Federal Needlestick Safety and Prevention Law

A Resource Primer

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Now... Effective compliance date April 18, 2001

January 2001
Provided by BD Advanced Protection Technologies
The Needlestick Safety and Prevention Act:
Revises the Bloodborne Pathogens Standard, in effect under the OSHA Occupational Safety and Health Act of 1970, to include safer medical devices, such as sharps with engineered sharps injury protections and needleless systems, as examples of engineering controls designed to eliminate or minimize occupational exposure to bloodborne pathogens through needlestick and other percutaneous injuries.

Requires certain employers to: (1) review and update exposure control plans to reflect changes in technology that eliminate or reduce such exposure, and document their consideration and implementation of appropriate commercially available and effective safer medical devices for such purpose, (2) maintain a sharps injury log, noting the type and brand of device used, where the injury occurred and an explanation of the incident (exempting employers who are not required to maintain specified OSHA logs) and (3) seek input on such engineering and work practice controls from the affected healthcare workers (exempting employers who are not required to establish exposure control plans).

Requires such modifications of the standard to: (1) be in force until superseded by regulations promulgated by the Secretary of Labor under OSHA and (2) take effect without regard to specified procedural requirements.
Needlestick Safety and Prevention Law
To require changes in the bloodborne pathogens standard in effect under the Occupational Safety and Health Act of 1970

IN THE HOUSE OF REPRESENTATIVE
AND THE SENATE OF THE UNITED STATES

HR5178        SB3067

Mr. JEFFORDS (for himself, Mr. ENZI, Mr. KENNEDY, and Mr. REID) introduced the following bill; which was read twice and referred back to Mr. BALLenger and Mr. OWENS, of the Committee on Health, Education, Labor, and Pensions

A BILL

To require changes in the bloodborne pathogens standard in effect under the Occupational Safety and Health Act of 1970

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.
This Act may be cited as the ‘Needlestick Safety and Prevention Act’.

SEC. 2. FINDINGS.
Congress makes the following findings:

(1) Numerous workers who are occupationally exposed to bloodborne pathogens have contracted fatal and other serious viruses and diseases, including the human immunodeficiency virus (HIV), hepatitis B, and hepatitis C from exposure to blood and other potentially infectious materials in their workplace.

(2) In 1991 the Occupational Safety and Health Administration issued a standard regulating occupational exposure to bloodborne pathogens, including the human immunodeficiency virus, (HIV), the hepatitis B virus (HBV), and the hepatitis C virus (HCV).

(3) Compliance with the bloodborne pathogens standard has significantly reduced the risk that workers will contract a bloodborne disease in the course of their work.

(4) Nevertheless, occupational exposure to bloodborne pathogens from accidental sharps injuries in health care settings continues to be a serious problem. In March
2000, the Centers for Disease Control and Prevention estimated that more than 380,000 percutaneous injuries from contaminated sharps occur annually among health care workers in United States hospital settings. Estimates for all health care settings are that 600,000 to 800,000 needlestick and other percutaneous injuries occur among health care workers annually. Such injuries can involve needles or other sharps contaminated with bloodborne pathogens, such as HIV, HBV, or HCV.

(5) Since publication of the bloodborne pathogens standard in 1991 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 concerning the effectiveness of newer engineering controls, including safer medical devices.

(6) 396 interested parties responded to a Request for Information (in this section referred to as the ‘RFI’) conducted by the Occupational Health and Safety Administration in 1998 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. Comments were provided by health care facilities, groups representing health care workers, researchers, educational institutions, professional and industry associations, and manufacturers of medical devices.

(7) Numerous studies have demonstrated that the use of safer medical devices, such as needleless systems and sharps with engineered sharps injury protections, when they are part of an overall bloodborne pathogens risk-reduction program, can be extremely effective in reducing accidental sharps injuries.

(8) In March 2000, the Centers for Disease Control and Prevention estimated that, depending on the type of device used and the procedure involved, 62 to 88 percent of sharps injuries can potentially be prevented by the use of safer medical devices.

(9) The OSHA 200 Log, as it is currently maintained, does not sufficiently reflect injuries that may involve exposure to bloodborne pathogens in health care facilities. More than 98 percent of health care facilities responding to the RFI have adopted surveillance systems in addition to the OSHA 200 Log. Information gathered through these surveillance systems is commonly used for hazard identification and evaluation of program and device effectiveness.

(10) Training and education in the use of safer medical devices and safer work practices are significant elements in the prevention of percutaneous exposure incidents. Staff involvement in the device selection and evaluation process is also an important element to achieving a reduction in sharps injuries, particularly as new safer devices are introduced into the work setting.

(11) Modification of the bloodborne pathogens standard is appropriate to set forth in greater detail its requirement that employers identify, evaluate, and make use of effective safer medical devices.
SEC. 3. BLOODBORNE PATHOGENS STANDARD.

The bloodborne pathogens standard published at 29 CFR 1910.1030 shall be revised as follows:

(1) The definition of ‘Engineering Controls’ (at 29 CFR 1930.1030(b)) shall include as additional examples of controls the following: ‘safer medical devices, such as sharps with engineered sharps injury protections and needleless systems’.

(2) The term ‘Sharps with Engineered Sharps Injury Protections’ shall be added to the definitions (at 29 CFR 1910.1030(b)) and 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’.

(3) The term ‘Needleless Systems’ shall be added to the definitions (at 29 CFR 1910.1030(b)) and defined as ‘a device that does not use needles for (A) the collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established, (B) the administration of medication or fluids, or (C) any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps’.

(4) In addition to the existing requirements concerning exposure control plans (29 CFR 1910.1030(c)(1)(iv)), the review and update of such plans shall be required to also--

(A) ‘reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens’; and

(B) ‘document consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure’.

(5) The following additional recordkeeping requirement shall be added to the bloodborne pathogens standard at 29 CFR 1910.1030(h): ‘The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum--

(A) ‘the type and brand of device involved in the incident’,

(B) ‘the department or work area where the exposure incident occurred’; and

(C) ‘an explanation of how the incident occurred’.

The requirement for such sharps injury log shall not apply to any employer who is not required to maintain a log of occupational injuries and illnesses under 29 CFR 1904 and the sharps injury log shall be maintained for the period required by 29 CFR 1904.6.

(6) The following new section shall be added to the bloodborne pathogens standard: ‘An employer, who is required to establish an Exposure Control Plan shall solicit
input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan.'

SEC. 4. EFFECT OF MODIFICATIONS.

The modifications under section 3 shall be in force until superseded in whole or in part by regulations promulgated by the Secretary of Labor under section 6(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655(b)) and shall be enforced in the same manner and to the same extent as any rule or regulation promulgated under section 6(b).

SEC. 5. PROCEDURE AND EFFECTIVE DATE.

(a) PROCEDURE- The modifications of the bloodborne pathogens standard prescribed by section 3 shall take effect without regard to the procedural requirements applicable to regulations promulgated under section 6(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655(b)) or the procedural requirements of chapter 5 of title 5, United States Code.

(b) EFFECTIVE DATE- The modifications to the bloodborne pathogens standard required by section 3 shall--

(1) within 6 months of the date of enactment of this Act, be made and published in the Federal Register by the Secretary of Labor acting through the Occupational Safety and Health Administration; and

(2) take effect on the date that is 90 days after the date of such publication.
Section 2

Letter of Intent
NEEDLESTICK SAFETY AND PREVENTION ACT
(Senate - October 26, 2000)

Mr. JEFFORDS

This bipartisan success resulted from a shared concern about this health hazard, and a shared belief of how to resolve it, among myself, and Senators Enzi, Kennedy and Reid. I must also thank our dedicated staffs, and also Representatives Cass Ballenger, and Major Owens, and their staffs. Senators Enzi, Kennedy, Reid, and I have also worked together on a Joint Statement of Legislative Intent. I ask unanimous consent that it be printed in the Congressional Record. I also ask unanimous consent that a letter from Charles N. Jeffress, Assistant Secretary for Occupational Safety and Health, to Senator Jim Bunning, and a letter from Representatives Ballenger and Owens, addressed to me, be made a part of the Record.

I thank all my colleagues who have joined in helping to adopt this important legislation. It is a vital step in ensuring worker safety in health care settings.

There being no objection, the material was ordered to be printed in the Record, as follows:

Joint Statement of Legislative Intent on HR 5178

The legislation derives from the convergence of two critical circumstances which have a profound effect on the safety of health care workers in the United States. The first circumstance is the increased concern over accidental needlestick injuries in health care settings. ‘Needlesticks’ is a term used broadly, as health care workers can suffer injuries from a broad array of ‘sharps’ used in health care settings, from needles to IV catheters to lancets. The second circumstance is the technological advancements made over the past decade in the many types of engineering controls that can be used in the workplace to help protect health care workers against sharps injuries. Because of the convergence of these two circumstances – and because of increasing concern over the public health issue related to the spread of hepatitis C, it is appropriate to take this action at this time.

Section 1 of the bill provides the title the Needlestick Safety and Prevention Act.

Section 2 of the bill provides the Congressional findings.

Section 3 of the bill directly modifies the Bloodborne Pathogens Standard, 29 C.F.R. 1910.1030, one of the health and safety standards promulgated by the Department of Labor’s Occupational Safety and Health Administration (OSHA). The legislation builds on the most recent action taken by OSHA related to the Bloodborne Pathogens Standard – the revision in November 1999 to OSHA's Compliance Directive on Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens (‘Compliance Directive’).

In modifying the Bloodborne Pathogens Standard (‘BBP standard’) this bill makes narrowly-tailored changes to the BBP standard. It makes clear in the BBP standard the direction already provided by OSHA in its Compliance Directive: namely, that employers who have employees with occupational exposure to bloodborne pathogens must consider and, where appropriate, use effective engineering controls, including safer medical devices, in order to reduce the risk of injury from needlesticks and from other sharp medical instruments (‘sharps’). This bill is not intended to change the existing application of OSHA's BBP standard to all employees who are reasonably anticipated to have occupational exposures to blood or other potentially infectious materials, including health care workers, laboratory personnel, housekeepers and waste disposal employees, among others.

The bill accomplishes this in several ways. First, the BBP standard is modified so that the definition of ‘engineering controls’ at 29 C.F.R. 1910.1030(b) includes as additional examples of such controls, safer medical devices, such as sharps with engineered sharps injury protections and ‘needleless systems.’ Following that step, the BBP standard is amended so that both ‘sharps with engineered sharps injury protections’ (‘SESIPS’) and ‘needleless systems’ are added to the definitions of the standard.
The citing of these examples should not be considered an endorsement or preference of a specific product or assurance of a specific product’s effectiveness. Rather, it is the intent of this legislation to reflect innovation and evolving technology in the marketplace, in particular development in safer medical devices such as SESB’S and needleless systems. This legislation anticipates that hospitals and other employers, in crafting their Exposure Control Plans, will adopt procedures and use devices that have been proven to reduce the risk of needlestick injuries. Employers use their Exposure Control Plans to evaluate appropriate practices and devices for reducing occupational exposure. To focus attention on the need for employers to look at changes in technology, this legislation further modifies the BBP standard by adding to the existing requirements concerning Exposure Control Plans at 29 C.F.R. 1910.1030(c)(1)(iv). Through these modifications, employers will be required to demonstrate in the review and update of their Exposure Control Plans that their Exposure Control Plans reflect changes in technology and also that they document annually the consideration and implementation of appropriate, commercially available and effective safer medical devices.

It is through an employer’s Exposure Control Plan that engineering controls, including safer medical devices, are considered and deployed in the workplace. It is not the intent of this legislation to disturb OSHA’s existing determination that to the extent that specific types of devices, such as catheter securement devices or sharps destruction devices can reduce the risk of needlestick injuries, such devices could be appropriate components of an employer’s comprehensive Exposure Control Plan. OSHA expressed its understanding of and agreement with this intent in a letter to Senator Jim Bunning, dated October 13, 2000. The letter is submitted as an attachment to this joint statement.

It is also not the intent of this legislation to disturb the underlying flexible, performance-oriented nature of the Bloodborne Pathogens Standard. For example, this legislation’s reference to the consideration and implementation of safer medical devices is hinged upon the ‘appropriateness’ and the ‘commercial availability’ of such devices. Finally, while this may be stating the obvious, it is not the intent of this legislation, nor for that matter of the current Bloodborne Pathogens Standard, for employers to implement use of any engineering control, including a safer medical device, in any situation where it may jeopardize a patient’s safety, an employee’s safety or where it may be medically contraindicated. Moreover, all of the affirmative defenses available to an employer under the current BBP standard remain intact with this legislation. It is not the intent of this legislation to alter OSHA’s current enforcement of the BBP standard in these circumstances. Attached to this Joint Statement is a letter from Representatives Ballenger and Owens, the co-sponsors of H.R. 5178, expressing their full support for the views expressed in this statement.

The drafters are aware that some of the newer most effective technologies are more expensive than others and may create higher costs for health care facilities. Because some entities largely dependent on Medicare and/or Medicaid, such as long term care providers, will be required to comply with this legislation, we encourage the Health Care Financing Administration to examine the costs of the new technologies and consider these costs when determining Medicare reimbursement rates. Similarly, we hope that the states will examine these costs and determine whether the costs should be reflected in the Medicaid reimbursement rates.

Section 3 of the bill amends the BBP standard in two additional ways. First, it adds a requirement that in addition to the recordkeeping requirements already found in the BBP standard, employers must record percutaneous injuries from contaminated sharps in a sharps injury log. The legislation sets out the minimum information to be included in such a log, namely the type of device used, an explanation of the incident, and where the injury occurred. Employers are free to include other information should they find it helpful. However, this legislation does require that in recording the information and maintaining the log, the confidentiality of the injured employee is to be protected.
The requirement for a sharps injury log is consistent with current OSHA recordkeeping in two specific ways. First, the sharps injury log requirement does not apply to any employer who is not already required to maintain a log of occupational injuries and illnesses under 29 C.F.R. 1904. Second, employers are not required to maintain the sharps injury logs for a period of time beyond that currently required for the OSHA 200 logs.

The sharps injury log is to be used as a tool for employers so that they may determine their high risk areas for sharps injuries and use it as a means to evaluate particular devices that may or may not be effective in reducing sharps injuries. At a House Subcommittee on Workforce Protections hearing in June, representatives of the American Hospital Association testified that many health care settings, particularly hospitals, already have in place some type of ‘surveillance system’ for tracking needlestick and other sharps injuries. The AHA witness noted that hospitals have found this to be an effective tool to provide necessary information to help reduce such injuries.

The second way in which Section 3 amends the BBP standard is by specifying that employers must solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation and selection of effective engineering and work practice controls. Employers are also to document this in the Exposure Control Plans. The intent of this section is simple – to involve in the selection of engineering controls those workers who are potentially exposed to needlestick injuries.

Section 4 of the legislation explains that the modifications as delineated by Section 3 of the bill can be changed by a future rulemaking by OSHA on the Bloodborne Pathogens Standard.

Finally, Section 5 of the bill directs that the modifications to the BBP standard are to be made without regard to the standard OSHA rulemaking requirements or the requirements of the Administrative Procedures Act. Admittedly, preemption of the OSHA rulemaking procedures is not an action to be undertaken lightly. Indeed, the requirements of this bill are driven by the unique circumstances surrounding this narrow and particular public health issue. Although there is no such thing as binding precedent for Congress, it is not the intent of this legislation, through the process used here, to diminish the carefully constructed requirements and procedures for OSHA rulemaking.

The legislation does prescribe, however, that the changes to the BBP standard are to be made by the Secretary of Labor and published in the Federal Register within six months of enactment and that the changes will take effect 90 days after such publication.


James M. Jeffords, Edward M. Kennedy, Michael B. Enzi, Harry Reid.

U.S. DEPARTMENT OF LABOR, ASSISTANT SECRETARY FOR OCCUPATIONAL SAFETY AND HEALTH,

Hon. Jim Bunning, U.S. Senate, Washington, DC.

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**Dear Senator Bunning:** Thank you for your inquiry regarding OSHA's enforcement of the bloodborne pathogens standard and the effect of OSHA's November 1999 Compliance Directive on Enforcement Procedures on Occupational Exposure to Bloodborne Pathogens.

OSHA has long required employers to protect employees from exposure to bloodborne pathogens through the use of engineering controls, which include sharps disposal devices such as sharps destruction devices. To the extent that specific types of engineering controls such as sharps destruction devices can reduce the risk of needlestick injuries, such controls could be appropriate components of an employer's comprehensive exposure control plan. OSHA has allowed, and intends to continue to allow, employers to use sharps destruction devices to help reduce the risk of
needlestick injuries in appropriate circumstances, as set forth in OSHA's November 1999 Compliance Directive.

It is my understanding that S. 3067, like the House companion bill, is entirely compatible with and closely tracks the language of OSHA's November 1999 Compliance Directive and will not change in any way OSHA's treatment of needle destruction devices or OSHA's enforcement of the bloodborne pathogens standard's obligation that employers use engineering controls.

I hope that this letter is responsive to your inquiry. Thank you for your interest in occupational safety and health.

Sincerely,

Charles N. Jeffress,
Assistant Secretary.

COMMITTEE ON EDUCATION AND THE WORKFORCE,

Hon. Jim M. Jeffords,
U.S. Senate,
Washington, DC.

Dear Chairman Jeffords: Thank you for your sponsorship of The Needlestick Safety and Prevention Act and for your work on this important legislation. We appreciate your sharing with us the Senate Joint Statement of Legislative Intent and want to express our full support for the views expressed in the Senate statement. We want to reiterate that it is not the intent of this legislation to alter OSHA's current enforcement of the Bloodborne Pathogens Standard.

Sincerely,
CASS BALLenger,
Chairman, Subcommittee on Workforce Protections.

MAJOR R. OWENS,
Ranking Member, Subcommittee on Workforce Protections.

Mr. JEFFORDS. Mr. President, I ask unanimous consent that the bill be read the third time and passed, the motion to reconsider be laid upon the table, and that any statements relating to the bill be printed in the Record.

The PRESIDING OFFICER. Without objection, it is so ordered.

The bill (HR 5178) was read the third time and passed.
Section 3

Frequently Asked Questions & Answers
In short, what does the new legislation accomplish?
The new legislation serves to reinforce the BBP standard preventing legal challenges to the November 5, 1999 Federal OSHA Compliance Directive.

Is this directive enforceable? How?
Yes. It will be enforced through the traditional OSHA inspection procedures. Employers are subject to monetary fines for violating the BBP standard.

Citations can be issued for:
- Failure to have an Exposure Control Plan.
- Failure to review and implement commercially available “safer medical devices.”
- Failure to include procedures for documenting exposure incidents.
- Failure to review and update plan at least annually.
- Failure to follow universal precautions.
- Failure to comply with most current CDC recommendations for post-exposure evaluation and follow-up.

Exactly what medical procedures require the use of “safer medical devices”?*
Any time a healthcare worker may be exposed to blood or other potentially infectious material, the employer must evaluate and implement safer medical devices that eliminate exposures to the lowest feasible extent.

What are “engineering controls”?*
The term “engineering controls” is now defined and means controls that isolate or remove the BBP hazard from the workplace. They are described as “safer medical devices used to prevent percutaneous injuries before, during or after use through safer design features.” Examples include needleless devices, shielded needle devices, blunt needles, plastic capillary tubes.

Is a specific product technology or brand recommended in the revised regulation?
No. As OSHA states in the Compliance Directive, “OSHA does not advocate the use of one particular device over another.”
When does the new legislation take effect?

- Federal Bill HR 5178 was signed into law by President Clinton on November 6, 2000. Publication of the legislation in the Federal Register took place on January 18, 2001, resulting in an April 18, 2001 compliance date.

- Please be mindful that throughout this time and until the time the legislation takes effect, the Federal OSHA Compliance Directive of November 5, 1999 remains in effect and fines are enforceable.

So, when do I have to be in compliance?
April 18, 2001.

What do I have to do to be in compliance?

- Update or create a BBP Exposure Control Plan.
- Evaluate and implement “safer medical devices” where they are found to be effective in eliminating or minimizing occupational exposures. Frontline healthcare workers are to be part of the evaluation and selection process.
- Continuously monitor the effectiveness of engineering controls.
- Update employee training to include training on HCV and the use of “safer medical devices.”
- Review new Compliance Directive to determine other specific changes necessary for the needs of your facility.

Who has to comply?
Hospitals, alternate site facilities, clinical laboratories and other facilities where employees may be exposed to blood or other potentially infectious material are covered by the BBP standard. Special rules apply in home health services and to personnel service firms that supply contract workers to hospitals and other healthcare facilities.

Are there any “loopholes” or exceptions to the use of “safer medical devices”?
There is no list of exceptions. Employers must review and consider commercially available devices to determine whether they are effective in reducing occupational exposures to the lowest feasible extent.

For additional information, what are the website addresses of OSHA, CDC and NIOSH?

CDC and NIOSH:  www.cdc.gov/niosh
Federal OSHA:  www.osha.gov
Section 4

Bloodborne Pathogen Standard
Bill numbers HR 5178 and SB 3067 mandate that the 1991 OSHA Bloodborne Pathogens Standard (29 CFR 1930.1030) be revised to require the use of safety-engineered sharp devices. The bill states that “modification of the bloodborne pathogens standard is appropriate to set forth in greater detail its requirement that employers identify, evaluate, and make use of effective safer medical devices.” Its main provisions are:

(1) A revised and expanded definition of “engineering controls” in the bloodborne pathogens standard that includes “safer medical devices, such as sharps with engineered sharps injury protection and needleless systems.”

(2) A definition of safety devices (which must be added to the list of definitions in section (b) of the standard) as “a non-needle 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.”

(3) A definition of “needleless systems” (which must also be added to the list of definitions) as “a device that does not use needles for collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established.”

(4) A new requirement that exposure control plans include evaluation of safety devices. They must be updated as necessary to “reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens” and “document consideration and implementation of appropriate commercially available and effective safer medical devices.”

(5) A requirement that sharps injury logs be kept, in addition to the OSHA 200 log. The sharps injury log must include detailed information on the injury, including 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.”

(6) A requirement that employers involve frontline healthcare workers when evaluating and selecting safer devices.

The bill includes a provision that the usual hearings process for amending an existing OSHA standard be bypassed, and says that within six months of the bill’s enactment, the modifications to the standard required by the bill must be published in the Federal Register, and that the revised standard will be in effect nine months after the bill is enacted (ninety days after publication in the Federal Register).
§1910.1030 Bloodborne pathogens.

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

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

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

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

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

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

Contaminated means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

Contaminated Laundry means laundry that has been soiled with blood or other potentially infectious materials or that may contain sharps.

Contaminated Sharps means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

Decontamination means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

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

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

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

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

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

HBV means hepatitis B virus.

HIV means human immunodeficiency virus.
Occupational Exposure means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee’s duties.

Other Potentially Infectious Materials means

1. The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;

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

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

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

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

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

Regulated Waste means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

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

Source Individual means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.
Sterilize means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

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

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

(c) Exposure control—(1) Exposure Control Plan. (i) Each employer having an employee(s) with occupational exposure as defined by paragraph (b) of this section shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure.

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

(A) The exposure determination required by paragraph (c)(2),

(B) The schedule and method of implementation for paragraphs (d) Methods of Compliance, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, (g) Communication of Hazards to Employees, and (h) Recordkeeping, of this standard, and

(C) The procedure for the evaluation of circumstances surrounding exposure incidents as required by paragraph (f)(3)(i) of this standard.

(iii) Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.20(e).

(iv) The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure.

(v) The Exposure Control Plan shall be made available to the Assistant Secretary and the Director upon request for examination and copying.

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

(A) A list of all job classifications in which all employees in those job classifications have occupational exposure;

(B) A list of job classifications in which some employees have occupational exposure, and

(C) A list of all tasks and procedures or groups of closely related task and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in accordance with the provisions of paragraph (c)(2)(i)(B) of this standard.

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

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

(2) *Engineering and work practice controls.* (i) Engineering and work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after institution of these controls, personal protective equipment shall also be used.

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

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

(iv) When provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible.

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

(vi) Employers shall ensure that employees wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials.

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

(A) Contaminated needles and other contaminated sharps shall not be bent, recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure.

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

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

(A) Puncture resistant;

(B) Labeled or color-coded in accordance with this standard;

(C) Leakproof on the sides and bottom; and

(D) In accordance with the requirements set forth in paragraph (d)(4)(ii)(E) for reusable sharps.

(ix) Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure.

(x) Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials are present.
(xi) All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.

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

(xiii) Specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping.

(A) The container for storage, transport, or shipping shall be labeled or color-coded according to paragraph (g)(1)(i) and closed prior to being stored, transported, or shipped. When a facility utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary provided containers are recognizable as containing specimens. This exemption only applies while such specimens/containers remain within the facility. Labeling or color-coding in accordance with paragraph (g)(1)(i) is required when such specimens/containers leave the facility.

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

(C) If the specimen could puncture the primary container, the primary container shall be placed within a secondary container which is puncture-resistant in addition to the above characteristics.

(xiv) Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible.

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

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

(3) **Personal protective equipment**—(i) **Provision.** When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Personal protective equipment will be considered “appropriate” only if it does not permit blood or other potentially infectious materials to pass through to or reach the employee’s work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.

(ii) **Use.** The employer shall ensure that the employee uses appropriate personal protective
equipment unless the employer shows that the employee temporarily and briefly declined to use personal protective equipment when, under rare and extraordinary circumstances, it was the employee's professional judgment that in the specific instance its use would have prevented the delivery of health care or public safety services or would have posed an increased hazard to the safety of the worker or co-worker. When the employee makes this judgement, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future.

(iii) **Accessibility.** The employer shall ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the worksite or is issued to employees. Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.

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

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

(vi) If a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible.

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

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

(ix) **Gloves.** Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin; when performing vascular access procedures except as specified in paragraph (d)(3)(ix)(D); and when handling or touching contaminated items or surfaces.

(A) Disposable (single use) gloves such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.

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

(C) Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.

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

(1) Periodically reevaluate this policy;

(2) Make gloves available to all employees who wish to use them for phlebotomy;

(3) Not discourage the use of gloves for phlebotomy; and

(4) Require that gloves be used for phlebotomy in the following circumstances:

(i) When the employee has cuts, scratches, or other breaks in his or her skin;
(ii) When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and

(iii) When the employee is receiving training in phlebotomy.

(x) Masks, Eye Protection, and Face Shields. Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

(xi) Gowns, Aprons, and Other Protective Body Clothing. Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments shall be worn in occupational exposure situations. The type and characteristics will depend upon the task and degree of exposure anticipated.

(xii) Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (e.g., autopsies, orthopaedic surgery).

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

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

(A) Contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning.

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

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

(D) Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dust pan, tongs, or forceps.

(E) Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed.

(iii) Regulated Waste—(A) Contaminated Sharps Discarding and Containment. (1) Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:
(i) Closable;
(ii) Puncture resistant;
(iii) Leakproof on sides and bottom; and
(iv) Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard.

(2) During use, containers for contaminated sharps shall be:

(i) Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries);
(ii) Maintained upright throughout use; and
(iii) Replaced routinely and not be allowed to overfill.

(3) When moving containers of contaminated sharps from the area of use, the containers shall be:

(i) Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping;
(ii) Placed in a secondary container if leakage is possible. The second container shall be:
   (A) Closable;
   (B) Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and
   (C) Labeled or color-coded according to paragraph (g)(1)(i) of this standard.

(4) Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.

(B) Other Regulated Waste Containment—(1) Regulated waste shall be placed in containers which are:

(i) Closable;
(ii) Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;
(iii) Labeled or color-coded in accordance with Paragraph (g)(1)(i) this standard; and
(iv) Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

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

(i) Closable;
(ii) Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;
(iii) Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and
(iv) Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.
(C) Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.

(iv) Laundry. (A) Contaminated laundry shall be handled as little as possible with a minimum of agitation. (1) Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.

(2) Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.

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

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

(C) When a facility ships contaminated laundry off-site to a second facility which does not utilize Universal Precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded in accordance with Paragraph (g)(1)(i).

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

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

(i) Standard microbiological practices. All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

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

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

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

(D) When other potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard
symbol shall be posted on all access doors. The hazard warning sign shall comply with Paragraph (g)(1)(ii) of this standard.

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

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

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

(H) Before disposal all waste from work areas and from animal rooms shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

(I) Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency and which are checked routinely and maintained or replaced as necessary.

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

(K) All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.

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

(M) A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

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

(B) Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually.
(3) HIV and HBV research laboratories shall meet the following criteria:

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

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

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

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

(ii) The surfaces of doors, walls, floors and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.

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

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

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

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

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

(f) Hepatitis B vaccination and post-exposure evaluation and follow-up—(1) General.

(i) The employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident.

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

(A) Made available at no cost to the employee;

(B) Made available to the employee at a reasonable time and place;
(C) Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and

(D) Provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place, except as specified by this paragraph (f).

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

(2) Hepatitis B Vaccination. (1) Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii)(I) and within 10 working days of initial assignment to all employees who have occupational exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.

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

(iii) If the employee initially declines hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time.

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

(v) If a routine booster dose(s) of hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii).

(3) Post-exposure Evaluation and Follow-up. Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements:

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

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

(A) The source individual’s blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual’s consent is not required by law, the source individual’s blood, if available, shall be tested and the results documented.

(B) When the source individual is already known to be infected with HBV or HIV, testing for the source individual’s known HBV or HIV status need not be repeated.

(C) Results of the source individual’s testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.
(iii) Collection and testing of blood for HBV and HIV serological status;

(A) The exposed employee’s blood shall be collected as soon as feasible and tested after consent is obtained.

(B) If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

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

(v) Counseling; and

(vi) Evaluation of reported illnesses.

(4) Information Provided to the Healthcare Professional. (i) The employer shall ensure that the healthcare professional responsible for the employee’s Hepatitis B vaccination is provided a copy of this regulation.

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

(A) A copy of this regulation;

(B) A description of the exposed employee’s duties as they relate to the exposure incident;

(C) Documentation of the route(s) of exposure and circumstances under which exposure occurred;

(D) Results of the source individual’s blood testing, if available; and

(E) All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer’s responsibility to maintain.
(5) **Healthcare Professional's Written Opinion.** The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional’s written opinion within 15 days of the completion of the evaluation.

(i) The healthcare professional’s written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.

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

(A) That the employee has been informed of the results of the evaluation; and

(B) That the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.

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

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

(g) **Communication of hazards to employees—(1) Labels and signs—(i) Labels.** (A) Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F) and (G).

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

![BIOHAZARD](image)

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

(D) Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

(B) Red bags or red containers may be substituted for labels.

(F) Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements of paragraph (g).
(G) Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.

(H) Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated.

(i) Regulated waste that has been decontaminated need not be labeled or color-coded.

(ii) Signs. (A) The employer shall post signs at the entrance to work areas specified in paragraph (e), HIV and HBV Research Laboratory and Production Facilities, which shall bear the following legend:

![BIOHAZARD](image)

(Name of the Infectious Agent)
(Special requirements for entering the area)
(Name, telephone number of the laboratory director or other responsible person.)

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

(2) Information and Training. (i) Employers shall ensure that all employees with occupational exposure participate in a training program which must be provided at no cost to the employee and during working hours.

(ii) Training shall be provided as follows:

(A) At the time of initial assignment to tasks where occupational exposure may take place;
(B) Within 90 days after the effective date of the standard; and
(C) At least annually thereafter.

(iii) For employees who have received training on bloodborne pathogens in the year preceding the effective date of the standard, only training with respect to the provisions of the standard which were not included need be provided.

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

(v) Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee’s occupational exposure. The additional training may be limited to addressing the new exposures created.
(vi) Material appropriate in content and vocabulary to educational level, literacy, and language of employees shall be used.

(vii) The training program shall contain at least the following elements:

(A) An accessible copy of the regulatory text of this standard and an explanation of its contents;

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

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

(D) An explanation of the employer’s exposure control plan and the means by which the employee can obtain a copy of the written plan;

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

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

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

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

(I) Information on the hepatitis B vaccine, including Information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;

(J) Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;

(K) An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available;

(L) Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;

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

(N) An opportunity for interactive questions and answers with the person conducting the training session.

(viii) The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.

(ix) Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements.
(A) The employer shall assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.

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

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

(h) *Recordkeeping*—(i) *Medical Records.* (i) The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.20.

(ii) This record shall include:

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

(B) A copy of the employee’s hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee’s ability to receive vaccination as required by paragraph (f)(2);

(C) A copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3);

(D) The employer’s copy of the healthcare professional’s written opinion as required by paragraph (f)(5); and

(E) A copy of the information provided to the healthcare professional as required by paragraphs (f)(4)(ii)(B)(C) and (D).

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

(A) Kept confidential; and

(B) Not disclosed or reported without the employee’s express written consent to any person within or outside the workplace except as required by this section or as may be required by law.

(iv) The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.20.

(2) *Training Records.* (1) Training records shall include the following information:

(A) The dates of the training sessions;

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

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

(D) The names and job titles of all persons attending the training sessions.
(ii) Training records shall be maintained for 3 years from the date on which the training occurred.

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

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

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

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

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

(i) Dates—(1) Effective Date. The standard shall become effective on March 6, 1992

(2) The Exposure Control Plan required by paragraph (c) of this section shall be completed on or before May 5, 1992.

(3) Paragraph (g)(2) Information and Training and (h) Recordkeeping shall take effect on or before June 4, 1992.


APPENDIX A TO SECTION 1910.1030-HEPATITIS B VACCINE DECLINATION (MANDATORY)

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

Existing Fed OSHA Compliance Directive
Summary of OSHA Instructions to Compliance Officers
issued November 5, 1999

Overview: Effective November 5, 1999, employers are required to update their Bloodborne Pathogen Exposure Control Plan to document consideration and implementation of appropriate engineering controls to reduce or minimize exposure which includes the implementation of “safer medical devices.” Employers are also required to use engineering and work practice controls that eliminate occupational exposure or reduce it to the lowest feasible extent through a comprehensive program including engineering controls (i.e. the use of “safer medical devices”) and proper work practices. Employers must provide training to all employees in the use of these safer medical devices.
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.


Cancellations: This instruction cancels OSHA Instruction CPL 2-2.44C

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

Action Offices: National, Regional and Area Offices.

Originating Office: Directorate of Compliance Programs.

Contact: Office of Health Compliance Assistance (202) 693-2190
200 Constitution Avenue, Room N3603
Washington, DC 20210

By and Under the Authority of
Charles Jeffress
Assistant Secretary
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XIV. Interface With Other Standards .................................. 65
I. **Purpose.** This instruction establishes policies and provides clarifications to ensure uniform inspection procedures are followed when conducting inspections to enforce the Occupational Exposure to Bloodborne Pathogens Standard.

II. **Scope.** This instruction applies OSHA-wide.


IV. **References**


   B. OSHA Instruction CPL 2.111, Citation Policy for Paperwork and Written Program Violations., November 27, 1995.


   G. OSHA Instruction, PER 8-2.4, CSHO Pre-Employment Medical Examinations, March 31, 1989.


J. Record Summary of the Request for Information (RFI) on Occupational Exposure to Bloodborne Pathogens due to Percutaneous Injury. May 20, 1999.


M. International Health Care Worker Safety Center, #407, Health Sciences Center, University of Virginia, Charlottesville, VA 22908, EPINet, Exposure Prevention Information Network, E-mail: epinet@virginia.edu


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. NOTE: 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.

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 has 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.

VIII. Inspection Scheduling and Scope.

A. Inspection scheduling should be conducted in accordance with the procedures outlined in the FIRM (CPL 2.103), Chapter 11, 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 file of “incident reports” that document the circumstances of exposure incidents in accordance with the provisions in the exposure control plan, or a first aid log of injuries (e.g., needlesticks), 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 record-keeping violations. Compliance Officers are reminded that the publication of the final recordkeeping standard may affect certain recording requirements that will impact their bloodborne inspections.

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.** For recordkeeping purposes, an occupational blood-borne pathogens exposure incident (e.g., needlestick, laceration, or splash) should be classified as an injury since it is usually the result of an instantaneous event or exposure. The compliance officer should review the most current Part 1904, to determine when injuries must be recorded.

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 Chapter III C6. of the FIRM, dealing with multi-employer worksites.

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 may be cited in accordance with the multi-employer worksite guidelines of the FIRM. Because the 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 the FIRM. 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 the FIRM.
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 the FIRM.

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, 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 considered employees, to state, county, or municipal employees, to healthcare professionals who are sole practitioners or partners, and to the self-employed.

   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 serosanguinous fluids (e.g., exudates from wounds). Also included are medications derived from blood, such as immune globulins, albumin, and factors 8 and 9. (See letter of interpretation, 5/5/98)

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),
HTL-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”:** “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 needleless devices, shielded needle devices, blunt needles, plastic capillary tubes.

5. **“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 uncapped needles or contacts other regulated waste in order to substantiate “occupational exposure.”

NOTE: This definition does not cover “Good Samaritan” acts which 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.
6. **“Other Potentially Infectious Materials” (OPIM):** Coverage under this definition also extends to blood and tissues of experimental animals who are infected with HIV or HBV.

7. **“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 personnel and police and in emergency rooms or psychiatric wards.

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.

   3) 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 exposure control plan to be reviewed and updated 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. According to the preamble to the standard, the requirement to review and update the plan means that the plan must reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens. [56 Fed. Reg. 64109-10(1991).] A periodic review ensures that the exposure control plan remains current with the latest information and scientific knowledge pertaining to bloodborne pathogens. The exposure control plan must document consideration and implementation of appropriate commercially available and effective engineering controls designed to eliminate or minimize exposure.

**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. This compliance instruction clarifies the agency’s position regarding the implementation of effective engineering controls to reduce needlesticks and other sharps injuries. Effective engineering controls include the 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.

According to OSHA’s “Record Summary of the Request for Information on Occupational Exposure to Bloodborne Pathogens Due to Percutaneous Injury (“Record Summary”)” issued on May 20,1999, <http://www.osha-slc.gov/html/ndlreport052099.html>, use of effective engineering controls such as safer medical devices appear to be steadily increasing in some applications. Nearly every healthcare facility responding to the RFI noted a reduction in injuries after use of effective engineering controls. Most IV line access is now accomplished using safer devices. Engineering controls are an effective and feasible method of hazard control in many instances.

NOTE: The Exposure Control Plan must include the procedure for evaluation of circumstances surrounding exposure incidents. See discussion of paragraph (f)(3)(i).

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.

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 expand 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. It is OSHA’s view that preventing exposures requires a comprehensive program, including 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). If engineering and work practice controls do not eliminate exposure, the use of personal protective equipment (e.g., eye protection) is required.

The employer must also make changes to its Exposure Control Plan to include 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. OSHA encourages 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.

NOTE: 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. OSHA does not advocate the use of one particular device over another.

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.
OSHA has changed the language of the compliance instruction to clarify the agency’s position regarding the use of engineering and work practice controls in light of the increased use and acknowledged feasibility of effective engineering controls, as discussed in the Record Summary. See the discussion of paragraph (c)(1)(iv). Furthermore, the preamble to the standard supports this change in the instruction. It states that the exposure control plan is to be updated to reflect new technology to control occupational exposure to bloodborne pathogens [56 Fed. Reg. 64109-10 (1991)].

**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 engineering or work practices have been 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 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 indicates that employers are using safer equipment and devices, e.g., over 87% of the respondents who provided information on device usage now use needleless or shielded needle IV line access. 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 required for the 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 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 by the employer and/or employee. The compliance officer should consult with the Regional Bloodborne Pathogens Coordinator to determine if a violation of (d)(2)(i) exists.
The citation should describe that the employer failed to use engineering controls or work practices that would “eliminate or minimize exposures,” [e.g., failed to identify opportunities for change based upon their evaluation of circumstances surrounding exposure incidents (f)(3)(i); failed to evaluate feasible alternatives; failed to incorporate the changes based on an annual review of the exposure control plan].

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 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 employees need to perform handwashing, they must have a location for washing available at a reasonable distance from their normal work area.

If an employee must thread his/her way through doorways and/or stairs, to wash with appropriate frequency so that there is a reasonable chance of resultant environmental surface contamination, a violation of paragraph (d)(2)(iii) exists.

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. Needles are
expected to be used and immediately discarded, 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, 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. Similarly, if the employer can demonstrate that no alternative, such as immediately discarding used needles into an accessible and appropriate sharps container, is feasible, recapping is also allowed.

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

d. An acceptable means of demonstrating that no alternative to bending, recapping, or removing contaminated needles is feasible or that such action is required by a specific medical procedure would be a written justification (supported by reliable evidence) included as part of the exposure control plan. 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, for example.

**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, gallstones 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. 97135) 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 wash up and change any contaminated clothing before leaving a work area. Then, for example, they may enter designated lunchrooms or break rooms.
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)(I) 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)(iii)(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 (List A), or products registered against HIV/HBV (List D). The lists of these EPA Registered Products are available from the National Antimicrobial Information Network at (800) 447-6349 or its web site at <http://ace.orst.edu/info/nain/lists.htm>. List D includes primarily quaternary ammonia products that EPA has approved as effective against HIV and HBV. OSHA allows the use of these products 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 lists contain the primary registrants’ products only. The same formulation is 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.
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 cleanup 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 the generation of bulk blood should be considered (e.g., 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.

**NOTES:** 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).** 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 vacutainer holders. 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 is **not** to be considered a “waste container” because it is viewed as a temporary measure. Self-sheathing needle products 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.
28. **Paragraph (d)(41)(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.

29. **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.

30. **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.

31. **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.

32. **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.

33. **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).

34. 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 employers 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).

35. **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.

36. **Laundry – 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.

37. **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).

38. **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
likelyhood 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.

39. **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.

40. **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 employees 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. The 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. **Training Requirements (e)(5).** The additional training requirements are specified in paragraph (g)(2)(ix). Any violations found would 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 employees 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 with respect to acceptance of 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 use of 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 “Immunization of Health-Care Workers: Recommendations of ACIP and HICPAC” in Vol. 46, No RR-18, published in the 12/26/1997 MMWR (See Appendix C for the web site address). It recommends that employees who have ongoing contact with patients or blood and are at ongoing risk for injuries with sharp instruments or needlesticks 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. Nonresponders 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 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, actual copies of the MMWR, and/or employee interviews where knowledge of the MMWR has been made evident.

**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 vaccines 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.** Citations should not be issued when designated first aid providers who have occupational exposure are not offered the pre-exposure hepatitis B vaccine if the following conditions exist:

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 provision does not apply to designated first aid providers who render assistance on a regular basis, for example, at a first aid station, clinic, dispensary or other location where injured employees routinely go for 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.

c. The employees 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:

a. 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.

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

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

d. 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.

e. 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).** Although the declination form set forth in 29 CFR 1910.1030, Appendix A need not be reproduced verbatim, any modifications to that language shall be made for the sole purpose of improving employee comprehension.

The standard does not make reference to consent forms. Medical informed consent forms, when they are a part of the healthcare professional’s standard medical practice, are acceptable. However, any waiver of liability 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 which are used by the employer for training or documentation purposes would violate paragraph (g)(2)(vii)(I) if the hazards of the vaccine are clearly exaggerated.

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 recommendation for HCV is found in Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease, October 16, 1998/Vol. 47/No. RR-19 <http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00055154.htm>. In addition, the most current HIV post-exposure follow-up recommendations for an exposure incident made applicable by the bloodborne pathogens standard, at paragraph (f)(3)(iv) are found in the CDC 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. <http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00052722.htm> (See Appendix C for the web site, address)

**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 healthcare 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 serological 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
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)(iii)(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. Employer access to the healthcare professional’s written opinion is specifically allowed.

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 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 encouraged but not required. (See above discussion in paragraphs (c)(1)(iv) 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 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 hotline. 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-mail 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 blood-borne 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.

   2. 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.

**XIV. Interface With Other Standards.**

A. 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.
B. 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 on site 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) 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 record.

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.)

D. 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.
Exposure
Control Plan
Summary
Exposure Control Plan Summary

§1910.1030(c) provides that “Each employer…shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposures.” “The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure.”

a) The Exposure Control Plan (the “Plan”) is the key provision that requires employers to identify individuals who will receive training, protective equipment, vaccination and other protections of the standard.

b) Employees must have access to the Plan during the workshift and be given a copy within 15 days of requesting a copy.

c) The Compliance Officer is to review the Plan to determine whether it is reviewed annually and updated to reflect significant modifications in tasks and procedures that may result in occupational exposure.

d) Lack of a Plan is part of a serious violation.

e) The Plan must be reviewed and updated by the employer at least annually.

i) This review “ensures that the plan remains current with the latest information and scientific knowledge pertaining to the BBP.” The plan “must document consideration and implementation of appropriate commercially available and effective engineering controls designed to eliminate or minimize exposure.”

ii) The instruction “clarifies” OSHA’s position that the implementation of “effective engineering controls” includes the “safer medical devices used to prevent percutaneous injuries before, during or after use through safer design features.” Research and data are available concerning the effectiveness of these engineering controls. “Engineering controls are an effective and feasible method of hazard control in many instances.”

iii) The Plan must include procedures for evaluating the circumstances surrounding exposure incidents.

iv) Citation guidelines state that employers must review and update the Plan annually to reflect changes in technology, such as the use of effective engineering controls and failure to do so requires a citation.
CDC/NIOSH ALERT
Summary
Alert

Preventing Needlestick Injuries in Health Care Settings
Employers of health care workers should implement the use of improved engineering controls to reduce needlestick injuries:

- Eliminate the use of needles where safe and effective alternatives are available.
- Implement the use of devices with safety features and evaluate their use to determine which are most effective and acceptable.

Needlestick injuries can best be reduced when the use of improved engineering controls is incorporated into a comprehensive program involving workers. Employers should implement the following program elements:

- Analyze needlestick and other sharps-related injuries in your workplace to identify hazards and injury trends.
- Set priorities and strategies for prevention by examining local and national information about risk factors for needlestick injuries and successful intervention efforts.
- Ensure that health care workers are properly trained in the safe use and disposal of needles.
- Modify work practices that pose a needlestick injury hazard to make them safer.
- Promote safety awareness in the work environment.
- Establish procedures for and encourage the reporting and timely followup of all needlestick and other sharps-related injuries.
- Evaluate the effectiveness of prevention efforts and provide feedback on performance.

**WARNING!**

Health care workers who use or may be exposed to needles are at increased risk of needlestick injury. Such injuries can lead to serious or fatal infections with bloodborne pathogens such as hepatitis B virus, hepatitis C virus, or human immunodeficiency virus (HIV).
Health care workers should take the following steps to protect themselves and their fellow workers from needlestick injuries:

- Avoid the use of needles where safe and effective alternatives are available.
- Help your employer select and evaluate devices with safety features.
- Use devices with safety features provided by your employer.
- Avoid recapping needles.
- Plan for safe handling and disposal before beginning any procedure using needles.
- Dispose of used needles promptly in appropriate sharps disposal containers.
- Report all needlestick and other sharps-related injuries promptly to ensure that you receive appropriate followup care.
- Tell your employer about hazards from needles that you observe in your work environment.
- Participate in bloodborne pathogen training and follow recommended infection prevention practices, including hepatitis B vaccination.

For additional information, see NIOSH Alert, Preventing Needlestick Injuries in Health Care Settings [DHHS (NIOSH) Publication No. 2000-108]. Single copies of the Alert are available from the following:

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U.S. Department of Health and Human Services
Public Health Service
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health
CDC Statement on Needlestick Injuries
Occupational Risk

CDC Urges Caution to Reduce Workplace Needlestick Injuries

1999 DEC 13 - (NewsRx.com) — The U.S. Centers for Disease Control and Prevention (CDC) National Institute of Occupational Safety and Health issued a recommendation on November 23, 1999 that employers adopt strategic measures to protect the 8 million health care workers in the U.S. from job-related injuries caused by needles in syringes, intravenous delivery systems, and related medical devices.

“Today’s health care workforce faces a multitude of risks,” said NIOSH director Linda Rosenstock, MD, MPH. “We know that needleless devices and safe needle devices can save lives. We must do everything we can to protect the health care workers who have devoted their lives to keeping America healthy.”

Every year 600,000 to 800,000 occupational needlestick injuries are estimated to occur and can lead to serious or potentially fatal infections with bloodborne pathogens such as hepatitis B virus, hepatitis C virus, or human immunodeficiency virus (HIV). The precise number of injuries is not known because needlesticks often go unreported. The risk of a bloodborne infection may not be immediately recognized, and symptoms may not become apparent until weeks or months after the needlestick.

NIOSH recommendations for work-related needlestick injuries are outlined in a new bulletin, “NIOSH Alert: Preventing Needlestick Injuries in Health Care Settings.” Developed in collaboration with other CDC centers and with extensive outside scientific review by diverse industry, labor, and public health organizations, the Alert provides detailed guidance and assistance to employers, workers, and others in reducing needlestick injuries.

“Building on the success that some institutions have achieved in reducing such injuries by as much as 88 percent, these suggestions offer achievable, practical guidance for protecting the Nation’s growing workforce of health care employees,” said Rosenstock.

NIOSH recommends that the use of needles be eliminated where possible. If safe and effective alternatives to needles are not available, devices with safety features such as shields and sheaths should be used. Devices should be selected, used, and evaluated as part of a comprehensive program in which safe work practices, such as prohibiting recapping, are established under written procedures, and workers are trained in those practices. Each health care setting should have its own carefully tailored program, developed with front line worker input and review.

Hollow-bore needles such as those used in syringes present the greatest risk for needlestick, but potential for injury exists whenever any sharp device is used, the NIOSH Alert reports. Most reported needlesticks involve nurses, but laboratory staff, doctors, housekeepers, and other health care workers are also injured.
The Alert suggests examples of devices that may reduce the risk of needlesticks, but advises that no one device will be appropriate or effective for every workplace. Examples of such devices include but are not limited to:

- Needleless devices, such as connectors for intravenous delivery systems that use blunt or valved ends rather than needles for attaching one length of IV tubing to another.
- Devices in which safety features are an integral part of the design, such as sheaths and shields over needles.
- Devices that operate passively without requiring user activation, such as an IV connector with a permanent rigid housing over the needle.
- Devices designed so that the user can tell easily whether the safety feature is activated, such as a visually obvious needle cover or the audible sound of a protective sheath being engaged.
- Devices in which the safety feature cannot be deactivated and remains protective through disposal.
- Devices that perform reliably, are easy to use and practical, and are safe and effective for patient care.

CDC is working with health care industry groups, employers, workers, unions, the public health community, and others to disseminate its guidance and recommendations. Copies of “NIOSH Alert: Preventing Needlestick Injuries in Health Care Settings,” HHS (NIOSH) Publication No. 2000-108, are available at no charge from the NIOSH toll-free information number, 1-800-35-NIOSH (1-800-356-4674). The document is also available online at <www.cdc.gov/niosh>.

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