State of Alaska Department of Labor Division of Labor Standards and Safety

AKOSH Program Directive 92-5

Date:

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To:

All AKOSH Staff

From:

Richard Arab, Deputy Director

Subject:

Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens

Standard, Subchapter 17.

This AKOSH Program Directive (PD) establishes policies and provides clarification to ensure uniform inspection procedures are followed when conducting inspections to enforce the Occupational Exposure to Bloodborne Pathogens Standard.

- Cancellation. This PD cancels PD 90-9, "Enforcement Procedures for Occupational В. Exposure to Hepatitis B and Aids" dated October 8, 1990.
- 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. OSHA published a proposed rule
 - 1. OSHA also concluded that the risk of contacting the hepatitis B virus (HBV) and human immunodeficiency virus (AIDS) among members of various occupations within the health care sector required an immediate response and therefore issued an OSHA Instruction. AKOSH complied with the OSHA Instruction by issuing PD 90-9 on October 8, 1990.
 - 2. On December 6, 1991, OSHA 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 infectious materials (OPIM) because they contain bloodborne pathogens. These pathogens include HBV which causes Hepatitis B, a serious liver disease, and HIV, which causes Acquired Immunodeficiency Syndrome (AIDS). The agency further concludes that this hazard can be minimized or eliminated using a combination of engineering and work practice controls, personal protective clothing and equipment, training, and medical surveillance, hepatitis B vaccination, signs and labels, and other provisions.

D. References.

- 1. Compliance Manual
- 2. OSHA Instruction ADM 1-1.12B, December 29, 1989, the Integrated Management Information System (IMIS) Forms Manual.
- 3. Centers for Disease Control Morbidity and Mortality Weekly Report: "Recommendations for Prevention of HIV Transmission in Health Care Settings." August 1987; Vol. 36, No. S-2.
- 4. Centers for Disease Control Morbidity and Mortality Weekly Report: 1988 Agent Summary Statement for Human Immunodeficiency Virus and Report on Laboratory-Acquired Infection with Human Immunodeficiency Virus. April 1, 1988; Vol. 37, No. S-4.
- 5. Centers for Disease Control Morbidity and Mortality Weekly Report: "Guidelines for Prevention of Transmission of HIV and HBV to Health Care and Public Safety Workers." June 23, 1989; Vol. 38, No. S-6.
- 6. Centers for Disease Control Morbidity and Mortality Weekly Report: "Update: Universal Precautions for the Prevention of Transmission of HIV, HBV and Other Bloodborne Pathogens in Health Care Settings." June 24, 1988; Vol. 37, No. 24.
- 7. Centers for Disease Control Morbidity and Mortality Weekly Report: "Public Health Service Statement on Management of Occupational Exposure to Human Immunodeficiency Virus, Including Consideration Regarding Zidovudine Postexposure Use." January 1990; Vol. 139, No. RR2. (See Appendix A)
- 8. Centers for Disease Control Morbidity and Mortality Weekly Report: "Protection Against Viral Hepatitis, Recommendations of the Immunization Practices Advisory Committee." February 1990; Vol. 39, No. S-2. (See Appendix B.)
- 9. U.S. Department of Health and Human Services: "Biosafety in Microbiological and Biomedical Laboratories," Publication No. (NIH) 88-8395, May 1988.

E. <u>Inspection Scheduling</u>, and Scope.

1. Inspection scheduling shall be conducted in accordance with the procedures outlined in the Compliance Manual, Chapter II, as modified in paragraphs 2., 3., and 4. below.

- All inspections, programmed or unprogrammed, shall 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) shall be performed when:
 - a. The exposure control plan or employee interviews indicate deficiencies in complying with OSHA requirements, as set forth in 29 CFR 1910.1030 or this instruction.
 - 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.
- 4. Regional Offices may develop and implement local emphasis programs as a supplement to complaint-generated inspection activities. (See the Compliance Manual, Chapter II).
- F. General Inspection Procedures. The procedures given in the Compliance Manual, Chapter III, shall be followed except as modified in the following sections:
 - 1. Where appropriate, the facility administrator, infection control director or occupational health nurse, "in-service" education (i.e., training) director, and head of central services and/or housekeeping shall be included in the opening conference or interviewed early in the inspection.
 - If the facility maintains a file of "incident reports" or a first aid log on injuries (e.g., needlesticks), this shall not be reviewed as it may contain injuries not included on the DOSH 200 log.
 - 3. Compliance officers shall take necessary precautions to avoid direct contact with body fluids and shall 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 shall establish the existence of hazards and adequacy of work practices through employee interviews and shall observe them at a safe distance.
 - 4. On occasions when entry into potentially hazardous areas are judged necessary, the compliance officer shall be properly equipped as required by the facility as

- well as by his/her own professional judgment, after consultation with the supervisor.
- 5. Compliance officers shall 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 shall be respected. Photographs of patients normally will not be necessary and in no event shall identifiable photographs be taken without their consent.
- G. Recording of Exposure Incidents. For DOSH 200 recordkeeping purposes, an occupational bloodborne pathogens exposure incident (e.g., needlestick, laceration, or splash) shall be classified as an injury since it is usually the result of an instantaneous event or exposure. It shall be recorded if it meets one of the following recordibility requirements:
 - The incident is a work-related injury that involves loss of consciousness, transfer to another job, or restriction of work or motion.
 - 2. The incident results in the recommendation of medical treatment beyond first aid (e.g., gamma globulin, hepatitis B immune globulin, hepatitis B vaccine, or zidovudine) regardless of dosage.
 - the incident results in a diagnosis of seroconversion. The serological status of the employee shall not be recorded on the DOSH 200. If a case of seroconversion is known, it shall be recorded on the DOSH 200 as an injury (e.g., "needlestick" rather than "seroconversion") in the following manner:
 - a. If the date of the event or exposure is known, the original injury shall be recorded with the date of the event or exposure in column B.
 - b. If there are multiple events or exposures, the most recent injury shall be recorded with the date that seroconversion is determined in column B.
- H. <u>Multi-employer Worksite.</u> The following citation guidelines apply in multi-employer worksites (See Compliance Manual, Chapter V, F.):
 - 1. Employers shall be cited for violations of the standard to which their own employees are exposed.
 - They shall also be cited for violations to which employees of other employers on their premises are exposed to the extent that they control the hazard. For example, they shall be cited for not providing personal protective equipment to unprotected employees of other employers on their premises.

- 3. Physicians who are members of professional corporations are generally considered to be employees of that corporation. Therefore, the corporation may be cited for violations affecting those physicians, such as failure to provide the hepatitis B vaccine. Also, the hospitals where they work may be cited for violations to which they are exposed.
- 4. No citation shall be issued where the only persons exposed are physicians who are sole practioners or partners, and thus not employees under the Occupational Safety and Health Act.
- I. <u>Federal Agency Facilities.</u> Agencies of the State Government are covered by this instruction.
- J. <u>Clarification of the Standard on Occupational Exposure to Bloodborne Pathogens.</u>
 <u>Subchapter 17.</u> The guidance that follows relates to specific provisions of Subchapter 17 and is provided to assist compliance officers in conducting inspections where the standard may be applicable.

NOTE: Compliance officers shall refer to OSHA's 29 CFR 1910.1030 regulatory text and preamble for further information.

- 1. Scope and Application 17.001(a). This section defines the range of employees covered by the standard.
 - a. 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.
 - b. 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 off 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 practioners, and other health care employees in clinics and physicians' offices;
 - Employees of clinical and diagnostic laboratories;
 - Housekeepers in health care 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;
- Medical equipment service and repair personnel;
- Emergency medical technicians, paramedics, and other emergency medical service providers; and
- Firefighters, law enforcement personnel, and correctional officers (employees in the private sector, the Federal Government, or a State or local government in a State that has an OSHA-approved State plan).

INSPECTION GUIDELINES. The scope section 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. Definitions of particular importance that the compliance officer must clearly understand before beginning an inspection are: Blood, Bloodborne Pathogens, Contaminated, Exposure Incident, Occupational Exposure, Other Potentially Infectious Materials, and Regulated Waste. These will be of use in determining if an employee in either a health care or a non-health care setting is covered by this standard.

NOTES:

- Part-time, temporary, and health care workers known as "per diem" employees are covered by this standard.
- If an employee is trained in first aid and designated by the employer as responsible for rendering medical assistance as part of his/her job duties, that employee is covered by the standard.
- 3. Employees in the construction and maritime industries who have occupational exposure to blood or OPIM are covered by the standard.
- 2. Definitions 17.001(b). The following provides further clarifications of some definitions found in this section:
 - a. "Blood": The term "human blood components" includes plasma, platelets, and serosanguineous fluids (e.g., exudates from wounds).
 - b. "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.
 - "Exposure Incident": "Non-intact skin" includes skin with dermatitis, hang-nails, cuts, abrasions, chafing, etc.
 - d. "Occupational Exposure": The term "reasonably anticipated" includes the potential for exposure as well as actual exposure. Lack of history of blood exposures among first aid personnel of a particular manufacturing site, for instance, does not preclude coverage.

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 encourages employers to offer follow-up procedures in such cases.

- e. "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.
- f. "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.
- g. "Regulated Waste": This definition is covered in detail at M.4.d.(3) of this instruction.
- 3. Exposure Control Plan 17.001(c). This section 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 section (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.

INSPECTION AND CITATION GUIDELINES. The compliance officer shall 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 shall determine whether the plan is reviewed annually and updated to reflect in occupational exposure as required in section (c)(1)(iv).
- The content of the exposure control plan shall be reviewed for at least the following elements:
- Sections (c)(1)(B)(i) and (c)(2)(A). The exposure determination requires employers to identify and document:

- (1) Those job classifications in which all employees have occupational exposure, and
- (2) Those job classifications in which some employees have occupational exposure.
 - (a) 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.
 - (b) 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.
- (3) The exposure determination shall have been made without taking into consideration the use of personal protective clothing or equipment.
- b. Section (c)(1)(B)(ii). The schedule and method of implementation for sections (d)-(h) in a manner appropriate to the circumstances of the particular workplace must be addressed in the exposure control plan. An annotated copy of the final standard may be adequate for small facilities. An employer may state on a copy of the final standard when and how he/she will implement the provisions of the standard. Larger facilities could develop a broad facility-wide program incorporating provisions from the standard that apply to their establishments.
- c. Section (c)(1)(B)(iii). The exposure control plan shall include the procedure for evaluating the circumstances surrounding exposure incidents, including an evaluation of the policies and "failures of control" at the time of the exposure incident. Also to be considered are the engineering controls and work practices in place, as well as protective equipment or clothing used, at the time of the exposure incident.
- d. Section (c)(1)(C). The location of the plan may be adapted to the circumstances of a particular workplace provided that the employee can access a copy at the workplace, during the workshift (e.g., if the plan is maintained solely on computer, employees must be trained to operate the computer). In accordance with 29 CFR 1910.20, a hard copy of the

exposure control plan shall be made available to the employee within 15 working days of the employee's request.

- e. Sections (c)(2)(A)(i) and (ii). As previously discussed in the exposure control plan, the employer is required to list the job classifications covered by the plan. The list is part of the exposure determination. If a job classification, task, or procedure with 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 (i.e., vaccinations, training, etc.), it is to be considered an other-than-serious violation.
- 4. Methods of Compliance Subchapter 17.001. Section (d) sets forth the methods by which employers shall 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.
 - a. Universal Precautions (d)(1). Universal precautions is 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.
 - (1) Another method of infection control is called Body Substance Isolation (BSI). This method defines all body fluids and substances as infectious. BSI incorporates not only the fluids and materials covered by this standard but expands coverage to include all body fluids and substances.
 - (2) BSI is an acceptable alternative to universal precautions provided facilities utilizing BSI 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.

J.4.b. Engineering Controls and Work Practices - (d)(2). This section requires the employer to institute engineering and work practice controls as the primary means of eliminating or minimizing employee exposure.

In those circumstances in which occupational exposure remains after institution of engineering and work practice controls, employers must provide, and ensure that employees use, personal protective equipment as additional protection.

INSPECTION GUIDELINES. The compliance officer shall determine through interviews or observation of work involving the use of needles whether proper engineering controls and work practices, such as immediate disposal of used needles into a sharps container, are used.

Most preferable is the use of devices which offer an alternative to needles being used to perform the procedure. Examples of such devices include stopcocks (on-off switch), needle-protected systems or needleless systems which can be used in place of open needles to connect intravenous lines. Other devices which are integral to the syringe, such as self-sheathing needles, allow both hands to remain behind the needle and require very little manipulation to isolate the needle safely.

When a health care worker must recap, such as during intermittent administration of various drugs during certain procedures, and when it is not feasible to use self-sheathing needle syringes, the employee must use some type of device that protects the hand or allows a safe one-handed recapping method. A proper one-handed scoop method is a work practice which may also be used in these circumstances. (See J.4.b.(3)(b) of this instruction on section (d)(2)(G) for details.)

The compliance officer shall evaluate the work practices used by health care providers to determine that they ensure the effectiveness of engineering controls. For example, some devices provide a fixed barrier between the hands and the needle after use. While some finger/hand shields available on the market offer full protection of the hand holding the needle sheath from accidental puncture, some do not. They may leave much of the hand area uncovered and are not considered acceptable protection for use in a two-handed recapping procedure. Both the shield and the cap must be constructed so that an employee is not exposed to puncture from a needle protruding from the side or end of the cap.

The compliance officer should note that sharps may include more than the traditional needles or scalpels. They also include anything that might produce a puncture wound which would expose employees to blood or OPIM (e.g., the ends of contaminated orthodontia wires or broken glass).

CITATION GUIDELINES. Section (d)(2) shall be cited for failure to use engineering/work practice controls. A citation for the appropriate section of (g)(2)(G) shall be grouped with it, if the compliance officer determines that inadequate training caused the failure to use such controls.

- Citations shall be issued if engineering or work practice controls are not used to eliminate or minimize employee exposure.
- While employers do not automatically have to institute the most sophisticated engineering controls (e.g., needleless IV connectors, self-sheathing needles), it is the employer's responsibility to evaluate the effectiveness of existing controls and to review the feasibility of instituting more advanced engineering controls.
- M.4.b.(1) Section (d)(2)(B). This section 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, section (d)(2)(B) shall be cited.

- If there is a check system, but the compliance officer finds, for example, that the biosafety cabinet is not functional, filters are overloaded (in research laboratories or production facilities), disposal containers are overfilled, or a hematron splash shield is broken or missing, section (d)(2)(B) shall be cited if an effective monitoring system would have uncovered the deficiency.
 - Additionally, if there is unprotected employee exposure, section (d)(2)(A) shall be cited for failure to use personal protective equipment after institution of engineering controls.

- M.4.b.(2) Sections (d)(2)((C) through (d)(2)(F). These sections 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) Section (d)(2)(D). This section 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. Antiseptic hand cleaner, in conjunction with clean cloth or paper towels, or antiseptic towellets are examples of alternative methods.
 - When these types of alternatives are used, employees shall 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), firefighters, police, and mobile blood collection personnel who are exposed to blood or OPIM with no means of washing up with running water.
 - J.4.b.(2)(b) Section (d)(2)(E). This section 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, section (d)(2)(C) shall be cited unless the employer demonstrates that handwashing facilities are not feasible. If infeasibility is demonstrated, section (d)(2)((D) shall be cited when the required alternatives are not used. If handwashing is not performed by the employees after exposures or removal of gloves, sections (d)(2)((D), (E), or (F) shall be cited. This may be grouped with the pertinent training sections 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; i.e., no further than what would be considered reasonable for location of restrooms.
- If an employee must thread his/her way through doorways and/or stairs to wash with appropriate frequency so that there is a reasonable chance of resultant environmental surface contamination, a violation of section (d)(2)(C) exists.
- J.4.b.(3) Section (d)(2)(G). Shearing or breaking of contaminated needles is completely prohibited by this section. Bending, recapping, or removing contaminated needles by hand is prohibited as a general practice. However, certain circumstances may exist in which these actions are necessary; e.g., when performing blood gas analyses, inoculating a blood culture bottle, administering incremental doses of a medication such as an anesthetic to the same patient, or removing the needle from a phlebotomy collection apparatus (e.g., vacutainer).
 - (a) In these procedures, if the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical procedure, recapping is allowed by some method other than the traditional two-handed procedure; e.g., by means of resheathing instruments or forceps.
 - (b) The use of the properly performed one-hand scoop method (in which the hand holding the sharp is used to scoop up the cap from a flat surface) for recapping is a recognized and acceptable method; however, the scoop method must be performed in a safe manner and must be limited to situations in which recapping is necessary.
 - (c) An acceptable means of demonstrating that no alternative is feasible would be a written justification included as part of the exposure control plan and stating that the particular medical procedure requires, for example, the bending of the needle and the use of forceps to accomplish this.
 - (4) Section (d)(2)(M). 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 (See I.4.d.(3)(b) of this PD on section (d)(4)(C)(i)a.), 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. (See I.4.d.(2)(e) of this PD on section (d)(4)(B)(v) for the manner in which these reusable sharps are to be stored and processed, and I.4.d.(3)(g) on section (d)(4)(C)(i)d. on the requirements for cleaning and processing of these reusable containers.)

- J.4.b.(5) Sections (d)(2)(I) and (J). These sections are intended primarily to eliminate or minimize indirect transmission of HBV from contaminated environmental surfaces.
 - (a) 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 section (d)(2)(E) and (d)(2)(F) shall be followed.
 - (b) 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 section 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 sections (d)(2)(D) through (j) shall be cited in conjunction with the appropriate section of (g)(2) if inadequate training exists.

- J.4.b.(6) Section (d)(2)(K). The intent of this section 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.
 - (a) Surgical power tools, lasers, and electrocautery devices may generate aerosols. However, OSHA does not believe that the data currently support the mandatory use of respiratory protection for exposure to aerosols, not is there an effective engineering control to address aerosol exposure or approved respirator and filter cartridges.
 - (b) Particularly hazardous is the use of sprays, brushes, and high pressure in equipment lines.
 - (c) Typically, spattering or generation of droplets would necessitate use of eye protection and mask or a face shield. (See J.4.c.(8) of this instruction on section (d)(3)(J).

CITATION GUIDELINES. A citation shall normally be issued for section (d)(2) - (K) if cleaning procedures unnecessarily cause splashing, spraying, spattering, and generation of droplets of blood or OPIM.

- J.4.b.(7) Section (d)(2)(L). While this section prohibits mouth pippetting/suctioning, the agency allows a recognized emergency care method of clearing an infant's airways called "DeLee suctioning" in the following situation:
 - (a) In an emergency,
 - (b) When no other method is available; and
 - (c) Provided that a trap which prevents suctioned fluid from reaching the employee's mouth is inserted in-line between the infant and the employee.

- (8) Sections (d)(2)(M) (d)(2)(M)(iii). These sections 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.
 - (a) The labeling exemption listed in section (d)(2)(M)(i) 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 would be required.
- J.4.b.(8)(b) Extracted teeth are subject to the containerization and labeling provisions of the standard.
 - (c) 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 shall be trained to regard the contents as biohazardous in nature. Employees who open biohazard carriers shall wear gloves in accordance

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with section (d)(3) when removing specimens from the tube system carrier, as it may be contaminated with leakage. They shall be trained in decontamination of the carrier and, if need be, the tube system in accordance with section (g)(2).

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.

J.4.b.(9) Section (d)(2)(N). 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, shall be accomplished.

INSPECTION AND CITATION GUIDELINES. The compliance officer shall ensure that the employer's program makes provision for the required equipment labels. A label shall 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.

- (a) Before citing (d)(2)(N), the compliance officer shall document that equipment is being shipped and/or serviced.
- (b) Compliance officers shall observe or document work practices used when employees are decontaminating equipment. (See M.4.b.(6) of this instruction on section (d)(2)(K).)

- (c) 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. (See I.4.d. -(2)(e) of this instruction for details.)
- J.4.c. Personal Protective Equipment (d)(3). PPE must be used 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, unless engineering controls and work practices have eliminated occupational exposure.
 - (1) Section (d)(3)(A). The type and amount of PPE shall be chosen to protect against contact with blood or OPIM based upon the type of exposure and quantity of these substances which can be 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.

- (a) Laboratory coats, uniforms and the like that are used as PPE shall be laundered by the employer and not sent home with the employee for cleaning. (See J.4.c.(4) of this instruction on section (d)(3)(D).)
- (b) 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 clothing are anticipated.
 - If a pullover scrub (as opposed to scrubs with snap closures) becomes minimally contaminated, employees should be trained in accordance with section (g)(2)(G)(vii) to remove the pull-over scrub in such a way as to avoid contact with the outer

J.4.c.(1)

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 exposure. It may be prudent to train employees to cut such a contaminated scrub to aid removal and prevent exposure to the face.
- (c) A gown which is frequently ripped or falls apart under normal use would not be considered "appropriate PPE".
- (d) Resuscitator devices are to be readily available and accessible to employees who can reasonably be expected to resuscitate a patient.
 - 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).

J.4.c.(1)(d)

Improper use of these devices shall be cited as a violation of section (d)(3)(B). In addition, section (g)(2)(G)(vii) which requires employees to be trained in the types, proper use, location, etc., of the PPE shall 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 Materials is currently (at the publication date of this document) testing and evaluating methods to be used for assessing the quality of PPE that is available for medical use.

Section(d)(3)(B). This section 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 his/her resuscitation equipment is lost/damaged and he/she must administer CPR;
- (c) A bleeding suspect unexpectedly attacks a police officer with a knife, threatening the safety of the officer and/or 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 shall 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 shall 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. Section (d)(3)(B) shall 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, section (g)(2)(G)(vii) shall 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 shall not receive the benefit of this exemption and section (d)(3)(B) shall be cited.
- (3) Section (d)(3)(C). This section requires that the employer provide PPE in appropriate sizes and accessible locations. In addition, hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided. The compliance officer shall review the employer's program and, through employee interviews, ensure that these provisions have been met.

CITATION GUIDELINES. If PPE is not provided, the compliance officer shall cite section (d)(3)(A). If PPE is not readily available, the compliance officer shall cite section (d)(3)(C). 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 o clothing is located at the ambulance's home base, and the ambulance does not return to base for prolonged periods, a violation of section (d)(3)(C) 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 section (d)(3)(B) would exist. If inaccessibility of PPE exists, section (d)(3)(C) shall also be cited.
- (4) Section (d)(3)(D). It is the employer's responsibility not only to provide PPE, but to clean, maintain, and/or dispose of it.
 - (a) 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 the employer's responsibility to provide, clean, repair, replace, and/or dispose of it.
 - (b) 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.
 - (c) If the employee wishes to choose, wear, and maintain his/her/own uniform or laboratory coat, then he/she would need to don additional employer-handled and employer-controlled PPE when performing tasks where it is reasonable to anticipate exposure to blood or OPIM.

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

If PPE is not removed when penetrated by blood or OPIM, the compliance officer shall cite section (d)(3)(F).

- If the PPE is not changed, and additional PPE was available, section (g)(2)(G)(vii) may also be cited if employees have not been adequately trained.
- J.4.c.(5) Section (d)(3)(G). To minimize migration of contamination beyond the work area, employees who are provided designated lunchrooms or break rooms are permitted to eat/drink/smoke in these areas as long as the employees wash up and change any contaminated clothing prior to entry.

INSPECTION AND CITATION GUIDELINES. The "work area" shall be evaluated on a case-by-case basis. While it is not the intent of the standard to require employees to change PPE when traveling, for example, from one hospital laboratory area to another, the compliance officer shall evaluate on a case-by-case basis whether the employee received adequate training in accordance with section (g)((2)(G)(vi) 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.
- (6) Section (d)(3)(I)(i) (iii). These sections discuss the use of gloves. Gloves of appropriate sizes must be made available in accordance with section (d)(3)(C). 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.
 - (a) While disposable gloves shall 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".
 - (b) 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.

- (c) The compliance officer should note that certain solutions, such as iodine, may cause discoloration of gloves without affecting their integrity and function.
- (d) At a minimum gloves shall be used where there is reasonable anticipation of employee hand contact with blood, OPIM, mucous membranes, or nonintact skin; when performing vascular access procedures; or when handling or touching contaminated surfaces or items.
- (7) Section (d)(3)(I)(iii). 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 plasmapherisis 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 shall document that the employer has fulfilled the requirements of sections (d)(3)(I)(iv)a. through (d)(3)(I)(iv)d.3., and that employees have received the training necessary to make an informed decision on the wearing of gloves.

CITATION GUIDELINES. Section (d)(3)(I)(iv) shall not be cited. Rather, the other sections of (d)(3) shall be cited if such an employer violates them and if the employer has not demonstrated fulfillment of all the requirements of the exemptions.

- (8) Section (d)(3)(J). This section requires protection for the mucous membranes of the face and upper respiratory tract from droplet spattering. Minimum protection would consist of a mask in conjunction with eye glasses with solid side shields or a chin length face shield.
 - (a) The employer would not necessarily have to provide prescription eyewear for employees. They could provide and mandate the use of side shields, goggles, and/or protective face shields, and provide proper training in decontamination procedures.
 - (b) During microsurgery, when it is not reasonably anticipated that there would be any spattering, it would not constitute a violation for the surgeon, while observing surgery through a microscope, not to wear other eye protection.
- (9) Sections (d)(3)(K) (L). 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 section (d)(d)(A). For example, laboratory coats or gowns with long sleeves shall 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.

NOTE:

There are no currently available standardized methods of testing and classification of performance specifications for resistance of clothing to biological hazards.

- d. Housekeeping (d)(4). The term "worksite" in this section 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.
 - (1) Section (d)(4)(H). Cleaning schedules and methods will vary according to the factors outlined in this section. While extra-ordinary attempts to disinfect or sterilize environmental surfaces such as walls or floors are rarely indicated, routine cleaning and removal of soil are required.
 - (a) The employer must determine and implement an appropriate written schedule of cleaning and decontamination based upon the location within the facility (e.g., surgical operatory versus patient room), type of surface to be cleaned (e.g., hard-surfaced flooring versus carpeting), type of soil present (e.g., gross contamination versus minor spattering), and tasks and procedures being performed (e.g., laboratory analyses versus normal patient care).
 - (b) 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.

INSPECTION AND CITATION GUIDELINES. Compliance officers should consult the Environmental Protection Agency (EPA) lists of registered sterilants (representing the highest level of antimicrobial activity

which 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 efficacy claims for verification that the disinfectant used is appropriate. These lists are available from the Regional bloodborne pathogens coordinators.

NOTE:

Products registered by the EPA as HIV-effective are not necessarily tuberculocidal and are therefore not necessarily effective against HBV which is more resistant to inactivation than is HIV. To determine the overall effectiveness of a particular product with an HIV-efficacy claim for use in a cleanup where HBV or other bloodborne pathogens are also of concern, the compliance officer must compare the listing of HIV-effective products with the other two listing to check if they overlap for the product of interest.

- (2) Section (d)(4)(B). 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), section (d)(4)(B) provides the minimum requirements for the cleaning and decontamination of equipment and environmental and working surfaces that come into contact with blood or OPIM.
 - (a) In section (d)(4)(B)(i), 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.
 - 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 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, rather only after procedures resulting in surface contamination.
- 3 There may be some instances in which "immediate" decontamination of overt contamination and spills may not be practical as with, for example, an operating table during surgery.
- 4 The third instance of mandated 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. 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.
- (b) The use of protective coverings described in section (d)(4)(B)(ii) 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; e.g., as soon as feasible following overt contamination or at the end of a workshift if they 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 OHSA's jurisdictional mandate to safeguard employee (not patient) health.
- (c) Section (d)(4)(B)(iii) 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 may be 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.
- (d) Since contaminated broken glass is capable of inflicting percutaneous injury and direct inoculation of bloodborne pathogens into the bloodstream, section (d)(4)(B)(iii) stipulates that broken glassware which may be contaminated shall not be picked up directly with the hands. The tools which are used in cleanup 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 section (g)(2). Vacuum cleaners are not appropriate for cleanup of contaminated broken glass.
- (e) Section (d)(4)(B)(v) prohibits employers from allowing employees to place their hands into containers whose contents include reusable sharps contaminated with blood or OPIM. (See I.4.d.(3)(g) of this instruction on section (d)(4)(C)(i)d.).
 - NOTE: 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) as it interferes with the efficacy of the disinfecting/sterilizing process and the number of products which can successfully penetrate a heavy bioburden is limited.
 - (f) Violations of sections (d)(4)(B) and (d)(4)(B)(i) (v) 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 section(s) of (g)(2).

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- (3) Regulated Waste (d)(4)(C). This section requires regulated waste to be properly contained and disposed of, so as not to become a means of transmission of disease to workers.
 - (a) To eliminate the implication that OSHA has determined the "infectivity" of certain medical wastes, the bloodborne pathogens standard uses the term "regulated waste" to refer to the following categories of waste which require special handling, at a minimum:
 - Liquid or semi-liquid blood or OPIM.
 - 2 Items contaminated with blood or OPIM and which would release these substances in a liquid or semiliquid state if compressed.
 - Items that are caked with dried blood or OPIM and are capable of releasing these materials during handling.
 - 4 Contaminated sharps.
 - 5 Pathological and microbiological wastes containing blood or OPIM.

INSPECTION AND CITATION GUIDELINES. The compliance officer shall 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, a item may adequately contain these materials when in a static state yet liberate them when compacted in the waste container.

- Rather, the potential for dripping of liquid blood or OPIM, or flaking off of dried blood or OPIM should be considered.
- Under no circumstances should a bag of waste be squeezed or shaken to determine this. The compliance officer shall 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:

- 1. The compliance officer should keep in mind that while OHSA 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 preview of the EPA and possibly State and local regulations.
- 2. The EPA's Standard for the Tracking and Management of Medical Waste and a number of State regulations consider used needles to be regulated medical waste regardless of the presence of infectious agents. Failing information to the contrary, the compliance officer should consider a used needle to be contaminated.
- (b) Section (d(4)(C)(i)a. The construction of the sharps containers must meet at least four criteria, two of which will be easily discernible. The compliance officer shall examine a container, preferably empty, to check that it is closable and color-coded or labeled.
 - 1 Sharps containers are made from a variety of products, from cardboard to plastic. As long as they meet the definition of a sharps container, the compliance officer should consider them to be acceptable no matter what the composition.
 - 2 At the time of this instruction, the American Biological Safety Association was in the process of developing a standard for puncture-resistance of sharps disposable containers.
 - If questions arise, the compliance officer shall consult the manufacturer's literature or contact the manufacturer directly to determine if the container is leak-proof on the sides and bottom, as well as puncture resistant.

- b If the container is considered punctureresistant by the manufacturer, but there is evidence, through observation or employee statements that sharps have been protruding through a container, section (d)(4)(C)(i)a.2. shall be cited.
- The sharps container should not create additional hazards. Some sharps containers have unwinders that are used to separate needles from syringes.
 - If this situation is encountered, the compliance officer shall determine if the circumstances warrant needle removal. If they do not, section (d)(2)(G)(i) which prohibits needle removal unless no alternative is feasible or it is required by a specific medical procedure, shall be cited.
 - b If needle removal must be accomplished, the employee shall be trained in the correct procedure as required by (g)(2)(G)(vi).
- 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.
 - Some self-sheathing devices contain a fastcuring colored liquid adhesive which is released inside the sheath after completion of administration of a substance through the needle. This product is intended to permanently adhere all components of the syringe needle and needle sheath, rending the syringe and needle assembly inoperable and incapable of causing injury.
 - b These devices shall still be disposed of in sharps containers since there is no guarantee of correct usage or proper functioning of the device.

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- Duct tape may be used to secure a sharps container lid but is not acceptable if it serves as the lid itself.
- (c) Section (d)(4)(C)(i)b.1. The compliance officer shall 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.
 - b The determination of whether or not the container is as close as feasible shall 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 shall be given the opportunity to explain the present location of the container. The acceptability of the new site shall also be discussed. The compliance officer shall then decide if a violation of this section exists.
 - Laundries shall 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, shall also have sharps containers available in the event a package accidentally opens and releases sharps.

- (d) Section (d)(4)(C)(i)b.e. The compliance officer shall ensure the employer's exposure control plan specifies how and when the sharps containers will be replaced and that the program is followed.
 - The employer's plan must include the method by which sharps containers will be determined to need to be replaced, such as sharps containers which have a transparent window or are at a height which allows employees to see if the container needs to be replaced.
 - If the employer has a plan but it is not followed, a citation for inadequate training on work practices, (g)(2)(G)(vi), shall be grouped with this section if a training violation exists.
- (e) Section (d)(4)(C)(i)c.1.-.2. If work practice violations of these sections exist (e.g., not closing the container prior to movement or not placing the container in a secondary container if leakage is possible), they shall be grouped with (g)(2)(G)(vi) if employees have not received adequate training.
- (f) Section (d)(4)(C)(i)w.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.
- (g) Section (d)(4)(C)(i)d. 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.
- (h) Section (d)(4)(C)(ii). While this section requires that regulated waste containers be closable, simply being closed does not ensure that wastes will be contained. Wastecontaining bags may break and spill their contents, including liquid blood, while, for example, being loaded onto incinerator hoppers, thus contaminating both the employee 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 section. 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 section of (g)(2) should be grouped with violations of paragraph (d).
- (i) Sections (d)(4)(C)(ii)a.3. and b.3. 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. (See M.4.d.-(4)(a) of this instruction on section (d)(4)(D)(i)b.)
 - Regulated waste that has been decontaminated need not be labeled or color-coded. The compliance officer in such a case shall verify that the employer's exposure control plan states the decontamination procedures to be followed.

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- 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. (See J.7.a.(2) of this instruction on section (g)(1)(A)(ix).)
- b 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 (1) date, time, and operator of each run, (2) type and approximate amount of waste tracked, (3) post-treatment reading of temperature-sensitive tape, (4) dates and results of calibration of the sterilizer, and (5) results of routine spore testing.
- decontamination, see guidelines at J.r.d.(1) of this instruction.
- Although these sections contain label requirements, failure to label can also be cited under section (g)(1)(A).
- (j) Section (d)(4)(C)(ii)b. 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.

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J.4.d.(4) Laundry - (d)(4)(D). This section 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. Sections (d)(4)(D)(i) and (D)a. limit the handling of laundry to removal and bagging or containerization. The compliance officer shall check the laundry collection program as well as the training of the employees assigned to these tasks.

- (a) Section (d)(4)(D)(i)b. The employer has been given the choice, by this section, to either:
 - 1 Label or color-code according to section (g)(1)(A), or
 - 2 Utilize universal precautions in the handling of all soiled (i.e., used) laundry.
 - a 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.
 - <u>b</u> Training violations would be cited under the appropriate section of (g)(2)(G).
 - Refer to I.4.d.(4)(d) on section (d)(4)(D)(iii) for labeling when laundry is shipped off-site.
- (b) Section (d)(4)(D)(i)c. 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.

- (c) Section (d)(4)(D)(ii). 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.
- (d) Section (d)(4)(D)(iii). 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 section (g)(1)(A). 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 shall check the employer's program to determine if laundry is shipped to another facility for cleaning and shall 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 section:

- The CL is not shipped labeled or in a red bag. Section (d)(4)(D)(iii) would be cited and grouped with the applicable subsection of (g)(1)(A).
- The CL is shipped with an improper label. Section (d)(4)(D)(iii) would be cited and grouped with the applicable subsections of (g)(1)(A)(ii), (iii) and/or (iv).
- The CL is shipped in a bag color-coded for inhouse use (in a color other than red). Section (d)(4)(D)(iii) would be cited and grouped with section (g)(1)(A)(v).
- 5. HTV and HBV Research Laboratories and Production Facilities 17.001(e). This section 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.

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- "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 patient's blood. Academic research laboratories are not 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 section.
 - "Production facilities" are those engaged in industrial scale, large volume, or high concentration production of HIV or HBV.
- NOTES: 1. Employers in such facilities remain responsible for complying with the entire standard. Requirements stated elsewhere in the standard are not repeated.
 - 2. 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 shall 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 section are met. Care shall 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:

- a. Section (e)(2)(A). The term "regulated waste" refers to the OSHA definition as found in section (b) of this standard. The purpose of decontaminating regulated waste is to prevent the accidental exposure of other employees to the concentrated virus.
- b. Sections (e)(2)(B)(i) through (xii). Sections (i), (iii) and (iv) 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.

- (1) Section (e)(2)(B)(v). 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.
- (2) Sections (e)(2)(B)(viii) and (ix). These sections prevent the spread of contamination to other work areas. Section (ix) allows for an alternative to a HEPA filter as long as it is of equivalent or superior efficiency. HEPA filters may be ineffective in humid atmospheres.
 - (a) The employer must also have made provisions for routine maintenance and/or replacement of all filters and traps.
 - (b) 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.
- (3) Section (e)(2)(B)(x). The compliance officer shall 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.
- (4) Section (e)(2)(B)(xiii). This section 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 section shall 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.
- c. Section (e)(2)(C). Specific containment equipment is required by this section to minimize or eliminate exposure to the viruses.
 - (1) 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.
 - (a) The compliance officer shall 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 shall be reviewed by the compliance officer. The report must be dated and signed by the trained technician performing the measurements and integrity tests.

- (b) See Appendix C for details on biological safety cabinets.
- (2) In the alternative, appropriate combinations of PPE or physical containment devices (examples listed in the standard) will be accepted.
- d. Sections (e)(3)(A) and (e)(4)(C). 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. A 15-minute supply of continuous free-flowing water is acceptable. The hands must be free to hold the eyelids open to aid in the complete flushing of the eyes. Portable facilities are acceptable only if they meet these requirements.
- e. Section (e)(4) covers additional requirements for production facilities only. The requirement in section (e)(4)(F) minimizes the potential for accidental exposure to other employees from the transport of culture fluids, plastic ware, and other contaminated equipment.
- f. Training Requirements (e)(5). The additional training requirements are specified in section (g)(2)(I). Any violations found would be cited under that section of the standard. (See I.7.b. (5) of this instruction for details.)
- 6. Hepatitis B Vaccination and Post Exposure Evaluation and Followup 17.001). This section 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 followup after each specific exposure incident. Appendix D provides general algorithms for these requirements.
 - a.- General (f)(1). This section 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 followup procedures are to be made available to all employees who experience an exposure incident. While it is OSHA's

intent to have the employer remove, as much as possible, obstacles to the employee's acceptance of the vaccine, the term "made available" emphasizes that it is the employee's option to participate in the vaccination and followup programs.

INSPECTION GUIDELINES. The compliance officer shall examine the employer's program to determine if the vaccination series and post-exposure followup procedures meet the requirements of section (f)(1)(B).

- (1) Section (f)(1)(B)(i). The term "no cost to the employee" means no "out of pocket" expense to the employee.
 - (a) The employer may not require the employee to use his/her 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.
 - (b) The employer may not institute a program in which the employee pays the original cost of the vaccine and is reimbursed by the employer if she/he remains employed for a specified period of time.
 - (c) An "amortization contract" which requires employees to reimburse the employer for the cost of the vaccination should they leave his/her employ prior to a specified period of time is similarly prohibited.
- (2) Section (f)(1)(B)(ii). The term "reasonable time and place" requires the medical procedures and evaluations to be convenient to the employee. They shall be offered during normally scheduled work hours. If participation requires travel away from the worksite, the employer must bear the cost.
- (3) Section (f)(1)(B)(iii). The compliance officer may have to contact the Regional bloodborne pathogens coordinator to determine if the State board of nursing licensing allows licensed health care professionals other than physicians to carry out the procedures and evaluations required by section (f).

(4) Section (f)(1)(B)(iv). This section takes into consideration the changing nature of medical treatment relating to bloodborne pathogens. The CDC is the U.S. Public Health Service (USPHS) agency responsible for issuing guidelines and making recommendations regarding infectious agents. OSHA will accept the CDC guidelines current at the time of the evaluation or procedure. Copies of the current guidelines can be obtained by contacting the Regional bloodborne pathogens coordinator or CDC. (See Appendices A and B.)

NOTE: This section requires that the current USPHS/CDC guidelines be followed for all vaccinations, evaluations, and followup procedures. Any additional requirements (such as obtaining a written health care professional's opinion) specified in section (f) must also be met.

- (5) Section (f)(1)(C) 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 (such as CDC or College of American Pathologists) or equivalent State agency which participates in a recognized quality assurance program.
- Hepatitis B Vaccination (f)(2). The compliance officer shall determine b. whether or not all occupationally exposed employees have the hepatitis B vaccination series made available to them after training required by section (g)(2)(G) 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 exemptions(s) set forth in section (f)(2), or (2) the signature of the employee on the mandatory declination form. (See Appendix A of Subchapter 17.)
 - (1) Section (f)(2)(A) 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 doe not have to be made available. If the employer

claims one of these exemptions, it must be documented in the employee's medical record.

- (a) 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. At the time of publication of this standard, intradermal inoculation of 0.1 of the normal dose of the hepatitis B vaccine is not recommended by the USPHS and therefore is not an acceptable administration method.
- (b) Current USPHS guidelines do not recommend routine postvaccination testing. Therefore, employers are not currently required to routinely test immune status after vaccination has been completed.
- (2) Section (f)(2)(B). Prevaccination screening for antibody status cannot be required of an employee, although if an employer wishes, he/she can make it available at no cost to employees. An employee may decline the prescreening, and the employer must still make the vaccination series available to the employee.
- (3) Section (f)(2)(C). 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.
- (4) Section (f)(2)(4). Although the declination form set forth in Subchapter 17, Appendix A, does not have to be reproduced, the declination statement used by the employer must contain the same language as that found in Appendix A—no words may be added or subtracted.
- (5) Section (f)(2)(E). 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.
- (6) Under section (f)(2) of the standard, hepatitis B vaccination must be offered to all employees who have occupational exposure to blood or other potentially infectious materials (OPIM). However, as a matter of policy violations will be considered minor and citations will not be issued when designated first aid providers who

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

- (a) The primary job assignment of such designated first aid providers is not the rendering of first aid.
 - Any first aid rendered by such persons is rendered only as a collateral duty responding solely to injuries resulting from workplace incidents, generally at the location where the incident occurred.
 - This provision does <u>not</u> 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 such assistance, nor does it apply to any health care, emergency, or public safety personnel who are expected to render first aid in the course of their work.
- (b) The employer's Exposure Control Plan specifically addresses the provision of hepatitis B vaccine to all unvaccinated first aid providers who have rendered assistance in any situation involving the presence of blood or OPIM (regardless of whether an actual "exposure incident" as defined by the standard occurred) and the provision of appropriate post-exposure evaluation, prophylaxis and follow-up for those employees who experience an "exposure incident," including:
 - Provision for a reporting procedure that insures that <u>all</u> first aid incidents involving the presence of blood or OPIM will be reported to the employer before the end of the work shift during which the first aid incident occurred.
 - The report must include the names of all first aid providers who rendered assistance, regardless of whether personal protective equipment was used and must describe the first aid incident, including time and date.

- The description must include a determination of whether or not, in addition to the presence of blood or other potentially infected 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 section (f)(3) of the standard are made available immediately if there has been an "exposure incident" as defined by the standard.
- b The report shall be recorded on a list of such first aid incidents. It shall be readily available to all employees and shall be provided to the Commissioner or his designated representative.
- 2 Provision for the bloodborne pathogens training program for designated first aiders to include the specifics of this reporting procedure.
- 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.
- (c) The employer must implement a procedure to ensure that all of the provisions of paragraph 2. are complied with if pre-exposure hepatitis B vaccine is not to be given to employees meeting the conditions of paragraph 1.

NOTE: All other requirements of the standard continue to apply. (See Note #2, subparagraph M.2.)

Post-Exposure Evaluation and Followup - (f)(3). This section requires the employer to make immediately available a confidential medical evaluation and followup to an employee reporting an exposure incident.

c:

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. In such a case, OSHA strongly encourages their employer to offer them the followup procedures set forth in this section.

INSPECTION GUIDELINES. The compliance officer must determine if the employer's plan provides for immediate and confidential procedures. 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.

- 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 since medical knowledge concerning the effectiveness of post-exposure prophylactic measures is constantly changing. AKOSH requires the evaluation and followup procedures to be given as soon as possible after exposure.
- If the compliance officer believes that an employer is not properly following accepted post-exposure procedures, or needs specific information about current accepted procedures, the Regional bloodborne pathogens coordinator should be contacted. A health care professional in the National Office will then be consulted.
- The employer must also have established a system that maintains the required medical records in a way that protects the confidentiality of the employee's identity and test results. If the employer has contracted with a clinic or other health care facility to provide the followup programs, the confidentiality requirements must be part of the contract.
- (1) Section (f)(3)(A). 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.
- (2) Section (f)(3)(B). This section 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.

- (a) Section (f)(3)(B)(i). This section requires testing of the source individual's blood after consent is obtained. The employer must ask for consent from the source individual or anyone legally authorized to give consent on his/her behalf. If consent is not obtained, the employer must document this in writing. The compliance officer shall ensure that the employer's plan includes this provision.
 - For those jurisdictions that do not require consent of the individual, available blood must be tested. The term "if available" applies to blood samples that have already been drawn from the source individual.
 - 2 OSHA does not require redrawing of blood specifically for HBV and HIV testing without consent of the source individual.
- (b) Section (f)(3)(B)(iii). This section 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.
 - The boundary between employer and health care professional may be blurred in a medical setting in which, for example, the physician is both the employer and the evaluating health care professional. In such cases, the compliance officer shall ensure that requirements for consent and confidentiality have been followed.
 - 2 "Applicable laws and regulations concerning disclosure" refers to State and Federal laws that specifically cover medical privacy and confidentiality.
- (c) Section (f)(3)(C). 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 seroloical testing.

- Section (f)(3)(C)(i). Although the consent of the employee must also be obtained before collection of blood and before hepatitis B serological testing, the 90-day holding requirement in section (f)(3)(C)(ii) does not apply.
- Section (f)(3)(C)(ii). This section 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 HTV.
 - Employers are required to preserve the blood the employee consented to have drawn, if it was not tested for HIV initially, for at least the 90-day period. Compliance officers shall check that if the employer contracts for post-exposure followup, the contractor has been informed of the 90-day requirement.
- (d) Section (f)(3)(D). See Appendices A and B for CDC's current guidelines on management of occupational exposure to HIV and HBV.
- d. Information Provided to the Health Care Professional (f)(4). This section requires the employer to provide information to the health care professional responsible for the employee's hepatitis B vaccination and post-exposure incident followup.

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.

(1) In the case of an exposure incident, the plan must provide for the transmission of the information required by

- (f)(4)(B)(i) (iii) and (v) to the health care professional. The information required by (f)(4)(B)(iv) must be provided only if available.
- (2) 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.
- (3) 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.
- e. Health Care Professional's Written Opinion (f)(5). The employer is required to obtain and provide a written opinion to the employee within 15 working days of completion of the original evaluation. Employer access is allowed to the health care professional's written opinion.
 - (1) Section (f)(5)(A) limits the health care professional's written opinion to very specific information regarding the employee's hepatitis B vaccine status, including indication for vaccine and whether such vaccination was completed.
 - (2) Section (f)(5)(B) requires documentation that a postexposure 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.
- 7. Employee Information and Training 17.001(g). Section (g) ensures that employees receive sufficient warning through labels, signs, and training to eliminate or minimize their exposure to bloodborne pathogens.
 - a. Labels (g)(1). Labels must be provided on containers of regulated waste, on refrigerators and freezers that are 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. (See Appendix E.)

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).

INSPECTION AND CITATION GUIDELINES. The compliance officer shall determine that the warning labels in the facility are used as required by sections (g)(1)(A)(i) - (iv) and include the term "BIOHAZARD". OSHA does not require nor prohibit the use of warning signs or labels indicating source individuals' or specimens' known infectivity status although, in accordance with universal precautions, the agency strongly recommends against such warning signs.

- (1) Sections (g)(1)(A)(v) through (vii). These sections list exemptions from the labeling requirements which are additional to those exemptions listed for specimens in section (d)(2)(M)(i) and for laundry in section (d)(4)(D)(i)b. (See I.4.b.(8)(a) and I.4.d.(4)(a) of this instruction.)
 - (a) 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.
 - (b) 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.
- (2) Section (g)(1)(A)(ix). Regulated waste that has been decontaminated by incineration, autoclaving, or chemical means, prior to disposal is not required to bear the BIOHAZARD warning label.
 - (a) Decontamination is discussed at J.4.d.(3)(i)(2) of this instruction.
 - (b) Failure to ensure adequate decontamination procedures prior to removal of the hazard label shall be cited under (g)(1)(A)(i), since the material would still be regulated waste.
- b. 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 shall 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 section (g)(2)(G) must be covered at a minimum. These requirements include some site-specific information.

INSPECTION GUIDELINES. The compliance officer shall 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 shall be trained prior to being placed in positions where occupational exposure may occur.

- Employees who received training on bloodborne pathogens within the year preceding March 6, 1992, shall receive information on the sections of the standard which were not included in their training. The annual retraining for these employees shall be provided within one year of their original 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 shall 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.
- (1) Sections (g)(2)(G)(ii) and (iii). These sections 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.
- (2) Section (g)(2)(G)(x). The word "emergency" in this section refers to blood exposure outside the normal scope of work. This does not refer to hospital emergency rooms or emergency medical technicians' work.

- (3) Section (g)(2)(G)(xiv). This section requires that there be an opportunity for interactive questions and answers with the person conducting the training session.
 - (a) Training the employees solely by means of a film or video without the opportunity for a discussion period would constitute a violation of this section.
 - (b) 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.
- (4) Section (g)(2)(H). 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.
 - (a) The compliance officer shall 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.
 - (b) 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.
 - (c) Non-health care professionals, such as industrial hygienists, epidemiologists, or professional trainers, may conduct the training provided they can demonstrate evidence of specialized training in the area of bloodborne pathogens.
 - (d) 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 sections (g)(2)(G)(i) (xiv).

- (5) Section (g)(2)(I) (A (C). "Standard microbiological practices" in these sections refer to procedures outlined in "Biosafety in Microbiological and Biomedical Laboratories." (See D.9. of this PD.)
 - (a) The requirement that "proficiency" be demonstrated means that employees who are experienced laboratorians may not need to be retrained in accordance with these sections.
 - (b) Education such as a graduate degree in the study of HIV or HBV, or another closely related subject area with a period of related laboratory research experience, would also constitute "proficiency".
 - (c) The employer is responsible for evaluating the employee's proficiency and for documenting the mechanism used to determine proficiency.
- 8. Recordkeeping 17.001(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.
 - a. Medical records required by section (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.

NOTE: While section (h)(1)(C) requires that medical records are to be kept confidential, section (h)(1)(C)(ii) 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 OSHA. The compliance officer must protect the confidentiality of these records. If they are copied for the case file, the following provisions must be followed:

The compliance officer shall 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 8 AAC 61.270.

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

K. Interface With Other Standards.

- 1. The hazard communication standard, Subchapter 15, applies only to the hazards of chemicals in the workplace and does not apply to biological hazards such as bloodborne diseases.
- 2. Records concerning employee exposure to bloodborne pathogens and records about HIV and/or HBV status are considered employee medical records within the meaning of 8 AAC 61.270. The compliance officer may review these records for purposes of determining compliance with 8 AAC 61.270.
- Generally, the respiratory protection standard, 01.0403 GSC does not apply since there are no respirators approved for biohazards. However, placing respirators in areas where they could be contaminated by body fluids constitutes a violation of 01.0403(b)(6) GSC.
- 4. The Hazardous Waste Operations and Emergency Response (HAZWOPER) standard, Subchapter 10, 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 of 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;
- Workers responding to an emergency caused by the uncontrolled release of infectious materials; 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 Subchapter 10 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.
- O. Recording in the IMIS. Current instructions for completing the appropriate inspection classification boxes on the AKOSH-1, Inspection Report, as found in the IMIS Manual, shall 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 shall be recorded as follows:

N 02 Blood

- 2. If local emphasis programs are approved at a later date, Item 25C of the OSHA-1 shall be completed with the appropriate value.
- P. Referrals. When a complaint or inquiry regarding occupational exposure to bloodborne disease in a federal government facility is received, the Chief of Compliance should refer it to the OSHA Area Office.