaying onset of drug resistance (*141,142*). A combination of drugs with activity at different stages in the viral replication cycle (e.g., nucleoside analogues with a PI) theoretically could offer an additional preventive effect in PEP, particularly for occupational exposures that pose an increased risk of transmission. Although the use of a three-drug regimen might be justified for exposures that pose an increased risk of transmission, whether the potential added toxicity of a third drug is justified for lower-risk exposures is uncertain. Therefore, the recommendations at the end of this document provide guidance for two- and three-drug PEP regimens that are based on the level of risk for HIV transmission represented by the exposure.

NRTI combinations that can be considered for PEP include ZDV and 3TC, 3TC and stavudine (d4T), and ddI and d4T. In previous PHS guidelines, a combination of ZDV and 3TC was considered the first choice for PEP regimens (*3*). Because ZDV and 3TC are available in a combination formulation (Combivir™, manufactured by Glaxo Wellcome, Inc., Research Triangle Park, NC), the use of this combination might be more convenient for HCP. However, recent data suggest that mutations associated with ZDV and 3TC resistance might be common in some areas (*143*). Thus, individual clinicians might prefer other NRTIs or combinations based on local knowledge and experience in treating HIV infection and disease.

TABLE 1. Reported instances of failure of combination drug postexposure prophylaxis to prevent HIV infection in health-care personnel exposed to HIV-infected blood

Report no.	Source of injury	Regimen*	Hours to first dose	Days to onset of retroviral illness	Days to seroconversions†	Source patient on antiretrovirals
1§	Biopsy needle	ZDV, ddI	0.50	23	23	yes
2¶	Hollow needle	ZDV, ddI**	1.50	45	97	no
3¶	Large-bore hollow needle	3-drugs††	1.50	40	55	yes§§
4¶¶	Hollow needle	ZDV, 3TC ddI, IDV	0.67	70	83	yes***
5†††	Unknown sharp	ddI, d4T NVP§§§	2.00	42	100	yes***

* ZDV = zidovudine, ddI = didanosine, 3TC = lamivudine, IDV = indinavir, d4T = stavudine, and NVP = nevirapine

† By enzyme immunoassay for HIV-1 antibody and Western blot.

§ Jochimsen EM. Failures of zidovudine postexposure prophylaxis. Am J Med 1997;102(suppl 5B):52–5.

¶ Lot F, Abiteboul D. Occupational HIV infection in France [Abstract WP-25]. In: Keynote addresses and abstracts of the 4th ICOH International Conference on Occupational Health for Health Care Workers. Montreal, Canada, 1999.

** Report 2: ZDV and ddI taken for 48 hours then changed to ZDV alone.

†† Report 3: ZDV, 3TC, and IDV taken for 48 hours then changed to d4T, 3TC, and IDV.

§§ HIV isolate tested and determined to be sensitive to antiretroviral agent(s).

¶¶ Perdue B, Wolderufael D, Mellors J, Quinn T, Margolick J. HIV-1 transmission by a needlestick injury despite rapid initiation of four-drug postexposure prophylaxis [Abstract 210]. In: Program and abstracts of the 6th Conference on Retroviruses and Opportunistic Infections. Chicago, IL: Foundation for Retrovirology and Human Health in scientific collaboration with the National Institute of Allergy and Infectious Diseases and CDC, 1999:107.

*** HIV isolate tested and determined to be resistant to antiretroviral agent(s).

††† Beltrami EM, Luo C-C, Dela Torre N, Cardo DM. HIV transmission after an occupational exposure despite postexposure prophylaxis with a combination drug regimen [Abstract P-S2-62]. In: Program and abstracts of the 4th Decennial International Conference on Nosocomial and Healthcare-Associated Infections in conjunction with the 10th Annual Meeting of SHEA. Atlanta, GA: CDC, 2000:125–6.

§§§ Report 5: ZDV and 3TC taken for one dose then changed to ddI, d4T, and NVP; ddI was discontinued after 3 days because of severe vomiting.

The addition of a third drug for PEP following high-risk exposures is based on demonstrated effectiveness in reducing viral burden in HIV-infected persons. Previously, indinavir (IDV) or nelfinavir (NFV) were recommended as first-choice agents for inclusion in an expanded PEP regimen (*5*). Since the publication of the 1998 PEP guidelines, efavirenz (EFV), an NNRTI; abacavir (ABC), a potent NRTI; and Kaletra™, a PI, have been approved by FDA. Although side effects might be common with the NNRTIs, EFV might be considered for expanded PEP regimens, especially when resistance to PIs in the source person's virus is known or suspected. ABC has been associated with dangerous hypersensitivity reactions but, with careful monitoring, may be considered as a third drug for PEP. Kaletra, a combination of lopinavir and ritonavir, is a potent HIV inhibitor that, with expert consultation, may be considered in an expanded PEP regimen.

Toxicity and Drug Interactions of Antiretroviral Agents. When administering PEP, an important goal is completion of a 4-week PEP regimen when PEP is indicated. Therefore, the toxicity profile of antiretroviral agents, including the frequency, severity, duration, and reversibility of side effects, is a relevant consideration. All of the antiretroviral agents have been associated with side effects (Table 2). However, studies of adverse events have been conducted primarily with persons who have advanced disease (and longer treatment courses) and who therefore might not reflect the experience in persons who are uninfected (*144*).

Several primary side effects are associated with antiretroviral agents (Table 2). Side effects associated with many of the NRTIs are chiefly gastrointestinal (e.g., nausea or diarrhea); however, ddI has been associated with cases of fatal and nonfatal pancreatitis among HIV-infected patients treated for >4 weeks. The use of PIs has been associated with new onset diabetes mellitus, hyperglycemia, diabetic ketoacidosis, exacerbation of preexisting diabetes mellitus, and dyslipidemia (*145–147*). Nephrolithiasis has been associated with IDV use; however, the incidence of this potential complication might be limited by drinking at least 48 ounces (1.5 L) of fluid per 24-hour period (e.g., six 8- ounce glasses of water throughout the day) (*148*). NFV has been associated with the development of diarrhea; however, this side effect might respond to treatment with antimotility agents that can be prescribed for use, if necessary, at the time the drug is recommended for PEP. The NNRTIs have been associated with severe skin reactions, including life-threatening cases of Stevens-Johnson syndrome and toxic epidermal necrolysis. Hepatotoxicity, including fatal hepatic necrosis, has occurred in patients treated with nevirapine (NVP); some episodes began during the first few weeks of therapy (FDA, unpublished data, 2000). EFV has been associated with central nervous system side effects, including dizziness, somnolence, insomnia, and abnormal dreaming.

All of the approved antiretroviral agents might have potentially serious drug interactions when used with certain other drugs (Appendix C). Careful evaluation of concomitant medications used by an exposed person is required before PEP is prescribed, and close monitoring for toxicity is also needed. Further information about potential drug interactions can be found in the manufacturer's package insert.

Toxicity Associated with PEP. Information from the National Surveillance System for Health Care Workers (NaSH) and the HIV Postexposure Registry indicates that nearly 50% of HCP experience adverse symptoms (e.g., nausea, malaise, headache, anorexia, and headache) while taking PEP and that approximately 33% stop taking PEP because of adverse signs and symptoms (*6,7,10,11*). Some studies have demonstrated that side effects and discontinuation of PEP are more common among HCP taking three-drug

TABLE 2. Primary side effects associated with antiretroviral agents

Antiretroviral class/agent	Primary side effects and toxicities
Nucleoside reverse transcriptase inhibitors (NRTIs)	
Zidovudine (Retrovir™; ZDV; AZT)	anemia, neutropenia, nausea, headache, insomnia, muscle pain, and weakness
Lamivudine (Epivir™; 3TC)	abdominal pain, nausea, diarrhea, rash, and pancreatitis
Stavudine (Zerit™; d4T)	peripheral neuropathy, headache, diarrhea, nausea, insomnia, anorexia, pancreatitis, increased liver function tests (LFTs), anemia, and neutropenia
Didanosine (Videx™; ddI)	pancreatitis, lactic acidosis, neuropathy, diarrhea, abdominal pain, and nausea
Abacavir (Ziagen™; ABC)	nausea, diarrhea, anorexia, abdominal pain, fatigue, headache, insomnia, and hypersensitivity reactions
Nonnucleoside reverse transcriptase inhibitors (NNRTIs)	
Nevirapine (Viramune™; NVP)	rash (including cases of Stevens-Johnson syndrome), fever, nausea, headache, hepatitis, and increased LFTs
Delavirdine (Rescriptor™; DLV)	rash (including cases of Stevens-Johnson syndrome), nausea, diarrhea, headache, fatigue, and increased LFTs
Efavirenz (Sustiva™; EFV)	rash (including cases of Stevens-Johnson syndrome), insomnia, somnolence, dizziness, trouble concentrating, and abnormal dreaming
Protease inhibitors (PIs)	
Indinavir (Crixivan™; IDV)	nausea, abdominal pain, nephrolithiasis, and indirect hyperbilirubinemia
Nelfinavir (Viracept™; NFV)	diarrhea, nausea, abdominal pain, weakness, and rash
Ritonavir (Norvir™; RTV)	weakness, diarrhea, nausea, circumoral paresthesia, taste alteration, and increased cholesterol and triglycerides
Saquinavir (Fortovase™; SQV)	diarrhea, abdominal pain, nausea, hyperglycemia, and increased LFTs
Amprenavir (Agenerase™; AMP)	nausea, diarrhea, rash, circumoral paresthesia, taste alteration, and depression
Lopinavir/Ritonavir (Kaletra™)	diarrhea, fatigue, headache, nausea, and increased cholesterol and triglycerides

combination regimens for PEP compared with HCP taking two-drug combination regimens (*7,10*). Although similar rates of side effects were observed among persons who took PEP after sexual or drug use exposures to HIV in the San Francisco Post-Exposure Prevention Project, 80% completed 4 weeks of therapy (*149*). Participants in the San Francisco Project were followed at 1, 2, 4, 26, and 52 weeks postexposure and received medication adherence counseling; most participants took only two drugs for PEP.

Serious side effects, including nephrolithiasis, hepatitis, and pancytopenia have been reported with the use of combination drugs for PEP (*6,7,150,151*). One case of NVP-associated fulminant liver failure requiring liver transplantation and one case of hypersensitivity syndrome have been reported in HCP taking NVP for HIV PEP (*152*). Including these two cases, from March 1997 through September 2000, FDA received reports of 22 cases of serious adverse events related to NVP taken for PEP (*153*). These events included 12 cases of hepatotoxicity, 14 cases of skin reaction (including one documented and two possible cases of Stevens-Johnson syndrome), and one case of rhabdomyolysis; four cases involved both hepatotoxicty and skin reaction, and one case involved both rhabdomyolysis and skin reaction.

Resistance to Antiretroviral Agents. Known or suspected resistance of the source virus to antiretroviral agents, particularly to agents that might be included in a PEP regimen, is a concern for persons making decisions about PEP. Resistance to HIV infection occurs with all of the available antiretroviral agents, and cross-resistance within drug classes is frequent (*154*). Recent studies have demonstrated an emergence of drug-resistant HIV among source persons for occupational exposures (*143,155*). A study conducted at seven U.S. sites during 1998–1999 found that 16 (39%) of 41 source persons whose virus was sequenced had primary genetic mutations associated with resistance to RTIs, and 4 (10%) had primary mutations associated with resistance to PIs (*143*). In addition, occupational transmission of resistant HIV strains, despite PEP with combination drug regimens, has been reported (*137,139*). In one case, a hospital worker became infected after an HIV exposure despite a PEP regimen that included ddI, d4T, and NVP (*139*). The transmitted HIV contained two primary genetic mutations associated with resistance to NNRTIs (the source person was taking EFV at the time of the exposure). Despite recent studies and case reports, the relevance of exposure to a resistant virus is still not well understood.

Empiric decisions about the presence of antiretroviral drug resistance are often difficult to make because patients generally take more than one antiretroviral agent. Resistance should be suspected in source persons when they are experiencing clinical progression of disease or a persistently increasing viral load, and/or decline in CD4 T-cell count, despite therapy or a lack of virologic response to therapy. However, resistance testing of the source virus at the time of an exposure is not practical because the results will not be available in time to influence the choice of the initial PEP regimen. Furthermore, in this situation, whether modification of the PEP regimen is necessary or will influence the outcome of an occupational exposure is unknown. No data exist to suggest that modification of a PEP regimen after receiving results from resistance testing (usually a minimum of 1–2 weeks) improves efficacy of PEP.

Antiretroviral Drugs During Pregnancy. Data are limited on the potential effects of antiretroviral drugs on the developing fetus or neonate (*156*). Carcinogenicity and/or mutagenicity is evident in several in vitro screening tests for ZDV and all other FDA-licensed NRTIs. The relevance of animal data to humans is unknown; however, because

teratogenic effects were observed in primates at drug exposures similar to those representing human therapeutic exposure, the use of EFV should be avoided in pregnant women (*140*). IDV is associated with infrequent side effects in adults (i.e., hyperbilirubinemia and renal stones) that could be problematic for a newborn. Because the half-life of IDV in adults is short, these concerns might be relevant only if the drug is administered shortly before delivery.

In a recent study in France of perinatal HIV transmission, two cases of progressive neurologic disease and death were reported in uninfected infants exposed to ZDV and 3TC (*157*). Laboratory studies of these children suggested mitochondrial dysfunction. In a careful review of deaths in children followed in U.S. perinatal HIV cohorts, no deaths attributable to mitochondrial disease have been found (*158*).

Recent reports of fatal and nonfatal lactic acidosis in pregnant women treated throughout gestation with a combination of d4T and ddI have prompted warnings about use of these drugs during pregnancy (*159*). Although the case-patients were HIV-infected women taking the drugs for >4 weeks, pregnant women and their providers should be advised to consider d4T and ddI only when the benefits of their use outweigh the risks.

PEP Use in Hospitals in the United States. Analysis of data from NaSH provides information on the use of PEP following occupational exposures in 47 hospitals in the United States. A total of 11,784 exposures to blood and body fluids was reported from June 1996 through November 2000 (CDC, unpublished data, 2001). For all exposures with known sources, 6% were to HIV-positive sources, 74% to HIV-negative sources, and 20% to sources with an unknown HIV status. Sixty-three percent of HCP exposed to a known HIV-positive source started PEP, and 54% of HCP took it for at least 20 days, whereas 14% of HCP exposed to a source person subsequently found to be HIV-negative initiated PEP, and 3% of those took it for at least 20 days. Information recorded about HIV exposures in NaSH indicates that 46% of exposures involving an HIV-positive source warranted only a two-drug PEP regimen (i.e., the exposure was to mucous membranes or skin or was a superficial percutaneous injury and the source person did not have end-stage AIDS or acute HIV illness); however, 53% of these exposed HCP took $\geq$3 drugs (CDC, unpublished data, 2000). Similarly, the National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline) reported that PEPline staff recommended stopping or not starting PEP for approximately one half of the HCP who consulted them about exposures (D. Bangsberg, San Francisco General Hospital, unpublished data, September 1999). The observation that some HCP exposed to HIV-negative source persons take PEP from several days to weeks following their exposures suggests that strategies be employed such as the use of a rapid HIV antibody assay, which could minimize exposure to unnecessary PEP (*11*). A recent study demonstrated that use of a rapid HIV test for evaluation of source persons after occupational exposures not only resulted in decreased use of PEP, but also was cost-effective compared with use of the standard enzyme immunoassay (EIA) test for source persons subsequently found to be HIV-negative (*160*).

RECOMMENDATIONS FOR THE MANAGEMENT OF HCP POTENTIALLY EXPOSED TO HBV, HCV, or HIV

Exposure prevention remains the primary strategy for reducing occupational bloodborne pathogen infections; however, occupational exposures will continue to occur. Health-care organizations should make available to their personnel a system that includes written protocols for prompt reporting, evaluation, counseling, treatment, and

follow-up of occupational exposures that might place HCP at risk for acquiring a bloodborne infection. HCP should be educated concerning the risk for and prevention of bloodborne infections, including the need to be vaccinated against hepatitis B *(17,21,161–163)*. Employers are required to establish exposure-control plans that include postexposure follow-up for their employees and to comply with incident reporting requirements mandated by the 1992 OSHA bloodborne pathogen standard (*2*). Access to clinicians who can provide postexposure care should be available during all working hours, including nights and weekends. HBIG, hepatitis B vaccine, and antiretroviral agents for HIV PEP should be available for timely administration (i.e., either by providing access on-site or by creating linkages with other facilities or providers to make them available off-site). Persons responsible for providing postexposure management should be familiar with evaluation and treatment protocols and the facility's plans for accessing HBIG, hepatitis B vaccine, and antiretroviral drugs for HIV PEP.

HCP should be educated to report occupational exposures immediately after they occur, particularly because HBIG, hepatitis B vaccine, and HIV PEP are most likely to be effective if administered as soon after the exposure as possible. HCP who are at risk for occupational exposure to bloodborne pathogens should be familiarized with the principles of postexposure management as part of job orientation and ongoing job training.

Hepatitis B Vaccination

Any person who performs tasks involving contact with blood, blood-contaminated body fluids, other body fluids, or sharps should be vaccinated against hepatitis B (*2,21*). Prevaccination serologic screening for previous infection is not indicated for persons being vaccinated because of occupational risk, unless the hospital or health-care organization considers screening cost-effective.

Hepatitis B vaccine should always be administered by the intramuscular route in the deltoid muscle with a needle 1–1.5 inches long. Hepatitis B vaccine can be administered at the same time as other vaccines with no interference with antibody response to the other vaccines (*164*). If the vaccination series is interrupted after the first dose, the second dose should be administered as soon as possible. The second and third doses should be separated by an interval of at least 2 months. If only the third dose is delayed, it should be administered when convenient. HCP who have contact with patients or blood and are at ongoing risk for percutaneous injuries should be tested 1–2 months after completion of the 3-dose vaccination series for anti-HBs (*21*). Persons who do not respond to the primary vaccine series (i.e., anti-HBs <10 mIU/mL) should complete a second 3-dose vaccine series or be evaluated to determine if they are HBsAg-positive. Revaccinated persons should be retested at the completion of the second vaccine series. Persons who do not respond to an initial 3-dose vaccine series have a 30%–50% chance of responding to a second 3-dose series (*165*). Persons who prove to be HBsAg-positive should be counseled regarding how to prevent HBV transmission to others and regarding the need for medical evaluation (*12,163,166*). Nonresponders to vaccination who are HBsAg-negative should be considered susceptible to HBV infection and should be counseled regarding precautions to prevent HBV infection and the need to obtain HBIG prophylaxis for any known or probable parenteral exposure to HBsAg-positive blood. Booster doses of hepatitis B vaccine are not necessary, and periodic serologic testing to monitor antibody concentrations after completion of the vaccine series is not recommended. Any blood or body fluid exposure sustained by an unvaccinated, susceptible person should lead to the initiation of the hepatitis B vaccine series.

Treatment of an Exposure Site

Wounds and skin sites that have been in contact with blood or body fluids should be washed with soap and water; mucous membranes should be flushed with water. No evidence exists that using antiseptics for wound care or expressing fluid by squeezing the wound further reduces the risk of bloodborne pathogen transmission; however, the use of antiseptics is not contraindicated. The application of caustic agents (e.g., bleach) or the injection of antiseptics or disinfectants into the wound is not recommended.

Exposure Report

If an occupational exposure occurs, the circumstances and postexposure management should be recorded in the exposed person's confidential medical record (usually on a form the facility designates for this purpose) (Box 1). In addition, employers should follow all federal (including OSHA) and state requirements for recording and reporting occupational injuries and exposures.

BOX 1. Recommendations for the contents of the occupational exposure report

- date and time of exposure;
- details of the procedure being performed, including where and how the exposure occurred; if related to a sharp device, the type and brand of device and how and when in the course of handling the device the exposure occurred;
- details of the exposure, including the type and amount of fluid or material and the severity of the exposure (e.g., for a percutaneous exposure, depth of injury and whether fluid was injected; for a skin or mucous membrane exposure, the estimated volume of material and the condition of the skin [e.g., chapped, abraded, intact]);
- details about the exposure source (e.g., whether the source material contained HBV, HCV, or HIV; if the source is HIV-infected, the stage of disease, history of antiretroviral therapy, viral load, and antiretroviral resistance information, if known);
- details about the exposed person (e.g., hepatitis B vaccination and vaccine-response status); and
- details about counseling, postexposure management, and follow-up.

Evaluation of the Exposure and the Exposure Source

Evaluation of the Exposure

The exposure should be evaluated for the potential to transmit HBV, HCV, and HIV based on the type of body substance involved and the route and severity of the exposure (Box 2). Blood, fluid containing visible blood, or other potentially infectious fluid (including semen; vaginal secretions; and cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids) or tissue can be infectious for bloodborne viruses. Exposures to

these fluids or tissue through a percutaneous injury (i.e., needlestick or other penetrating sharps-related event) or through contact with a mucous membrane are situations that pose a risk for bloodborne virus transmission and require further evaluation. For HCV and HIV, exposure to a blood-filled hollow needle or visibly bloody device suggests a higher risk exposure than exposure to a needle that was most likely used for giving an injection. In addition, any direct contact (i.e, personal protective equipment either was not present or was ineffective in protecting skin or mucous membranes) with concentrated virus in a research laboratory or production facility is considered an exposure that requires clinical evaluation.

For skin exposure, follow-up is indicated only if it involves exposure to a body fluid previously listed and evidence exists of compromised skin integrity (e.g., dermatitis, abrasion, or open wound). In the clinical evaluation for human bites, possible exposure of both the person bitten and the person who inflicted the bite must be considered. If a bite results in blood exposure to either person involved, postexposure follow-up should be provided.

BOX 2. Factors to consider in assessing the need for follow-up of occupational exposures

- **Type of exposure**
  - — Percutaneous injury
  - — Mucous membrane exposure
  - — Nonintact skin exposure
  - — Bites resulting in blood exposure to either person involved
- **Type and amount of fluid/tissue**
  - — Blood
  - — Fluids containing blood
  - — Potentially infectious fluid or tissue (semen; vaginal secretions; and cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids)
  - — Direct contact with concentrated virus
- **Infectious status of source**
  - — Presence of HBsAg
  - — Presence of HCV antibody
  - — Presence of HIV antibody
- **Susceptibility of exposed person**
  - — Hepatitis B vaccine and vaccine response status
  - — HBV, HCV, and HIV immune status

Evaluation of the Exposure Source

The person whose blood or body fluid is the source of an occupational exposure should be evaluated for HBV, HCV, and HIV infection (Box 3). Information available in the medical record at the time of exposure (e.g., laboratory test results, admitting diagnosis, or previous medical history) or from the source person, might confirm or exclude bloodborne virus infection.

If the HBV, HCV, and/or HIV infection status of the source is unknown, the source person should be informed of the incident and tested for serologic evidence of bloodborne virus infection. Procedures should be followed for testing source persons, including obtaining informed consent, in accordance with applicable state and local laws. Any persons determined to be infected with HBV, HCV, or HIV should be referred for appropriate counseling and treatment. Confidentiality of the source person should be maintained at all times.

Testing to determine the HBV, HCV, and HIV infection status of an exposure source should be performed as soon as possible. Hospitals, clinics and other sites that manage exposed HCP should consult their laboratories regarding the most appropriate test to use to expedite obtaining these results. An FDA-approved rapid HIV-antibody test kit should be considered for use in this situation, particularly if testing by EIA cannot be completed within 24–48 hours. Repeatedly reactive results by EIA or rapid HIV-antibody tests are considered to be highly suggestive of infection, whereas a negative result is an excellent indicator of the absence of HIV antibody. Confirmation of a reactive result by Western blot or immunofluorescent antibody is not necessary to make initial decisions about postexposure management but should be done to complete the testing process and before informing the source person. Repeatedly reactive results by EIA for anti-HCV should be confirmed by a supplemental test (i.e., recombinant immunoblot assay [RIBA™] or HCV PCR). Direct virus assays (e.g., HIV p24 antigen EIA or tests for HIV RNA or HCV RNA) for routine HIV or HCV screening of source persons are not recommended.

If the exposure source is unknown or cannot be tested, information about where and under what circumstances the exposure occurred should be assessed epidemiologically for the likelihood of transmission of HBV, HCV, or HIV. Certain situations as well as the type of exposure might suggest an increased or decreased risk; an important consideration is the prevalence of HBV, HCV, or HIV in the population group (i.e., institution or community) from which the contaminated source material is derived. For example, an exposure that occurs in a geographic area where injection-drug use is prevalent or involves a needle discarded in a drug-treatment facility would be considered epidemiologically to have a higher risk for transmission than an exposure that occurs in a nursing home for the elderly.

Testing of needles or other sharp instruments implicated in an exposure, regardless of whether the source is known or unknown, is not recommended. The reliability and interpretation of findings in such circumstances are unknown, and testing might be hazardous to persons handling the sharp instrument.

Examples of information to consider when evaluating an exposure source for possible HBV, HCV, or HIV infection include laboratory information (e.g., previous HBV, HCV, or HIV test results or results of immunologic testing [e.g., CD4+ T-cell count]) or liver enzymes (e.g., ALT), clinical symptoms (e.g., acute syndrome suggestive of primary HIV infection or undiagnosed immunodeficiency disease), and history of recent (i.e., within 3 months) possible HBV, HCV, or HIV exposures (e.g., injection-drug use or sexual contact

with a known positive partner). Health-care providers should be aware of local and state laws governing the collection and release of HIV serostatus information on a source person, following an occupational exposure.

If the source person is known to have HIV infection, available information about this person's stage of infection (i.e., asymptomatic, symptomatic, or AIDS), CD4+ T-cell count, results of viral load testing, current and previous antiretroviral therapy, and results of any genotypic or phenotypic viral resistance testing should be gathered for consideration in choosing an appropriate PEP regimen. If this information is not immediately available, initiation of PEP, if indicated, should not be delayed; changes in the PEP regimen can be made after PEP has been started, as appropriate. Reevaluation of exposed HCP should be considered within 72 hours postexposure, especially as additional information about the exposure or source person becomes available.

If the source person is HIV seronegative and has no clinical evidence of AIDS or symptoms of HIV infection, no further testing of the person for HIV infection is indicated. The likelihood of the source person being in the "window period" of HIV infection in the absence of symptoms of acute retroviral syndrome is extremely small.

BOX 3. Evaluation of occupational exposure sources

Known sources

- Test known sources for HBsAg, anti-HCV, and HIV antibody
  - — Direct virus assays for routine screening of source patients are **not** recommended
  - — Consider using a rapid HIV-antibody test
  - — If the source person is **not** infected with a bloodborne pathogen, baseline testing or further follow-up of the exposed person is **not** necessary
- For sources whose infection status remains unknown (e.g., the source person refuses testing), consider medical diagnoses, clinical symptoms, and history of risk behaviors
- Do not test discarded needles for bloodborne pathogens

Unknown sources

- For unknown sources, evaluate the likelihood of exposure to a source at high risk for infection
  - — Consider likelihood of bloodborne pathogen infection among patients in the exposure setting

Management of Exposures to HBV

For percutaneous or mucosal exposures to blood, several factors must be considered when making a decision to provide prophylaxis, including the HBsAg status of the source and the hepatitis B vaccination and vaccine-response status of the exposed person. Such exposures usually involve persons for whom hepatitis B vaccination is recommended.

Any blood or body fluid exposure to an unvaccinated person should lead to initiation of the hepatitis B vaccine series.

The hepatitis B vaccination status and the vaccine-response status (if known) of the exposed person should be reviewed. A summary of prophylaxis recommendations for percutaneous or mucosal exposure to blood according to the HBsAg status of the exposure source and the vaccination and vaccine-response status of the exposed person is included in this report (Table 3).

When HBIG is indicated, it should be administered as soon as possible after exposure (preferably within 24 hours). The effectiveness of HBIG when administered >7 days after exposure is unknown. When hepatitis B vaccine is indicated, it should also be administered as soon as possible (preferably within 24 hours) and can be administered simultaneously with HBIG at a separate site (vaccine should always be administered in the deltoid muscle).

For exposed persons who are in the process of being vaccinated but have not completed the vaccination series, vaccination should be completed as scheduled, and HBIG should be added as indicated (Table 3). Persons exposed to HBsAg-positive blood or body fluids who are known not to have responded to a primary vaccine series should receive a single dose of HBIG and reinitiate the hepatitis B vaccine series with the first dose of the hepatitis B vaccine as soon as possible after exposure. Alternatively, they should receive two doses of HBIG, one dose as soon as possible after exposure, and the second dose 1 month later. The option of administering one dose of HBIG and reinitiating the vaccine series is preferred for nonresponders who did not complete a second 3-dose vaccine series. For persons who previously completed a second vaccine series but failed to respond, two doses of HBIG are preferred.

Management of Exposures to HCV

Individual institutions should establish policies and procedures for testing HCP for HCV after percutaneous or mucosal exposures to blood and ensure that all personnel are familiar with these policies and procedures. The following are recommendations for follow-up of occupational HCV exposures:

- For the source, perform testing for anti-HCV.
- For the person exposed to an HCV-positive source
  - — perform baseline testing for anti-HCV and ALT activity; and
  - — perform follow-up testing (e.g., at 4–6 months) for anti-HCV and ALT activity (if earlier diagnosis of HCV infection is desired, testing for HCV RNA may be performed at 4–6 weeks).
- Confirm all anti-HCV results reported positive by enzyme immunoassay using supplemental anti-HCV testing (e.g., recombinant immunoblot assay [RIBA™]) (*13*).

Health-care professionals who provide care to persons exposed to HCV in the occupational setting should be knowledgeable regarding the risk for HCV infection and appropriate counseling, testing, and medical follow-up.

IG and antiviral agents are not recommended for PEP after exposure to HCV-positive blood. In addition, no guidelines exist for administration of therapy during the acute

TABLE 3. Recommended postexposure prophylaxis for exposure to hepatitis B virus

Vaccination and antibody response status of exposed workers*	Treatment		
	Source HBsAg† positive	Source HBsAg† negative	Source unknown or not available for testing
Unvaccinated	HBIG§ x 1 and initiate HB vaccine series¶	Initiate HB vaccine series	Initiate HB vaccine series
Previously vaccinated			
Known responder**	No treatment	No treatment	No treatment
Known nonresponder††	HBIG x 1 and initiate revaccination or HBIG x 2§§	No treatment	If known high risk source, treat as if source were HBsAg positive
Antibody response unknown	Test exposed person for anti-HBs¶¶ 1. If adequate,** no treatment is necessary 2. If inadequate,†† administer HBIG x 1 and vaccine booster	No treatment	Test exposed person for anti-HBs 1. If adequate,¶ no treatment is necessary 2. If inadequate,¶ administer vaccine booster and recheck titer in 1–2 months

* Persons who have previously been infected with HBV are immune to reinfection and do not require postexposure prophylaxis.

† Hepatitis B surface antigen.

§ Hepatitis B immune globulin; dose is 0.06 mL/kg intramuscularly.

¶ Hepatitis B vaccine.

** A responder is a person with adequate levels of serum antibody to HBsAg (i.e., anti-HBs $\geq$10 mIU/mL).

†† A nonresponder is a person with inadequate response to vaccination (i.e., serum anti-HBs < 10 mIU/mL).

§§ The option of giving one dose of HBIG and reinitiating the vaccine series is preferred for nonresponders who have not completed a second 3-dose vaccine series. For persons who previously completed a second vaccine series but failed to respond, two doses of HBIG are preferred.

¶¶ Antibody to HBsAg.

phase of HCV infection. However, limited data indicate that antiviral therapy might be beneficial when started early in the course of HCV infection. When HCV infection is identified early, the person should be referred for medical management to a specialist knowledgeable in this area.

Counseling for HCP Exposed to Viral Hepatitis

HCP exposed to HBV- or HCV-infected blood do not need to take any special precautions to prevent secondary transmission during the follow-up period (*12,13*); however, they should refrain from donating blood, plasma, organs, tissue, or semen. The exposed person does not need to modify sexual practices or refrain from becoming pregnant. If an exposed woman is breast feeding, she does not need to discontinue.

No modifications to an exposed person's patient-care responsibilities are necessary to prevent transmission to patients based solely on exposure to HBV- or HCV-positive blood. If an exposed person becomes acutely infected with HBV, the person should be evaluated according to published recommendations for infected HCP (*165*). No recommendations exist regarding restricting the professional activities of HCP with HCV infection (*13*). As recommended for all HCP, those who are chronically infected with HBV or HCV should follow all recommended infection-control practices, including standard precautions and appropriate use of hand washing, protective barriers, and care in the use and disposal of needles and other sharp instruments (*162*).

Management of Exposures to HIV

Clinical Evaluation and Baseline Testing of Exposed HCP

HCP exposed to HIV should be evaluated within hours (rather than days) after their exposure and should be tested for HIV at baseline (i.e., to establish infection status at the time of exposure). If the source person is seronegative for HIV, baseline testing or further follow-up of the exposed person normally is not necessary. Serologic testing should be made available to all HCP who are concerned that they might have been occupationally infected with HIV. For purposes of considering HIV PEP, the evaluation also should include information about medications the exposed person might be taking and any current or underlying medical conditions or circumstances (i.e., pregnancy, breast feeding, or renal or hepatic disease) that might influence drug selection.

PEP for HIV

The following recommendations (Tables 4 and 5) apply to situations when a person has been exposed to a source person with HIV infection or when information suggests the likelihood that the source person is HIV-infected. These recommendations are based on the risk for HIV infection after different types of exposure and on limited data regarding efficacy and toxicity of PEP. Because most occupational HIV exposures do not result in the transmission of HIV, potential toxicity must be carefully considered when prescribing PEP. To assist with the initial management of an HIV exposure, health-care facilities should have drugs for an initial PEP regimen selected and available for use. When possible, these recommendations should be implemented in consultation with persons who have expertise in antiretroviral therapy and HIV transmission (Box 4).

TABLE 4. Recommended HIV postexposure prophylaxis for percutaneous injuries

	Infection status of source				
Exposure type	**HIV-Positive Class 1***	**HIV-Positive Class 2***	**Source of unknown HIV status†**	**Unknown source§**	**HIV-Negative**
Less severe¶	Recommend basic 2-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP** for source with HIV risk factors††	Generally, no PEP warranted; however, consider basic 2-drug PEP** in settings where exposure to HIV-infected persons is likely	No PEP warranted
More severe§§	Recommend expanded 3-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP** for source with HIV risk factors††	Generally, no PEP warranted; however, consider basic 2-drug PEP** in settings where exposure to HIV-infected persons is likely	No PEP warranted

* HIV-Positive, Class 1 — asymptomatic HIV infection or known low viral load (e.g., <1,500 RNA copies/mL). HIV-Positive, Class 2 — symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of postexposure prophylaxis (PEP) should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

† Source of unknown HIV status (e.g., deceased source person with no samples available for HIV testing).

§ Unknown source (e.g., a needle from a sharps disposal container).

¶ Less severe (e.g., solid needle and superficial injury).

** The designation "consider PEP" indicates that PEP is optional and should be based on an individualized decision between the exposed person and the treating clinician.

†† If PEP is offered and taken and the source is later determined to be HIV-negative, PEP should be discontinued.

§§ More severe (e.g., large-bore hollow needle, deep puncture, visible blood on device, or needle used in patient's artery or vein).

TABLE 5. Recommended HIV postexposure prophylaxis for mucous membrane exposures and nonintact skin* exposures

	Infection status of source				
Exposure type	**HIV-Positive Class 1†**	**HIV-Positive Class 2†**	**Source of unknown HIV status§**	**Unknown source¶**	**HIV-Negative**
Small volume**	Consider basic 2-drug PEP††	Recommend basic 2-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP†† for source with HIV risk factors§§	Generally, no PEP warranted; however, consider basic 2-drug PEP†† in settings where exposure to HIV-infected persons is likely	No PEP warranted
Large volume¶¶	Recommend basic 2-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP†† for source with HIV risk factors§§	Generally, no PEP warranted; however, consider basic 2-drug PEP†† in settings where exposure to HIV-infected persons is likely	No PEP warranted

* For skin exposures, follow-up is indicated only if there is evidence of compromised skin integrity (e.g., dermatitis, abrasion, or open wound).

† HIV-Positive, Class 1 — asymptomatic HIV infection or known low viral load (e.g., <1,500 RNA copies/mL). HIV-Positive, Class 2 — symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of postexposure prophylaxis (PEP) should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

§ Source of unknown HIV status (e.g., deceased source person with no samples available for HIV testing).

¶ Unknown source (e.g., splash from inappropriately disposed blood).

** Small volume (i.e., a few drops).

†† The designation, "consider PEP," indicates that PEP is optional and should be based on an individualized decision between the exposed person and the treating clinician.

§§ If PEP is offered and taken and the source is later determined to be HIV-negative, PEP should be discontinued.

¶¶ Large volume (i.e., major blood splash).

Timing and Duration of PEP. PEP should be initiated as soon as possible. The interval within which PEP should be initiated for optimal efficacy is not known. Animal studies have demonstrated the importance of starting PEP soon after an exposure (*111,112,118*). If questions exist about which antiretroviral drugs to use or whether to use a basic or expanded regimen, starting the basic regimen immediately rather than delaying PEP administration is probably better. Although animal studies suggest that PEP probably is substantially less effective when started more than 24–36 hours postexposure (*112,119,122*), the interval after which no benefit is gained from PEP for humans is undefined. Therefore, if appropriate for the exposure, PEP should be started even when the interval since exposure exceeds 36 hours. Initiating therapy after a longer interval (e.g., 1 week) might be considered for exposures that represent an increased risk for transmission. The optimal duration of PEP is unknown. Because 4 weeks of ZDV appeared protective in occupational and animal studies (*100,123*), PEP probably should be administered for 4 weeks, if tolerated.

Use of PEP When HIV Infection Status of Source Person is Unknown. If the source person's HIV infection status is unknown at the time of exposure, use of PEP should be decided on a case-by-case basis, after considering the type of exposure and the clinical and/or epidemiologic likelihood of HIV infection in the source (Tables 4 and 5). If these considerations suggest a possibility for HIV transmission and HIV testing of the source person is pending, initiating a two-drug PEP regimen until laboratory results have been obtained and later modifying or discontinuing the regimen accordingly is reasonable. The following are recommendations regarding HIV postexposure prophylaxis:

- If indicated, start PEP as soon as possible after an exposure.
- Reevaluation of the exposed person should be considered within 72 hours postexposure, especially as additional information about the exposure or source person becomes available.
- Administer PEP for 4 weeks, if tolerated.
- If a source person is determined to be HIV-negative, PEP should be discontinued.

PEP for Pregnant HCP. If the exposed person is pregnant, the evaluation of risk of infection and need for PEP should be approached as with any other person who has had an HIV exposure. However, the decision to use any antiretroviral drug during pregnancy should involve discussion between the woman and her health-care provider(s) regarding the potential benefits and risks to her and her fetus.

Certain drugs should be avoided in pregnant women. Because teratogenic effects were observed in primate studies, EFV is not recommended during pregnancy. Reports of fatal lactic acidosis in pregnant women treated with a combination of d4T and ddI have prompted warnings about these drugs during pregnancy. Because of the risk of hyperbilirubinemia in newborns, IDV should not be administered to pregnant women shortly before delivery.

Recommendations for the Selection of Drugs for HIV PEP

Health-care providers must strive to balance the risk for infection against the potential toxicity of the agent(s) used when selecting a drug regimen for HIV PEP. Because PEP is potentially toxic, its use is not justified for exposures that pose a negligible risk for

transmission (Tables 4 and 5). Also, insufficient evidence exists to support recommending a three-drug regimen for all HIV exposures. Therefore, two regimens for PEP are provided (Appendix C): a "basic" two-drug regimen that should be appropriate for most HIV exposures and an "expanded" three-drug regimen that should be used for exposures that pose an increased risk for transmission (Tables 4 and 5). When possible, the regimens should be implemented in consultation with persons who have expertise in antiretroviral treatment and HIV transmission.

Most HIV exposures will warrant a two-drug regimen using two nucleoside analogues (e.g., ZDV and 3TC; or 3TC and d4T; or d4T and ddI). The addition of a third drug should be considered for exposures that pose an increased risk for transmission. Selection of the PEP regimen should consider the comparative risk represented by the exposure and information about the exposure source, including history of and response to antiretroviral therapy based on clinical response, CD4+ T-cell counts, viral load measurements, and current disease stage. When the source person's virus is known or suspected to be resistant to one or more of the drugs considered for the PEP regimen, the selection of drugs to which the source person's virus is unlikely to be resistant is recommended; expert consultation is advised. If this information is not immediately available, initiation of PEP, if indicated, should not be delayed; changes in the PEP regimen can be made after PEP has been started, as appropriate. Reevaluation of the exposed person should be considered within 72 hours postexposure, especially as additional information about the exposure or source person becomes available.

Follow-up of HCP Exposed to HIV

Postexposure Testing. HCP with occupational exposure to HIV should receive follow-up counseling, postexposure testing, and medical evaluation, regardless of whether they receive PEP. HIV-antibody testing should be performed for at least 6 months postexposure (e.g., at 6 weeks, 12 weeks, and 6 months). Extended HIV follow-up (e.g., for 12 months) is recommended for HCP who become infected with HCV following exposure to a source coinfected with HIV and HCV. Whether extended follow-up is indicated in other circumstances (e.g., exposure to a source coinfected with HIV and HCV in the absence of HCV seroconversion or for exposed persons with a medical history suggesting an impaired ability to develop an antibody response to acute infection) is unclear. Although rare instances of delayed HIV seroconversion have been reported (*167,168*), the infrequency of this occurrence does not warrant adding to the anxiety level of the exposed persons by routinely extending the duration of postexposure follow-up. However, this recommendation should not preclude a decision to extend follow-up in an individual situation based on the clinical judgement of the exposed person's health-care provider. HIV testing should be performed on any exposed person who has an illness that is compatible with an acute retroviral syndrome, regardless of the interval since exposure. When HIV infection is identified, the person should be referred to a specialist knowledgeable in the area of HIV treatment and counseling for medical management.

HIV-antibody testing with EIA should be used to monitor for seroconversion. The routine use of direct virus assays (e.g., HIV p24 antigen EIA or tests for HIV RNA) to detect infection in exposed HCP generally is not recommended (*169*). The high rate of false-positive results of these tests in this setting could lead to unnecessary anxiety and/or treatment (*170,171*). Despite the ability of direct virus assays to detect HIV infection a few days earlier than EIA, the infrequency of occupational seroconversion and increased costs of these tests do not warrant their routine use in this setting.

- HIV-antibody testing should be performed for at least 6 months postexposure.
- Direct virus assays for routine follow-up of HCP are not recommended.
- HIV testing should be performed on any exposed person who has an illness compatible with an acute retroviral syndrome.

Monitoring and Management of PEP Toxicity. If PEP is used, HCP should be monitored for drug toxicity by testing at baseline and again 2 weeks after starting PEP. The scope of testing should be based on medical conditions in the exposed person and the toxicity of drugs included in the PEP regimen. Minimally, lab monitoring for toxicity should include a complete blood count and renal and hepatic function tests. Monitoring for evidence of hyperglycemia should be included for HCP whose regimens include any PI; if the exposed person is receiving IDV, monitoring for crystalluria, hematuria, hemolytic anemia, and hepatitis also should be included. If toxicity is noted, modification of the regimen should be considered after expert consultation; further diagnostic studies may be indicated.

Exposed HCP who choose to take PEP should be advised of the importance of completing the prescribed regimen. Information should be provided to HCP about potential drug interactions and the drugs that should not be taken with PEP, the side effects of the drugs that have been prescribed, measures to minimize these effects, and the methods of clinical monitoring for toxicity during the follow-up period. HCP should be advised that the evaluation of certain symptoms should not be delayed (e.g., rash, fever, back or abdominal pain, pain on urination or blood in the urine, or symptoms of hyperglycemia [increased thirst and/or frequent urination]).

HCP who fail to complete the recommended regimen often do so because of the side effects they experience (e.g., nausea and diarrhea). These symptoms often can be managed with antimotility and antiemetic agents or other medications that target the specific symptoms without changing the regimen. In other situations, modifying the dose interval (i.e., administering a lower dose of drug more frequently throughout the day, as recommended by the manufacturer), might facilitate adherence to the regimen. Serious adverse events should be reported to FDA's MedWatch Program.

Counseling and Education. Although HIV infection following an occupational exposure occurs infrequently, the emotional effect of an exposure often is substantial (*172–174*). In addition, HCP are given seemingly conflicting information. Although HCP are told that a low risk exists for HIV transmission, a 4-week regimen of PEP might be recommended, and they are asked to commit to behavioral measures (e.g., sexual abstinence or condom use) to prevent secondary transmission, all of which influence their lives for several weeks to months (*172*). Therefore, access to persons who are knowledgeable about occupational HIV transmission and who can deal with the many concerns an HIV exposure might generate for the exposed person is an important element of postexposure management. HIV-exposed HCP should be advised to use the following measures to prevent secondary transmission during the follow-up period, especially the first 6–12 weeks after the exposure when most HIV-infected persons are expected to seroconvert: exercise sexual abstinence or use condoms to prevent sexual transmission and to avoid pregnancy; and refrain from donating blood, plasma, organs, tissue, or semen. If an exposed woman is breast feeding, she should be counseled about the risk of HIV transmission through breast milk, and discontinuation of breast feeding should be considered, especially for high-risk exposures. Additionally, NRTIs are known to pass into breast milk, as is NVP; whether this also is true for the other approved antiretroviral drugs is unknown.

The patient-care responsibilities of an exposed person do not need to be modified, based solely on an HIV exposure, to prevent transmission to patients. If HIV seroconversion is detected, the person should be evaluated according to published recommendations for infected HCP (*175*).

Exposed HCP should be advised to seek medical evaluation for any acute illness that occurs during the follow-up period. Such an illness, particularly if characterized by fever, rash, myalgia, fatigue, malaise, or lymphadenopathy, might be indicative of acute HIV infection but also might be indicative of a drug reaction or another medical condition.

For exposures for which PEP is considered appropriate, HCP should be informed that a) knowledge about the efficacy of drugs used for PEP is limited; b) experts recommend combination drug regimens because of increased potency and concerns about drug-resistant virus; c) data regarding toxicity of antiretroviral drugs in persons without HIV infection or in pregnant women are limited; d) although the short-term toxicity of antiretroviral drugs is usually limited, serious adverse events have occurred in persons taking PEP; and e) any or all drugs for PEP may be declined or stopped by the exposed person. HCP who experience HIV occupational exposures for which PEP is not recommended should be informed that the potential side effects and toxicity of taking PEP outweigh the negligible risk of transmission posed by the type of exposure.

Guidelines for counseling and educating HCP with HIV exposure include

- Exposed HCP should be advised to use precautions to prevent secondary transmission during the follow-up period.
- For exposures for which PEP is prescribed, HCP should be informed about possible drug toxicities and the need for monitoring, and possible drug interactions.

Occupational Exposure Management Resources

Several resources are available that provide guidance to HCP regarding the management of occupational exposures. These resources include PEPline; the Needlestick! website; the Hepatitis Hotline; CDC (receives reports of occupationally acquired HIV infections and failures of PEP); the HIV Antiretroviral Pregnancy Registry; FDA (receives reports of unusual or severe toxicity to antiretroviral agents); and the HIV/AIDS Treatment Information Service (Box 5).

BOX 4. Situations for which expert* consultation for HIV postexposure prophylaxis is advised

- Delayed (i.e., later than 24–36 hours) exposure report
  - — the interval after which there is no benefit from postexposure prophylaxis (PEP) is undefined
- Unknown source (e.g., needle in sharps disposal container or laundry)
  - — decide use of PEP on a case-by-case basis
  - — consider the severity of the exposure and the epidemiologic likelihood of HIV exposure
  - — do not test needles or other sharp instruments for HIV
- Known or suspected pregnancy in the exposed person
  - — does not preclude the use of optimal PEP regimens
  - — do not deny PEP solely on the basis of pregnancy
- Resistance of the source virus to antiretroviral agents
  - — influence of drug resistance on transmission risk is unknown
  - — selection of drugs to which the source person's virus is unlikely to be resistant is recommended, if the source person's virus is known or suspected to be resistant to ≥1 of the drugs considered for the PEP regimen
  - — resistance testing of the source person's virus at the time of the exposure is not recommended
- Toxicity of the initial PEP regimen
  - — adverse symptoms, such as nausea and diarrhea are common with PEP
  - — symptoms often can be managed without changing the PEP regimen by prescribing antimotility and/or antiemetic agents
  - — modification of dose intervals (i.e., administering a lower dose of drug more frequently throughout the day, as recommended by the manufacturer), in other situations, might help alleviate symptoms

*Local experts and/or the National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline [1-888-448-4911]).

BOX 5. Occupational exposure management resources

National Clinicians' Postexposure Prophylaxis Hotline (PEPline) Run by University of California–San Francisco/San Francisco General Hospital staff; supported by the Health Resources and Services Administration Ryan White CARE Act, HIV/AIDS Bureau, AIDS Education and Training Centers, and CDC.	Phone: (888) 448-4911 Internet: <http://www.ucsf.edu/hivcntr>
Needlestick! A website to help clinicians manage and document occupational blood and body fluid exposures. Developed and maintained by the University of California, Los Angeles (UCLA), Emergency Medicine Center, UCLA School of Medicine, and funded in party by CDC and the Agency for Healthcare Research and Quality.	Internet: <http://www.needlestick.mednet.ucla.edu>
Hepatitis Hotline.	Phone: (888) 443-7232 Internet: <http://www.cdc.gov/hepatitis>
Reporting to CDC: Occupationally acquired HIV infections and failures of PEP.	Phone: (800) 893-0485
HIV Antiretroviral Pregnancy Registry.	Phone:(800) 258-4263 Fax: (800) 800-1052 Address: 1410 Commonwealth Drive Suite 215 Wilmington, NC 28405 Internet: <http://www.glaxowellcome.com/preg_reg/antiretroviral>

BOX 5. (*Continued*) Occupational exposure management resources

Food and Drug Administration Report unusual or severe toxicity to antiretroviral agents.	Phone: (800) 332-1088 Address: MedWatch HF-2, FDA 5600 Fishers Lane Rockville, MD 20857 Internet: <http://www.fda.gov/medwatch>
HIV/AIDS Treatment Information Service.	Internet: <http://www.hivatis.org>

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APPENDIX A.

Practice Recommendations for Health-Care Facilities Implementing the U.S. Public Health Service Guidelines for Management of Occupational Exposures to Bloodborne Pathogens

Practice recommendation	Implementation checklist
Establish a bloodborne pathogen policy.	All institutions where health-care personnel (HCP) might experience exposures should have a written policy for management of exposures. The policy should be based on the U.S. Public Health Service (PHS) guidelines. The policy should be reviewed periodically to ensure that it is consistent with PHS recommendations.
Implement management policies.	Health-care facilities (HCF) should provide appropriate training to all personnel on the prevention of and response to occupational exposures. HCF should establish hepatitis B vaccination programs. HCF should establish exposure-reporting systems. HCF should have personnel who can manage an exposure readily available at all hours of the day. HCF should have ready access to postexposure prophylaxis (PEP) for use by exposed personnel as necessary.
Establish laboratory capacity for bloodborne pathogen testing.	HCF should provide prompt processing of exposed person and source person specimens to guide management of occupational exposures. Testing should be performed with appropriate counseling and consent.

Practice recommendation	Implementation checklist
Select and use appropriate PEP regimens.	HCF should develop a policy for the selection and use of PEP antiretroviral regimens for HIV exposures within their institution. Hepatitis B vaccine and HBIG should be available for timely administration. HCF should have access to resources with expertise in the selection and use of PEP.
Provide access to counseling for exposed HCP.	HCF should provide counseling for HCP who might need help dealing with the emotional effect of an exposure. HCF should provide medication adherence counseling to assist HCP in completing HIV PEP as necessary.
Monitor for adverse effects of PEP.	HCP taking antiretroviral PEP should be monitored periodically for adverse effects of PEP through baseline and testing (every 2 weeks) and clinical evaluation.
Monitor for seroconversion.	HCF should develop a system to encourage exposed HCP to return for follow-up testing. Exposed HCP should be tested for HCV and HIV.
Monitor exposure management programs.	HCF should develop a system to monitor reporting and management of occupational exposures to ensure timely and appropriate response. **Evaluate** • exposure reports for completeness and accuracy, • access to care (i.e., the time of exposure to the time of evaluation), and • laboratory result reporting time. **Review** • exposures to ensure that HCP exposed to sources not infected with bloodborne pathogens do not receive PEP or that PEP is stopped. **Monitor** • completion rates of HBV vaccination and HIV PEP and • completion of exposure follow-up.

APPENDIX B.

Management of Occupational Blood Exposures

Provide immediate care to the exposure site.

- Wash wounds and skin with soap and water.
- Flush mucous membranes with water.

Determine risk associated with exposure by

- type of fluid (e.g., blood, visibly bloody fluid, other potentially infectious fluid or tissue, and concentrated virus) and
- type of exposure (i.e., percutaneous injury, mucous membrane or nonintact skin exposure, and bites resulting in blood exposure).

Evaluate exposure source.

- Assess the risk of infection using available information.
- Test known sources for HBsAg, anti-HCV, and HIV antibody (consider using rapid testing).
- For unknown sources, assess risk of exposure to HBV, HCV, or HIV infection.
- Do not test discarded needles or syringes for virus contamination.

Evaluate the exposed person.

- Assess immune status for HBV infection (i.e., by history of hepatitis B vaccination and vaccine response).

Give PEP for exposures posing risk of infection transmission.

- HBV: See Table 3.
- HCV: PEP not recommended.
- HIV: See Tables 4 and 5.
  - — Initiate PEP as soon as possible, preferably within hours of exposure.
  - — Offer pregnancy testing to all women of childbearing age not known to be pregnant.
  - — Seek expert consultation if viral resistance is suspected.
  - — Administer PEP for 4 weeks if tolerated.

Perform follow-up testing and provide counseling.

- Advise exposed persons to seek medical evaluation for any acute illness occurring during follow-up.

HBV exposures

- Perform follow-up anti-HBs testing in persons who receive hepatitis B vaccine.
  - — Test for anti-HBs 1–2 months after last dose of vaccine.
  - — Anti-HBs response to vaccine cannot be ascertained if HBIG was received in the previous 3–4 months.

HCV exposures

- Perform baseline and follow-up testing for anti-HCV and alanine amino-transferase (ALT) 4–6 months after exposures.
- Perform HCV RNA at 4–6 weeks if earlier diagnosis of HCV infection desired.
- Confirm repeatedly reactive anti-HCV enzyme immunoassays (EIAs) with supplemental tests.

HIV exposures

- Perform HIV-antibody testing for at least 6 months postexposure (e.g., at baseline, 6 weeks, 3 months, and 6 months).
- Perform HIV antibody testing if illness compatible with an acute retroviral syndrome occurs.
- Advise exposed persons to use precautions to prevent secondary transmission during the follow-up period.
- Evaluate exposed persons taking PEP within 72 hours after exposure and monitor for drug toxicity for at least 2 weeks.

APPENDIX C.

Basic and Expanded HIV Postexposure Prophylaxis Regimens

BASIC REGIMEN

- **Zidovudine (RETROVIR™; ZDV; AZT) + Lamivudine (EPIVIR™; 3TC); available as COMBIVIR™**
  - — ZDV: 600 mg per day, in two or three divided doses, and
  - — 3TC: 150 mg twice daily.

Advantages

- — ZDV is associated with decreased risk of HIV transmission in the CDC case-control study of occupational HIV infection.
- — ZDV has been used more than the other drugs for PEP in HCP.
- — Serious toxicity is rare when used for PEP.
- — Side effects are predictable and manageable with antimotility and antiemetic agents.
- — Probably a safe regimen for pregnant HCP.
- — Can be given as a single tablet (COMBIVIR™) twice daily.

Disadvantages

- — Side effects are common and might result in low adherence.
- — Source patient virus might have resistance to this regimen.
- — Potential for delayed toxicity (oncogenic/teratogenic) is unknown.

ALTERNATE BASIC REGIMENS

- **Lamivudine (3TC) + Stavudine (ZERIT™; d4T)**
  - — 3TC: 150 mg twice daily, and
  - — d4T: 40 mg (if body weight is <60 kg, 30 mg twice daily) twice daily.

Advantages

- — well tolerated in patients with HIV infection, resulting in good adherence,
- — serious toxicity appears to be rare, and
- — twice daily dosing might improve adherence.

Disadvantages

— Source patient virus might be resistant to this regimen.

— Potential for delayed toxicity (oncogenic/teratogenic) is unknown.

- **Didanosine (VIDEX™, chewable/dispersable buffered tablet; VIDEX™ EC, delayed-release capsule; ddI) + Stavudine (d4T)**

— ddI: 400 mg (if body weight is <60 kg, 125 mg twice daily) daily, on an empty stomach.

— d4T: 40 mg (if body weight is <60 kg, 30 mg twice daily) twice daily.

Advantages

— Likely to be effective against HIV strains from source patients who are taking ZDV and 3TC.

Disadvantages

— ddI is difficult to administer and unpalatable.

— Chewable/dispersable buffered tablet formulation of ddI interferes with absorption of some drugs (e.g., quinolone antibiotics, and indinavir).

— Serious toxicity (e.g., neuropathy, pancreatitis, or hepatitis) can occur. Fatal and nonfatal pancreatitis has occurred in HIV-positive, treatment-naive patients. Patients taking ddI and d4T should be carefully assessed and closely monitored for pancreatitis, lactic acidosis, and hepatitis.

— Side effects are common; anticipate diarrhea and low adherence.

— Potential for delayed toxicity (oncogenic/teratogenic) is unknown.

EXPANDED REGIMEN

Basic regimen plus one of the following:

- **Indinavir (CRIXIVAN™; IDV)**

— 800 mg every 8 hours, on an empty stomach.

Advantages

— Potent HIV inhibitor.

Disadvantages

— Serious toxicity (e.g., nephrolithiasis) can occur; must take 8 glasses of fluid per day.

— Hyperbilirubinemia common; must avoid this drug during late pregnancy.

— Requires acid for absorption and cannot be taken simultaneously with ddI in chewable/dispersable buffered tablet formulation (doses must be separated by at least 1 hour).

— Concomitant use of astemizole, terfenadine, dihydroergotamine, ergotamine, ergonovine, methylergonovine, rifampin, cisapride, St. John's Wort, lovastatin, simvastatin, pimozide, midazolam, or triazolam is not recommended.

— Potential for delayed toxicity (oncogenic/teratogenic) is unknown.

- **Nelfinavir (VIRACEPT™; NFV)**

— 750 mg three times daily, with meals or snack, or

— 1250 mg twice daily, with meals or snack.

Advantages

— potent HIV inhibitor, and

— twice dosing per day might improve adherence.

Disadvantages

— Concomitant use of astemizole, terfenadine, dihydroergotamine, ergotamine, ergonovine, methylergonovine, rifampin, cisapride, St. John's Wort, lovastatin, simvastatin, pimozide, midazolam, or triazolam is not recommended.

— Might accelerate the clearance of certain drugs, including oral contraceptives (requiring alternative or additional contraceptive measures for women taking these drugs).

— Potential for delayed toxicity (oncogenic/teratogenic) is unknown.

- **Efavirenz (SUSTIVA™; EFV)**

— 600 mg daily, at bedtime.

Advantages

— Does not require phosphorylation before activation and might be active earlier than other antiretroviral agents (note: this might be only a theoretical advantage of no clinical benefit.)

— One dose daily might improve adherence.

Disadvantages

— Drug is associated with rash (early onset) that can be severe and might rarely progress to Stevens-Johnson syndrome.

- — Differentiating between early drug-associated rash and acute seroconversion can be difficult and cause extraordinary concern for the exposed person.
- — Nervous system side effects (e.g., dizziness, somnolence, insomnia, and/or abnormal dreaming) are common. Severe psychiatric symptoms are possible (dosing before bedtime might minimize these side effects).
- — Should not be used during pregnancy because of concerns about teratogenicity.
- — Concomitant use of astemizole, cisapride, midazolam, triazolam, ergot derivatives, or St. John's Wort is not recommended because inhibition of the metabolism of these drugs could create the potential for serious and/or life-threatening adverse events (e.g., cardiac arrhythmias, prolonged sedation, or respiratory depression).
- — Potential for oncogenic toxicity is unknown.

- **Abacavir (ZIAGEN™; ABC); available as TRIZIVIR™, a combination of ZDV, 3TC, and ABC**
  - — 300 mg twice daily.

Advantages

- — potent HIV inhibitor, and
- — well tolerated in patients with HIV infection.

Disadvantages

- — Severe hypersensitivity reactions can occur, usually within the first 6 weeks of treatment.
- — Potential for delayed toxicity (oncogenic/teratogenic) is unknown.

ANTIRETROVIRAL AGENTS FOR USE AS PEP ONLY WITH EXPERT CONSULTATION

- **Ritonavir (NORVIR™; RTV)**

Disadvantages

- — difficult to take (requires dose escalation),
- — poor tolerability, and
- — many drug interactions.

- **Saquinavir (FORTOVASE™, soft-gel formulation; SQV)**

Disadvantages

- — Bioavailability is relatively poor, even with new formulation.

- **Amprenavir (AGENERASE™; AMP)**

Disadvantages

— Dosage consists of eight large pills taken twice daily.

— Many drug interactions.

- **Delavirdine (RESCRIPTOR™; DLV)**

Disadvantages

— Drug is associated with rash (early onset) that can be severe and progress to Stevens-Johnson syndrome.

— Many drug interactions.

- **Lopinavir/Ritonavir (KALETRA™)**

— 400/100 mg twice daily.

Advantages

— potent HIV inhibitor, and

— well tolerated in patients with HIV infection.

Disadvantages

— Concomitant use of flecainide, propafenone, astemizole, terfenadine, dihydroergotamine, ergotamine, ergonovine, methylergonovine, rifampin, cisapride, St. John's Wort, lovastatin, simvastatin, pimozide, midazolam, or triazolam is not recommended because inhibition of the metabolism of these drugs could create the potential for serious and/or life-threatening adverse events (e.g., cardiac arrhythmias, prolonged sedation, or respiratory depression).

— May accelerate the clearance of certain drugs, including oral contraceptives (requiring alternative or additional contraceptive measures for women taking these drugs).

— Potential for delayed toxicity (oncogenic/teratogenic) is unknown.

ANTIRETROVIRAL AGENTS GENERALLY NOT RECOMMENDED FOR USE AS PEP

- **Nevirapine (VIRAMUNE™; NVP)**

— 200 mg daily for 2 weeks, then 200 mg twice daily.

Disadvantages

— Associated with severe hepatotoxicity (including at least one case of liver failure requiring liver transplantation in an exposed person taking PEP),

— Associated with rash (early onset) that can be severe and progress to Stevens-Johnson syndrome,

— Differentiating between early drug-associated rash and acute seroconversion can be difficult and cause extraordinary concern for the exposed person, and

— Concomitant use of St. John's Wort is not recommended because this might result in suboptimal antiretroviral drug concentrations.

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