OSHA BLOODBORNE PATHOGENS

EXPOSURE CONTROL PLAN FOR

UNIVERSITY OF MOUNT UNION

Revised and Restated June 2009
Reviewed October 2013

I. GENERAL POLICY.

A. BACKGROUND.

One of the major goals of the Occupational Safety and Health Administration (OSHA) is to promote safe work practices in an effort to minimize the incidence of illness and injury experienced by employees. In furtherance of this goal, OSHA enacted the Occupational Exposure to Bloodborne Pathogens Standard, codified as 29 CFR §1910.1030 (the "OSHA Standard"). The purpose of the OSHA Standard is to "reduce occupational exposure to hepatitis B Virus ("HBV"), human immunodeficiency virus ("HIV") and other bloodborne pathogens" that employees may encounter in their workplace.

B. CONTENTS AND AVAILABILITY OF EXPOSURE CONTROL PLAN.

University of Mount Union ("Mount Union") realizes that occupational exposure to blood or other potentially infectious materials can occur to its employees. Therefore, in order to protect the health and welfare of its employees, Mount Union has established certain precautions and safeguards for all employees who may come into contact with blood or blood products.

Mount Union has created this Exposure Control Plan (the "Plan") to comply with the OSHA Standard. The Plan provides for the following:

1. A schedule of how and when the provisions of the OSHA Standard will be implemented.

2. Exposure determinations.

3. Methods of compliance.

4. Hepatitis B vaccination and postexposure evaluation and follow-up.

5. Labeling.

6. Training.

7. Recordkeeping.

This Plan is accessible to all employees and will be reviewed and updated annually at least annually and as necessary to:

1. Reflect new or modified tasks and procedures which affect occupational exposure;

2. Reflect new or revised employee positions with occupational exposure;

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

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

Copies of the Plan will be kept at the following locations: (1) the Human Resources Department; (2) on reserve at the university library; (3) the Student Health Center; (4) in the office of the Head Athletic Trainer; (5) in the office of the Director of Physical Plant; and (7) in the office of with responsibility for the supervision of lifeguards. The Director of the Health Center has been designated by Mount Union to be the Bloodborne Pathogens Exposure Control Plan compliance manager (the "Compliance Manager")for Mount Union and will be responsible for initial implementation and continuing oversight of this Exposure Control Plan, including retention of records related to employee compliance with the Plan.

C. DISCIPLINE-FAILURE TO COMPLY WITH EXPOSURE CONTROL PLAN.

Mount Union has established the following Plan in accordance with the OSHA Standard. The Plan is intended to protect Mount Union's employees from occupational exposure to Bloodborne Pathogens. Employees must abide by the procedures set forth in the Exposure Control Plan . Failure to follow procedures will result in disciplinary action up to and including termination.

For example, employee's must schedule and attend bloodborne pathogens training in a timely manner after being hired by Mount Union and annually thereafter so as to comply with the Plan. Employees must also schedule and receive Hepatitis B vaccination, unless the employee has declined the vaccination in accordance with the requirements of the Plan or has executed a verification of previous vaccination and provides the dates of such vaccination.

A staff member or non-tenured employee who fails to receive bloodborne pathogens training within 10 days after initial hiring or within 10 days after initial assignment at Mount Union will receive one (1) written warning and thereafter is subject to termination for failure to comply with his or her obligations under the Plan. Similarly, a non-tenured employee who fails to complete or waive his/her Hepatitis B vaccination within 10 days of commencing employment at Mount Union will receive one (1) written warning from the appropriate employee handbook of discipline and thereafter is subject to termination for failure to comply with his or her obligations under the Plan.

A tenured employee who fails to comply with bloodborne pathogens requirements is subject to discipline in accordance with tenured employee discipline policies.

II. DEFINITIONS.

The following definitions govern the terms used throughout the plan:

"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).

"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.

"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.

“HBV” means hepatitis B virus.

“HIV” or “AIDS” 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.

"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.

"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).

III. SCHEDULE OF IMPLEMENTATION OF THE OSHA BLOODBORNE PATHOGENS STANDARD.

In 1994, Mount Union implemented the following components of the OSHA Standard:

1. Existence of Written exposure control plan.

2. Exposure determination.

3. Methods of compliance.

(a) Engineering/work practice controls.

(b) Personal protective equipment.

(c) Housekeeping.

4. HBV vaccination/postexposure procedures.

5. Labeling.

6. Training.

7. Recordkeeping.

This Plan has been subsequently reviewed and updated, the most recent revision of which was completed in June 2009. The Plan was again reviewed in 2012.

IV. EXPOSURE DETERMINATION.

The Standard requires each employer that has one or more employees with "occupational exposure" to prepare an exposure determination which lists the job classifications of all employees who have occupational exposure.

A. JOB CLASSIFICATIONS - ALL EMPLOYEES HAVE EXPOSURE.

All employees at Mount Union that hold the following indicated positions have occupational exposure to "blood" or "other potentially infectious materials":

1. Nurses, and faculty in the Nursing Program engaged in instructing on blood draws;

2. Faculty in the Physician Assistant Program engaged in instructing on blood draws:

3. Laundry Workers (including paid student laundry workers);

4. Certified Athletic Trainers;

5. Housekeeping Employees;

6. Paid Student Athletic Trainers (this category includes only eligible students whose names are provided to the Student Health Center on an annual basis by the Head Athletic Trainer);

7. Lifeguards;

8. Security Guards

9. Human Performance and Sports Business Personnel who engage in drawing blood; and

10. Others with responsibility for responding to emergencies.

A list of the names of the individuals in the above-listed positions is kept by the Director of Human Resources. The Director of Human Resources will furnish the Compliance Manager with updates to this list or a current list of names on a regular basis. The names of student workers will be held and updated through the office of student financial services.

B. JOB CLASSIFICATIONS - SOME EMPLOYEES HAVE EXPOSURE.

Some employees at Mount Union holding the positions indicated below (but not all such employees, i.e. student workers) have occupational exposure to "blood" or "other potentially infectious materials." That is, they are occasionally called upon to perform tasks that may result in occupational exposure to blood or other potentially infectious materials:

1. Employees in the Physical Plant that are designated to perform blood spill cleanup.

2. Grounds Crew Members; excluding all student workers.

For those job classifications listed above, the following are a list of the tasks and procedures or groups of closely related tasks and procedures in which occupational exposure to blood or other potentially infectious material occurs:

1. Blood spill cleanup

2. Responding to emergency situations or situations requiring first aid.

A list of the names of the individuals in the above-listed positions is kept by the Director of Human Resources and by the Compliance Manager.

C. JOB CLASSIFICATIONS - NO EMPLOYEES HAVE EXPOSURE.

The employees at Mount Union in the following job classifications have no occupational exposure:

1. All Mount Union employees except those listed above.

V. METHODS OF IMPLEMENTATION.

Mount Union has adopted the following concepts and procedures, which are specifically required

by the OSHA Standard.

A. UNIVERSAL PRECAUTIONS.

The OSHA Standard requires the use of "universal precautions" to prevent contact with blood or other potentially infectious materials. In addition, whenever it is difficult or impossible to distinguish between different body fluids, all body fluids must be treated as if contaminated by HIV, HBV, and other bloodborne pathogens.

B. ENGINEERING AND WORK PRACTICE CONTROLS.

Engineering controls reduce exposure to blood or other potentially infectious materials in the work place by either removing the hazard or isolating the worker from the hazard. Generally, this is achieved by using equipment designed for this purpose. An example of an engineering control is the use of sharps disposal containers, which isolate the hazard from the employee by physical means.

Work practice controls reduce the chance of exposure through changing the way in which a task is performed. Examples of work practice controls are proper hand washing and prohibiting recapping of contaminated needles.

The engineering and work practice controls listed below are specifically required in the OSHA Standard.

The engineering controls listed below will be examined and maintained or replaced on a regular schedule to ensure their effectiveness, by the following individuals for the following areas:

Individual	Area
Head Athletic Trainer	Human Performance and Sport Business
Housekeeping Supervisor	Housekeeping
Director of the Physical Plant	Physical Plant
Grounds Supervisor	Grounds Crew
Person supervising lifeguards	Pools, Pool Areas, and Lifeguard Areas

1. Handwashing.

(a) Handwashing facilities (an adequate supply of running potable water, soap, and single-use towels or hot-drying machines) are available in most areas in which an employee has occupational exposure to blood or other potentially infectious materials. Handwashing facilities are available in two (2) examination rooms, laundry area, and the laboratory of the Student Health Center; training room and laundry area in Timken; and in all other university buildings.

(b) In locations where employees may have occupational exposure to blood or other potentially infectious materials but soap and running water are not available, the employer has provided antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. These handwashing alternatives are located in two (2) of the examination rooms, the training rooms, in each certified athletic trainer's first aid kit, and in the Physical Plant trucks.

(c) Whenever employees use antiseptic hand cleansers or towelettes, the employer requires that the employees wash their hands with soap and running water as soon as feasible.

(d) The employer and the Head Athletic Trainer (for the Human Performance and Sports Business Department), the Housekeeping Supervisor (for Housekeeping), Grounds Supervisor (for Grounds Crew), and the Director of the Physical Plant (for Physical Plant), and the person supervising the lifeguards (for the lifeguards) will ensure that employees wash their hands immediately or as soon as feasible after removing gloves or any other personal protective equipment (for example, masks, goggles, gowns).

(e) The employer the Head Athletic Trainer (for the Human Performance and Sports Business Department), the Housekeeping Supervisor (for Housekeeping), Grounds Supervisor (for Grounds Crew), and the Director of the Physical Plant (for Physical Plant), and the person supervising the lifeguards (for the lifeguards) will ensure that employees wash their hands and any other skin with soap and water, or flush mucus membranes with water immediately or as soon as feasible after contact of such body areas with blood or other potentially infectious materials.

2. Contaminated Needles and Other Contaminated Sharps.

(a) Contaminated needles and other contaminated sharps are not sheared or broken.

(b) Contaminated needles and other contaminated sharps are not bent, recapped, or removed unless the employer has complied with the following:

(i) Contaminated needles and other contaminated sharps are not recapped or removed unless the employer has documented that no alternative to such recapping or removal is feasible or that such action is required by a specific medical procedure.

In addition, even in these situations, recapping or needle removal is accomplished through the use of a mechanical device or a one-handed technique.

(ii) The employer has completed the documentation, Recapping/Removing Contaminated Needles, attached as Exhibit 1.

3. Containers for Contaminated Reusable Sharps.

As soon as feasible after use, employees must place contaminated reusable sharps into a container that is:

- puncture resistant
- labeled with the biohazard symbol or color coded red in accord with the OSHA Standard
- leakproof on the sides and bottom
- stored and processed in a manner so that employees do not reach into the reusable sharps container by hand

The reusable sharps containers for the Mount Union are stainless steel containers with lids and an appropriate biohazard sticker and are located in the laundry area.

4. Restrictions on Eating, Drinking, Etc. 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 to blood or other potentially infectious materials.

5. Restrictions on Storage of Food, Drink, Etc. Food and drink are not kept in refrigerators, freezers, shelves, cabinets, or on countertops or benchtops where blood or other potentially infectious materials are present or routinely stored. Food and drink may be kept in separate storage areas where blood or other potentially infectious materials are not present or are not routinely stored.

6. Minimizing Splashing, Spraying, Spattering. Procedures that involve blood or other potentially infectious materials are performed in such a manner as to minimize splashing, spraying, spatting, and generation of droplets of these substances.

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

8. Specimens of Blood or Other Potentially Infectious Materials.

(a) Specimens of blood or other potentially infectious materials are placed in the following type of container:

(i) prevents leakage during collection, handling, processing, storage, transport, or

shipping

(ii) labeled with the biohazard symbol or color coded in red

(iii) closed prior to being stored, transported, or shipped

(b) Specimen containers used by Mount Union are placed in transport containers and then placed in a leak-proof bag that is color coded in red or labeled with the biohazard symbol.

(c) If outside contamination of the primary container occurs, the primary container should be placed into a second container that prevents leakage, is closed, and is labeled with the biohazard symbol or color coded in red.

(d) If the specimen could puncture the primary container, the primary container is placed in a second container that prevents leakage, is closed, is labeled with the biohazard symbol or color coded in red, and is puncture resistant.

9. Servicing/Shipping of Equipment.

Equipment that may become contaminated with blood or other potentially infectious materials is examined by the Human Performance and Sports Business Chairman (for the Human Performance and Sports Business Department), the Housekeeping Supervisor (for the Housekeeping area), Grounds Supervisor (for Grounds Crew), and the Director of the Physical Plant (for the Physical Plant), and the person supervising the lifeguards (for the lifeguards) prior to servicing (whether by employees or outside servicing personnel) or shipping and is decontaminated by the individuals listed above for each area or an appropriate designated individual covered by this Plan if necessary unless the employer can demonstrate that decontamination of the equipment or portions of the equipment is not feasible. If the employer demonstrates that decontamination of such equipment or portions of such is not feasible, the Human Performance and Sports Business Chairman (for the Human Performance and Sports Business Department), the Housekeeping Supervisor (for the Housekeeping area), Grounds Supervisor (for Grounds Crew), and the Director of the Physical Plant (for Physical Plant situations), and the person supervising the lifeguards (for the lifeguards) should attach a biohazard label that states what portions of the equipment are contaminated. In addition, in situations in which the equipment or portions of the equipment are not decontaminated prior to servicing or shipping the Human Performance and Sports Business Chairman (for the Human Performance and Sports Business Department), the Housekeeping Supervisor (for the Housekeeping area), Grounds Supervisor (for Grounds Crew), and the Director of the Physical Plant (for Physical Plant situations), and the person supervising the lifeguards (for the lifeguards) must inform the following persons, as appropriate, that the equipment or portions of the equipment are contaminated prior to handling, servicing, or shipping so that such person can take appropriate precautions:

- Affected employees;
- Servicing representative; and/or

- The manufacturer.

C. PERSONAL PROTECTIVE EQUIPMENT.

1. Provision of Personal Protective Equipment. When it is reasonably anticipated that an employee(s) will have skin, eye, mucus membrane, or parenteral contact with blood or other potentially infectious materials during the performance of his or her duties as an employee, the OSHA Standard requires that the employer provide, at no cost to the employee, appropriate personal protective equipment such as gloves, gowns, laboratory coats, clinic jackets, face shields or masks, mouth pieces, resuscitation bags, pocket masks, or other ventilation devices. The personal protective equipment provided by this employer is listed in Section 3. below.

2. Use of Personal Protective Equipment. Employees must use personal protective equipment when appropriate unless under rare and extraordinary circumstances, it is the employee's professional judgment that in the specific instance its use of personal protective equipment 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. The introduction to the OSHA Standard gives examples of what OSHA considers "rare and extraordinary circumstances." These include: sudden changes in patient status that puts the patient's life in immediate jeopardy; a firefighter discovers that his/her resuscitation equipment is damaged and he/she must administer CPR.

   Whenever an employee makes this judgment, the matter should be reported to the Compliance Manager as soon as possible. The Compliance Manager will investigate and document the circumstances. The Compliance Manager will use the form entitled "Investigation/Documentation of Employee's Non-Use of Personal Protective Equipment", a copy of which is attached as Exhibit 2, to determine, in conjunction with other College Personnel, if appropriate, whether changes can be made to prevent such occurrences in the future.

3. Personal protective equipment - availability and accessibility. Appropriate personal protective equipment in appropriate sizes is readily accessible at the following work sites:

   (a) Disposable, single-use gloves, in appropriate sizes, are provided in each examination room, the training room, each certified athletic trainer's first aid kit. Also, antiseptic hand cleaner and gloves are provided in each of the University Physical Plant trucks.

   (b) Utility gloves are available in the Housekeeping Department and the Physical Plant Department.

   (c) Masks, goggles, and disposable protective gowns are available in the each examination room, the training room, and in each certified athletic trainer's first aid kit. They can also be found in Housekeeper's closets and Physical Plant trucks.

(d) A pocket mask is available in each examination room, the training room, and each certified athletic trainer's first aid kit. This will minimize the need for emergency mouth-to-mouth resuscitation without proper equipment.

If an employee is allergic to the gloves normally provided, the employer will make available to such employees hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives which provide effective barrier protection.

4. Gloves

(a) Gloves are required to be worn whenever it can be reasonably anticipated than an employee may have had contact with:

(i) blood,
(ii) other potentially infectious materials,
(iii) mucous membranes,
(iv) non-intact skin,
(v) when performing vascular access procedures,
(vi) when handling or touching contaminated items or surfaces.

(b) Disposable (single-use) gloves, such as surgical or examination gloves, must 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.

(c) Disposable (single-use) gloves should not be washed or decontaminated for reuse.

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

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

Gowns, aprons, and lab coats are required when necessary to prevent blood or other potentially infectious materials from reaching the employee's skin or work clothes.

6. Cleaning, Laundering, Disposal, Repair, Replacement of Personal Protective Equipment.

(a) The employer cleans, launders, and disposes of the personal protective equipment

required by the OSHA Standard, at no cost to the employee.

(b) The employer repairs or replaces the personal protective equipment as needed, at no cost to the employee.

7. Removal and Storage of Personal Protective Equipment.

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

(b) All personal protective equipment is required to be removed prior to leaving the work area.

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

D. HOUSEKEEPING.

1. Cleaning Schedule. The Head Athletic Trainer (for the Human Performance and Sports Business Department), the Housekeeping Supervisor (for the Housekeeping area), Grounds Supervisor (for Grounds Crew), and the Director of the Physical Plant (for Physical Plant), and the person supervising the lifeguards (for the lifeguards) will each ensure that their respective areas are maintained in a clean and sanitary condition. The individuals listed in the preceding sentence (for the areas listed in the preceding sentence) will determine and implement the Written Schedule For Cleaning attached as Exhibit 3 hereto, which schedule will include the appropriate method of disinfection for the different surfaces, equipment, and rooms in their respective areas (based on the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures performed in the area).

2. Requirement to Wear Gloves. All employees should wear protective gloves when cleaning and disinfecting surfaces or items contaminated with blood or other potentially infectious materials. Utility gloves should be worn when cleaning contaminated reusable sharps.

3. Cleaning and Disinfection.

(a) All equipment/surfaces. Equipment and working surfaces must be cleaned and decontaminated with an appropriate disinfectant after contact with blood or other potentially infectious materials.

(b) Work surface decontamination. Work surfaces must also be decontaminated with an appropriate disinfectant at the following times:

(i) after completion of procedures;

(ii) immediately or as soon as feasible when surfaces become obviously contaminated;

(iii) after any spill of blood or any potentially infectious materials; and

(iv) at the end of the work shift.

(c) Protective coverings. Protective coverings such as plastic wrap, aluminum foil or imperviously backed absorbent paper may be used to cover equipment and environmental surfaces, but they are not required. If used, the protective coverings shall be removed and replaced as soon as feasible when they are obviously contaminated or at the end of the work shift.

(d) Decontamination prior to servicing/shipping. As stated above, equipment that may become contaminated with blood or other potentially infectious materials should be checked by the Chairman of Human Performance and Sports Business (for the Human Performance and Sports Business Department), and the Head Athletic Trainer. These infectious materials should also be checked by the Director of the Physical Plant (for the Physical Plant Department), and the person supervising the lifeguards (for the lifeguards) routinely and prior to servicing or shipping. It should be decontaminated as necessary. See Engineering and Work Practices Section 9 above for labeling requirements and other information requirements required prior to shipping or servicing (whether by in-house employees or by outside servicers).

e) Bins, pails, cans, other receptacles. All bins, pails, cans, and similar items intended for reuse that may become contaminated with blood or other potentially infectious materials should be inspected and decontaminated by the Housekeeping Department on a bi-weekly basis. In addition, these items will be cleaned and decontaminated immediately or as soon as feasible if visible contamination occurs.

(f) Broken glassware. Broken glassware that may be contaminated shall not be picked up with the hands. Instead, it will be cleaned up using a brush and dustpan or tongs or forceps and placed in a sharps container.

(g) Reusable sharps. Reusable sharps that are contaminated with blood or other potentially infectious materials are not stored or processed in a manner that requires employees to reach by hand into the containers where the reusable sharps have been placed. Employees use tongs or forceps to remove reusable sharps from these containers.

Reusable contaminated sharps must be cleaned as follows. Such sharps are placed into the appropriate containers and taken to the decontamination area in the laboratory. These items are then cleaned and rinsed. They are then allowed to dry and are put into appropriate packets prior to heat sterilization. The items are then autoclaved.

E. REGULATED WASTE.

1. Contaminated disposable sharps.

   (a) Immediately or as soon as feasible after use, contaminated disposable sharps should be disposed of in closable, puncture-resistant, disposal containers that are leakproof on the sides and bottom and that are labeled with the biohazard symbol or color coded in red. This office uses disposable sharps containers that are located in each examination room, each certified athletic trainer's first aid kit, and the training room.

   (b) The disposable sharps containers are maintained upright throughout use. They are replaced immediately when full, closed securely, and stored for disposal with the disposal company.

   (c) When moving disposable contaminated sharps containers, the containers are closed immediately prior to removal or replacement to prevent spillage or protrusion of contents. If leakage is possible, the containers should be placed into a second container that is closable, prevents leakage during handling, is color coded in red, or labeled with the biohazard symbol.

2. Reusable Sharps Containers. Reusable sharps containers are not opened, emptied, or cleaned manually or in any other way that would expose employees to risk of percutaneous injury.
3. Other Regulated Waste.

   (a) Regulated wastes other than contaminated sharps are put in leak-proof bags that are labeled with the biohazard symbol or color coded in red and that are located in each examination room, the training room, each certified athletic trainer's first aid kit, and each housekeeping closet.

   These containers are closable, constructed to contain all contents and prevent leakage of fluids during handling, storage, transport, or shipping, labeled with the biohazard symbol or color coded in red, closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

   (b) If outside contamination of these regulated waste containers occurs, the container should be placed in a second container. The second container should also be closable, constructed to contain all contents and to prevent leakage of fluids, labeled with the biohazard symbol or color coded in red, and closed prior to removal.

F. CONTAMINATED LAUNDRY.

1. Generally. The OSHA Standard prohibits employees from taking contaminated laundry

home to be washed at home. Contaminated laundry must be washed at the office or by an outside laundry service. However, it is not the responsibility of the employer to launder uniforms or clothing (i.e., street clothes) worn under personal protective equipment.

2. Handling Requirements/Restrictions. Contaminated laundry is:

   - handled as little as possible with a minimum of agitation

   - put into a red plastic bag or other container at the location where it was used and is not sorted or rinsed in the location of use

   - placed into and transported in red colored bags or bags that are labeled with the biohazard symbol

   - whenever contaminated laundry is wet and might soak through the laundry bag, the laundry is placed and transported in a bag or container that prevents leakage

   - cleaned or laundered by the employer and not taken home by the employee

3. Requirement to Wear Gloves. Employees that have contact with contaminated laundry must wear protective gloves.

4. Shipping to Outside Laundry. Contaminated laundry shipped off-site to a second facility must be placed in laundry bags or containers that are color coded in red or are labeled with the biohazard symbol.

G. POTENTIAL OCCUPATIONAL EXPOSURE AT THE HOSPITAL.

Some of the Mount Union employees also have occupational exposure to blood or other potentially infectious materials at hospital(s).

Mount Union has instructed all employees that have occupational exposure at such hospital(s) to follow such hospital(s)' Exposure Control Plan(s) as it pertains to the activities that the employees perform at the hospital.

Because of the dynamic nature of such hospital(s)' Exposure Control Plan(s), any employee wishing to obtain information about that hospital's Exposure Control Plan, should contact the infection control nurse at Alliance Community Hospital (330) 829-4000. In any event, each employee of this office who also works at a hospital will be instructed to review, become familiar with, and to ask any questions that it may have concerning the Plan at any hospital at which it also has occupational exposure to blood or other potentially infectious materials.

VI. HEPATITIS B VACCINATION AND POSTEXPOSURE FOLLOW-UP.

A. PROVIDING THE HEPATITIS B VACCINE.

1. Hepatitis B Vaccine. The hepatitis B vaccine is provided free of charge by the employer to:

   (a) all employees who have occupational exposure within ten (10) working days of initial assignment after the bloodborne pathogens training is complete unless the employee has previously received the complete hepatitis B vaccination series, antibody testing reveals that the employee is immune, or the vaccine is contraindicated for medical reasons.

2. Certification of Previous HBV Vaccination. If the employee has already had the hepatitis B vaccination, the employee must sign and complete the Certification of Previous Vaccination Form, a copy of which is attached as Exhibit 5 hereto. If the employee is a minor, that person's parent or guardian must sign this form.

3. Declination Statement. If the employee declines the vaccine, the employee must sign a Declination Form, a copy of which is attached as Exhibit 6 hereto. If the employee is a minor, that person's parent or guardian must sign the declination statement.

4. Consent to HBV Vaccination Form. If the employee consents to taking the hepatitis B vaccine, the employee must sign the Consent Form attached as Exhibit 7 hereto. If the employee is a minor, that person's parent or guardian must sign this form

5. Subsequent Vaccination Request. If the employee originally declines hepatitis B vaccination, but at a later date, while still covered under the Plan or OSHA Standard, decides to accept the vaccination, the employer will make the hepatitis B vaccination available at that time.

6. Titers and Booster Doses. Mount Union will provide the employee, at no cost, post-vaccination testing for antibodies to the hepatitis B surface antigen, booster doses, and other related measures to the extent that the U.S. Public Health Guidelines, a copy of which is attached as Exhibit 8 hereto, recommend such measures. A copy of the Titers and Booster Consent Form is also attached as Exhibit 9.

7. Documents to Healthcare Professional. The employer will provide a copy of the OSHA Standard to the healthcare professional who evaluates the employee and/or administers the vaccine to the employee. A copy of the OSHA Standard is attached as Exhibit 10 hereto.

8. Healthcare Professional Opinion Form. Any employee receiving the hepatitis B vaccination will give the Healthcare Professional's Opinion Form - Vaccination Status attached hereto as Exhibit 11 to the healthcare professional to be completed. The employer must have the healthcare professional return the completed form within fifteen (15) days after the employee receives the hepatitis B vaccination. The completed Healthcare Professional's Opinion Form

- Vaccination Status will be filed in the employee's medical record.

B. POST-EXPOSURE EVALUATION AND FOLLOW-UP.

1. Exposure incident. After an employee reports an "exposure incident," the employer will make available to the employee a confidential medical evaluation and follow-up, as described below.

2. Report of exposure incident. Employees in the Human Performance and Sports Business Department should report each exposure incident to the Head Athletic Trainer; Employees in the Housekeeping area should report each exposure incident to the Housekeeping Supervisor; Grounds Crew Employees should report each exposure incident to the Grounds Supervisor; and Employees in the Physical Plant Department should report each exposure incident to the Director of the Physical Plant; and the Lifeguard Employees should report each exposure incident to the person supervising the lifeguards. Subsequently, each such exposure incident should be reported as soon as possible to the Compliance Manager.

3. Documentation of exposure incident. After a report of an exposure incident, the Compliance Manager , if available, and, if not available, the Head Athletic Trainer, Housekeeping Supervisor, Grounds Supervisor, Director of the Physical Plant, as applicable, will record the following items of information concerning the exposure incident on the Exposure Incident Form, a copy of which is provided at the end of this section as Exhibit 12 hereto.

   (a) Documentation of the routes of exposure and the circumstances under which the exposure incident occurred.

   (b) Identification and documentation of the source individual unless the Compliance Manager, Head Athletic Trainer, the Housekeeping Supervisor, Grounds Supervisor, Director of the Physical Plant, and/or the person supervising the lifeguards, as applicable, notes that such identification is not possible or is prohibited by state or local law. If identification is not possible, the Compliance Manager, Head Athletic Trainer, Housekeeping Supervisor, Grounds Supervisor, Director of the Physical Plant, and/or the person supervising the lifeguards, as applicable, will note that fact on the Exposure Incident Report Form.

   (c) Any source individual that consents to the test will be required to sign a Source Consent form Exhibit 13, attached hereto. The source individual's blood will be drawn and tested as soon as feasible after consent is obtained from the source individual, to determine HBV or HIV infectibility. If the source individual is already known to be infected with HBV or HIV, testing for that virus need not be done.

   (d) If consent cannot be obtained from the source individual, the Compliance Manager, Head Athletic Trainer, Housekeeping Supervisor, Grounds Supervisor, Director of the Physical Plant, and/or the person supervising the lifeguards, as applicable, should note in writing

on the Exposure Incident Report Form that legally required consent cannot be obtained from the source individual. Even if the source individual's consent is not obtained, the source individual's blood, if available, shall be tested and the results documented.

(e) Results of the source individual's testing will be made available to the exposed employee. The employee will also be informed of all then applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

(f) The exposed employee will be asked to consent to blood collection and testing for HIV and HBV (the employee has the right to refuse consent for the blood collection and testing). Any exposed employee that consents to the testing will be required to sign an Employee Consent To Test Form, a copy of which is attached as Exhibit 14 hereto.

(g) If the employee consents to the HIV and HBV testing, the blood is collected and tested for HIV and HBV as soon as possible. If the employee declines testing but consents to blood collection, the blood sample must be held for ninety (90) days in the laboratory. If, within this ninety (90)-day time period, the employee decides to consent to have the baseline blood sample tested, a consent form should be signed and such testing must be done as soon as feasible.

(i) If the employee refuses to have the HIV and/or HBV testing done, the Compliance Manager , Head Athletic Trainer, Housekeeping Supervisor, Grounds Supervisor, Director of the Physical Plant, and/or the person supervising the lifeguards, as applicable, must complete the form entitled Employee Refusal to Test attached as Exhibit 15 hereto.

(j) The employer will provide, a copy of which is attached as Exhibit 16, a postexposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service. This is provided in accordance with the provisions of the Healthcare Postexposure Evaluation Opinion.

(k) Counseling as well as evaluation of illnesses that are reported after exposure will be provided in accord with the recommendations of the United States Public Health Service.

C. HEALTHCARE PROFESSIONAL POSTEXPOSURE EVALUATION OPINION.

1. Information Provided to Healthcare Professional After Exposure Incident. The employer is required to provide certain information to the healthcare professional who is responsible for the postexposure evaluation of the employee. The Compliance Manager, Head Athletic Trainer, Housekeeping Supervisor, Grounds Supervisor, Director of the Physical Plant, and/or the person supervising the lifeguards, as applicable, should give the evaluating healthcare professional the following:

(a) A copy of the OSHA Standard, attached as Exhibit 10 hereto;

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

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

(d) The results of the source individual's blood testing, if available; and

(e) All medical records relevant to the appropriate treatment of the employee (including vaccination status) which the employer is responsible to maintain (see Medical Records section of this Exposure Control Plan).

2. Written Opinion of Healthcare Professional. The employer is required to make sure that the healthcare professional provides to both the employer and the employee a copy of a written opinion within fifteen (15) days after completion of the evaluation. The written opinion must contain the information listed below and be in the form of Exhibit 16 hereto. Further, the healthcare professional must use the standards set forth in Exhibit 10 hereto to evaluate an employee who has had an exposure incident. However, all other findings and diagnoses shall remain confidential and shall not be included in the written report. The items required to be in the written report are as follows:

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

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

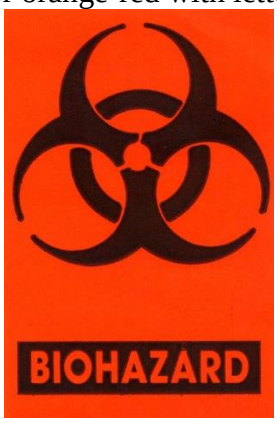
   PLEASE NOTE: A sample letter to the evaluating healthcare professional is provided as Exhibit 16 and attached to the end of this Section. This letter sets out the information required to be given to the healthcare professional when evaluating an employee who has had an exposure incident and also informs the healthcare professional of his obligation concerning the written opinion.

   PLEASE NOTE: A copy of a form healthcare professional postexposure written opinion is attached to the end of this section as Exhibit 17. You should send a copy of this form opinion letter to the healthcare professional who is evaluating an employee after an exposure incident.

VII. LABELS AND SIGNS.

The OSHA Standard has a section entitled "communication of hazards to employees." This portion of the Plan lists requirements for labels. The labels and signs are required to be used to warn employees of exposure to blood or other potentially infectious materials.

1. Type of Label Required. The OSHA Standard requires a label that displays the biohazard symbol and the legend "Biohazard." A picture of the biohazard symbol is shown below. The label must be fluorescent orange or orange-red with letters or symbols in a contrasting color.



Red bags or red containers can be substituted for the labels.

2. How to Attach Labels. Labels must be affixed or attached as closely as possible to the container by string, wire, adhesive, or other method so that the label is not lost or unintentionally removed. Alternatively, labels can be imprinted on the bag or container.

3. When to Use Labels. The biohazard labels are to be placed on all containers of regulated waste and other items (e.g., refrigerators, freezers) that contain blood or other potentially infectious materials. Biohazard labels must also be placed on all containers used to store, transport, or ship blood or other potentially infectious materials (for example, sharps containers, specimen containers). Likewise, laundry contaminated with blood or other potentially infectious materials must also be labeled or color coded.

   Some examples of the items that must have biohazard labels affixed to them or must be contained in red containers are as follows:

   - all regulated waste containers, including but not limited to disposable and reusable sharps containers

   - all containers used to store, transport, or ship specimens of blood or other potentially infectious materials

   - refrigerators and freezers containing blood or other potentially infectious materials

   - contaminated equipment or portions of equipment that are contaminated

4. When Labels/Color Coded Containers are not Required. Any regulated waste that has been decontaminated need not be labeled or placed in red containers.

VIII. INFORMATION AND TRAINING.

A. OSHA TRAINING REQUIREMENT.

The OSHA Standard includes requirements for providing information and training to employees with occupational exposure to blood or other potentially infectious materials. All employees with such occupational exposure must participate in a training program which will be provided at no cost to the employee and during working hours.

B. TIME OF TRAINING.

Current employees with occupational exposure to blood or other potentially infectious materials will be trained. The training must be done within ten (10) days after the date of initial hiring (or within ten (10) days after initial assignment to a task in which occupational exposure may take place). All employees with occupational exposure to blood or other potentially infectious materials must receive training at least annually thereafter. At the time of training, the Compliance Manager, or the on-site BBP trainer will require each employee to sign the Training Log Form, a copy of which is attached as Exhibit 18 hereto and the Acknowledgment of Training Form, a copy of which is attached as Exhibit 19 hereto.

C. TRAINING PROGRAM CONTENT.

The training program will contain the following elements:

1. An accessible copy of the regulatory text of the OSHA Standard and an explanation of its contents;

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

3. An explanation of the modes of transmission of bloodborne pathogens;

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

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

6. 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;

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

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

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

11. 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;

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

13. An explanation of the signs and labels and/or color coding required by the OSHA Standard;

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

IX. RECORDKEEPING.

A. EMPLOYEE MEDICAL RECORDS.

1. Medical Recordkeeping Requirement. The OSHA Standard requires the employer to maintain accurate employee medical records for each employee with occupational exposure to blood or other potentially infectious materials.

2. General Requirements-Medical Records. The employee medical records must be kept confidential and separate from other personnel records. The employee medical records cannot be disclosed or reported without the employee's express written consent to any person inside or outside of the work place except as is required by law and by the OSHA Standard. It is understood, however, that the Assistant Secretary of Labor for Occupational Safety and Health, or its designated representative, as well as the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or its designated representative, have access to these records. The records can be maintained on-site or by the healthcare professional who provides the services. The medical records must be retained for the duration of the employee's employment plus thirty (30) years.

3. Contents of Employee Medical Records. The employee medical records must be entered onto a form substantially in the Employee File, form Exhibit 20 hereto and include the following for each employee with occupational exposure:

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

(b) The employee's HBV vaccination status, including dates of all the HBV vaccinations, and any medical records relative to the employee's ability to receive the vaccination;

(c) For every occupational exposure incident that occurs, copies of all results of examinations, medical testing, and follow-up procedures required by this Standard, and the written opinion of the healthcare professional required after an exposure incident.

(d) Copies of the information provided to the healthcare professional regarding the exposed employee's duties as they relate to the exposure incident, the documentation of the routes of exposure and circumstances under which exposure occurred, and the results of the source individual's blood testing, if available.

B. EMPLOYEE TRAINING RECORDS

1. Training record requirements. Training records documenting each training session, in the Training Log, form Exhibit 18 hereto, must be retained by the employer for three (3) years from the date on which the training occurred. The Employee Acknowledgment of Training form, a copy of which is attached as Exhibit 19 hereto, must be maintained for three (3) years. These records are required to be made available upon request to employees or OSHA representatives.
2. Contents of training records. The training records must include:

(a) The dates of the training sessions;

(b) Contents or a summary of the training sessions;

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

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

C. SHARPS INJURY LOG.

Mount Union will establish and maintain a sharps injury log, a copy of which is attached as Exhibit 21 hereto, for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log will be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log will contain:

(1) the type and brand of device involved in the incident,

(2) the department or work area where the exposure incident occurred, and

(3) an explanation of how the incident occurred.

D. TRANSFER OF RECORDS WHEN EMPLOYER CEASES OPERATIONS.

If Mount Union ceases operations, medical and training records will be transferred to any successor entity. If Mount Union ceases to do business, and there is no successor to receive and retain the records for three (3) years (for training records), or thirty (30) years in the case of medical records, the employer will notify the Director of OSHA at least three (3) months prior to disposal of the records and will transmit the records to OSHA if requested to do so within that three (3)-month period.

«AK3:587014_3»

Bloodborne Pathogens Exposure Control Plan
Exhibit List

Exhibit	Description
1	Documentation Recapping/Removing Contaminating Needles
2	Investigation/Documentation of Employee's Non-Use of Personal Protective Equipment
3	Written Schedule for Cleaning
4	Certification of Previous Vaccination
5	Declination Statement
6	Consent to HBV Vaccination
7	U.S. Public Health Guidelines
8	Consent to Titers and Booster
9	OSHA Standard
10	Healthcare Professional's Opinion – Vaccination Status
11	Exposure Incident
12	Consent to Testing
13	Exposed Source Consent to Testing
14	Exposed Source Refusal to Consent to Testing
15	Healthcare Professional Post Exposure Evaluation Opinion
16	Healthcare Professional Written Opinion to Employer – Postexposure Evaluation
17	Employee Training Log
18	Acknowledgement of Training
19	Employee Medical Recordkeeping Form
20	Sharps Injury Log

EXHIBIT 1

DOCUMENTATION - RECAPPING/REMOVING CONTAMINATING NEEDLES

1. Contaminated needles/contaminated sharps (circle one or both as appropriate) are recapped and/or removed (circle one or both as appropriate) because:

_____ A. No alternative to such recapping or removal is feasible. If this section is checked, please describe why no alternative to recapping or removal is feasible: _____
_____
_____

_____ B. Recapping or removing is required by a specific medical procedure. If this section is checked, state which specific medical procedures require recapping or removal: _____
_____
_____

2. Employees in this office that recap or remove contaminated needles, are required to use the following methods to recap or remove contaminated needles:

_____ A. A mechanical device. If this section is checked, please describe the mechanical device required to be used: _____
_____
_____

_____ B. A one-handed technique. If a one-handed technique is used, describe the one-handed technique(s) required to be used by employees in this office:
_____
_____
_____
_____

_____
Employer

Date:_____

EXHIBIT 2

INVESTIGATION/DOCUMENTATION OF EMPLOYEE'S NON-USE OF PERSONAL PROTECTIVE EQUIPMENT

1. Name of person completing this form: _____

2. Date this form is completed: _____

3. Employees are required to use appropriate personal protective equipment unless, under **rare and extraordinary circumstances**, it is the employee's professional judgment that in the specific instance its use of personal protective equipment would have prevented the delivery of healthcare or public safety services or would have posed an increased hazard to the safety of the worker or co-worker.

A. Name of employee that declined to use the personal protective equipment: _____
_____

B. Date employee declined to use personal protective equipment: _____

C. Type of personal protective equipment not used: _____
_____

D. Record the rare and extraordinary circumstances that led to the employee's professional judgment, in accord with the above Standard not to use the personal protective equipment:
_____
_____
_____
_____
_____
_____

E. Can changes be made to prevent a similar situation (in which an employee properly declines to use personal protective equipment) from arising in the future? If so, please list changes to be instituted and on what date such changes will be instituted:
_____
_____
_____
_____
_____
_____

_____
Employer

Date: _____

EXHIBIT 3

Cleaning Schedule

Protective equipment such as gloves are mandatory and goggles or face shields are required when
cleaning were backsplash is a possibility .

Director of the Physical Plant

Cleaning Schedule:

High/Low dusting- weekly
Disinfect telephones- daily
Spot Clean walls –daily
Vacuum - daily
Wet mop – Tuesday/Thursday
Remove trash - daily
Drinking fountain – daily
Restrooms – daily
Trashcans – daily

Products used for disinfecting:

Netcare Lemon Disinfectant
Lysol Disinfectant spray and Fabric Freshener

Lysol Bathroom Cleaner and Disinfectant

Masterpiece neutral floor cleaner
Spic and Span disinfecting all purpose spray and glass cleaner

Grounds and Fleet Supervisor

Cleaning Schedule:

Restrooms in Fleet area – daily
Break room in Fleet area tables - microwave – daily

Products used for disinfecting:

Netcare Lemon Disinfectant – Hard surfaces are wiped down and allowed to air- dried

Lysol Disinfectant spray – Phones- Trashcans

Lysol Bathroom Cleaner and Disinfectant - Restrooms toilets, sinks and counters all receptacles

Spic and Span Disinfecting all purpose spray and glass cleaner – mirrors glass and surfaces

Timken: Head Athletic Trainer – and Life guard Supervisor

Cleaning Schedule:

Common areas around the pool, the deck the balcony hand rails – daily
Locker rooms, showers and restrooms - daily
Disinfecting all areas – daily

Products used for disinfecting:

Netcare Lemon Disinfectant – Hard surfaces and floors are wiped down and allowed to air dry

Lysol Disinfecting Bathroom Cleaner – Restrooms toilets, sinks and counters all receptacles

Germ Free Disinfecting Cleaner- All common areas around the pool hand rails any equipment that has been used is wiped down and allowed to air dry.

Lysol Disinfecting all purpose spray and glass cleaner – All mirrors and glass surfaces

EXHIBIT 4

CONFIDENTIAL

Retain this for duration of
Employment plus 30 years

CERTIFICATION OF PREVIOUS VACCINATION

I certify to my employer that I previously received the hepatitis B vaccination. The healthcare professional who administered the vaccine to me was _____ _____.

(insert both the name and address of the healthcare professional)

The dates on which I received the vaccine are as follows:

Date Vaccinated	**Lot Number**
(1) _____	_____
(2) _____	_____

(3) _____ _____

Witness:

_____ _____

Employee Signature
(or signature of employee's parent/guardian if employee is a minor or if otherwise appropriate)

Dated: _____ Dated: _____

EXHIBIT 5

CONFIDENTIAL

Retain this record for duration of employment plus 30 years

DECLINATION STATEMENT

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that be 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 at no charge to me.

WITNESS:

_____ _____

Employee Signature
(or signature of employee's parent/guardian if employee is a minor or if otherwise appropriate)

Dated: _____ Dated: _____

EXHIBIT 6

CONFIDENTIAL

Retain this for duration of
employment plus 30 years

CONSENT TO HBV VACCINATION FORM

I received OSHA Bloodborne Pathogens training. This training included a discussion about hepatitis B and the hepatitis B vaccine. I have had an opportunity to ask questions and understand the benefits and risks of the hepatitis B vaccination. I understand that I must have three (3) doses of vaccine to confer immunity. However, as with all medical treatment, there is no guarantee that I will become immune or that I will not experience and adverse effect from the vaccine.

In consideration of receiving without cost the hepatitis B vaccination, the undersigned hereby agrees and represents that the hepatitis B vaccination shall be undertaken at his or her own risk, that he or she is in good physical condition and physically able to receive the hepatitis B vaccination.

I request that the hepatitis B vaccination be given to me.

Witness:

_____ _____

Employee Signature
(or signature of employee's parent/guardian if employee is a minor or if otherwise appropriate)

Dated: _____ Dated: _____

EXHIBIT 7

Recommendations and Reports

June 29, 2001 / 50(RR11);1-42

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

Summary

This report updates and consolidates all previous U.S. Public Health Service recommendations for the management of health-care personnel (HCP) who have

occupational exposure to blood and other body fluids that might contain hepatitis B virus (HBV), hepatitis C virus (HCV), or human immunodeficiency virus (HIV).

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

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

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

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

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

INTRODUCTION

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

The U.S. Public Health Service (PHS) has published previous guidelines for the management of HIV exposures that included considerations for postexposure prophylaxis (PEP) (*3*--*5*). Since publication of the 1998 HIV exposure guidelines (*5*), several new antiretroviral agents have been approved by the Food and Drug Administration (FDA), and more information is available about the use and safety of HIV PEP (*6*--*11*). In

addition, questions exist regarding considerations about PEP regimens when the source person's virus is known or suspected to be resistant to one or more of the antiretroviral agents that might be used for PEP. Concern also has arisen about the use of PEP when it is not warranted. Data indicate that some health-care personnel (HCP) take a full course of HIV PEP after exposures that do not confer an HIV transmission risk (*10,11*).

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

Definition of Health-Care Personnel and Exposure

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

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

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

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

BACKGROUND

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

Occupational Transmission of HBV

Risk for Occupational Transmission of HBV

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

Although percutaneous injuries are among the most efficient modes of HBV transmission, these exposures probably account for only a minority of HBV infections among HCP. In several investigations of nosocomial hepatitis B outbreaks, most infected HCP could not recall an overt percutaneous injury (*27,28*), although in some studies, up to one third of infected HCP recalled caring for a patient who was HBsAg-positive (*29,30*). In addition, HBV has been demonstrated to survive in dried blood at room temperature on environmental surfaces for at least 1 week (*31*). Thus, HBV infections that occur in HCP with no history of nonoccupational exposure or occupational percutaneous injury might have resulted from direct or indirect blood or body fluid exposures that inoculated HBV into cutaneous scratches, abrasions, burns, other lesions, or on mucosal surfaces (*32*--*34*). The potential for HBV transmission through contact with environmental surfaces has been demonstrated in investigations of HBV outbreaks among patients and staff of hemodialysis units (*35*--*37*).

Blood contains the highest HBV titers of all body fluids and is the most important vehicle of transmission in the health-care setting. HBsAg is also found in several other body fluids, including breast milk, bile, cerebrospinal fluid, feces, nasopharyngeal washings, saliva, semen, sweat, and synovial fluid (*38*). However, the concentration of HBsAg in body fluids can be 100--1000---fold higher than the concentration of infectious HBV

particles. Therefore, most body fluids are not efficient vehicles of transmission because they contain low quantities of infectious HBV, despite the presence of HBsAg.

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

PEP for HBV

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

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

Approximately 45 reports have been received by the Vaccine Adverse Event Reporting System (VAERS) of alopecia (hair loss) in children and adults after administration of plasma-derived and recombinant hepatitis B vaccine; four persons sustained hair loss following vaccination on more than one occasion (*56*). Hair loss was temporary for approximately two thirds of persons who experienced hair loss. An epidemiologic study conducted in the Vaccine Safety Datalink found no statistical association between alopecia and receipt of hepatitis B vaccine in children (CDC, unpublished data, 1998). A low rate of anaphylaxis has been observed in vaccine recipients based on reports to VAERS; the estimated incidence is 1 in 600,000 vaccine doses distributed. Although none of the persons who developed anaphylaxis died, anaphylactic reactions can be life-

threatening; therefore, further vaccination with hepatitis B vaccine is contraindicated in persons with a history of anaphylaxis after a previous dose of vaccine.

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

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

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

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

Occupational Transmission of HCV

Risk for Occupational Transmission of HCV

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

Postexposure Management for HCV

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

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

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

In the absence of PEP for HCV, recommendations for postexposure management are intended to achieve early identification of chronic disease and, if present, referral for evaluation of treatment options. However, a theoretical argument is that intervention with antivirals when HCV RNA first becomes detectable might prevent the development of

chronic infection. Data from studies conducted outside the United States suggest that a short course of interferon started early in the course of acute hepatitis C is associated with a higher rate of resolved infection than that achieved when therapy is begun after chronic hepatitis C has been well established (*90--92*). These studies used various treatment regimens and included persons with acute disease whose peak ALT levels were 500--1,000 IU/L at the time therapy was initiated (2.6--4 months after exposure).

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

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

Occupational Transmission of HIV

Risk for Occupational Transmission of HIV

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

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

Epidemiologic and laboratory studies suggest that several factors might affect the risk of HIV transmission after an occupational exposure. In a retrospective case-control study of HCP who had percutaneous exposure to HIV, the risk for HIV infection was found to be increased with exposure to a larger quantity of blood from the source person as indicated by a) a device visibly contaminated with the patient's blood, b) a procedure that involved

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

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

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

Rationale for HIV PEP

Considerations that influence the rationale and recommendations for PEP include

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

The following discussion considers each of these concerns.

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

systemic infection by limiting the proliferation of virus in the initial target cells or lymph nodes.

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

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

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

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

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

and Uganda also have demonstrated that rates of perinatal HIV transmission have been reduced with the use of abbreviated PEP regimens started intrapartum or during the first 48--72 hours of life (*130--132*).

The limitations of all of these studies with animals and humans must be considered when reviewing evidence of PEP efficacy. The extent to which data from animal studies can be extrapolated to humans is largely unknown, and the exposure route for mother-to-infant HIV transmission is not similar to occupational exposures; therefore, these findings might not be directly applicable to PEP in HCP.

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

Antiretroviral Agents for PEP

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

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

provide guidance for two- and three-drug PEP regimens that are based on the level of risk for HIV transmission represented by the exposure.

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

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

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

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

therapy (FDA, unpublished data, 2000). EFV has been associated with central nervous system side effects, including dizziness, somnolence, insomnia, and abnormal dreaming.

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

Toxicity Associated with PEP. Information from the National Surveillance System for Health Care Workers (NaSH) and the HIV Postexposure Registry indicates that nearly 50% of HCP experience adverse symptoms (e.g., nausea, malaise, headache, anorexia, and headache) while taking PEP and that approximately 33% stop taking PEP because of adverse signs and symptoms (*6,7,10,11*). Some studies have demonstrated that side effects and discontinuation of PEP are more common among HCP taking three-drug combination regimens for PEP compared with HCP taking two-drug combination regimens (*7,10*). Although similar rates of side effects were observed among persons who took PEP after sexual or drug use exposures to HIV in the San Francisco Post-Exposure Prevention Project, 80% completed 4 weeks of therapy (*149*). Participants in the San Francisco Project were followed at 1, 2, 4, 26, and 52 weeks postexposure and received medication adherence counseling; most participants took only two drugs for PEP.

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

Resistance to Antiretroviral Agents. Known or suspected resistance of the source virus to antiretroviral agents, particularly to agents that might be included in a PEP regimen, is a concern for persons making decisions about PEP. Resistance to HIV infection occurs with all of the available antiretroviral agents, and cross-resistance within drug classes is frequent (*154*). Recent studies have demonstrated an emergence of drug-resistant HIV among source persons for occupational exposures (*143,155*). A study conducted at seven U.S. sites during 1998--1999 found that 16 (39%) of 41 source persons whose virus was sequenced had primary genetic mutations associated with resistance to RTIs, and 4 (10%) had primary mutations associated with resistance to PIs (*143*). In addition, occupational transmission of resistant HIV strains, despite PEP with combination drug regimens, has been reported (*137,139*). In one case, a hospital worker became infected after an HIV exposure despite a PEP regimen that included ddI, d4T, and NVP (*139*). The transmitted HIV contained two primary genetic mutations associated with resistance to NNRTIs (the source person was taking EFV at the time of the exposure).

Despite recent studies and case reports, the relevance of exposure to a resistant virus is still not well understood.

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

Antiretroviral Drugs During Pregnancy. Data are limited on the potential effects of antiretroviral drugs on the developing fetus or neonate (*156*). Carcinogenicity and/or mutagenicity is evident in several in vitro screening tests for ZDV and all other FDA-licensed NRTIs. The relevance of animal data to humans is unknown; however, because teratogenic effects were observed in primates at drug exposures similar to those representing human therapeutic exposure, the use of EFV should be avoided in pregnant women (*140*). IDV is associated with infrequent side effects in adults (i.e., hyperbilirubinemia and renal stones) that could be problematic for a newborn. Because the half-life of IDV in adults is short, these concerns might be relevant only if the drug is administered shortly before delivery.

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

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

PEP Use in Hospitals in the United States. Analysis of data from NaSH provides information on the use of PEP following occupational exposures in 47 hospitals in the United States. A total of 11,784 exposures to blood and body fluids was reported from June 1996 through November 2000 (CDC, unpublished data, 2001). For all exposures with known sources, 6% were to HIV-positive sources, 74% to HIV-negative sources, and 20% to sources with an unknown HIV status. Sixty-three percent of HCP exposed to a known HIV-positive source started PEP, and 54% of HCP took it for at least 20 days, whereas 14% of HCP exposed to a source person subsequently found to be HIV-negative initiated PEP, and 3% of those took it for at least 20 days. Information recorded about HIV exposures in NaSH indicates that 46% of exposures involving an HIV-positive source warranted only a two-drug PEP regimen (i.e., the exposure was to mucous membranes or

skin or was a superficial percutaneous injury and the source person did not have end-stage AIDS or acute HIV illness); however, 53% of these exposed HCP took ≥3 drugs (CDC, unpublished data, 2000). Similarly, the National Clinicians' Post-Exposure Prophylaxis Hotline (PEPline) reported that PEPline staff recommended stopping or not starting PEP for approximately one half of the HCP who consulted them about exposures (D. Bangsberg, San Francisco General Hospital, unpublished data, September 1999). The observation that some HCP exposed to HIV-negative source persons take PEP from several days to weeks following their exposures suggests that strategies be employed such as the use of a rapid HIV antibody assay, which could minimize exposure to unnecessary PEP (*11*). A recent study demonstrated that use of a rapid HIV test for evaluation of source persons after occupational exposures not only resulted in decreased use of PEP, but also was cost-effective compared with use of the standard enzyme immunoassay (EIA) test for source persons subsequently found to be HIV-negative (*160*).

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

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

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

Hepatitis B Vaccination

Any person who performs tasks involving contact with blood, blood-contaminated body fluids, other body fluids, or sharps should be vaccinated against hepatitis B (*2*,*21*). Prevaccination serologic screening for previous infection is not indicated for persons being

vaccinated because of occupational risk, unless the hospital or health-care organization considers screening cost-effective.

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

Treatment of an Exposure Site

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

Exposure Report

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

Evaluation of the Exposure and the Exposure Source

Evaluation of the Exposure

The exposure should be evaluated for the potential to transmit HBV, HCV, and HIV based on the type of body substance involved and the route and severity of the exposure (Box 2). Blood, fluid containing visible blood, or other potentially infectious fluid (including semen; vaginal secretions; and cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids) or tissue can be infectious for bloodborne viruses. Exposures to these fluids or tissue through a percutaneous injury (i.e., needlestick or other penetrating sharps-related event) or through contact with a mucous membrane are situations that pose a risk for bloodborne virus transmission and require further evaluation. For HCV and HIV, exposure to a blood-filled hollow needle or visibly bloody device suggests a higher risk exposure than exposure to a needle that was most likely used for giving an injection. In addition, any direct contact (i.e, personal protective equipment either was not present or was ineffective in protecting skin or mucous membranes) with concentrated virus in a research laboratory or production facility is considered an exposure that requires clinical evaluation.

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

Evaluation of the Exposure Source

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

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

Testing to determine the HBV, HCV, and HIV infection status of an exposure source should be performed as soon as possible. Hospitals, clinics and other sites that manage exposed HCP should consult their laboratories regarding the most appropriate test to use to expedite obtaining these results. An FDA-approved rapid HIV-antibody test kit should be considered for use in this situation, particularly if testing by EIA cannot be completed within 24--48 hours. Repeatedly reactive results by EIA or rapid HIV-antibody tests are considered to be highly suggestive of infection, whereas a negative result is an excellent indicator of the absence of HIV antibody. Confirmation of a reactive result by Western blot or immunofluorescent antibody is not necessary to make initial decisions about postexposure management but should be done to complete the testing process and before informing the source person. Repeatedly reactive results by EIA for anti-HCV

should be confirmed by a supplemental test (i.e., recombinant immunoblot assay [RIBA™] or HCV PCR). Direct virus assays (e.g., HIV p24 antigen EIA or tests for HIV RNA or HCV RNA) for routine HIV or HCV screening of source persons are not recommended.

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

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

Examples of information to consider when evaluating an exposure source for possible HBV, HCV, or HIV infection include laboratory information (e.g., previous HBV, HCV, or HIV test results or results of immunologic testing [e.g., CD4+ T-cell count]) or liver enzymes (e.g., ALT), clinical symptoms (e.g., acute syndrome suggestive of primary HIV infection or undiagnosed immunodeficiency disease), and history of recent (i.e., within 3 months) possible HBV, HCV, or HIV exposures (e.g., injection-drug use or sexual contact with a known positive partner). Health-care providers should be aware of local and state laws governing the collection and release of HIV serostatus information on a source person, following an occupational exposure.

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

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

Management of Exposures to HBV

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

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

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

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

Management of Exposures to HCV

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

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

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

IG and antiviral agents are not recommended for PEP after exposure to HCV-positive blood. In addition, no guidelines exist for administration of therapy during the acute phase of HCV infection. However, limited data indicate that antiviral therapy might be beneficial when started early in the course of HCV infection. When HCV infection is identified early, the person should be referred for medical management to a specialist knowledgeable in this area.

Counseling for HCP Exposed to Viral Hepatitis

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

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

Management of Exposures to HIV

Clinical Evaluation and Baseline Testing of Exposed HCP

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

PEP for HIV

The following recommendations (Table 4 and Table 5) apply to situations when a person has been exposed to a source person with HIV infection or when information suggests the likelihood that the source person is HIV-infected. These recommendations are based on the risk for HIV infection after different types of exposure and on limited data regarding

efficacy and toxicity of PEP. Because most occupational HIV exposures do not result in the transmission of HIV, potential toxicity must be carefully considered when prescribing PEP. To assist with the initial management of an HIV exposure, health-care facilities should have drugs for an initial PEP regimen selected and available for use. When possible, these recommendations should be implemented in consultation with persons who have expertise in antiretroviral therapy and HIV transmission (Box 4).

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

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

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

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

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

hyperbilirubinemia in newborns, IDV should not be administered to pregnant women shortly before delivery.

Recommendations for the Selection of Drugs for HIV PEP

Health-care providers must strive to balance the risk for infection against the potential toxicity of the agent(s) used when selecting a drug regimen for HIV PEP. Because PEP is potentially toxic, its use is not justified for exposures that pose a negligible risk for transmission (Table 4 and Table 5). Also, insufficient evidence exists to support recommending a three-drug regimen for all HIV exposures. Therefore, two regimens for PEP are provided (Appendix C): a "basic" two-drug regimen that should be appropriate for most HIV exposures and an "expanded" three-drug regimen that should be used for exposures that pose an increased risk for transmission (Table 4 and Table 5). When possible, the regimens should be implemented in consultation with persons who have expertise in antiretroviral treatment and HIV transmission.

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

Follow-up of HCP Exposed to HIV

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

exposure. When HIV infection is identified, the person should be referred to a specialist knowledgeable in the area of HIV treatment and counseling for medical management.

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

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

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

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

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

Counseling and Education. Although HIV infection following an occupational exposure occurs infrequently, the emotional effect of an exposure often is substantial (*172--174*). In addition, HCP are given seemingly conflicting information. Although HCP are told that a low risk exists for HIV transmission, a 4-week regimen of PEP might be recommended, and they are asked to commit to behavioral measures (e.g., sexual abstinence or condom

use) to prevent secondary transmission, all of which influence their lives for several weeks to months (*172*). Therefore, access to persons who are knowledgeable about occupational HIV transmission and who can deal with the many concerns an HIV exposure might generate for the exposed person is an important element of postexposure management. HIV-exposed HCP should be advised to use the following measures to prevent secondary transmission during the follow-up period, especially the first 6--12 weeks after the exposure when most HIV-infected persons are expected to seroconvert: exercise sexual abstinence or use condoms to prevent sexual transmission and to avoid pregnancy; and refrain from donating blood, plasma, organs, tissue, or semen. If an exposed woman is breast feeding, she should be counseled about the risk of HIV transmission through breast milk, and discontinuation of breast feeding should be considered, especially for high-risk exposures. Additionally, NRTIs are known to pass into breast milk, as is NVP; whether this also is true for the other approved antiretroviral drugs is unknown.

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

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

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

Guidelines for counseling and educating HCP with HIV exposure include

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

Occupational Exposure Management Resources

Several resources are available that provide guidance to HCP regarding the management of occupational exposures. These resources include PEPline; the Needlestick! website; the Hepatitis Hotline; CDC (receives reports of occupationally acquired HIV infections and failures of PEP); the HIV Antiretroviral Pregnancy Registry; FDA (receives reports of

unusual or severe toxicity to antiretroviral agents); and the HIV/AIDS Treatment Information Service (Box 5).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

TABLE 2. Primary side effects associated with antiretroviral agents

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

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

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

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

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

BOX 3. Evaluation of occupational exposure sources

Known sources

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

Unknown sources

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

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

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

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

† Hepatitis B surface antigen.

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

¶ Hepatitis B vaccine.

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

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

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

¶¶ Antibody to HBsAg.

TABLE 4. Recommended HIV postexposure prophylaxis for percutaneous injuries

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

BOX 5. Occupational exposure management resources

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

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

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

EXHIBIT 8

CONSENT FOR HEPATITIS B TITER

I, _____, understand that after receiving the Hepatitis B vaccination, University of Mount Union may need to verify the effectiveness of the vaccination. By signing this consent form, I am agreeing to receive a Hepatitis B titer. I understand that this titer may be necessary to confirm that the initial Hepatitis B vaccination was successful in providing the necessary antibody. I also understand that it might become necessary to receive a second titer booster, if the first titer booster does not provide me with the necessary antibody count.

_____ _____

Employee Signature Date

EXHIBIT 9

Regulations (Standards - 29 CFR)

Bloodborne pathogens. - 1910.1030

- **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 of 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]

EXHIBIT 10

CONFIDENTIAL

Retain this for the duration
of employment plus 30 years

HEALTHCARE PROFESSIONAL'S WRITTEN OPINION - HEPATITIS B VACCINATION STATUS

1. Name of healthcare professional: _____

2. Date of completion of this opinion form: _____

3. Hepatitis B vaccination status opinion. Evaluating healthcare professional must check one of the following:

_____ A. HBV vaccination indicated for this employee, vaccination not received;

_____ B. HBV vaccination not indicated for this employee, vaccination not received;

_____ C. HBV vaccination indicated for this employee, vaccination received.

"HBV" is defined to mean "hepatitis B virus."

_____
Signature of evaluating healthcare professional

Dated: _____

EXHIBIT 11

CONFIDENTIAL

Retain this record for duration or employment plus 30 years

EXPOSURE INCIDENT FOLLOW-UP FORM

1. Information Concerning Exposed Employee:

   A. Name of exposed employee: _____
   B. Address of exposed employee: _____
   C. Social security number of exposed employee: _____
   D. Date of exposure incident: _____
   E. Exposure incident reported to: _____
   F. Date exposure incident was reported to employer: _____

G. Employee hepatitis B vaccine history:

_____ Exposed employee did not receive the vaccine
_____ Exposed employee received the vaccine on these dates:

_____

H. Status of consent for blood testing after exposure incident:

_____ Employee consented to have blood tested, date written consent executed:
_____

_____ Employee consented only to having blood drawn. Blood was drawn on_____
The blood will be held for 90 days, and employee may request HIV or HBV testing during that time.

_____ Employee refused to have blood drawn for testing.

2. Description of Exposure Incident:

A. Circumstances under which exposure incident occurred (describe what happened):
_____

B. Routes of exposure (e.g. needle stick, splash to nose, eyes, mouth, puncture wound, abraded skin exposure):_____

3. Source individual (Patient Information):

A. Source (patient) name:_____
Account No.:_____

B. If identification and documentation of the source individual is not feasible, state why:
_____

C. Did the source (patient) individual consent to HIV/HBV blood testing?
(1) Yes/No (circle one). Date: _____
(2) If yes, attach a copy of the consent form signed by the source individual.

D. Was source individual already known to be infected with HBV/HIV?
(1) Yes/No (circle one).
(2) If yes, list HBV and HIV infection status:_____
_____

4. **<u>Lab Results of Testing After Exposure</u>**

A. Employee:

(1) HBV test performed on following date: _____
(2) HIV test performed on following date: _____

B. Source (patient):
(1) HBV test performed on following date: _____
(2) HIV test performed on following date: _____

5. **Treatment. Counseling. Evaluation**:

A. Prophylactic treatment given/recommended: _____
B. Other treatment, observations, recommendations: _____
_____
C. Counseling provided or recommended: _____
D. Evaluation of reported illnesses: _____
_____

6. Information Given to Employee (have employee initial each below):

____ I have been informed of the above information, including laboratory results of the source individual (if available) and myself (if applicable).

____ I have been advised concerning safety measures necessary to prevent or minimize recurrence of the above exposure incident.

_____
Employee Signature

Date: _____

EXHIBIT 12

CONFIDENTIAL
Retain this record for duration of
employment plus 30 years

Ohio Department of Health
246 N. High Street, P.O. Box 118
Columbus, Ohio 43266-0118
CONSENT FORM FOR HIV ANTIBODY TEST

What is HIV? The Human Immunodeficiency Virus (HIV) is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

How Do People Get HIV? People may be infected by:

(1) By having sex with someone whom is HIV infected and not using a condom. Vaginal, anal and oral sex can spread HIV.
(2) Sharing the same needle while using drugs with someone who is HIV infected.
(3) Having a blood transfusion before 1985.
(4) Being born to a mother who is infected with HIV.

How is an HIV Test Done? A sample of your blood or other body fluid is tested for antibodies. If the test is positive, more tests are done on the same sample to make sure the first test was right. If the other tests come back positive, you are considered to be infected.

What Does A Positive Test Mean? A positive test does NOT mean you have AIDS. It means that you have the virus that can lead to AIDS, which can take up to 10 years to develop. It also means you could pass the virus to someone else through sex or sharing needles. If you test is positive, you should:

- See a doctor to find out what medicines you can take to help keep you healthy.
- Talk with an expert about how to keep from passing the virus to others. The person who gives you the test can help you.
- Work with staff from the Ohio Department of Health to tell anyone you have had sex or shared needles with that they need to get an HIV test. Your name will NOT be used.

What If The Test Is Negative? It means no antibodies to the virus were found. However, you may need to take another test if you have had unsafe sex or shared needles in the last three months. It can sometimes take as long as six months for antibodies to show up on a test.

You Have A Choice: You can choose NOT to take this test at any point during your clinic visit by simply leaving the clinic site. If you are in a hospital or other health care facility, you need to let someone know <u>within one hour after blood is drawn</u> that you have changed your mind.

- If you choose to take this test, you can take a confidential test. This means you may have a written copy of your results. This means your name is on the results. Your test results can not be given to anyone unless you sign a paper giving consent. The law requires that positive HIV tests be reported to the Ohio Department of Health.
- If you do not want your name used, you can take an anonymous test. Your name is not used. Someone tells you the results, but no written results are given to you.

Please Ask Questions!! If you have any questions about this test, please ask a doctor, a counselor or call the Ohio AIDS/HIV/STD Hotline at 1-800-332-AIDS (2437). The hotline is a free call.
I have read the above, or have had it read to me, and I agree to be tested for HIV.

Name_____ Date_____

Prepared under the authority of Ohio Revised Code 3701.242 (A)(3)

Ohio Department of Health
246 N. High Street, P.O. Box 118
Columbus, Ohio 43266-0188

Informed Consent to HIV Test for Pregnant Women

What is HIV? The Human Immunodeficiency Virus (HIV) is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

How is HIV Spread?

-Passed from an HIV infected mother to her unborn child
-Passed from an HIV infected mother to her child during breast feeding
-Having vaginal, anal, or oral sex with an HIV infected person without a condom or barrier
-Sharing a needle with an HIV infected person while injecting drugs
-Having a blood transfusion before 1985

How is an HIV Test Done? A sample of your blood or other body fluid is tested for signs of infection. If the first test is positive, other tests are done on the sample to make sure the first test was right. If the other tests come back positive you are considered to be infected.

What Does a Positive Test Mean? A positive test does NOT mean that you have AIDS. It means that you have the virus that can lead to AIDS, which can take up to ten years or more to develop. **It also means that you can pass HIV to your unborn baby while you are pregnant or by breast feeding.** You can also pass the virus to someone else through sex or by sharing needles. If your test is positive you should:

-See a doctor about medicine you can take to help prevent passing HIV to your unborn baby
-NOT breast feed your baby
-Talk to the person giving you your test results about how to keep from passing the virus to others
-Talk to a doctor to find out what you can do to keep healthy
-Work with staff from the Ohio Department of Health to help notify current or past sex partners that they may be at risk.

What if the Test is Negative? It means that no signs of infection were found. However, you and your baby may need to be tested in several months if you have shared a needle or had unsafe sex in the past three months. It can sometimes take up to six months for signs of infection to show up.

You Have a Choice.

-You can have a **confidential** HIV test. This means that you will have a written copy of your results. This also means that your name will be on the results. Your test results cannot be given to anyone unless you sign a paper giving consent. The law requires that positive HIV tests be reported to the Ohio Department of Health.

-You can have an **anonymous** HIV test. Your name is not used. Someone tells you the test results, but no written results are given to you. Anonymous HIV tests are done at specific counseling testing sites. Your doctor can help you find one of these sites. If your anonymous HIV test is positive you will need to have a confidential test done by your doctor before you can get HIV-related treatment or services.

-You can **refuse** to be tested for HIV at this time. If a sample of your blood or body fluid has already been taken you can still refuse to be tested for HIV by simply telling your doctor or nurse that you have changed your mind. If a sample of blood or body fluid has been taken you must tell someone within one hour if you change your mind and don't want to be tested for HIV. Even if you don't want to have an HIV test at this time you can still have the other medical care that both you and your baby need.

Please Ask Questions!!! If you have any questions about this test, please ask a doctor, nurse, or counselor, or call the OHIO HIV/AIDS/STD Hotline at: **1-800-332-AIDS (2437).** Calls to the hotline are **FREE.**

I understand the information on this form and: (check one box)

- I Want a CONFIDENTIAL HIV Test.
- I Want a referral for an ANONYMOUS HIV Test.
- I DO NOT Want an HIV Test. After getting the information on this sheet I have decided not to be tested for HIV at this time. I realize that if I am not tested I will not know if I am infected with HIV and will not be able to get HIV medicine for me or my unborn baby. I know I can get tested for HIV in the future if I want to.

Name_____ Date_____

Prepared under authority of Ohio Revised Code 3701.242 (A)(3)

WITHDRAWAL OF CONSENT FOR THE HIV TEST

When I came into this clinic or care facility, I wanted to take the HIV test and had a blood or body fluid sample collected for that purpose.

After speaking with an HIV counselor, I changed my mind and do not want to have an HIV test. Please do not test my blood or body fluid for HIV infection.

I understand that if I do not take the HIV test, I won't know my HIV status. Therefore, I will not know if I need to seek the care and treatment that is necessary if I am infected with HIV.

_____
Date

_____
Client

_____
HIV Counselor

EXHIBIT 13

CONFIDENTIAL

Retain this record for duration of
Employment plus 30 years

EXPOSED SOURCE CONSENT TO TESTING

I understand that I have been involved in an exposure incident concerning blood or other potentially infectious materials and that I may be at risk of spreading the hepatitis B virus (HBV) infection or human immunodeficiency (HIV) virus.

I have been given the opportunity by my employer, free of charge, to have a sample of my blood collected and tested for HBV and HIV serological status.

As indicated below, I have consented to have certain parts of the testing or all of the testing performed (have employee initial appropriate sentence below):

_____ I have consented to have blood drawn for any testing.

_____ I have consented to have my blood drawn at this time and tested. I understand that my blood will be held for 90 days from the date that is drawn and that I may request during that 90-day period that HIV of HBV testing be done during that 90-day time period.

_____ I have consented to have hepatitis B virus (HBV) testing performed.

_____ I have consented to have human immunodeficiency (HIV) virus testing performed.

WITNESS:

_____ _____

Employee's signature

Date:_____ Date: _____

EXHIBIT 14

CONFIDENTIAL

Retain this record for duration of
Employment plus 30 years

EXPOSED SOURCE REFUSAL TO CONSENT TO TESTING

I understand that I have been involved in an exposure incident concerning blood or other potentially infectious materials and that I may be at risk of spreading the hepatitis B virus (HBV) infection or human immunodeficiency (HIV) virus.

I have been given the opportunity by my employer, free of charge, to have a sample of my blood collected and tested for HBV and HIV serological status.

However, as indicated below, I have refused to have certain parts of the testing or all of the testing performed (have employee initial appropriate sentence below):

_____ I have refused to have blood drawn for any testing.

_____ I have consented to have my blood drawn at this time but not tested. I understand that my blood will be held for 90 days from the date that is drawn and that I may request during that 90-day period that HIV of HBV testing be done during that 90-day time period.

_____ I have refused to have hepatitis B virus (HBV) testing performed.

_____ I have refused to have human immunodeficiency (HIV) virus testing performed.

WITNESS:

_____ _____

Employee's signature

Date:_____ Date: _____

EXHIBIT 15

CONFIDENTIAL

Retain this record for duration
of employment plus 30 years

HEALTHCARE PROFESSIONAL'S WRITTEN OPINION TO EMPLOYER - POSTEXPOSURE EVALUATION

I evaluated_____("Employee") after Employee had an exposure incident (as defined in the OSHA Bloodborne Pathogens Standard) concerning blood or other potentially infectious materials. In accord with the OSHA Bloodborne Pathogens Standard, I am returning this written opinion to Employee's employer within fifteen (15) days after I completed my evaluation, confirming the following:

1. I informed the Employee of the results of the evaluation; and

2. 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.

_____
Signature of evaluating healthcare professional

Dated: _____

EXHIBIT 16

CONFIDENTIAL
Retain this record for duration
of employment plus three years

LETTER TO EVALUATING HEALTHCARE PROFESSIONAL - POSTEXPOSURE EVALUATION AND WRITTEN OPINION

_____, 20____

_____
_____
_____

RE: Evaluation of _____after Occupational Exposure
to Blood or Other Potentially Infectious Material

Dear_____:

_____has had an "exposure incident" as defined under the OSHA Bloodborne Pathogens Standard. As a result, _____ has been exposed to either blood or other potentially infectious materials.

The OSHA Bloodborne Pathogens Standard requires that the employer provide to the employee post exposure evaluation and follow-up after each exposure incident. You have been selected as the healthcare professional to evaluate the employee after the exposure incident.

The OSHA Bloodborne Pathogens Standard also requires that you provide to me, the employer, a copy of your written opinion concerning your evaluation of the exposed employee within fifteen (15) days after you complete your evaluation. Although your evaluation may include additional information, your written opinion to me can only include the following information:

1. That the employee has been informed of the results of your evaluation and

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

All of your other findings or diagnoses must remain confidential and shall not be included in your written report to me. I have attached a form that you may use when completing your written opinion to me concerning _____'s exposure. Please return this form to me within fifteen (15) days after you complete your evaluation

_____

_____, 20_____

The OSHA Bloodborne Pathogens Standard also requires that I give to you the following information that may be helpful in your evaluation of this exposure incident.

1. A copy of the OSHA Bloodborne Pathogens Standard;

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

3. Documentation of the routes of exposure and circumstances under which exposure occured;

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

5. All medical records relevant to the appropriate treatment of the employee (including vaccination status) that is my responsibility to maintain.

I have enclosed this information.

If you should have any questions al all concerning the enclosed information, this letter, or any other issue, please do not hesitate to give me a call.

Very truly yours,

_____

EXHIBIT 17

(Note: Maintain this record for three years)

OSHA BLOODBORNE PATHOGENS STANDARD
EMPLOYEE TRAINING RECORD

1. Name of Office: Human Resource Office
2. Address of Office: 1972 Clark Ave. Alliance, Ohio 44601
3. Date of Training Session: _____
4. Name(s) and qualifications of person(s) conducting training session: _____
   _____
   _____
5. Contents/summary of training session:
6. Names and Job Titles of all Persons Attending Training Session:

Names	Job Titles	Signature

EXHIBIT 18

(Note: Maintain this record for three years)

ACKNOWLEDGEMENT OF TRAINING

I, an employee of _____ ("Employer"), received OSHA Bloodborne Pathogens training on _____, 20____. During the training program, I received information and training regarding occupational exposure to blood or other potentially infectious materials. Further, I had a full opportunity to ask questions pertaining to the OSHA Bloodborne Pathogens Standard, my employer's OSHA Bloodborne Pathogens Exposure Control Plan, any my potential exposure to blood or other potentially infectious materials. The training program was conducted at no cost to me and during working hours.

Date:_____ _____

Employee Signature

Date:_____ _____

Witness Signature

EXHIBIT 19

CONFIDENTIAL

Retain this for duration of
employment plus 30 years

EMPLOYEE MEDICAL RECORDKEEPING FORM

1. Employee Name: _____
2. Employee Address: _____
3. Employee Social Security No. _____
4. Employee Starting Date: _____
5. Employee Termination Date (if any): _____
6. History of HBV Vaccination:

   A. Dates received:

	Dates Received	Lot Number
(1)	_____	_____
(2)	_____	_____
(3)	_____	_____

   B. Dates that any booster doses were received: _____
   _____

   C. If not received, a brief explanation of why not (for example, declined pursuant to Declination Statement): _____
   _____
   _____

   D. Attach copies of any medical records relative to the employee's ability to receive the vaccination (for example, the healthcare professional's written opinion concerning HBV vaccination status): _____
   _____

7. For each occupational exposure incident that occurs to this employee, please attach the following:

   A. Results of all medical examinations, medical testing, and follow-up procedures required by the OSHA Bloodborne Pathogens Standard, and the written opinion of the healthcare professional required after an exposure incident: _____
   _____

   B. Give the history of the exposure incident(s) and attach the completed exposure incident form for each such exposure incident (dates, brief explanation,

attachments): _____
_____

C. Enclose a copy of all of the information provided to the healthcare professional regarding the HBV vaccination and/or exposure incidents: _____
_____

EXHIBIT 20

SHARPS INJURY LOG

1. _____ _____

NAME OF EXPOSED EMPLOYEE JOB CLASSIFICATION/DEPARTMENT

2. Date and time of exposure incident: _____

3. Type and brand of sharp involved in the exposure incident: _____

4. Department or work area where the exposure incident occurred: _____

5. The procedure that the exposed employee was performing at the time the incident occurred: _____

_____

_____

6. How did the incident occur: _____

_____

7. The body part involved in the exposure: _____

_____

8. Did the sharp have engineering sharps injury protection:

- ❑ NO (proceed to question #9)
- ❑ YES Was the protective mechanism activated: _____
  Did the injury occur before, during or after the protective mechanism was activated: _____

9. If the sharp did not have an engineered sharps injury protection, the injured employee's opinion as to whether and how such a mechanism could have prevented the injury: _____

_____

10. The employee's opinion about whether any other engineering, administrative or work practice control could have prevented the injury: _____

_____

_____ _____

EMPLOYEE SIGNATURE DATE
(or signature of employee's parent/guardian
if employee is a minor or otherwise appropriate)