

UMBI POLICIES AND PROCEDURES
VI-11.00(C) PROCEDURE ON BLOODBORNE PATHOGENS EXPOSURE
CONTROL PLAN

(Approved by the President August 30, 2005)

I. Introduction

Certain activities within the University of Maryland Biotechnology Institute (UMBI) have the potential for exposure to human blood and/or body fluids. Human blood, other body fluids, and unfixed human tissues are potential sources of harmful and lethal diseases such as hepatitis caused by hepatitis B virus and hepatitis C virus and Acquired Immunodeficiency Syndrome (AIDS) caused by human immunodeficiency virus. Therefore, to minimize the risk of occupational exposure to potentially contaminated blood and body fluids a combination of education, personal protective equipment (PPE), vaccinations, engineering controls, and application of recommended work practices will be used.

II. Background

The following Bloodborne Pathogens Exposure Control Plan (ECP) has been developed in accordance with the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard, 29 CFR 1910.1030 (reproduced as Appendix C of this control plan); and the University of Maryland Biotechnology Institute (UMBI) Policy VI-11.00(B) titled "Occupational Exposure to Bloodborne Pathogens" (July 2003) and UMBII Policy VI-11.00(A) titled "UMBI Policy Concerning HIV Infection and AIDS"

II. Definitions

Glossary	
AIDS	Acquired Immunodeficiency Syndrome
ECP	Bloodborne Pathogens Exposure Control Plan
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
OPIM	Other Potentially Infectious Material
OSHA	Occupational Safety & Health Administration
PPE	Personal Protective Equipment
SEH	Student and Employee Health Service
UHC	University Health Center, College Park
UMBI	University of Maryland Biotechnology Institute

- A. Bloodborne Pathogens means hepatitis B virus, human immunodeficiency virus, and hepatitis C virus. In the future, the President of UMBI may identify additional pathogens as bloodborne pathogens if such pathogens are identified by OSHA, the Centers for Disease Control and Prevention (CDC), or a relevant State or federal law or regulation as requiring control or prevention measures similar to those required for HIV, HBV, or HCV under the OSHA Standard.
- B. Exposure Incident means specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that result from the performance of the duties or assignments of any UMBI personnel.
- C. Needleless Systems are defined as devices that do not use needles for the collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established, or the administration of medication or fluids, or any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps. Examples of needleless systems include, but are not limited to, intravenous medication delivery systems that administer medication or fluids through a catheter port or connector site using a blunt cannula or other non-needle connection, and jet injections that deliver injections through the skin without use of a needle.
- D. Occupational Exposure means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials (OPIM) that may result from the performance of UMBI personnel's duties or assignments, including assigned work, volunteer tasks, academic programs and practicum experiences. Occupational exposure may occur in many contexts, including, but not limited to, patient care, client services, research activities, laboratory activities, classroom work, and housekeeping, maintenance, and security services.
- E. OSHA Standard means the Bloodborne Pathogens Standard issued by OSHA, United States Department of Labor, as amended from time to time and published as 29 CFR 1910.1030.
- F. Other Medical Devices are defined as those devices designed to reduce the risk of percutaneous exposure to bloodborne pathogens, including, but not limited to, blunt suture needles, plastic or mylar-wrapped glass capillary tubes, sharps disposal containers, and biosafety cabinets.
- G. Personal Protective Equipment (PPE) is specialized clothing or equipment worn for protection against potentially infectious materials as well as the spread of contamination of these materials.

- H. Potentially Infectious Materials, as referenced by the OSHA Bloodborne Pathogen Standard, are defined as (i) the following human body fluids (in liquid or dried state): blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva (in dental procedures only), any material visibly contaminated with blood, any body fluid in a situation where it is difficult to differentiate between types of body fluids; (ii) any unfixed tissue or organ (excluding skin) from a human (living or dead); (iii) HIV-containing cell or tissue cultures, organ cultures, and HIV or HBV-containing culture media or solutions; (iv) blood, tissues, or cultures from animals experimentally infected with HIV, HBV, HCV or other bloodborne pathogens.
- I. Center means any of the following centers which constitute UMBI's research units: Center for Advanced Research in Biotechnology, Center of Marine Biotechnology, Medical Biotechnology Center, Center for Biosystems Research, and Institute of Human Virology.
- J. Sharps with Engineered Sharps Injury Protections are defined as nonneedle sharps or needle devices used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident. They include, but are not limited to, syringes or catheters with a sliding sheath over the needle or needles that retract.
- K. Source Individual means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to UMBI personnel. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.
- L. UMBI Personnel means (i) all part-time and full-time students of UMBI as well as any special students who are not registered; (ii) all employees of UMBI, including full-time, part-time, temporary, contractual, and visiting personnel in any employment category; and (iii) all volunteers participating in UMBI activities.
- M. Universal Precautions (Standard Precautions) is an approach to infection control according to which all human blood and certain human body fluids are treated as if known to be infectious for bloodborne pathogens.
- N. Universal Precautions means the universal precautions recommended by the Centers for Disease Control and Prevention, U.S. Public Health Service <http://www.cdc.gov/ncidod/hip/Blood/UNIVERSA.HTM>

- O. Standard Precautions means the standard precautions recommended by Garner, J. S. Hospital Infection Control Practices Advisory Committee. Guideline for isolation precautions in hospitals. Infect Control Hosp Epidemiol. 1996;17:53-80.
- P. Work Practice Controls refer to controls that reduce the likelihood of exposure by altering the manner in which a task is performed.
- Q. Any term used in this Plan which is defined in paragraph (b) of the OSHA Standard shall have the meaning set forth in the OSHA Standard unless a different meaning is set forth in this part of the Policy.

III. Exposure Determination

- A. OSHA requires employers to perform an exposure determination concerning which employees may incur occupational exposure to blood or OPIM. The exposure determination is made without regard to the use of personal protective equipment (i.e., employees are considered to be exposed even if they wear personal protective equipment).
- B. The exposure determination should identify job classifications in which all employees may be expected to incur such occupational exposure, regardless of frequency and listing job classifications in which some employees may have occupational exposure. Since not all the employees in these categories would be expected to have exposure to blood and other body fluids that are to be considered potentially infectious materials, the tasks, procedures or groups of closely related tasks and procedures that would have occupational exposure for employees are listed by each Center's administration.

IV. Methods of Compliance

- A. OSHA requires that this plan include a schedule and method of implementation for the various requirements of the standard.
- B. The Centers for Disease Control and Prevention (CDC) Standard/Universal Precautions are observed at UMBI in order to prevent contact with blood or other potentially infectious materials. All blood or OPIM will be considered infectious regardless of the perceived status of the source individual.

- C. Engineering controls and work practice controls will be utilized to eliminate or minimize exposure to UMBI personnel. Where occupational exposure remains after institution of these controls, personal protective equipment shall also be utilized. The following engineering controls will be utilized:
1. Specimen Containers. Containers for specimens of blood or OPIM must be designed to prevent leakage during collection, handling, and storage. They must be inspected for leakage prior to use and on a daily basis. Contamination of the outside of the container should be avoided. The lid shall be tightly secured. The outside of the container shall be decontaminated before transporting. All specimen containers must be clearly labeled as to contents, labeled with a biohazard label, and then double containerized for transport.
 2. Containers for Special Medical Waste. Special medical waste such as used disposable containers, gloves, etc., must be kept in closed containers that can hold all contents without leakage during handling, storage, and transport. Waste containers must be clearly labeled with the biohazard symbol, indicating that they contain biohazardous waste. Containers are to be inspected for leakage daily.
 3. Sharps Containers. Sharps include syringes, needles, slides, scalpels, cover slips, glass pipettes, and broken glass that may be contaminated with infectious materials. Sharps containers are leak-proof, puncture-resistant, labeled with the universal biohazard symbol, and closeable. Full sharps containers must be properly closed and discarded into a properly lined biohazard box.
 4. Sharps with engineered sharps injury protection. Sharps that have a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident must be used whenever possible.
 5. Labels. Warning labels must be affixed to containers of regulated waste, refrigerators, freezers, incubators, or other containers that contain blood or OPIM. They also must be placed on containers used to transport regulated materials, and are required for any equipment that is reasonably expected to become contaminated during the course of its use. The warning label must contain the word "Biohazard" along with the universal biohazard symbol and printed in fluorescent orange or orange-red color with lettering or symbols in a contrasting color.
 6. Signs. Signs will be posted at the entrance to work areas in which infectious and potentially infectious materials is used. Required signs will be fluorescent orange in a contrasting color and they must contain the following information: The universal biohazard symbol; The name of the infectious agent, when appropriate; Special requirements for entering the area; and Name and daytime/nighttime telephone numbers of the laboratory supervisor and/or other responsible person(s).

V. Personal Protective Equipment (PPE)

- A. Personal protective equipment (PPE) is provided without cost to UMBI personnel. PPE is chosen based on the anticipated exposure to blood or OPIM. Protective equipment will be considered appropriate only if it does not permit blood or OPIM to pass through or reach the individual's clothing, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.
- B. Supervisors shall ensure that appropriate PPE in the appropriate sizes is readily accessible at the work site or is issued without cost to UMBI personnel. Hypoallergenic gloves, glove liners, powder free gloves, or other similar alternatives shall be readily accessible to those who are allergic to the gloves normally provided. PPE shall be removed before leaving the work site and either be stored or disposed of appropriately.
- C. The following pieces of PPE shall be available and used when there is potential for exposure to bloodborne pathogens:
 1. Gloves - Disposable, single-use latex or nitrile gloves shall be worn where it is reasonably anticipated that UMBI Personnel will have hand contact with blood or other potentially infectious materials, when collecting and processing human specimens and when handling or touching contaminated items or surfaces. Disposable gloves are not to be washed or decontaminated for reuse and are to be replaced as soon as practical when they become contaminated or as soon as feasible if they are torn or punctured, or when their ability to function as a barrier is compromised. Utility gloves can be washed or decontaminated for reuse. Utility gloves must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised. Double gloving has been shown to provide more protection from punctures and abrasion that can occur during use than does a single glove layer. Gloves shall be checked for leaks prior to wearing them. If gloves are damaged (torn or punctured) or become damaged or contaminated during a procedure, they shall be replaced. Hands must be washed with soap and water for 10 seconds or an approved alcohol-based cleaner immediately after gloves are removed.
 2. Protective clothing should be worn when there is a risk of body fluids spattering or becoming aerosolized and contacting an individual's skin or clothing. Protective clothing should be resistant to fluids, and may be disposable or reusable. Reusable clothing must be properly laundered prior to reuse.
 3. Face Protection - Face shields or masks in combination with eye protection such as goggles or glasses with solid side shield are recommended when splashes, sprays, aerosolized blood, or other potentially infectious materials may contact eye, nose, mouth, or mucous membranes.

4. Eyewear - Safety glasses with side shields or face shields should be worn during all work with potentially infectious material whenever there is a potential for splashes or sprays.
 5. Protective Footwear and Headwear - Disposable shoe covers and caps should be worn in situations where cross contamination of materials or personnel is possible.
- D. Supervisors shall ensure that all PPE is removed when penetrated by blood and then double bagged for laundering. All PPE shall be removed prior to leaving the immediate laboratory work area. When PPE is removed, it shall be placed in an appropriately designated container for storage, washing, decontamination, or disposal. All repairs and replacements will be made by UMBI at no cost to UMBI personnel.

VI. Work Practice Controls

Work practice controls are procedures that reduce the risk of occupational exposure by altering the way a task is performed. The following work practice controls are to be followed by all UMBI personnel when working with human blood or OPIM.

- A. Hand Washing. After the removal of personal protective gloves, UMBI personnel shall wash hands and any other potentially contaminated skin area immediately or as soon as feasible with soap and running tap water for at least ten seconds. In certain circumstances an alcohol hand cleaner may be used <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5116a1.htm>. If UMBI personnel incur exposure to their skin or mucous membranes, then those areas shall be washed with soap and water for at least 10 minutes, or for mucus membranes, flushed with running tap water for at least 15 minutes as soon as feasible following contact.
- B. Needles and Sharps. Contaminated needles and other contaminated sharps shall not be bent, recapped, removed, sheared, or purposely broken. OSHA allows an exception to this if the procedure would require that the contaminated needle be recapped or removed, no alternative is feasible, and the action is required by the medical procedure. If such action is required, the recapping or removal of the needle must be done by the use of a mechanical device or a one-handed technique. Procedures that require recapping of needles are discouraged.
- C. Personal Hygiene. Applying cosmetics and handling contact lenses in the laboratory should be discouraged at all times. Hands shall be washed with soap and water before leaving the work site.
- D. Food and Drink. Food and drink are never to be stored or consumed in a laboratory.

- E. Handling of Materials - Packages marked with the universal biohazard symbol or otherwise identified as containing potentially infectious materials are to be inspected for leaks immediately upon arrival.
 - F. All procedures are to be conducted in a manner which will minimize splashing, spraying, splattering, and generation of droplets of blood or OPIM. Specific methods include the use of protective clothing, gloves, chin length face shields, eye protection, and the use of utility gloves to protect latex/nitrile gloves from abrasion and tearing when large items are handled.
 - G. Sharp objects must be handled with safety awareness. Eye contact must be maintained with the item. Machines that splash and splatter shall be shielded. Capped tubes and safety cups shall be used when vortexing and centrifuging. Cotton or gauze pads moistened with disinfectant shall be wrapped around rubber stoppers or lyophilized containers when opening them. To the extent possible, all procedures that could aerosolize material shall be performed in a biosafety cabinet.
 - H. Specimens of blood or OPIM are to be placed in a container that prevents leakage during the collection, handling, processing, storage, and transport of the specimens. The container used for this purpose shall be labeled in accordance with the requirements of the OSHA standard. Supervisors shall ensure that all equipment has been decontaminated prior to servicing and shipping.
 - I. Any specimen container(s) shall be placed within a secondary container that is leak-proof and closed to prevent spillage of infectious materials.
 - J. Specimen Collection - When specimens are collected, the liquid must never be forced into a tube or other container.
- VII. Housekeeping
- A. Routine Cleaning - All areas of the worksite must be maintained in a clean and sanitary condition. All tables must be disinfected with an appropriate disinfectant solution at least daily and immediately following completion of procedures involving human blood and OPIM.
 - B. Contaminated Work Surfaces – Contaminated work surfaces must be decontaminated with an appropriate disinfectant solution after completion of procedures involving and/or immediately following any spill of blood or OPIM. Recommended liquid disinfectant contact time for effective decontamination is 20-30 minutes.
 - C. Broken Glass – Broken glass must never be picked up by hand. Recommended mechanical means of cleanup include use of a brush and dustpan, stiff paper, tongs, or forceps. Utensils must be cleaned and decontaminated immediately after use. The contaminated glass should be discarded into a sharps container or biohazard box.

- D. Contaminated Sharps – Contaminated sharps must be placed in a properly marked sharps container and labeled with a biohazard symbol. Containers for contaminated sharps shall be easily accessible to UMBI personnel and located in each separate work or procedure area. The container shall be maintained upright throughout its use and replaced as needed and shall not be overfilled. When a contaminated sharps container is removed from the area of use, the container shall be closed immediately prior to removal. The sharps container shall be discarded into a plastic-bag-lined biohazard box.
- D. Laundry - Contaminated protective clothing is to be placed in labeled bags and sent to a commercial laundry service that has the capability to properly handle and launder potentially infectious material. Home laundering is not permitted.

VIII. Standard Operating Procedures

- A. The above controls will be examined and maintained on a regular schedule. The effectiveness of the controls will be reviewed annually and updated as needed.
- B. To achieve the goals of this Plan, supervisors and managers should develop Standard Operating Procedures (SOPs), available near the work area, for activities in which UMBI personnel may be exposed to bloodborne pathogens. A copy of the SOP should be forwarded to the UMBI Research Compliance Coordinator.
- C. The procedure must contain the following elements:
 - 1. A clear and descriptive position description (title);
 - 2. The names and classifications of all individuals who will participate in the bloodborne pathogen activities;
 - 3. Identification of the area where duties are performed and a description of the procedures to be used to prevent unauthorized persons from being exposed to a potential hazard;
 - 4. A listing of the possible sources of exposure to bloodborne pathogens or other potentially infectious material in the specific task or procedure (Note: All liquids or media that come into contact with blood, unfixed human tissue, or human cell lines are to be considered potentially infectious material until the source tissue has been disinfected.);
 - 5. A detailed description of the task or procedure including all of the applicable safety precautions detailed in the Bloodborne Pathogens Exposure Control Plan (ECP);
 - 6. Identification of the departmental point of contact for exposure incidents.

IX. Hepatitis B Vaccination Program

- A. UMBI offers the hepatitis B vaccination series to UMBI employees who have reasonably anticipated occupational exposure. Hepatitis B vaccination shall be available to UMBI employees at a reasonable time and place, performed by or under the supervision of a licensed physician or by or under the supervision of another licensed health care professional, and provided according to the recommendations of the U.S. Public Health Service.
- B. The hepatitis B vaccination shall be offered by UMBI, at no cost, to all employees who have reasonably anticipated occupational exposure. Students who have reasonably anticipated occupational exposure will be offered the hepatitis B vaccination at their expense.
- C. Any persons who are neither students nor employees, and who have potential occupational exposure, shall be offered the hepatitis B vaccination at their expense.
- D. Participation in a pre-screening program shall not be a prerequisite for receiving hepatitis B vaccination. If an individual initially declines hepatitis B vaccination but at a later date, while still covered under the standard, decides to accept the vaccination, the vaccination shall then be made available. Employees and students at risk of exposure who decline the hepatitis B vaccination offered shall sign the OSHA waiver indicating their refusal (see forms in Appendix A).
- E. If a future routine booster dose of hepatitis B vaccine is recommended by the U.S. Public Health Service, such booster shall be made available.

X. Bloodborne Pathogen Post-Exposure Evaluation and Follow-Up

A. Post-Exposure Facilities

- 1. Baltimore Centers (COMB, IHV and MBC). Individuals exposed to a bloodborne pathogen on the Baltimore campuses shall first wash the exposed site with soap and water and then contact their supervisor. If appropriate, the individual will be referred to Student and Employee Health (SEH), 29 South Paca Street, (410) 328-6791 9 (8:30 am – 7 pm Monday – Thursday; 8:30 am – 4:30 pm Friday; 9 am – 10 pm on Saturday), or to the UMMC Emergency Department, NGE13, (410) 328-6722 after business hours. See Table 1 for a detailed list of responsibilities for each unit. Current CDC guidelines call for medical treatment of high risk exposures to be initiated immediately.
- 2. College Park (CBR). Individuals exposed to a bloodborne pathogen on the College Park campus shall first wash the exposed site with soap and water and then contact their supervisor. If appropriate, the individual will be referred to University Health Center (UHC) located on Campus Drive across from the Stamp Student Union (301) 314-8090 (8 am – 7 pm Monday through Friday; and 11 am – 3 pm on Saturday), or to the nearest hospital emergency department after

UHC hours. See Table 1 for a detailed list of responsibilities for each center. Current CDC guidelines call for medical treatment of high risk exposures to be initiated immediately.

3. Shady Grove (CARB). Individuals exposed to a bloodborne pathogen on the Shady Grove campus shall first wash the exposed site with soap and water and then contact their supervisor. If appropriate, the individual will be referred to Shady Grove Adventist Hospital Emergency Department, 9901 Medical Center Drive (301) 279-6000. See Table 1 for a detailed list of responsibilities for each center. Current CDC guidelines call for medical treatment of high risk exposures to be initiated immediately.
- B. Incident Reporting and Follow-Up. All employee exposure incidents shall be reported, investigated, and documented. If an employee incurs an exposure incident, the employee shall report the incident to his or her supervisor. If a student incurs an exposure, the student shall be encouraged to report the incident to the Center Administrator.
1. Baltimore Centers (COMB, IHV and MBC). Follow-up care will be available at Student and Employee Health (SEH), 29 South Paca Street, (410) 328-6791 9 (8:30 am – 7 pm Monday – Thursday; 8:30 am – 4:30 pm Friday; 9 am – 10 pm on Saturday).
 2. College Park and Shady Grove Centers (CARB and CBR): Follow-up care will be available at University Health Center (UHC) located on Campus Drive across from the Stamp Student Union (301) 314-8090 (8 am – 7 pm Monday through Friday; and 11 am – 3 pm on Saturday).
- C. Following a report of an exposure incident, an exposed employee shall receive a confidential medical evaluation and follow-up, including at least the following elements:
1. Documentation of the route of exposure and the circumstances under which the exposure incident occurred;
 2. Identification and documentation of the source individual, unless it can be established that identification is infeasible or prohibited by state or local law;
 3. The source individual's blood shall be tested as soon as feasible after consent is obtained in order to determine HBV, HCV, and HIV infectivity. If consent is not obtained, the person responsible for the hepatitis B vaccination program shall establish that legally required consent cannot be obtained. If the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented;

4. Results of the source individual's testing shall be made available to the exposed employee along with information on applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.
- D. Collection and testing of blood for HBV, HCV, and HIV serological status will comply with the following:
1. The exposed individual's blood shall be collected as soon as feasible and tested after consent is obtained;
 2. The exposed individual shall be offered the option of having his or her blood collected for testing of HIV/HBV/HCV serological status. The blood sample shall be preserved for up to 90 days to allow the individual to decide if the blood should be tested for HIV serological status.
- E. Employees who experience an exposure incident shall be offered post-exposure evaluation and follow-up in accordance with the OSHA standard.
- F. The health care professional responsible for the person's hepatitis B vaccination and post-exposure evaluation shall be provided with the following:
1. A copy of 29 CFR 1910.1030 (Appendix B);
 2. A written description of the exposed individual's duties as they relate to the exposure incident;
 3. Written documentation of the route of exposure and circumstances under which exposure occurred;
 4. Results of the source individual's blood testing, if available;
 5. All medical records relevant to the appropriate treatment of the person including vaccination status.
- G. UMBI shall obtain and provide to an exposed employee a copy of the evaluating health care professional's written opinion within 15 days of the completion of the evaluation.
- H. The health care professional's written opinion for hepatitis B vaccination must be limited to whether hepatitis B vaccination is indicated, and whether the employee has received such vaccination. It shall include a statement that the employee has been informed of the results of the evaluation and of any medical conditions resulting from exposure to blood or OPIM that require further evaluation or treatment. All other findings or diagnosis shall remain confidential and shall not be included in the written report.

XI. Information

- A. The annual review and update of the exposure control plan is required to:
1. Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens;
 2. Document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure used for direct patient care. Documentation should include a description of the safer devices identified as candidates for adoption, the methods used to evaluate devices, the results of evaluations, and the justification for selection decisions.
- B. UMBI Centers should base selection and evaluation of devices designed to eliminate or minimize occupational exposure used for direct patient care on the following factors:
1. The device's ability to perform the function for which it was designed;
 2. The effect of the engineered sharps injury protection on patient care;
 3. Expected effectiveness in reducing injuries;
 4. Anticipated costs;
 5. Ease of use;
 6. Staff preference;
 7. Compatibility with other devices and systems;
 8. Purchasing agreements.
- C. Solicitation of employee input during selection of safe sharps:
1. Regulations require that input be solicited from some non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps. Such input may be solicited through periodic conversations, informal problem-solving groups, participating in safety audits, worksite inspections, exposure incident investigations, or evaluation through pilot testing.
 2. The Research Compliance Coordinator at the UMBI Office of Research and Development (410) 385-6329 can assist Centers with examples of safe sharps evaluation forms obtained from OSHA Instruction Directive CPL 2-2.69, Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens, effective date November 29, 2001. This publication is also available online: http://www.osha-slc.gov/OshDoc/Directive_pdf/CPL_2-2_69.pdf

3. Solicitations will identify the employees involved, the process by which input was requested, and the input obtained using meeting minutes. Copies of documents used to request participation and records of responses received will be incorporated into the Exposure Control Plan.
4. Employees solicited may include lab technicians, housekeeping staff, maintenance workers, and management-level personnel who may be at risk of injury involving contaminated sharps.

XII. Training

- A. Training shall be required for all UMBI personnel who may have reasonably anticipated exposure to bloodborne pathogens in the course of their employment, studies, or volunteer effort. UMBI shall ensure that bloodborne pathogens trainers are knowledgeable in the subject matter. UMBI Centers will ensure that training is provided at the time of initial assignment to tasks where occupational exposure may occur and be repeated annually.
- B. Training shall be tailored to the education and language level of UMBI personnel being trained, provided at no cost and during the normal work hours.
- C. The training will be interactive and cover the following:
 1. OSHA Bloodborne Pathogen Standards and contents of the regulations;
 2. The epidemiology and symptoms of bloodborne diseases;
 3. The modes of transmission of bloodborne pathogens;
 4. The Exposure Control Plan and a method for obtaining a copy;
 5. The recognition of tasks that may involve exposure;
 6. The use and limitations of methods to reduce exposure, for example, engineering controls, work practices and PPE;
 7. The types, use, location, removal, handling, decontamination, and disposal of PPE;
 8. The basis of selection of PPE;
 9. The hepatitis B vaccine, including efficacy, safety, method of administration, benefits, and cost, if any;
 10. The appropriate actions to take and persons to contact in an emergency involving blood or OPIM;

11. The procedures to follow if an exposure incident occurs, including the method of reporting and medical follow-up;
 12. The evaluation and follow-up required after an exposure incident;
 13. The signs, labels, and color coding systems used to identify potentially infectious materials.
- D. Additional training shall be provided to UMBI personnel when there are any changes of tasks or procedures affecting the personnel's occupational exposure.

XIII. Record Keeping

- A. The Director in each Center will maintain employee, student and volunteer training records. Training records shall be maintained for three years from the date of training and be available to the UMBI Office of Research and Development (410) 385-6330.
- B. The following training information will be documented:
1. The dates of the training sessions;
 2. An outline describing the material presented;
 3. The names and qualifications of persons conducting the training;
 4. The names, employee identification numbers, and titles of all persons that attend the training sessions.
- C. The UMBI Office of Operations and Finance, Office of Human Resources (410) 385-6337, will maintain OSHA Standard 29 CFR 1910.20 records.
1. Baltimore Centers (COMB, IHV and MBC):
The Student and Employee Health Service (SEH) is responsible for maintaining employee medical records as indicated below. Medical records shall be maintained in accordance with OSHA Standard 29 CFR 1910. 20. These records shall be kept confidential, and must be maintained for at least the duration of employment, studies, or volunteer effort plus 30 years.
 2. College Park and Shady Grove Centers (CARB and CBR):
The University Health Center is responsible for maintaining employee medical records as indicated below. Medical records shall be maintained in accordance with OSHA Standard 29 CFR 1910. 20. These records shall be kept confidential, and must be maintained for at least the duration of employment, studies, or volunteer effort plus 30 years.

- D. The records shall include the following:
1. The name and social security number of the individual;
 2. A copy of the individual's HBV vaccination status, including the dates of vaccination;
 3. A copy of all results of examinations, medical testing, and follow-up procedures;
 4. A copy of the information provided to the health care professional, including a description of the individual's duties as they relate to the exposure incident, and documentation of the routes of exposure and circumstances of the exposure.
 5. UMBI Office of Operations and Finance shall maintain a sharps injury log for recording percutaneous injuries from contaminated sharps. The information in the log shall be recorded and maintained in a manner that will protect the confidentiality of exposed UMBI personnel to the extent permitted by law. The log will serve as a tool for UMBI to identify high risk areas and devices. It shall contain at least:
 - a. The type and brand of device involved in the incident;
 - b. The department or work area where the exposure incident occurred;
 - c. An explanation of how the incident occurred and the circumstances surrounding the exposure incident (procedure being performed, the body part affected, objects or substances involved, and how they were involved);
 - d. The log can be maintained as a paper file or electronically, so long as privacy is protected.
 6. The OSHA 300 Log of Work-Related Injuries and Illnesses and the OSHA 301 Injury and Illness Incident Report forms shall be used to meet the sharps injury log requirements, provided that:
 - a. The forms contain information on the type and brand of the device involved;
 - b. Reports of sharps injuries can be segregated from other types of work-related injuries and illnesses.
- E. Employee medical records in the possession of UMBI shall be made available to the employee in accordance with 29 CFR 1910. 20. Medical records shall be made available to the Assistant Secretary of Labor for the Occupational Safety and Health Administration and the Director of the National Institute for Occupational Safety and Health (NIOSH) upon request.

- F. Transfer of Records. If UMBI has closed and there is no successor employer to receive and retain the medical records for the prescribed period, the Director of NIOSH shall be contacted for final disposition.

XIV. Evaluation and Review

This program and its effectiveness will be reviewed every year by UMBI Office of Research and Development, Office of Research Compliance, and updated as needed.

APPROVED:

Dr. Jennie Hunter-Cevera
President

August 30, 2005
Date

**TABLE 1
RESPONSIBILITIES**

<p>UMBI Employee or Student</p>	<p>Wash exposed site with soap and water or flush eyes with water. Contact supervisor.</p> <p>Baltimore: Call (410) 328-6791 or (410) 328-6722 College Park: Call (301) 314-8090 Shady Grove: Call ((301) 279-6000</p> <p>Report all incidents, exposures and potential exposures. Report all conditions that may endanger the health of staff, students and patients</p>
<p>Department Manager, Principal Investigator, Laboratory Supervisor, or Shift Supervisor</p>	<p>Determine the circumstances of an exposure to a bloodborne pathogen and assist with completion of an Employee's First Report of Injury form (Appendix A)</p> <p>Direct employee/student exposed to bloodborne pathogens to Emergency Department for confidential evaluation</p>
<p>Emergency Department, Attending Resident, Physician on call</p>	<p>Initiate treatment, counseling and referral of the exposed individual</p> <p>Evaluate all incidents of potential bloodborne pathogen exposure reported via the 24-hour Exposure Hotline</p> <p>With the assistance of the hotline clinician, obtain information about the source patient status with respect to bloodborne infections</p> <p>Discuss treatment options with affected UMBI personnel per established protocol: "Post-exposure Anti-Viral Therapy for HIV" http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm</p>
<p>Student & Employee Health University Health Service</p>	<p>Manage HBV employee vaccinations. Offer hepatitis B vaccination to all employees included in the UMBI Bloodborne Pathogen Exposure Program</p> <p>Confer with the infectious disease professionals to determine treatment guidelines, medical oversight, and coordination of all activities related to medical management of employees/students who have sustained an exposure to bloodborne pathogens</p> <p>Conduct follow-up internal testing, and maintain documentation as required</p>
<p>Office of Research and Development</p>	<p>Oversee the coordination of management resources to address both individual and institutional concerns in regard to health and safety issues pertaining to bloodborne pathogens</p> <p>Maintain copies of training documentation regarding bloodborne pathogens supplied by the Centers</p> <p>Review, evaluate, and assist in the selection of proper personal protective equipment</p>

	<p>Participate in the resolution of health and safety issues in the workplace</p> <p>Coordinate the provision of required training and retraining with the Center administrator</p> <p>Coordinate, and disseminate educational programs for staff and students</p> <p>Coordinate training and/or retraining of all appropriate employees/students as needed</p> <p>Coordinate monitoring of work practices to determine the need for training/retraining and to ensure compliance with policy.</p> <p>Coordinate scheduling and documentation of the training process; coordinate education programs.</p> <p>Coordinate evaluation of incidents involving potential exposure to bloodborne pathogens by staff and students</p>
Source patient Hospitals	<p>Provide the serostatus of the source patient or material, when appropriate, when sought by the student or employee healthcare giver or Emergency Department or attending physician after requesting that the HIV test consent form be read and signed by the source patient.</p>

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Hospital Infection Control Practices Advisory Committee. Guideline for prevention of nosocomial pneumonia. Parts I and II. *Am J Infect Control* 1994;22:247-292.

Martin, MA, Reichelderfer, M. APIC guideline for infection prevention and control in flexible endoscopy. *Am J Infect Control* 1994;22:19-38.

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Public Health Service Guidelines for the Management of Health-Care Worker Exposures to HIV and Recommendations for Postexposure Prophylaxis. CDC Publication: *MMWR*, May 15, 1998, Vol. 47, No. RR-7.

Rutala WA. Guideline for selection and use of disinfectants. *Am J Infect Control* 1996;24:313-342.

APPENDIX A - FORMS

Employee's First Report of Injury

(To be completed by employee at time of accident)

UNIVERSITY OF MARYLAND BIOTECHNOLOGY ISNTITUTE

WC Policy No. 921094

IWIF CASE #:

Employee Name: _____ SSN: _____
Last First Middle

Date of Birth: _____ Marital Status: _____ Biweekly Salary: \$ _____

No. of Dependents: _____ Full Time or Part Time (circle one): FT/PT

Home Address: _____
Street Phone

City State Zip Code
Present Job Title: _____ Employment Start Date: _____

UMBI Unit: _____ Supervisor: _____
Last First

Work Address: _____
City State Zip Code

Accident Date: _____ Time: _____ am pm Time Shift Began: _____

Accident Location: _____
Bldg. Address Area (hallway, etc.)

When Accident reported to Supervisor _____

Describe fully how accident occurred (your activities at that time):

(Continue on other side, if necessary)

Describe bodily injury sustained (be specific about part(s) of body affected) (continue on other side, if necessary):

Was medical treatment sought? If so, where: _____
Name Address

City State Zip Code Phone

Safety equipment (list items in use): _____

Name(s) of witness(es): _____
Name Phone

Recommendation on how to prevent this accident from recurring: _____

Signature of employee: _____ Date: _____

Fax immediately to Kathy DeShong at (410) 385-6345

rev 2/05/01

Accident Witness Statement

(To be completed by accident witness)

Employer: **University of Maryland Biotechnology Institute**

Injured employee: _____
Last First Middle

UMBI Unit: _____

Job Title: _____

Location of accident: _____
Bldg Address Area (hallway, etc.)

Date of accident: _____ Time of accident: _____

Describe fully how accident occurred:

Describe bodily injury sustained (be specific about part(s) of body affected):

Recommendation on how to prevent this accident from recurring:

Name of witness: _____ Work Phone: _____

Signature of witness: _____ Date: _____

*Fax immediately to Kathy DeShong, (410) 385-6345

rev 2/01

Employee/Student/Volunteer Hepatitis B Vaccine Declination (Mandatory)

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

Full Time or Part Time or Student (circle one): FT / PT / ST

Name: _____
(Print)

Signature: _____

Date: _____

Social Security Number: _____

Witness Signature: _____

Witness Name: _____

APPENDIX B

BLOODBORNE PATHOGENS STANDARD

U.S. Department of Labor Occupational Safety & Health Administration

www.osha.gov

Standard - 29 CFR Bloodborne pathogens. - 1910.1030

Regulations (Standards - 29 CFR) - Table of Contents

- Part Number: 1910
- Part Title: Occupational Safety and Health Standards
- Subpart: Z
- Subpart Title: Toxic and Hazardous Substances
- Standard Number: 1910.1030
- Title: Bloodborne pathogens.
- Appendix: A

1910.1030(a)

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

1910.1030(b)

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

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

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

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

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

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

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

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

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

Director means the Director of the National Institute for Occupational Safety and Health, U.S.

Department of Health and Human Services, or designated representative.

Engineering Controls means controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace.

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

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

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

HBV means hepatitis B virus.

HIV means human immunodeficiency virus.

Needleless systems means a device that does not use needles for:

(1) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (2) The administration of medication or fluids; or (3) Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

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

Other Potentially Infectious Materials means (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

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

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

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

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

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

Sharps with engineered sharps injury protections means a nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

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

Sterilize means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

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

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

1910.1030(c)

Exposure Control --

1910.1030(c)(1)

Exposure Control Plan.

1910.1030(c)(1)(i)

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

1910.1030(c)(1)(ii)

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

1910.1030(c)(1)(ii)(A)

The exposure determination required by paragraph (c)(2), 1910.1030(c)(1)(ii)(B)

1910.1030(c)(1)(ii)(B)

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

1910.1030(c)(1)(ii)(C)

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

1910.1030(c)(1)(iii)

Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.1020(e).

1910.1030(c)(1)(iv)

The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure. The review and update of such plans shall also:

1910.1030(c)(1)(iv)(A)

Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and

1910.1030(c)(1)(iv)(B)

Document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.

1910.1030(c)(1)(v)

An employer, who is required to establish an Exposure Control Plan shall solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan.

1910.1030(c)(1)(vi)

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

1910.1030(c)(2)

Exposure Determination.

1910.1030(c)(2)(i)

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

1910.1030(c)(2)(i)(A)

A list of all job classifications in which all employees in those job classifications have occupational exposure; .1910.1030(c)(2)(i)(B)

1910.1030(c)(2)(i)(B)

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

1910.1030(c)(2)(i)(C)

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

1910.1030(c)(2)(ii)

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

1910.1030(d)

Methods of Compliance --

1910.1030(d)(1)

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

1910.1030(d)(2)

Engineering and Work Practice Controls.

1910.1030(d)(2)(i)

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

..1910.1030(d)(2)(ii)

1910.1030(d)(2)(ii)

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

1910.1030(d)(2)(iii)

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

1910.1030(d)(2)(iv)

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

1910.1030(d)(2)(v)

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

1910.1030(d)(2)(vi)

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

1910.1030(d)(2)(vii)

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

..1910.1030(d)(2)(vii)(A)

1910.1030(d)(2)(vii)(A)

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

1910.1030(d)(2)(vii)(B)

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

1910.1030(d)(2)(viii)

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

1910.1030(d)(2)(viii)(A)

Puncture resistant;

1910.1030(d)(2)(viii)(B)

Labeled or color-coded in accordance with this standard;

1910.1030(d)(2)(viii)(C)

Leakproof on the sides and bottom; and

1910.1030(d)(2)(viii)(D)

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

1910.1030(d)(2)(ix)

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

1910.1030(d)(2)(x)

Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials are present.

..1910.1030(d)(2)(xi)

1910.1030(d)(2)(xi)

All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.

1910.1030(d)(2)(xii)

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

1910.1030(d)(2)(xiii)

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

1910.1030(d)(2)(xiii)(A)

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

1910.1030(d)(2)(xiii)(B)

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

..1910.1030(d)(2)(xiii)(C)

1910.1030(d)(2)(xiii)(C)

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

1910.1030(d)(2)(xiv)

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

1910.1030(d)(2)(xiv)(A)

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

1910.1030(d)(2)(xiv)(B)

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

1910.1030(d)(3)

Personal Protective Equipment --

1910.1030(d)(3)(i)

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

1910.1030(d)(3)(ii)

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

1910.1030(d)(3)(iii)

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

1910.1030(d)(3)(iv)

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

..1910.1030(d)(3)(v)

1910.1030(d)(3)(v)

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

1910.1030(d)(3)(vi)

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

1910.1030(d)(3)(vii)

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

1910.1030(d)(3)(viii)

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

1910.1030(d)(3)(ix)

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

1910.1030(d)(3)(ix)(A)

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

..1910.1030(d)(3)(ix)(B)

1910.1030(d)(3)(ix)(B)

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

1910.1030(d)(3)(ix)(C)

Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised.

However, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.

1910.1030(d)(3)(ix)(D)

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

1910.1030(d)(3)(ix)(D)(1)

Periodically reevaluate this policy;

1910.1030(d)(3)(ix)(D)(2)

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

1910.1030(d)(3)(ix)(D)(3)

Not discourage the use of gloves for phlebotomy; and

1910.1030(d)(3)(ix)(D)(4)

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

1910.1030(d)(3)(ix)(D)(4)(i)

When the employee has cuts, scratches, or other breaks in his or her skin;

1910.1030(d)(3)(ix)(D)(4)(ii)

When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and

1910.1030(d)(3)(ix)(D)(4)(iii)

When the employee is receiving training in phlebotomy.

..1910.1030(d)(3)(x)

1910.1030(d)(3)(x)

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

1910.1030(d)(3)(xi)

Gowns, Aprons, and Other Protective Body Clothing. Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments shall be worn in

occupational exposure situations. The type and characteristics will depend upon the task and degree of exposure anticipated.

1910.1030(d)(3)(xii)

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

1910.1030(d)(4)

Housekeeping --

1910.1030(d)(4)(i)

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

1910.1030(d)(4)(ii)

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

..1910.1030(d)(4)(ii)(A)

1910.1030(d)(4)(ii)(A)

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

1910.1030(d)(4)(ii)(B)

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

1910.1030(d)(4)(ii)(C)

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

1910.1030(d)(4)(ii)(D)

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

1910.1030(d)(4)(ii)(E)

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

1910.1030(d)(4)(iii)

Regulated Waste --

..1910.1030(d)(4)(iii)(A)

1910.1030(d)(4)(iii)(A)

Contaminated Sharps Discarding and Containment.

1910.1030(d)(4)(iii)(A)(1)

Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:

1910.1030(d)(4)(iii)(A)(1)(i)

Closable;

1910.1030(d)(4)(iii)(A)(1)(ii)

Puncture resistant;

1910.1030(d)(4)(iii)(A)(1)(iii)

Leakproof on sides and bottom; and

1910.1030(d)(4)(iii)(A)(1)(iv)

Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard.

1910.1030(d)(4)(iii)(A)(2)

During use, containers for contaminated sharps shall be:

1910.1030(d)(4)(iii)(A)(2)(i)

Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries);
1910.1030(d)(4)(iii)(A)(2)(ii)
Maintained upright throughout use; and
1910.1030(d)(4)(iii)(A)(2)(iii)
Replaced routinely and not be allowed to overfill.
1910.1030(d)(4)(iii)(A)(3)
When moving containers of contaminated sharps from the area of use, the containers shall be:
1910.1030(d)(4)(iii)(A)(3)(i)
Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping;
1910.1030(d)(4)(iii)(A)(3)(ii)
Placed in a secondary container if leakage is possible. The second container shall be:
1910.1030(d)(4)(iii)(A)(3)(ii)(A)
Closable;
1910.1030(d)(4)(iii)(A)(3)(ii)(B)
Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and
1910.1030(d)(4)(iii)(A)(3)(ii)(C)
Labeled or color-coded according to paragraph (g)(1)(i) of this standard.
1910.1030(d)(4)(iii)(A)(4)
Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.
1910.1030(d)(4)(iii)(B)
Other Regulated Waste Containment --
1910.1030(d)(4)(iii)(B)(1)
Regulated waste shall be placed in containers which are:
1910.1030(d)(4)(iii)(B)(1)(i)
Closable;
1910.1030(d)(4)(iii)(B)(1)(ii)
Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;
1910.1030(d)(4)(iii)(B)(1)(iii)
Labeled or color-coded in accordance with paragraph (g)(1)(i) this standard; and
1910.1030(d)(4)(iii)(B)(1)(iv)
Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.
1910.1030(d)(4)(iii)(B)(2)
If outside contamination of the regulated waste container occurs, it shall be placed in a second container. The second container shall be:
1910.1030(d)(4)(iii)(B)(2)(i)
Closable;
1910.1030(d)(4)(iii)(B)(2)(ii)
Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;
1910.1030(d)(4)(iii)(B)(2)(iii)
Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and
1910.1030(d)(4)(iii)(B)(2)(iv)
Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.
1910.1030(d)(4)(iii)(C)
Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.
..1910.1030(d)(4)(iv)
1910.1030(d)(4)(iv)
Laundry.
1910.1030(d)(4)(iv)(A)

Contaminated laundry shall be handled as little as possible with a minimum of agitation.

1910.1030(d)(4)(iv)(A)(1)

Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.

1910.1030(d)(4)(iv)(A)(2)

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

1910.1030(d)(4)(iv)(A)(3)

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

1910.1030(d)(4)(iv)(B)

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

..1910.1030(d)(4)(iv)(C)

1910.1030(d)(4)(iv)(C)

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

1910.1030(e)

HIV and HBV Research Laboratories and Production Facilities.

1910.1030(e)(1)

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

1910.1030(e)(2)

Research laboratories and production facilities shall meet the following criteria:

1910.1030(e)(2)(i)

Standard Microbiological Practices. All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

1910.1030(e)(2)(ii)

Special Practices.

1910.1030(e)(2)(ii)(A)

Laboratory doors shall be kept closed when work involving HIV or HBV is in progress.

..1910.1030(e)(2)(ii)(B)

1910.1030(e)(2)(ii)(B)

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

1910.1030(e)(2)(ii)(C)

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

1910.1030(e)(2)(ii)(D)

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

1910.1030(e)(2)(ii)(E)

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

1910.1030(e)(2)(ii)(F)

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

..1910.1030(e)(2)(ii)(G)

1910.1030(e)(2)(ii)(G)

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

1910.1030(e)(2)(ii)(H)

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

1910.1030(e)(2)(ii)(I)

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

1910.1030(e)(2)(ii)(J)

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

1910.1030(e)(2)(ii)(K)

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

..1910.1030(e)(2)(ii)(L)

1910.1030(e)(2)(ii)(L)

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

1910.1030(e)(2)(ii)(M)

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

1910.1030(e)(2)(iii)

Containment Equipment.

1910.1030(e)(2)(iii)(A)

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

1910.1030(e)(2)(iii)(B)

Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually.

1910.1030(e)(3)

HIV and HBV research laboratories shall meet the following criteria:

..1910.1030(e)(3)(i)

1910.1030(e)(3)(i)

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

1910.1030(e)(3)(ii)

An autoclave for decontamination of regulated waste shall be available.

1910.1030(e)(4)

HIV and HBV production facilities shall meet the following criteria:

1910.1030(e)(4)(i)

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

1910.1030(e)(4)(ii)

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

..1910.1030(e)(4)(iii)

1910.1030(e)(4)(iii)

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

1910.1030(e)(4)(iv)

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

1910.1030(e)(4)(v)

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

1910.1030(e)(4)(vi)

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

1910.1030(e)(5)

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

1910.1030(f)

Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up --

..1910.1030(f)(1)

1910.1030(f)(1)

General.

1910.1030(f)(1)(i)

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

1910.1030(f)(1)(ii)

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

1910.1030(f)(1)(ii)(A)

Made available at no cost to the employee;

1910.1030(f)(1)(ii)(B)

Made available to the employee at a reasonable time and place;

1910.1030(f)(1)(ii)(C)

Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and

1910.1030(f)(1)(ii)(D)

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

1910.1030(f)(1)(iii)

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

..1910.1030(f)(2)

1910.1030(f)(2)

Hepatitis B Vaccination.

1910.1030(f)(2)(i)

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

1910.1030(f)(2)(ii)

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

1910.1030(f)(2)(iii)

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

1910.1030(f)(2)(iv)

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

1910.1030(f)(2)(v)

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

1910.1030(f)(3)

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

1910.1030(f)(3)(i)

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

..1910.1030(f)(3)(ii)

1910.1030(f)(3)(ii)

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

1910.1030(f)(3)(ii)(A)

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

1910.1030(f)(3)(ii)(B)

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

1910.1030(f)(3)(ii)(C)

Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

1910.1030(f)(3)(iii)

Collection and testing of blood for HBV and HIV serological status;

1910.1030(f)(3)(iii)(A)

The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

..1910.1030(f)(3)(iii)(B)

1910.1030(f)(3)(iii)(B)

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

1910.1030(f)(3)(iv)

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

1910.1030(f)(3)(v)

Counseling; and

1910.1030(f)(3)(vi)

Evaluation of reported illnesses.

1910.1030(f)(4)

Information Provided to the Healthcare Professional.

1910.1030(f)(4)(i)

The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

1910.1030(f)(4)(ii)

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

1910.1030(f)(4)(ii)(A)

A copy of this regulation;

1910.1030(f)(4)(ii)(B)

A description of the exposed employee's duties as they relate to the exposure incident;

1910.1030(f)(4)(ii)(C)

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

..1910.1030(f)(4)(ii)(D)

1910.1030(f)(4)(ii)(D)

Results of the source individual's blood testing, if available; and

1910.1030(f)(4)(ii)(E)

All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer's responsibility to maintain.

1910.1030(f)(5)

Healthcare Professional's Written Opinion. The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.

1910.1030(f)(5)(i)

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

1910.1030(f)(5)(ii)

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

1910.1030(f)(5)(ii)(A)

That the employee has been informed of the results of the evaluation; and

1910.1030(f)(5)(ii)(B)

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

..1910.1030(f)(5)(iii)

1910.1030(f)(5)(iii)

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

1910.1030(f)(6)

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

1910.1030(g)

Communication of Hazards to Employees --

1910.1030(g)(1)

Labels and Signs --

1910.1030(g)(1)(i)

Labels.

1910.1030(g)(1)(i)(A)

Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship

blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F) and (G).

1910.1030(g)(1)(i)(B)

Labels required by this section shall include the following legend:

1910.1030(g)(1)(i)(C)

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

1910.1030(g)(1)(i)(D)

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

..1910.1030(g)(1)(i)(E)

1910.1030(g)(1)(i)(E)

Red bags or red containers may be substituted for labels.

1910.1030(g)(1)(i)(F)

Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements of paragraph (g).

1910.1030(g)(1)(i)(G)

Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.

1910.1030(g)(1)(i)(H)

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

1910.1030(g)(1)(i)(I)

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

1910.1030(g)(1)(ii)

Signs.

1910.1030(g)(1)(ii)(A)

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

(Name of the Infectious Agent)

(Special requirements for entering the area)

(Name, telephone number of the laboratory director or other responsible person.)

..1910.1030(g)(1)(ii)(B)

1910.1030(g)(1)(ii)(B)

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

1910.1030(g)(2)

Information and Training.

1910.1030(g)(2)(i)

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

1910.1030(g)(2)(ii)

Training shall be provided as follows:

1910.1030(g)(2)(ii)(A)

At the time of initial assignment to tasks where occupational exposure may take place;

1910.1030(g)(2)(ii)(B)

Within 90 days after the effective date of the standard; and

1910.1030(g)(2)(ii)(C)

At least annually thereafter.

1910.1030(g)(2)(iii)

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

1910.1030(g)(2)(iv)

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

..1910.1030(g)(2)(v)

1910.1030(g)(2)(v)

Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

1910.1030(g)(2)(vi)

Material appropriate in content and vocabulary to educational level, literacy, and language of employees shall be used.

1910.1030(g)(2)(vii)

The training program shall contain at a minimum the following elements:

1910.1030(g)(2)(vii)(A)

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

1910.1030(g)(2)(vii)(B)

A general explanation of the epidemiology and symptoms of bloodborne diseases;

1910.1030(g)(2)(vii)(C)

An explanation of the modes of transmission of bloodborne pathogens;

1910.1030(g)(2)(vii)(D)

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

1910.1030(g)(2)(vii)(E)

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

..1910.1030(g)(2)(vii)(F)

1910.1030(g)(2)(vii)(F)

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

1910.1030(g)(2)(vii)(G)

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

1910.1030(g)(2)(vii)(H)

An explanation of the basis for selection of personal protective equipment;

1910.1030(g)(2)(vii)(I)

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

1910.1030(g)(2)(vii)(J)

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

1910.1030(g)(2)(vii)(K)

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

1910.1030(g)(2)(vii)(L)

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

..1910.1030(g)(2)(vii)(M)

1910.1030(g)(2)(vii)(M)

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

1910.1030(g)(2)(vii)(N)

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

1910.1030(g)(2)(viii)

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

1910.1030(g)(2)(ix)

Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities.

Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements.

1910.1030(g)(2)(ix)(A)

The employer shall assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.

1910.1030(g)(2)(ix)(B)

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

..1910.1030(g)(2)(ix)(C)

1910.1030(g)(2)(ix)(C)

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

1910.1030(h)

Recordkeeping --

1910.1030(h)(1)

Medical Records.

1910.1030(h)(1)(i)

The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020.

1910.1030(h)(1)(ii)

This record shall include:

1910.1030(h)(1)(ii)(A)

The name and social security number of the employee;

1910.1030(h)(1)(ii)(B)

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

1910.1030(h)(1)(ii)(C)

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

1910.1030(h)(1)(ii)(D)

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

..1910.1030(h)(1)(ii)(E)

1910.1030(h)(1)(ii)(E)

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

1910.1030(h)(1)(iii)

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

1910.1030(h)(1)(iii)(A)

Kept confidential; and

1910.1030(h)(1)(iii)(B)

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

1910.1030(h)(1)(iv)

The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020.

1910.1030(h)(2)

Training Records.

1910.1030(h)(2)(i)

Training records shall include the following information:

1910.1030(h)(2)(i)(A)

The dates of the training sessions;

1910.1030(h)(2)(i)(B)

The contents or a summary of the training sessions;

1910.1030(h)(2)(i)(C)

The names and qualifications of persons conducting the training; and

..1910.1030(h)(2)(i)(D)

1910.1030(h)(2)(i)(D)

The names and job titles of all persons attending the training sessions.

1910.1030(h)(2)(ii)

Training records shall be maintained for 3 years from the date on which the training occurred.

1910.1030(h)(3)

Availability.

1910.1030(h)(3)(i)

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

1910.1030(h)(3)(ii)

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

1910.1030(h)(3)(iii)

Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.1020.

..1910.1030(h)(4)

1910.1030(h)(4)

Transfer of Records.

1910.1030(h)(4)(i)

The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h).

1910.1030(h)(4)(ii)

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

1910.1030(h)(5)

Sharps injury log.

1910.1030(h)(5)(i)

The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum:

1910.1030(h)(5)(i)(A)

The type and brand of device involved in the incident,

1910.1030(h)(5)(i)(B)

The department or work area where the exposure incident occurred, and

1910.1030(h)(5)(i)(C)

An explanation of how the incident occurred.

1910.1030(h)(5)(ii)

The requirement to establish and maintain a sharps injury log shall apply to any employer who is required to maintain a log of occupational injuries and illnesses under 29 CFR 1904.

1910.1030(h)(5)(iii)

The sharps injury log shall be maintained for the period required by 29 CFR 1904.6.

1910.1030(i)

Dates --

1910.1030(i)(1)

Effective Date. The standard shall become effective on March 6, 1992.

1910.1030(i)(2)

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

1910.1030(i)(3)

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

1910.1030(i)(4)

Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, and (g)(1) Labels and Signs, shall take effect July 6, 1992.

[56 FR 64004, Dec. 06, 1991, as amended at 57 FR 12717, April 13, 1992; 57 FR 29206, July 1, 1992; 61 FR 5507, Feb. 13, 1996; 66 FR 5325 Jan., 18, 2001]

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