

**OREGON OCCUPATIONAL SAFETY AND HEALTH DIVISION
DEPARTMENT OF CONSUMER AND BUSINESS SERVICES**

PROGRAM DIRECTIVE

Program Directive **A-154**
Issued June 1, 1988
Revised March 11, 2002

SUBJECT: Bloodborne Pathogens

**AFFECTED CODES/
DIRECTIVES:** OAR 437-002-1910.1030

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.

SCOPE: This instruction applies OR-OSHA-wide.

CANCELLATION: This revision of this Program Directive replaces the version of April 24, 2000.

- REFERENCES:**
1. Oregon OSHA Field Inspection Reference Manual (FIRM).
 2. Program Directive A-216, Citation Policy for Paperwork and Written Program Requirement Violations, July 1, 1997.
 3. Program Directive A-91, Access to Exposure and Medical Records, October 8, 1993.
 4. Program Directive A-200, Authorization and Procedures for Reviewing Specific Medical Records to Verify Compliance with 29 CFR 1904, October 11, 1993.
 5. Standard Operating Procedure 24, Access to Employee Medical Records, February 20, 1991.
 6. Centers for Disease Control Morbidity and Mortality Weekly Report: "Public Health Service Guidelines for the Management of Health-Care Worker Exposures to HIV and Recommendations for Postexposure Prophylaxis." May 15, 1998; Vol. 47, No. RR-7.
 7. Centers for Disease Control Morbidity and Mortality Weekly Report: "Recommendations for Follow-Up of Health-Care Workers After

Occupational Exposure to Hepatitis C Virus,” July 4, 1997; Vol. 46, No. 26.

8. Record Summary of the Request for Information (RFI) on Occupational Exposure to Bloodborne Pathogens due to Percutaneous Injury, May 20, 1999.
9. Safer Needle Devices: Protecting Health Care Workers, Directorate of Technical Support, Office of Occupational Health Nursing, October 1997.
10. Needlestick Injuries Among Health Care Workers: A Literature Review, Directorate of Technical Support, Office of Occupational Health Nursing, July, 1998.
11. International HealthCare Worker Safety Center, #407, Health Sciences Center, University of Virginia, Charlottesville, VA 22908, EPINet, Exposure Prevention Information Network, E-mail: epinet@virginia.edu.
12. DHHS, Public Health Service, “FDA Safety Alert: Needlestick and Other Risks from Hypodermic Needles on Secondary IV Administration Sets – Piggyback and Intermittent IV,” April 16, 1992.
13. Glass Capillary Tubes: Joint Safety Advisory About Potential Risks, OSHA/NIOSH/FDA, February, 1999 and Memorandum dated February 18, 1999, from Steve Witt to the Regional Administrators.
14. NIOSH, “Selecting, Evaluating, and Using Sharps Disposal Containers,” DHHS (NIOSH) Publication No. 97-111, January 1998.
15. Centers for Disease Control, MMWR, October 16, 1998/Vol. 47/No. RR-19 “Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease.”
16. Centers for Disease Control, American Journal of Infection Control, June 1998, Vol. 26, “Guideline for Infection Control in Health Care Personnel, 1998.”
(<http://www.cdc.gov/ncidod/hip/Guide/guide.htm>)
17. Centers for Disease Control, MMWR, December 26, 1997, Vol. 46, No. RR-18, Immunization of Health-Care Workers: Recommendations.
18. 29 CFR Part 1910.1030, Occupational Exposure to Bloodborne Pathogens; Final Rule, Federal Register/Vol. 56, No. 235/December 6, 1991.

19. Training for Development of Innovative Control Technology Project, "Safety Feature Evaluation Forms."
20. 29 CFR Part 1910.1030, Occupational Exposure to Bloodborne Pathogens; Needlesticks and Other Sharps Injuries; Final Rule, Federal Register/Vol. 66, No. 12/January 18, 2001.
21. Centers for Disease Control, *MMWR*, June 29, 2001, Vol. 50, No. RR-11, Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis.

ACTION: OR-OSHA Health Compliance Officers, Safety Compliance Officers, Health Supervisors and Safety Supervisors should use the guidelines in this instruction to ensure uniform enforcement of the Bloodborne Pathogens Standard. The Manager of Enforcement will provide support as necessary in enforcing the Bloodborne Pathogens Standard.

BACKGROUND: In September 1986, Federal OSHA was petitioned by various unions representing health care 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 Paragraph 6(b) of the Act standard and published a proposed rule on May 30, 1989.

1. 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 health care sector required an immediate response and therefore issued OSHA Instruction CPL 2-2.44, January 19, 1988. That instruction was canceled by CPL 2-2.44A, August 15, 1988, and subsequently, CPL 2-2.44B was issued February 27, 1990. Those CPLs were incorporated into the preceding versions of this Program Directive (A-154).
2. 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. On July 1, 1992, OR-OSHA adopted the same regulations.

3. On September 9, 1998 OSHA published a Request for Information (RFI) on engineering and work practice controls used to eliminate or minimize the risk of occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps. The responses indicated that safer medical devices along with training are the most effective means of reducing injury rates. A Summary of the comments received on response to the RFI was published in March 1999. On November 5, 1999 CPL 2-2.44D was issued. It incorporated information from the RFI, past interpretations and several CDC guidelines on vaccination and post-exposure prophylaxis. Oregon OSHA adopted these changes into Program Directive A-154 in April 2000.
4. On November 6, 2000 the Needlestick Safety and Prevention Act was signed into law (Public Law 106-430). It directed OSHA to revise the Bloodborne Pathogens standard to include new examples in the definition of engineering controls; to require that exposure control plans reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; to require employers to document annually in the exposure control plans consideration and implementation of safer medical devices; to require employers to solicit input from non-managerial employees responsible for direct patient care in the identification, evaluation, and selection of engineering and work practice controls; to document this input in the exposure control plan; and to require certain employers to establish and maintain a log of percutaneous injuries from contaminated sharps. OSHA published these revisions on January 18, 2001 with an effective date of April 18, 2001.
5. On August 22, 2001, Oregon OSHA held public hearings on the proposed changes, and additional rules were added based on information gathered at those hearings. Oregon OSHA adopted the federal revisions and new Oregon initiated rules on September 14, 2001, effective October 18, 2001.

**INSPECTION
SCHEDULING
AND SCOPE:**

1. Inspection scheduling must be conducted in accordance with the procedures outlined in the FIRM, Chapter 1.
2. 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.

3. Expansion of an inspection to areas involving the hazard of occupational exposure to body fluids (including onsite health care units and emergency response or first aid personnel) should be performed when:
 - a. The exposure control plan or employee interviews indicate deficiencies in complying with OR-OSHA requirements, as set forth in OAR 437-002-1910.1030 or this instruction.
 - b. Relevant formal employee complaints are received which are specifically related to occupational exposure to blood or OPIM.
 - c. A fatality/catastrophe inspection is conducted as the result of occupational exposure to blood or OPIM.

**GENERAL
INSPECTION
PROCEDURES:**

The procedures given in the FIRM, Chapter 2, should be followed except as modified in the following paragraphs:

1. Where appropriate, include the facility administrator, as well as the directors of infection control, employee (occupational) health, training and education, and environmental services (housekeeping) in the opening conference or interview them early in the inspection.
2. The facility's sharps injury log and any other file of "incident reports" that document the circumstances of exposure incidents in accordance with the provisions in the exposure control plan, and any other first aid log of injuries, should be reviewed. The compliance officer should ask for any other additional records that track bloodborne incidents. The compliance officer should review 437-001-0700 Recordkeeping and Reporting prior to citing recordkeeping violations. Compliance Officers are reminded that the publication of the final recordkeeping standard may affect certain recording requirements that will impact their bloodborne inspections.
3. Compliance officers should take necessary precautions to avoid direct contact with body fluids and should not participate in activities that will require them to come into contact with body fluids, needles or other sharp instruments contaminated with blood. 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.
4. On occasions when entry into potentially hazardous areas are judged necessary, the compliance officer should be properly equipped as required by the facility as well as by their own professional judgment, after consultation with the supervisor.

5. 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 should be respected. Photographs of patients normally will not be necessary and in no event should identifiable photographs be taken without their consent.

**RECORDING
OF EXPOSURE
INCIDENTS:**

Federal OSHA published new recordkeeping rules under 29 CFR 1904. Oregon OSHA adopted these rules under OAR 437-001-0700. These new recordkeeping rules, effective January 1, 2002, require that all employers who must keep records under OAR 437-001-0700, whether or not they are covered by the bloodborne pathogens standard, record all work-related needlesticks and cuts from sharp objects that are contaminated with another person's blood or OPIM on the 300 Log as an injury. The employee's name must not be entered on the 300 Log. [See the requirements for privacy cases in **OAR 437-001-0700(g)** through **(j)**.] If the employee is later diagnosed with an infectious bloodborne disease, the identity of the disease must be entered and the classification must be changed to an illness. If an employee is splashed or exposed to blood or OPIM without being cut or punctured, the incident must be recorded on the OSHA 300, if it results in the diagnosis of a bloodborne illness or it meets one or more of the recording criteria of **OAR 437-001-0700(5)**.

**MULTI-EMPLOYER
WORKSITE:**

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

1. **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 should 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 should be cited for all violations affecting them.
2. **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.

3. **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, OR-OSHA may not cite those employers for site-dependent provisions of the standard when the hazard is site-specific.

In implementing this decision, OR-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. OR-OSHA will also cite employers

for failure to supply appropriate personal protective equipment to employees.

4. **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.

5. **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.

CLARIFICATION

OF STANDARD:

Clarification of the Standard on Occupational Exposure to Bloodborne Pathogens, OAR 437-002-1910.1030. The guidance that follows relates to specific provisions of OAR 437-002-1910.1030 and is provided to assist compliance officers in conducting inspections where the standard may be applicable:

- a. Scope and Application – OAR 437-002-1910.1030(a). This paragraph defines the range of employees covered by the standard.
 1. Since there is no population that is risk free for HIV or HBV infectivity, 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 in no way 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 health care industry. At the same time, employees in the following jobs are not automatically covered unless they have occupational exposure:
 - Physicians, physician's assistants, nurses, nurse practitioners, and other health care employees in clinics and physicians' offices;
 - Employees of clinical and diagnostic laboratories;
 - Housekeepers in health care and other facilities;
 - Personnel in hospital laundries or commercial laundries that service health care 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 assigned to provide emergency first aid;
- Dentists, dental hygienists, dental assistants and dental laboratory technicians;
- Staff of institutions for the developmentally disabled;
- Hospice employees;
- Home health care 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;
- Firefighters, law enforcement personnel, and correctional officers; and
- maintenance workers, such as plumbers, in healthcare facilities and employees of substance abuse clinics.

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 phrase “as defined by paragraph (b)” when determining coverage.

- NOTES:**
1. Part-time, temporary, and health care workers known as “per diem” employees are covered by this standard.
 2. OR-OSHA jurisdiction extends only to employees in the workplace. It does not extend to students if they are not

considered employees or if they are not covered under workers compensation insurance, to health care professionals who are sole practitioners or partners, and to the self-employed.

3. If an employee is trained in first aid and identified by the employer as responsible for rendering medical assistance as part of their 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.
4. Employees in the construction, agriculture and maritime industries who have occupational exposure to blood or OPIM are covered by the standard.

b. Definitions – OAR 437-002-1910.1030(b). The following provides further clarifications of some definitions found in this paragraph:

1. “Blood:” The term “human blood components” includes plasma, platelets, and serosanguineous fluids (e.g., exudates from wounds). Also included are medications derived from blood, such as immune globulins, albumin, and factors 8 and 9. (See Federal OSHA 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 and can infect and cause disease in persons who are exposed to blood containing the pathogen. Other examples include hepatitis C, malaria, syphilis, babesiosis, brucellosis, leptospirosis, arboviral infections, relapsing fever, Creutzfeld-Jakob disease, Human T-lymphotrophic Virus Type 1, 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, hang-nails, cuts, abrasions, chafing, 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 assisting a fellow employee, although OSHA and OR-OSHA encourages employers to offer follow-up procedures in such cases.

6. “Other Potentially Infectious Materials” (OPIM): Coverage under this definition also extends to blood and tissues of animals who are deliberately 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 – OAR 437-002-1910.1030(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 with 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 benefits 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 OAR 437-002-1910.1020, 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
 - (B) Those job classifications in which some employees have occupational exposure.
 - (i) 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.
 - (ii) The tasks and procedures that are grouped must be related; i.e., they must share a common activity such as “vascular access procedures,” “handling of contaminated sharps,” or “handling of deceased persons,” etc.

NOTE: If a job classification, task, or procedure involving occupational exposure is omitted from the list, but all employees in the job or performing the task or procedure have been included in all other aspects of the plan (e.g., vaccinations, training, etc.), it is to be considered an other-than-serious violation.

(C) The exposure determination should 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. A review of the sharps log required in paragraph (h)(5) can identify problem areas and/or ineffective devices which may need replacement. The exposure control plan must document consideration and implementation of appropriate commercially available and

effective engineering controls designed to eliminate or minimize exposure.

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, OR-OSHA, and to the public concerning the effectiveness of these engineering controls. 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.

6. Oregon OSHA did not adopt (c)(1)(v). See D.4 below for the Oregon-initiated rules on safer needle device selection.
- d. Methods of Compliance – OAR 437-002-1910.1030(d). Paragraph (d) sets forth the methods employers must use to 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 – (d)(1). Universal precautions is OR-OSHA's accepted method 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, or other bloodborne pathogens regardless of the perceived “low risk” of a patient or patient population.

Alternative concepts in infection control are called Body Substance Isolation (BSI) and Standard Precautions. These methods define all body fluids and substances as infectious. These methods incorporate not only the fluids and materials covered by this standard but expands coverage to include all body fluids and substances. These concepts are acceptable alternatives to universal precautions, provided that facilities utilizing them adhere to all other provisions of this standard.

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

2. Engineering Controls and Work Practices – Paragraph (d)(2)(i). This paragraph requires the employer to institute engineering and work practice controls as the primary means of eliminating or minimizing employee exposure. It conforms to OR-OSHA’s traditional adherence to a hierarchy of controls [See 56 Fed. Reg. 64114-15 (1991)]. OR-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 OR-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 use of sharps containers is not an acceptable means of complying with **(d)(2)(i)**. The specific provisions of **(d)(4)(iii)(A)** covers sharps containers and thus preempts this section.

NOTE: Needles that will not become contaminated by blood during use (such as those used only to draw medication from vials) are not required to have engineering controls under this standard. The needle used for the actual injection, however, must incorporate engineering controls.

The employer must also make changes to the 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. OAR 437-002-1030 requires employers to involve employees in the selection of effective engineering controls to improve employee acceptance of the newer devices and to improve the quality of the selection process.

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

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

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

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

- A. A fixed safety feature provides a barrier between the hands and the needle after use; the safety feature should allow or require the worker’s hands to remain behind the needle at all times;

- B. The safety feature is an integral part of the device and not an accessory;
- C. The safety feature is in effect before disassembly and remains in effect after disposal to protect users and trash handlers, and for environmental safety;
- D. The safety feature is as simple as possible, and requiring little or no training to use effectively.

INSPECTION GUIDELINES. The Compliance Officer should determine through interviews or observation of work involving exposure to blood or OPIM whether sufficient engineering controls and work practices are used. While it is generally accepted that an exposure incident can occur at any time or place, a review of the facility records can better direct the Compliance Officer to areas that are more likely to be sites of exposure incidents. Data from The Uniform Needlestick and Sharp Object Injury Report, 77 Hospitals, 1993-1995 (Exposure Prevention Information Network EPINet at <http://www.med.virginia.edu/~epinet/soio.html>) show that injuries occurred, in order of frequency, in patient rooms, operating rooms, emergency departments, and intensive/critical care units. The report indicates that nurses (RN's and LPN's) were injured more often than any other type of healthcare worker. Furthermore, the report finds that an overwhelming majority (93%) of the injuries were caused by items that were not a "safe design with a shielded, recessed, or retractable needle." The Compliance Officer should determine if there were occasions where injuries were incurred during the same procedure, using the same equipment, in the same location or among similar employees (e.g., housekeepers) and determine whether 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 lack of recorded injuries on the sharps injury log or OSHA 200 (through the end of 2001) or OSHA 300 (effective January 1, 2002) does not exempt the employer from this provision. The Compliance Officer should carefully evaluate the exposure control measures, such as effective engineering controls, that are in use at the facility. Part of this evaluation should include whether other devices that are commercially available were reviewed or considered by the

employer and whether there is evidence that other engineering controls would reduce exposures. Such evidence might include CDC studies of efficacy, pilot tests by the employer, or data available in published studies. The Record Summary 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 no engineering controls are being used to eliminate or minimize exposure, a citation should be issued.

If a combination of engineering and work practice controls used by the employer does not eliminate or minimize exposure, the employer should 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 Enforcement Manager to determine if a violation of (d)(2)(i) exists.

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

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

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

3. Paragraph (d)(2)(ii). This paragraph requires that engineering controls be examined and maintained or replaced on a regular schedule to ensure their effectiveness. Regularly scheduled inspections are required to confirm, for instance, that engineering controls such as protective shields have not been removed or broken, that sharps disposal containers are being replaced in sufficiently frequent intervals and that other 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, paragraph (d)(2)(ii) should be cited.

4. OAR 437-002-1030. The employer is required to solicit input from non-managerial front-line employees responsible for direct patient care in the identification, selection and evaluation of effective engineering and work practice controls and document the solicitation in the Exposure Control Plan. The employer must solicit employee input in a manner appropriate to the circumstances in the workplace. Methods for soliciting employee input may include joint labor-management safety committees; involvement in informal problem-solving groups; participation in safety meetings and audits, employee surveys, worksite inspections, or exposure incident investigations; using a suggestion box or other effective methods for obtaining written employee comments; and participation in the evaluation of devices through pilot testing. The opportunities for employee input shall be effectively communicated to employees, and the employer must ensure that all employees

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

When the only employees who use medical sharps are managerial employees, the employer needs only to solicit input from them.

After a device is evaluated, the employer must decide whether or not to purchase that device. If it is not purchased because of either employee or employer concerns with the device, these concerns must be documented. If a device had employee support and is not purchased, the employer must document that support as well as the justifications for not purchasing it. When a device is purchased without employee support, the employer must document the concerns the employees have about the device as well as the justifications for purchasing the device.

Once the employer decides on a device, all effected employees must be trained on the use of that device before it is implemented.

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

CITATION GUIDELINES: This section should be cited if input was not solicited from non-managerial front-line employees involved in administering treatment or performing any procedure in the presence of an individual receiving care.

Any employee who, for example, collects blood from patients in a nursing home; administers flu vaccinations in a factory employee health unit, or collects blood from other employees for research purposes would be performing “patient care.” Laboratory workers, on the other hand, who do not have patient contact, would not be included in this provision. This section should also be cited if the evaluation did not occur for all affected departments or facilities, when employees do not understand the process for evaluating new devices, or when employees who are expected to use new devices do not know how to use them.

5. 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.

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

6. 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.
7. 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.
8. Paragraphs (d)(2)(ix) and (x). These paragraphs are intended primarily to eliminate or minimize indirect transmission of HBV 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 handwashing 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 key to this paragraph is whether food and drink may be contaminated by such processes as leakage/spilling of specimen containers, contact with contaminated items, or the performance of

activities (e.g., laboratory analysis) that could generate splashes, sprays, or droplets of blood or OPIM.

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

9. 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.

10. 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.
11. 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, OR-OSHA does not issue citations to dentists and doctors for non-employee exposures, such as patient exposures. Extracted teeth, gall stones and kidney stones may be given to the patients. In these situations, the teeth and stones are not subject to the containerization and labeling provisions of the standard.

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

All workers who might potentially open a carrier should be trained to regard the contents as biohazardous in nature. Employees who open biohazard carriers should wear gloves in accordance with paragraph (d)(3) when removing specimens from the tube system carrier, as it may be contaminated with leakage. They should 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.

12. 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, should 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 should 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 (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.

13. 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.
14. 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)

15. 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 health care or public safety services, or would pose an increased hazard to the personal safety of the worker. The following represents 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 firefighter rescues an individual who is not breathing from a burning building and discovers that their 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 co-workers.

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 should 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 PPE.

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.

- 16. Paragraph (d)(3)(iii). This paragraph requires that the employer provide PPE in appropriate sizes and accessible locations. In addition, "hypoallergenic" gloves (see Note below), glove liners, powderless gloves, or other similar

alternatives must be readily available and accessible at no cost to those employees who are allergic to the gloves normally provided. Similar alternatives must supply appropriate barrier protection and must be approved by the FDA for use as a medical glove. The compliance officer should review the employer's program and, through employee interviews and inspection of places where PPE is kept, ensure that these provisions have been met.

NOTE: In accordance with a notice published in the Federal Register, Volume 62, No. 189, effective September 30, 1998, the FDA now requires labeling statements for medical devices which contain natural rubber and prohibits the use of the word "hypoallergenic" to describe such products. Additional information on the incidence of hypersensitivity reactions to natural rubber latex can be found in the following documents: NIOSH Alert, Preventing Allergic Reactions to Natural Rubber Latex in the Workplace (Publication No. 97-135) published in June 1997; Directorate of Technical Support, Technical Information Bulletin: Potential for Allergy to Natural Rubber Latex Gloves and other Natural Rubber Products, <http://www.osha-slc.gov/html/hotfoias/tib/TIB19990412>.

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.

17. Paragraph (d)(3)(iv). It is the employer's responsibility not only to provide PPE, but to clean, maintain, and/or dispose of it.

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 is not permitted since the employer cannot guarantee that proper handling or laundering procedures are being followed; it could also lead to the migration of contaminants to the home.

If the employee wishes to choose, wear, and maintain their 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/launched/ 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 PPE is not removed 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.

18. 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.

19. 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, handwashing after glove removal is required. Disposable gloves must be replaced as soon as practical or as soon as feasible when contaminated.

While disposable gloves should 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 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 should 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.

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

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

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

21. 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.

22. 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.

23. 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 operator 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 normal 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.

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

Under paragraph (d)(4)(ii)(A), cleaning of contaminated work surfaces after completion of procedures is required to ensure that employees are not unwittingly exposed to blood or OPIM remaining on a surface from previous procedures. This paragraph requires contaminated work surfaces to be cleaned with an “appropriate disinfectant.” Appropriate disinfectants include a diluted bleach solution and EPA-registered tuberculocides (List B), sterilants (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. OR-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 clean up job at hand is also an effective disinfectant, although bleach may cause damage to some medical instruments and therefore cannot be used in all cases. In addition, gross contamination must be cleaned up first with a soap and water solution, to ensure the disinfectant is completely effective.

Where procedures are performed on a continual basis throughout a shift or a day, as may be the case with a clinical laboratory technician performing blood analyses, it is not the agency's intent for the work surface to be decontaminated before the technician can proceed to the next analysis; rather the intention is for contaminated work surfaces to be decontaminated after the procedures are completed which, in the above example, would include a set of analyses. The completion of procedures might also occur when the employee is going to leave the work area for a period of time. Decontamination is not automatically required after each patient care procedure, but is required only after procedures resulting in surface contamination.

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

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

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

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

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

25. 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.

26. 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).

27. Regulated Waste – (d)(4)(iii). This paragraph requires regulated waste to be properly contained and disposed of, so as not to become a means of transmission of disease to workers.

To eliminate the implication that OR-OSHA or 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:

- (A) Liquid or semi-liquid blood or OPIM.
- (B) Items contaminated with blood or OPIM and which could release these substances in a liquid or semi-liquid state if compressed.
- (C) Items that are caked with dried blood or OPIM and are capable of releasing these materials during handling.
- (D) Contaminated sharps.
- (E) Pathological and microbiological wastes containing blood or OPIM.

INSPECTION AND CITATION GUIDELINES. The compliance officer should not use the actual volume of blood as the determining factor as to 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 dripping of liquid blood or OPIM, or flaking off of dried 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 OR-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, DEQ, Oregon Health Division and possibly other State and local regulations.

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

28. 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.

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

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

Areas such as correctional facilities, psychiatric units, or pediatric units may have difficulty placing containers in the immediate use area. If a mobile cart is used by health care workers in these units, an alternative would be to lock a sharps container in the cart.

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

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

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

31. Paragraph (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), they should be grouped with (g)(2)(vii)(F) if employees have not received adequate training.
32. Paragraph (d)(4)(iii)(A)(3)(ii)(B). It is reasonable to presume that some sharps containers will contain residual liquids. If the container cannot be sealed to prevent leakage, it must be placed in a secondary container.
33. Paragraph (d)(4)(iii)(A)(4). A reusable sharps container system will be acceptable if it does not expose employees to the risk of percutaneous injury. No system involving the manual opening, emptying, or cleaning of the containers will be allowed. The only acceptable system is a fully automated container cleaning system that eliminates employee exposure to sharps.
34. Paragraph (d)(4)(iii)(B). While this paragraph requires that regulated waste containers be closable, simply being closed does not ensure that wastes 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 (g)(2) should be grouped with violations of paragraph (d).

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

Even if a facility considers all of its waste to be regulated waste, the waste containers must still bear the required label or color coding in order to protect new employees, who would not normally come into contact with wastes, and employees from outside the facility. This requirement is in contrast to the labeling alternative allowed when laundries use universal precautions for the handling of all soiled laundry.

Regulated waste that has been decontaminated need not be labeled or color-coded. The compliance officer in such a case should verify that the employer's exposure control plan states the decontamination procedures to be followed. In order to ensure that the decontamination process is successful, the employer must monitor factors such as the content, volume, density, configuration, and organic content of the load of waste. The temperature needed for the complete breakdown of plastics, as required by EPA, 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:

- (A) Date, time, and operator of each run
- (B) Type and approximate amount of waste tracked
- (C) Post-treatment reading of temperature-sensitive tape
- (D) Dates and results of calibration of the sterilizer
- (E) Results of routine spore testing

Although these paragraphs contain label requirements, failure to label can also be cited under paragraph (g)(1)(i).

36. Paragraph (d)(4)(iii)(B)(2). A second container is required to be used when outside contamination of the first waste container occurs. This provision does not require routine double-bagging but rather requires double-bagging in such circumstances as a

waste container being splashed with blood during surgery or autopsy, when a container has been handled by an employee with bloody gloves, or when a waste bag leaks blood or OPIM onto an adjacent bag.

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

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

38. Paragraph (d)(4)(iv)(A)(2). The employer has been given the choice, by this paragraph, to either:
- (A) Label or color-code according to paragraph (g)(1)(i), or
 - (B) Utilize universal precautions in the handling of all soiled (i.e., used) laundry.

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

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

39. Paragraph (d)(4)(iv)(A)(3). The material for the bags or containers used in laundry collection must prevent soak-through or leakage of fluids to the exterior, if the contaminated laundry is wet and presents a reasonable likelihood of soak-through or leakage. Not all contaminated laundry must be placed in such bags or containers, only laundry wet enough to leak or soak through and expose workers handling the bags/containers to blood or OPIM.
40. Paragraph (d)(4)(iv)(B). Employees having direct contact with contaminated laundry must wear protective gloves and any other appropriate personal protective equipment, in order to prevent or reduce contact exposure to blood or OPIM. Any other personal protective equipment required must be

determined on a case-by-case basis. Gowns, aprons, eyewear, and masks may be necessary to prevent employee exposure.

41. Paragraph (d)(4)(iv)(C). The generator of the laundry must have determined if the facility to which it is shipped utilizes universal precautions. 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 generator of the laundry chooses to color-code rather than label, the color of the bag must be red.

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

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

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

The CL is shipped with an improper label. Paragraph (d)(4)(iv)(C) would be cited and could be grouped with the applicable subparagraphs of (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 could be grouped with paragraph (g)(1)(i)(E).

- e. HIV and HBV Research Laboratories and Production Facilities – OAR 437-002-1910.1030(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 unrelated to HIV or HBV on blood and other body fluids, or who 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.

NOTES: Employers in such a facilities remain responsible for complying with the entire standard. Requirements stated elsewhere in the standard are not repeated. These requirements are based largely on information from published guidelines of the Centers for Disease Control (CDC) and the National Institutes of Health (NIH) (See D.9. of this instruction, “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 OR-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) limit access to the laboratory and warn of the hazards associated with bloodborne pathogens. The compliance officer must review the written policies and procedures to determine if they are adequate to ensure that unauthorized individuals are not placed at risk nor that they can distract or otherwise interfere with the work of the authorized employees. 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 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.

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 should 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) 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 handwashing 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. At a minimum, a 15-minute supply of continuous free-flowing water is recommended. 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 to 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. (See M.7.b.(5) of this instruction for details.)
- f. Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up – OAR 437-002-1910.1030(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 – (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 OR-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 it is the employee's option to participate in the vaccination and follow-up programs.

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

2. Paragraph (f)(1)(ii)(A). The term “no cost to the employee” means no “out of pocket” expense to the employee.

The employer may not require the employee to use their health care 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, co-payments, 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.

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 they remain 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 their employ prior to a specified period of time is similarly 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 should be offered during normally scheduled work hours. If participation requires travel away from the worksite, the employer must bear the cost.
4. Paragraph (f)(1)(ii)(C). To determine if the State board of nursing licensing allows licensed health care professionals other than physicians to carry out specific procedures and evaluations required by paragraph (f), see Appendix H, ORS 677.495 through 677.550, and OAR Chapters 847 and 851.
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. OR-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 “Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis,” published in Morbidity and Mortality Weekly Report Vol. 50, No. RR-11, June 29, 2001 (See Appendix E for the web site address). It recommends that employees who have ongoing contact with patients or blood and are at on going 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. Non-responders must be medically evaluated.

INSPECTION GUIDELINES: It is important that the compliance officer investigate thoroughly whether the employer knows of the contents of the CDC guidelines. Evidence may include 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. (See Appendix H, ORS 438 and OAR 333.)
7. Hepatitis B Vaccination – (f)(2). The compliance officer should determine whether or not all occupationally exposed employees have the hepatitis B vaccination series made available to them after training required by paragraph (g)(2)(vii)(I) and within 10 working days of their initial assignment. The term “made available” includes the health care 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 reasonably anticipated 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 (1) the

exemption(s) set forth in paragraph (f)(2), or (2) the signature of the employee on the mandatory declination form. (See Appendix A of OAR 437-002-1910.1030.)

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, 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.

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 employees with occupational exposure are not offered the pre-exposure hepatitis B vaccine if the following conditions exist:

- (A) The primary job assignment of such an employee is not the rendering of first aid or other medical assistance, or any other task that involves routine exposure to blood or OPIM.
- (B) Any task involving potential exposure to blood or OPIM is done only as a collateral duty, responding solely to 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. This provision also does not apply to any other employees who have routine exposure to blood or OPIM, such as janitorial staff.

- (C) The employer must have procedures in place to provide the hepatitis B vaccine to all unvaccinated employees 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.” These procedures do not necessarily need to be in writing, but all affected employees must be trained on and understand them. The procedures must include:

- (1) Provision for a reporting procedure that ensures that all 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 employees actively involved in the incident, such as first aid responders or janitorial staff performing clean-up, regardless of whether personal protective equipment was used and must describe the incident, including time and date. The description must include a determination of whether or not, in addition to the presence of blood or other potentially infectious materials, an “exposure incident,” as defined by the standard, occurred. This determination is necessary in order to ensure that the proper post-exposure evaluation, prophylaxis, and follow-up procedures required by paragraph (f)(3) of the standard are made available immediately, whenever there has been an “exposure incident” as defined by the standard.
- (2) A log of incidents, that is readily available to all employees and to Oregon OSHA upon request.
- (3) Provision for the bloodborne pathogens training program to include the specifics of this reporting procedure.
- (4) Provision for the full hepatitis B vaccination series to be made available as soon as possible, but in no event later than 24 hours, to all unvaccinated first aid providers who have rendered assistance in any situation involving the presence of blood or OPIM, regardless of whether or not a specific “exposure incident,” as defined by the standard, has occurred.
- (5) If an exposure incident, as defined in OAR 437-002-1910.1030 occurs, all other post-exposure follow-up procedures in accordance with the standard must be initiated immediately, and the employer must ensure that the medical provider is familiar with and follows the recommendations for

post-exposure follow-up set forth by the Oregon Health Department and/or the Centers for Disease Control.

- (6) All other provisions of OAR 437-002-1910.1030 must be met, i.e., employees must receive the required training at the time of initial assignment and the appropriate PPE must be made available.
 - (7) 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.
- 8. Paragraph (f)(2)(ii). Pre vaccination 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.
 - 9. 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.
 - 10. Paragraph (f)(2)(iv). Although the declination form set forth in OAR 437-002-1910.1030, Appendix A, need not be reproduced verbatim, any modifications to that language should 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.

- 11. Paragraph (f)(2)(v). At the time of this publication, the possible need for booster doses of the hepatitis B vaccine is still being assessed. There is no current requirement to provide boosters unless the USPHS recommends it at a later date.

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 – (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 Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis published in Morbidity and Mortality Weekly Report Vol. 50, No. RR-11, June 29, 2001.

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

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

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

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

Following an exposure incident, such as a needlestick or other sharps injury, employers are required to document, at a minimum, "the route(s) of exposure, and the circumstances under which the exposure incident occurred," as per paragraph (f)(3)(i). The documentation of circumstances surrounding an incident by the employer allows identification and correction of

hazards. To be useful, the documentation must contain sufficient detail about the incident. There should be information about the following: engineering controls in use at the time, work practices followed, a description of the device in use, protective equipment or clothing that was used at the time of the exposure incident, location, procedure being performed when the incident occurred, and the employee's training. Additional information might also include a comparison of similar occurrences and recommendations to avoid future incidents, although this information is not mandatory. The Compliance Officer should request copies of the employer's documentation on exposure incidents to determine if they are in compliance with paragraphs (c)(1)(ii)(C) and (f)(3)(i).

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

15. Paragraph (f)(3)(ii). This paragraph requires the employer to identify the source individual in an exposure incident, unless this is infeasible. The employer must document in writing the identity of, or infeasibility of identifying, the source individual. Examples of when it may not be feasible to identify the source individual include incidents of needlesticks by unmarked syringes left in laundry or those involving blood samples which are not properly labeled, as well as prohibition by State or local law.
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 their behalf. If consent is not obtained, the employer must document this in writing. The compliance officer should ensure that the employer's plan includes this provision.

For those situations that do not require consent of the individual (See Appendix H, OAR 333-12-269), available blood must be tested. The term "if available" applies to blood

samples that have already been drawn from the source individual.

OR-OSHA and OSHA do not require (re)drawing of blood specifically for HBV and HIV testing if the source individual does not give consent except as provided for in OAR 333-12-269.

(See Appendix H, ORS 433.045 through .080.)

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.
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 is not dependent on the employee's electing to have baseline HBV and HIV serological testing.
19. Paragraph (f)(3)(iii)(A). The consent of the employee must be obtained before the collection and testing of his or her blood.
20. Paragraph (f)(3)(iii)(B). This paragraph allows employees the opportunity for future testing without the need for an immediate decision. Employees involved in an exposure incident have at least 90 days following baseline blood collection to decide if they wish to have their blood tested for HIV.

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

Employers are required to preserve the blood the employee consented to have drawn, if it was not tested for HIV initially, for at least the 90-day period. If the employer contracts for post-exposure follow-up, compliance officers should check that 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 Health Care Professional – (f)(4). This paragraph requires the employer to provide information to the health care 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 health care 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 (f)(4)(ii)(A-C) and (E) to the health care professional. The information required by (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 health care professional. If the evaluating health care professional is also the employer, the information must still be in the employee's record and made available at the time of a post-exposure incident. All applicable laws and standards of confidentiality apply in this situation.

23. Health Care Professional's Written Opinion – (f)(5). The employer is required to obtain and provide a written statement to the employee within 15 working days of completion of the original evaluation. Employer access is allowed to the health care professional's written statement.
24. Paragraph (f)(5)(i) limits the health care professional's written statement to very specific information regarding the employee's hepatitis B vaccine status, including indication for vaccine and whether such vaccination was completed.
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 – OAR 437-002-1910.1030(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 – (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, dispose of, 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: This does 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 OAR 437-002-1910.1030 requires the biohazard label. Where there is an overlap between the OR-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 OR-OSHA-mandated label appears on any internal containers which may be present. Containers serving as collection receptacles within a facility must bear the OR-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., 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 (g)(1)(i)(A), since the material would still be regulated waste.
4. Information and Training – (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 should 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 should 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 health care 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, and also that the trainer was able to answer questions as needed. 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 or syphilis. At the same time, the employer need not cover such uncommon diseases as Cruetzfeld-Jacob disease unless, for example, it is appropriate for employees working in a research facility with that particular virus.
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 exposure outside the normal scope of work. This does not refer to hospital emergency rooms or emergency medical technicians' work.
8. Paragraph (g)(2)(vii)(N). This paragraph requires that there be an opportunity for interactive questions and answers with the person conducting the training session. During training, it is critical that trainees have an opportunity to ask and receive answers to questions where material is unfamiliar to them. Frequently, a trainee may be unable to go further with the

training or to understand related training content until a response is received.

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

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

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

9. Paragraph (g)(2)(viii). The person conducting the training is required to be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address. In addition to demonstrating expertise in the area of the occupational hazard of bloodborne pathogens, the trainer must be familiar with the manner in which the elements in the training program relate to the particular workplace.

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

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

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

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

10. Paragraph (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 – OAR 437-002-1910.1030(h). Records are required to be kept for each employee covered by this standard for training, as well as for medical evaluations, treatment, and surveillance.
 1. Medical records required by paragraph (h)(1) will be of particular importance to the health care professional in determining vaccination status and courses of treatment to follow 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 health care professional located off-site and that person or company may retain the records.

The requirements of OAR 437-002-1910.1020 apply. In particular, OAR 437-002-1910.1020(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 regulations.

INSPECTION GUIDELINES. All medical records required to be kept by this standard are also required to be made available to OR-OSHA. The compliance officer must protect the confidentiality of these records. If they are copied for the case

file, the provisions of CFR 1913.10 (available from the Federal OSHA web site at www.osha.gov) 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 OAR 437-002-1910.1020. While OAR 437-002-1910.1020(a) makes allowances for its provisions being carried out on behalf of the employer, paragraph OAR 437-002-1910.1020(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 they 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 OR-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 on-site and therefore 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 and may be maintained in any file. They must be retained for 3 years from the training date.

3. Paragraph (h)(5) and OAR 437-002-1035 requires employers to establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. This log is separate from the log of injuries and illnesses kept under OAR 437-001-0700, although the 300 form can be used as long as it is a separate sheet or, if kept electronically, the sharps injury information can be extracted separately. This log is required for all employers who establish an Exposure Control Plan under 1910.1030(c).

The log must include the type and brand of device involved in the incident, the department or work area where the exposure

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

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

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

**INSPECTION
GUIDELINES:**

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

**CITATION
GUIDELINES:**

Employers partially exempt from recordkeeping requirements under OAR 437-001-0700 are **NOT** exempt from the requirement of maintaining a sharps injury log.

**INTERFACE
WITH OTHER
STANDARDS:**

- a. The hazard communication rule OAR 437-002-1910.1200, 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 OAR 437-002-1910.1020. Under 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 should 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 should follow Program Directive A-91, Access to Exposure and Medical Records, and Standard Operating Procedure 24 for obtaining an employee medical release form. 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 should contact their supervisor to obtain an administrative subpoena (from the Department of Justice) in addition to the medical release form before looking at any confidential medical information or medical record.

- c. Generally, the respiratory protection standard, OAR 437-002-1910.134, does not apply. However, placing or storing respirators in areas where they could be contaminated by body fluids constitutes a violation of OAR 437-002-1910.134(h)(2)(i) (or OAR 437-002-1910.139(b)(6), if the respirator is used for protection against tuberculosis.)
 1. The Hazardous Waste Operations and Emergency Response (HAZWOPER) standard, OAR 437-002-1910.120, covers three 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; and those workers expected to respond to emergencies caused by the uncontrolled release of a hazardous substance.
 - (a) 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:
 - (1) Workers involved in cleanup operations at hazardous waste sites involving infectious waste;

- (2) Workers responding to an emergency caused by the uncontrolled release of infectious material; e.g., a transportation accident; and
 - (3) Workers at RCRA permitted incinerators that burn infectious waste.
- (b) Employers of employees engaged in these types of activities must comply with the requirements in OAR 437-002-1910.120 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.

**RECORDING
IN THE IMIS:**

Current instructions for completing the appropriate inspection classification boxes on the OR-OSHA-1, Inspection Report, as found in the IMIS Manual, should be applied when recording bloodborne pathogens inspections:

1. For any inspection which includes an evaluation of the hazards of bloodborne pathogens, Item 42 of the OSHA-1 should be recorded as follows:

N 02 Blood

2. If local emphasis programs are approved at a later date, Item 25C of the OR-OSHA-1 should be completed with the appropriate value.

**EFFECTIVE
DATE:**

This directive is effective immediately and will remain in effect until canceled or superseded.

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. OR-OSHA's restatement, clarification or explanation of the requirements of the standard does not amend the standard or create new legal duties, obligations or defenses.

APPENDIX A – TYPICAL COMMITTEES IN HEALTH CARE FACILITIES

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

ASSURING IMPLEMENTATION OF THE EXPOSURE CONTROL PLAN:

Safety Committee/Employee Health Committee

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

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

Infection Control Committee

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

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

HAZARD IDENTIFICATION (Including worksite inspections and tracking trends)

Safety Committee (see description above)

Facilities Maintenance/Hazardous Waste Committee

Typically composed of the facilities engineer and representatives from various departments. The duties of this committee usually include:

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

Quality Assurance/Utilization Review/Risk Management Committee

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

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

SELECTION, EVALUATION & RECOMMENDATIONS FOR PPE AND NEW DEVICES

Products Management Committee

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

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

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

Safety Committee (See description above)

EDUCATION/TRAINING/ORIENTATION

Education Committee

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

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

Products Management Committee (see description above)

RECORDKEEPING

Safety Committee (see description above)

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

Infection Control Committee (see description above)

ASSURE COMPLIANCE BY PHYSICIAN STAFF

Medical Executive Committee

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

The duties of this committee usually include:

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

OTHER COMMITTEES WHICH THE CSHO MAY ENCOUNTER

Budget/Finance and Audit Committee

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

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

Ethics Committee

Typically composed of facility staff such as nurses, physicians, attorneys, hospital administrators, social workers and clergy. May also include community members. The duties of this committee usually include:

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

Information Systems Committee

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

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

Pharmacy and Therapeutics Committee

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

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

APPENDIX B – ENGINEERING CONTROL EVALUATION FORMS

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

Sample Forms:

ECRI©

ECRI's Needlestick-Prevention Device Evaluation Form

NPD Cost Calculation Worksheet

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

SAFETY FEATURE EVALUATION FORMS

SAFETY SYRINGES

IV ACCESS DEVICES

SHARPS DISPOSAL CONTAINERS

IV CONNECTORS

VACUUM TUBE BLOOD COLLECTION SYSTEMS

E. R. SHARPS DISPOSAL CONTAINERS

SAFETY DENTAL SYRINGES

HOME USE SHARPS DISPOSAL CONTAINER

ECRI's Needlestick-Prevention Device Evaluation Form

Device: _____

Supplies/Trade Name: _____

Applications: _____

Reviewer: _____ Date: _____

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

Healthcare Worker Safety

1. A. Does the NPD prevent needlesticks during use (i.e., before disposal)? Yes No
 B. Does it do so after use (i.e., does the safety mechanism remain activated through disposal of the NPD)? Yes No
2. A. Does NPD provide protection one of the following ways: Either intrinsically or automatically?
 (Answer "No" if a specific action by the user is required to activate the safety mechanism.) Yes No
 B. If "No," is the mechanism activated in one of the following ways: either by one-handed technique or by a two-handed
 technique accomplished as part of the usual procedure? Yes No
3. During the use of NPD do user's hands remain behind the needle until activation of the safety mechanism is complete? Yes No
4. Is the safety mechanism reliable when activated properly? Yes No
5. Does the NPD minimize the risk of user exposure to the patient's blood? Yes No

Patient Safety and Comfort

6. Does the NPD minimize the risk of infection to the patient (e.g., through cross-contamination)? Yes No
7. Can the NPD be used without causing more patient discomfort than a conventional device? Yes No
8. *For IV NPDs:* Does the NPD attach comfortably (i.e., without causing patient discomfort at the catheter port or IV tubing)? . . . Yes No

Ease of use and Training

9. Is NPD Operation obvious? That is can the device be used properly without extensive training? Yes No
10. Can the NPD be used by a left-handed person as easily as by a right handed person? Yes No
11. Is the technique required for using the NPD the same as that for using a conventional device? Yes No
12. Is it easy to identify the type and size of the product from the packaging? Yes No
13. *For intravenous (IV) catheters and blood collection needle sets:* Does the NPD provide a visible blood flashback during
 initial insertion? Yes No
14. Please rate the ease of using this NPD Exc. Good Fair Poor
15. Please rate the quality of the in-service training Exc. Good Fair Poor

Compatibility

16. Is the NPD compatible with devices (e.g., blood collection tubes) from a variety of suppliers? Yes No
17. *For IV NPDs:*
 - A. Is the NPD compatible with intralipid solutions? Yes No
 - B. Does the NPD attach securely at the catheter port? Yes No
 - C. Does the NPD attach securely or lock at a Y-site (e.g., for piggybacking)? Yes No
18. Is the NPD easy to dispose of in sharps containers of all sizes (if required)? Yes No
19. Does using the NPD instead of a conventional device result in only a modest (if any) increase in sharps container waste
 volume? (Answer "No" if the NPD will increase waste volume significantly.) Yes No

Overall

20. Would you recommend using this device? Yes No

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

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NPD Cost Calculation Worksheet*



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

*The figures obtained by completing this worksheet should be used for comparison purposes only. These figures will not reflect the actual costs and cost savings associated with implementing the alternative under consideration, and they cannot reflect the true value of using an NPD in terms of staff safety and the economic impact on NSIs that result in seroconversion.
 **Calculated by multiplying the estimated volume of one needle (0.23 cm³) by the number of needles per year (130,000) and then dividing by the volume of one sharps container (1 qt = 943 cm³). Note that this analysis assume 100% packing efficiency.

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GUIDELINES FOR THE USE OF SAFETY FEATURE EVALUATION SHEETS

Coordinators:

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

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

Provide visual instructions and demonstrate proper use of each device.

Review the instructions and rating system with each evaluator.

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

Evaluators:

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

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

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

NOTE: Certain assumptions have been made in the development of these forms based on information about currently available products. We recognize the likelihood that the ideal product may not exist. TDICT welcomes your comments on the use of these tools.

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San Francisco General Hospital
1001 Potrero Avenue
San Francisco, CA 94110



SAFETY FEATURE EVALUATION FORM

SAFETY SYRINGES

Date: _____ **Department:** _____ **Occupation:** _____

Product: _____ **Number of times used:** _____

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

agree.....disagree

DURING USE:

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

AFTER USE:

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

TRAINING:

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

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

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

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SAFETY FEATURE EVALUATION FORM

IV ACCESS DEVICES

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

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

agree.....disagree

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

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

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

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SAFETY FEATURE EVALUATION FORM

SHARPS DISPOSAL CONTAINERS

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

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

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

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

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

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SAFETY FEATURE EVALUATION FORM

IV CONNECTORS

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

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

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

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

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

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SAFETY FEATURE EVALUATION FORM

VACUUM TUBE BLOOD COLLECTION SYSTEMS

Date: _____ **Department:** _____ **Occupation:** _____

Product: _____ **Number of times used:** _____

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

agree.....disagree

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

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

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

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SAFETY FEATURE EVALUATION FORM

E. R. SHARPS DISPOSAL CONTAINERS

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

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

agree.....disagree

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

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

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

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SAFETY FEATURE EVALUATION FORM

SAFETY DENTAL SYRINGES

Date: _____ **Department:** _____ **Occupation:** _____

Product: _____ **Number of times used:** _____

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

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

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SAFETY FEATURE EVALUATION FORM

HOME USE SHARPS DISPOSAL CONTAINER

Date: _____ **Department:** _____ **Occupation:** _____

Product: _____ **Number of times used:** _____

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

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

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

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

Source: Reprinted with permission of Training for Development of Innovative Control Technology Project
June Fisher, M.D.
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APPENDIX C – WEB SITE RESOURCE LIST

Effective Engineering Controls CDC Guidelines and Recommendations Vaccine Safety

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

EFFECTIVE ENGINEERING CONTROLS

ECRI

Available: <http://healthcare.ecri.org/site/whatsnew/press.releases/980724hdneedle.html>

ECRI, designated as an Evidence-based Practice Center by the Agency for Health Care Policy and Research, is a nonprofit international health services research organization. This web site discusses the June 1998 issue of ECRI's Health Devices, which evaluated 19 needlestick-prevention devices, and provides information on how to obtain this document.

Food and Drug Administration (FDA) Safety Alert: Needlestick and Other Risks from Hypodermic Needles on Secondary IV Administration Sets – Piggyback and Intermittent IV

Available: <http://www.fda.gov/cdrh/safety.html>

Warns of the risk of needlestick injuries from the use of hypodermic needles as a connection between two pieces of intravenous (IV) equipment. Describes characteristics of devices which have the potential to decrease the risk of needlestick injuries.

International Health Care Worker Safety Center, University of Virginia

Available: <http://www.people.virginia.edu/~epinet/products.html>

Features a list of safety devices with manufacturers and specific product names.

National Institute for Occupational Safety and Health (NIOSH) Sharps Disposal Containers

Available: <http://www.cdc.gov/niosh/sharps1.html>

Features information on selecting, evaluating, and using sharps disposal containers.

Occupational Safety and Health Administration (OSHA) Glass Capillary Tubes: Joint Safety Advisory About Potential Risks

Available: http://www.osha-slc.gov/OshDoc/Interp_data/I19990222.html

Describes safer alternatives to conventional glass capillary tubes.

Occupational Safety and Health Administration (OSHA) Needlestick Injuries

Available: <http://www.osha-slc.gov/SLTC/needlestick/index.html>

Features recent news, recognition, evaluation, controls, compliance, and links to information on effective engineering controls.

Safety Sharp Device Contracts

Available: <http://www.va.gov/vasafety/osh-issues/needlesafety/safetysharpcontracts.htm>

Features safety sharp devices on contract with the US Department of Veterans Affairs (VA).

SHARPS Injury Control Program

Available: <http://www.ohb.org/sharps.htm>

Established by Senate Bill 2005 to study sharps injuries in hospitals, skilled nursing facilities, and home health agencies in California. Features a Beta version of Safety Enhanced Device Database Listing by Manufacturer.

Training for Development of Innovative Control Technologies (TDICT) Project

Available: <http://www.tdict.org/criteria.html>

Features “Safety Feature Evaluation Forms” for specific devices.

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

CDC Prevention Guidelines Database

Available: <http://aepo-xdv-www.epo.cdc.gov/wonder/PrevGuid/PrevGuid.htm>

Provides access to the CDC Prevention Guidelines Database, which is a compilation of all of the official guidelines and recommendations published by the CDC for the prevention of diseases, disabilities, and injuries. Information on how to find a specific CDC Prevention Guideline.

Morbidity and Mortality Weekly Report (MMWR)

Available: <http://www2.cdc.gov/mmwr/mmwr.html>

Provides access to the MMWR, a series which is prepared by the CDC. Contains comprehensive information on policy statements for prevention and treatment that are within the CDC’s scope of responsibility, for example, recommendations from the Advisory Committee on Immunization Practices (ACIP).

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

Guideline for infection control in health care personnel, 1998.

Available: <http://www.cdc.gov/ncidod/hip/GUIDE/InfectControl98.pdf>

Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease. Publication date 10/16/1998.

Available: <http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00055154.htm>

Public Health Service Guidelines for the Management of Health-Care Worker Exposures to HIV and Recommendations for Postexposure Prophylaxis. Publication date 05/15/1998.

Available: <http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00052722.htm>

Appendix – First-Line Drugs for HIV Postexposure Prophylaxis (PEP). Publication date 05/15/1998.

Available: <http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00052801.htm>

Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC).

Publication date 12/26/1997.

(Provides recommendations for Hepatitis B.)

Available: <http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00050577.htm>

VACCINE SAFETY

Centers for Disease Control and Prevention (CDC)

Available: <http://www.cdc.gov/nip/vacsafe/>

The National Immunization Program (NIP) of the CDC features information on vaccine safety.

Food and Drug Administration (FDA)

Available: http://www.fda.gov/fdac/features/095_vacc.html and

<http://www.fda.gov/cber/vaers/vaers.htm>

The first site features information on how the FDA ensures vaccine safety. The second site features information on the Vaccine Adverse Event Reporting System (VAERS), a cooperative program for vaccine safety of the FDA and CDC.

Immunization Action Coalition (IAC)

Available: <http://www.immunize.org/>

The IAC is a nonprofit organization working to increase immunization rates and prevent disease. Features Vaccine Information Statements, free print materials, and other hepatitis and immunization sites.

Infectious Diseases Society of America (IDSA)

Available: <http://www.idsociety.org/vaccine/index.html>

The Vaccine Initiative is a project of the IDSA and the Pediatric Infectious Diseases Society. Features information on vaccination and vaccination-related issues.

Institute for Vaccine Safety, Johns Hopkins School of Public Health

Available: <http://www.vaccinesafety.edu/>

The purpose of the Institute is to obtain and distribute information on the safety of recommended immunizations. This is a new web site, which is not currently fully operational. Its official launch will occur later in 1999.

National Institutes of Health (NIH)

Available: <http://www.niaid.nih.gov/publications/vaccine/undvacc.htm>

Features a 40 page brochure "Understanding Vaccines."

World Health Organization (WHO)

Available: <http://www.who.int/gpv-safety/>

Features a vaccine safety home page which offers links to vaccine safety-related information.

APPENDIX D – MODEL EXPOSURE CONTROL PLAN

The Model Exposure Control Plan is intended to serve as an employer guide to the OSHA Bloodborne Pathogens standard. A central component of the requirements of the standard is the development of an exposure control plan (ECP).

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

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

POLICY

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

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

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

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

PROGRAM ADMINISTRATION

- * *(Name of responsible person or department)* is (are) responsible for the implementation of the ECP. *(Name of responsible person or department)* will maintain, review, and update the ECP at least annually, and whenever necessary to include new or modified tasks and procedures. Contact location/phone number: _____.
- * Those employees who are determined to have occupational exposure to blood or other potentially infectious materials (OPIM) must comply with the procedures and work practices outlined in this ECP.
- * *(Name of responsible person or department)* will maintain and provide all necessary personal protective equipment (PPE), engineering controls (e.g., sharps containers), labels, and red bags as required by the standard. *(Name of responsible person or department)* will ensure that adequate supplies of the aforementioned equipment are available in the appropriate sizes. Contact location/phone number: _____.
- * *(Name of responsible person or department)* will be responsible for ensuring that all medical actions required are performed and that appropriate employee health and OSHA records are maintained. Contact location/phone number: _____.
- * *(Name of responsible person or department)* will be responsible for training, documentation of training, and making the written ECP available to employees, OSHA, and NIOSH representatives. Contact location/phone number: _____.

EMPLOYEE EXPOSURE DETERMINATION

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

<u>JOB TITLE</u>	<u>DEPARTMENT/LOCATION</u>
<i>(Example: Phlebotomists)</i>	<i>(Clinical Lab)</i>
_____	_____
_____	_____

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

<u>JOB TITLE</u>	<u>DEPARTMENT/LOCATION</u>	<u>TASK/PROCEDURE</u>
<i>(Example: Housekeeper)</i>	<i>(Environmental Services)</i>	<i>(Handling Regulated Waste)</i>
_____	_____	_____

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

METHODS OF IMPLEMENTATION AND CONTROL

Universal Precautions

All employees will utilize universal precautions.

Exposure Control Plan

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

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

Engineering Controls and Work Practices

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

- * (For example: glass capillary tubes in the clinical laboratory, outpatient clinics, and pediatric units)
- * _____
- * _____

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

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

We evaluate need procedures or new products by (Describe the process) _____

The following staff are involved in this process: (Describe how employees will be involved)

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

Personal Protective Equipment (PPE)

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

The types of PPE available to employees are as follows:

(Ex., gloves, eye protection, etc.)

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

All employees using PPE must observe the following precautions:

- * Wash hands immediately or as soon as feasible after removal of gloves or other PPE.
- * Remove PPE after it becomes contaminated, and before leaving the work area.
- * Used PPE may be disposed of in _____ (List appropriate containers for storage, laundering, decontamination, or disposal.)
- * Wear appropriate gloves when it can be reasonably anticipated that there may be hand contact with blood or OPIM, and when handling or touching contaminated items or surfaces; replace gloves if torn, punctured, contaminated, or if their ability to function as a barrier is compromised.
- * Utility gloves may be decontaminated for reuse if their integrity is not compromised; discard utility gloves if they show signs of cracking, peeling, tearing, puncturing, or deterioration.
- * Never wash or decontaminate disposable gloves for reuse.
- * Wear appropriate face and eye protection when splashes, sprays, spatters, or droplets of blood or OPIM pose a hazard to the eye, nose, or mouth.
- * Remove immediately or as soon as feasible any garment contaminated by blood or OPIM, in such a way as to avoid contact with the outer surface.

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

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

Housekeeping

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

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

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

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

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

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

Laundry

The following contaminated articles will be laundered by this company:

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

The following laundering requirements must be met:

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

Labels

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

EQUIPMENT TO BE LABELED
(e.g., specimens, contaminated laundry, etc.)

LABEL TYPE (size, color, etc.)
(red bag, biohazard label, etc.)

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

HEPATITIS B VACCINATION

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

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

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

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

Following hepatitis B vaccinations, the health care professional's Written Opinion will be limited to whether the employee requires the hepatitis vaccine, and whether the vaccine was administered.

POST-EXPOSURE EVALUATION AND FOLLOW-UP

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

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

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

ADMINISTRATION OF POST-EXPOSURE EVALUATION AND FOLLOW-UP

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

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

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

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

PROCEDURES FOR EVALUATING THE CIRCUMSTANCES SURROUNDING AN EXPOSURE INCIDENT

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

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

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

EMPLOYEE TRAINING

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

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

- * a copy and explanation of the standard
- * an explanation of our ECP and how to obtain a copy
- * an explanation of methods to recognize tasks and other activities that may involve exposure to blood and OPIM, including what constitutes an exposure incident
- * an explanation of the use and limitations of engineering controls, work practices, and PPE
- * an explanation of the types, uses, location, removal, handling, decontamination, and disposal of PPE
- * an explanation of the basis for PPE selection
- * information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine will be offered free of charge
- * information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM
- * an explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available

- * information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident
- * an explanation of the signs and labels and/or color coding required by the standard and used at this facility
- * an opportunity for interactive questions and answers with the person conducting the training session.

Training materials for this facility are available at _____.

RECORDKEEPING

Training Records

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

The training records include:

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

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

Medical Records

Medical records are maintained for each employee with occupational exposure in accordance with OAR 437-002-1910.1020, "Access to Employee Exposure and Medical Records."

(Name of Responsible person or department) is responsible for maintenance of the required medical records. These **confidential** records are kept at (List location) for at least the **duration of employment plus 30 years**.

Employee medical records are provided upon request of the employee or to anyone having written consent of the employee within 15 working days. Such requests should be sent to (Name of responsible person or department and address).

OSHA Recordkeeping

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

HEPATITIS B VACCINE DECLINATION (MANDATORY)

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

Signed: _____ Date: _____
(Employee Name)

APPENDIX E

Centers for Disease Control *Morbidity and Mortality Weekly Report*:
“Updated U.S. Public Health Service Guidelines for the
Management of Occupational Exposures to HBV, HCV, and HIV and
Recommendations for Postexposure Prophylaxis.”
Vol. 50, No. RR11;1 06/29/2001

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm>

or

<http://www.cdc.gov/mmwr/PDF/RR/RR5011.pdf>

APPENDIX H

For OAR 847, contact
Oregon Board of Medical Examiners
1500 SW First Avenue, Suite 620
Portland, Oregon 97201
(877) 254-6263 (toll-free in Oregon)
(503) 229-5770
FAX (503) 229-6543
<http://www.bme.state.or.us/>

For OAR 851, contact
Oregon State Board of Nursing
800 NE Oregon Street, Suite 465
Portland, Oregon 97232-2162
Telephone: (503) 731-4745
FAX: (503) 731-4755
<http://www.osbn.state.or.us/>

For ORS 677, contact
Oregon State Library
250 Winter Street NE
Salem, Oregon 97310
(503) 378-4277
or visit
<http://www.leg.state.or.us/ors/677.html>

INDEX

1904	1, 5, 6, D-9
1910.1020	13, 63, 64, 66
1910.1200	66
1910.134	66
aerosols	25
agriculture	11
annually	4, 13-15, 47, 60, D-2, D-3
antibody testing	51, D-6
ASTM	29
biohazard	26, 42, 59, 60, B-12, D-5, D-6
bleach	35, 36
capillary tubes	2, 12, 16, 17, 37, 55, C-1, D-3
CDC	4, 11, 19, 35, 46, 49, 50, 54, 58, C-1-3
closable	24, 39, 42, B-10, D-5
collateral duty	11, 51
color-coded	39, 42-45, D-5
construction	11, 39, 42
container	2, 16, 20, 23-27, 36-44, 47, 59, 60, B-1-3, B-7, B-10, B-12, C-1-6
contaminated	4-6, 10, 13, 14, 16, 17, 20, 22-28, 32, 33, 35-39, 41, 43-45, 48, 64, 66, D-4-6
correctional officers	10
custodial	10
declination	50, 53, D-6, D-10
decontamination	27, 33-38, 43, 60, D-4, D-8
dentists	10, 26
device	2, 4, 12, 15-23, 25, 28-30, 46, 47, 56, 61, 65, A-2, B-1-6, B-8, B-9, B-11, C-1, C-2, D-8
disinfectants	27, 35, 36
disposable	15, 24, 32, 33, 37, 39, D-4
DOT	59
emergency	3, 5, 10, 12, 18, 21, 22, 25, 26, 29, 31, 51, 61, 62, 66, 67, B-10, D-8
engineering controls	4, 7, 12, 15-20, 46, 56, 61, C-1-3, D-8
environmental surfaces	24, 34-36
EPA	35, 39, 43
exposure control plan	4, 5, 8, 12-15, 17, 20, 24, 43, 56, 62, 65, D-1, D-3
exposure incident	5, 6, 12, 14, 15, 17, 18, 21, 48, 51, 52, 54-58, 62-65, D-7-9
eye protection	16, 25, 34, D-4
FDA	2, 17, 30, C-1, C-3
FIRM	1, 6-8
first aid	5, 10-12, 51, 52, D-7
follow-up	7, 8, 12, 48, 50-52, 54, 55, 57, 58, D-1, D-7-9

funeral homes	10
gloves	23, 26, 30, 32, 33, 43, 44, B-5, B-11, D-4, D-8
Good Samaritan	12, 54
gowns	28, 34, 44
hand cream	24
handwashing	7, 22-24, 32, 47
HBV	3, 9-12, 16, 24, 35, 45, 49, 54, 57, 59, 61, 66, D-7, D-10, E-1
hepatitis	2-4, 7, 8, 11, 35, 48-54, 58, 61, C-2, C-3, D-1, D-6-8, D-10
HIV	1, 3, 9-12, 16, 35, 45, 49, 54, 57-59, 61, 66, C-2, D-7, E-1
home health services	7
housekeepers	9, 18
housekeeping	5, 7, 8, 16, 34, 35, 38, D-1, D-5
human blood	11, 16, 54
hypodermic	2, C-1
incident report	5, 54
incineration	60
IV	2, 17, 19, B-1, B-2, B-6, B-8, C-1
kidney stones	26
labeling	25-27, 30, 43, 59, 60, D-6
laboratory	10, 22, 25, 26, 28, 30-32, 34, 36, 45, 46, 50, 55, 60, 63, D-3
lasers	25
latex	30, 32
laundering	31, D-4, D-5
laundries	9, 41, 43
laundry	13, 41, 43-45, 56, 59, D-5, D-6
medical equipment	10
medical records	1, 54, 63, 64, 66, D-7, D-9
medical waste	38, 39
microsurgery	34
mucous membranes	25, 28, 33, 46
multi-employer	6-8
needle sheath	40
needleless	12, 16, 17, 19
needlestick	2-4, 6, 12, 15, 18, 19, 40, 41, 49, 55, 56, 64, B-1, B-2, C-1
NIOSH	2, 30, 40, 41, C-1, D-2
occupational exposure	1-5, 9, 11-14, 16, 27, 32, 48-51, 54, 60, D-1-3, D-8-10, E-1
OPIM	3, 5, 6, 10-12, 16, 18, 22-28, 31, 33-35, 37-39, 43, 44, 48, 51, 52, 59, 60, D-2, D-4, D-6, D-8
OSHA 200	19

per diem employees	60, D-2
phlebotomy	19, 33, 37
physicians	8, 9, 49, 63, A-3, A-4
plasma centers	9
pneumatic tube	26
post-exposure	4, 7, 8, 48, 51, 52, 54, 55, 57, 58, D-1, D-7, D-9
PPE	23, 27-32, 34, 47, 53, 55, D-4, D-5, D-8
prescreening	53
prophylaxis	1, 3, 4, 49, 51, 52, 54, 55, 58, C-2, E-1
recapping	20, 23, 24, 55, B-5, B-11
Record Summary	2, 19, 61
recordkeeping	5-8, 63-65, A-3, D-1, D-6, D-9
regulated waste	7, 10, 12, 16, 37-39, 42, 43, 46, 59, 60, D-2, D-5, D-6
research laboratories	45
resuscitator devices	28
retraining	60
reusable sharps	24, 38, 42
RFI	2, 4
safer medical devices	4, 15, 17
scrubs	28
sharps containers	16, 20, 23, 39-42, B-2, B-3, D-2
sharps injury log	5, 19, 64, 65
solicit	4, 20, 21
spattering	25
specimen	25-27, 37, 59, D-6
standard precautions	16
sterilize	34
surfaces	24-26, 32-37, 43, B-7, D-4
syphilis	4, 11, 61
teeth	26
towelettes	22
training	3-5, 7, 8, 12, 14, 18, 19, 23, 25, 29, 32, 33, 38, 41, 42, 44, 48, 50, 52, 53, 55, 56, 59-64, A-3, A-4, B-1, B-2, B-4-12, C-2, D-1-4, D-6, D-8, D-9
U.S. Public Health Service	3, 49, 54, E-1
vaccination	4, 7, 8, 12, 14, 22, 48-53, 58, 63, C-3, D-1, D-6, D-7, D-10
vaccine	12, 48-51, 53, 58, A-4, C-1, C-3, D-6, D-8, D-10
volunteer	33, A-1
wicking	32
work areas	32, 46, 61
work practices	5, 7, 16, 18, 20, 27, 41, 46, 56, 61, D-2, D-3, D-8
written opinion	58, D-6, D-7