COUNTY OF RIVERSIDE
STANDARD SAFETY OPERATIONS MANUAL

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PURPOSE: The County of Riverside recognizes the Bloodborne Pathogen Exposure (BPE) issue as an important one, potentially impacting how work is done by a large segment of those individuals who work for the County. To address this impact, the Bloodborne Pathogen Exposure Control Plan (BPECP) is hereby established. When implemented, this plan will protect County employees by eliminating or reducing the risk of exposure to infectious agents, specifically Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV), and preventing diseases that might occur as a result of exposure to those or other bloodborne pathogens.

POLICY: It is the policy of Human Resources/Safety Office to take every reasonable action to protect the health and safety of County employees and the general public, and to provide a healthful and safe work environment. All programs will conform with private accreditation and industry-wide standards of practice, and comply with Federal, State, and local regulations.

OBJECTIVE:
1. To protect employees and the public.
2. To establish standards and controls to which all employees with a potential for exposure to bloodborne pathogens must comply.

SCOPE: All County employees with occupational exposure to blood or other potentially infectious materials (OPIM).

REFERENCE: California Code of Regulations, General Industry Safety Orders (GISO), Title 8, Section 5193, 3203, 3204, Cal-OSHA Enforcement Policy & Procedure C-1D, California Labor Code Section 144.7, California Medical Waste Act, California Health and Safety Code, MMWR Recommendations and Reports, December 26, 1997, Volume 46, Number RR-18, MMWR Recommendations and Reports, May 15, 1998, Volume 47-RR-7, Needle Safety and Prevention Act, November 6, 2000.

I. GENERAL OVERVIEW

The information outlined describes the BCECP for the County of Riverside. The intent of this plan is to provide a framework to assist Managers/Supervisors to address BPE concerns. Included are procedures addressing the evaluation and prevention of exposures to bloodborne pathogens. The extent of occupational contact with blood and other potentially infectious materials will vary depending on the work assignment of each employee. This procedure is to serve as a guideline for organizations to use when creating their plan.

Many employees have the potential for exposure to blood or OPIM while performing work for the County every day. Since there is no reliable means to identify infectious blood or infectious materials (see Appendix A) before they are encountered, all blood and OPIM should be viewed as being infectious. Since the BPE issue has far reaching impact, this plan does not set mandatory criteria. Rather, it sets out basic elements for a BPE plan, guides determination of applicability and points to specific/detailed sources of information for those whose work activities require specifics. To manage the aspects of this plan, specific criteria have been assembled which include Work Activity/Hazard Identification and Evaluation, Engineering, Administrative and Protective Equipment Controls; and Hepatitis-B Vaccination/Post-Exposure Medical Follow-up and Training.

II. APPLICABILITY

All organizations within the county are involved with the BPE issue and need to provide assurances to employees that proper measures have been taken. All Managers and Supervisors must take steps to determine the extent of exposure potential for their employees.

III. RESPONSIBILITIES

A. Safety Office

1. Direct and plan an effective Bloodborne Pathogen Exposure Control Plan (BPECP) program for the County on an organization-wide basis.

2. Coordinate bloodborne pathogen needs with organizations by providing appropriate professional and technical resources.

3. Review and approve annually all aspects of the BPECP (i.e., job classifications involved, hazard evaluations, protective measures, post-exposure follow-up, organizational plans, consultants and information/training).

4. Recommend engineering and administrative controls as needed and determine which County organizations are to be included in this program.

5. Ensure quality and timeliness of training programs.

6. Evaluate the BPECP by monitoring overall quality and effectiveness of County programs by periodically reviewing each organization's procedures and making recommendations as required.

B. Health Services

1. Provide Hepatitis B vaccinations and post-vaccination testing for hepatitis B antibody for employees in identified risk job classifications. Validate organization Manager/Supervisor verification of occupational occurrences and exposure incidents and provide initial and follow-up care based on established protocols. (See Appendix B)

2. Ensure appropriate notification and documentation of vaccination, antibody test, declination of vaccination, post-exposure medical evaluation to include appropriate lab-tests, post-exposure prophylaxis procedures and counseling, as recommended by current CDC guidelines. Healthcare Provider will then provide to the County a written opinion which must include the following information: that the employee has been informed of the results of the evaluation and that the employee has been told about any medical conditions resulting from exposure that may require further evaluation and treatment and any work restrictions recommended relative the exposure. All other findings or diagnoses will be kept confidential and not included in the written report.

3. Maintain medical evaluations, exposure data and related BPECP documentation.

III. RESPONSIBILITIES - continued

C. Human Resources

1. Ensure Bloodborne Pathogen Exposure Control plans are incorporated into job descriptions of specified job classifications through the Human Resources Department and/or organization representative.

2. Coordinate with the Safety Office for hazard evaluations or training deficiencies noted.

D. Organization Management Responsibilities

1. Coordinate with the Safety Office to identify “at risk” job classifications and processes/procedures and with Human Resources/Health Services for individual medical evaluation, vaccinations and lab work.

2. Establish and implement organization specific BPECP (see Appendix C) and submit to Human Resources/Safety Office for review. (Note: Maintain copies of both the County BPECP and specific organization BPECP together for ready reference).

3. Assess the program annually for overall effectiveness by evaluating the organization’s program through periodic inspection of engineering/ administrative controls and protective equipment, ensuring that training has been conducted in accordance with Appendix D with proper maintenance of training records. Ensure the active involvement of employees (managerial & non-managerial) in reviewing and updating the ECP with respect to the procedures performed by employees in their respective work areas or organizations.

4. Follow-up and take corrective action after all occupational occurrences or exposure incidents and resolve deficiencies promptly.

E. Manager/Supervisor Responsibilities

1. Ensure that employees are evaluated for potential exposure to bloodborne pathogens by identifying and reviewing job classifications, work assignments, hazard evaluations, and exposure history.

2. Be knowledgeable about bloodborne pathogens and how this issue impacts employees (i.e., know exposure incident trends and injury rates).

3. Use resources and programs available within the County and through the Safety Office to address bloodborne pathogen concerns and needs.

4. All managers and supervisors must ensure that their employees receive BPECP training. Once training has been performed, the employer must offer the employee the initial Hepatitis B vaccination and be provided with documentation of initial vaccination or proof of immunity within 10 days of the initial work assignment to duties with occupational exposure to blood or OPIM, or the employee must sign a declination form.

III. RESPONSIBILITIES – continued

5. All managers and supervisors will review and verify all reported occupational occurrences and exposure incidents.

E. Manager/Supervisor Responsibilities (continued)

6. Upon verification of exposure, all involved managers and supervisors will process a Bloodborne Pathogen Employer's Report of Injury. Management will promptly follow-up on all incidents with affected employees. Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up. Information provided to the examining Healthcare Provider will include at least the following elements: (A) documented routes of exposure and circumstances under which the exposure incident occurred and (B) identify and document the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law.

7. Ensure that any employee who has a Sharps Injury, complete information to be placed in the Sharps Injury Log within 14 days following the exposure.

8. All managers and supervisors will provide budgetary resources to ensure information/training and protective control measures are available to their employees.

F. Employee Participant Responsibilities

1. Understand and participate in the BPECP by following all procedures within the County Plan and Agency/Department/District BPECP.

2. Use engineering and administrative controls established and report malfunctions/deficiencies to Managers/Supervisors.

3. Use all personal protective equipment as outlined in established procedures.

4. Participate in initial and annual BPECP Information/Training.

5. Report all occupational occurrences and exposure incidents immediately to Management/Supervisors.

6. Participate in the annual review of the BPECP.

IV. PRACTICES/PROCEDURES

The following practices will be followed by employees who have potential exposure to blood or OPIM, as determined, based on job classification, hazard evaluation and/or exposure history. Definitions are included in Appendix A. Other engineering or administrative controls will be implemented as needed to prevent or minimize exposure to bloodborne pathogens.

IV. PRACTICES/PROCEDURES - continued

General: Universal precautions shall be observed to prevent contact with blood or OPIM. All body fluids shall be considered potentially infectious materials. All procedures involving blood or OPIM shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.

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.

Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or bench tops where blood or OPIM are present.

Handwashing: Hands and other skin surfaces are to be immediately and thoroughly washed if contaminated with blood or OPIM. Hands must be washed after gloves are removed. Antiseptic hand cleaners are to be used when hand-washing facilities are not available and hands must be washed as soon as feasible.

Gloves: Gloves must be worn when it can reasonably be anticipated that the employee may have hand contact with blood, mucous membranes, non-intact skin, when performing vascular access procedures, and for handling items or surfaces soiled with blood or OPIM.

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

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

Protective 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. Protective clothing is to be changed when soiled or before leaving the work area. Disposable, protective clothing will be discarded as regulated waste/regular trash. Non-disposable protective clothing will be laundered as contaminated/non-contaminated through the organization. At no time will protective clothing be laundered at home or outside of internal-County or County-contracted facilities.

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

Eye-Face Protection: Protective devices must be worn during procedures that are likely to generate droplets of blood/OPIM onto the face or into the mucous membranes of the eyes, nose or mouth. These include masks in combination with chin length face shields, goggles, or glasses with solid side shields.

IV. PRACTICES/PROCEDURES - continued

Needleless Systems, Needle Devices with Engineered Sharps Injury Protection and Non-Needle Sharps: These shall be used for (A) withdrawal of body fluids after initial venous or arterial access is established (B) administration of medications or fluids and (C) any other procedure involving the potential for an exposure incident for which a needless system or needle with engineered sharps injury protection is available as an alternative to the use of needle devices. The only exceptions for use of these devices would be (1) if the engineering control is not available in the marketplace (2) if it is determined that the use of the engineering control will jeopardize the patient's safety or the success of the procedure involving the patient (3) if it can be demonstrated by means of objective product evaluation criteria that the engineering control is not more effective in preventing exposure incidents than the alternative used by the employer and (4) it can be demonstrated that reasonable specific and reliable information is not available on the safety performance of the engineering control for the procedure and the department is actively determining by means of objective product evaluation criteria whether use of the engineering control will reduce the risk of exposure incidents occurring in the workplace.

To prevent needle and sharp stick injuries, needles and sharps are not to be recapped or purposely bent, broken or manipulated by hand.

Sharps Containers for Contaminated Sharps: Needles and sharps are to be placed in puncture-resistant, waterproof containers labeled "BIOHAZARD" and have the international biohazard symbol displayed. Containers are to be easily accessible to personnel and located as close as feasible to the immediate area where sharps are used, are to be maintained upright through use and are to be collected for disposal when ¾ full. Reusable containers shall not be opened, emptied or cleaned manually. Prior to removal or replacement, the container shall be closed to prevent spillage

Cleaning and Decontamination: Employers shall ensure that the worksite is maintained in a clean and sanitary condition. Written methods and schedules for cleaning and decontamination of the worksite must be implemented and appropriate for the location, type of surface or equipment to be treated, type of soil or contamination present and tasks or procedures being performed in the area. All equipment and environmental and work surfaces shall be cleaned and decontaminated after contact with blood or OPIM no later than at the end of the shift and more often if surfaces become overtly contaminated, there is a spill of blood or OPIM, procedures are completed and, at the end of the shift, if the surface may have become contaminated since the last cleaning

Spills of Blood or OPIM: All spills must be immediately contained. Gloves must be worn. Absorb the spill with paper towels. Place bloody towels in a plastic lined trash container marked "BIOHAZARD" and have the international biohazard symbol displayed. Do not dispose this bag with regular trash. Contact Health Services for disposal procedures. Broken glassware, which may be contaminated with blood, shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as brush and dustpan, tongs or forceps. Clean the area with (1) soap and water then disinfect with 1:10 solution of household bleach (e.g., 1 oz. Bleach and 9 oz. water) or (2) clean and disinfect with an approved hospital grade detergent/disinfectant.

Laundry: Contaminated laundry shall be handled as little as possible with a minimum of agitation. Contaminated laundry is to be bagged or containerized in color-coded containers or bags at the location where it was used and shall not be sorted or rinsed in the location of use. When contaminated laundry is wet and presents a reasonable likelihood of soak-through or leakage from the bag or container, the laundry shall be placed and transported in bags or containers, which prevent soak-through and/or leakage of fluids to the exterior.

IV. PRACTICES/PROCEDURES - continued

Regulated Waste: Liquid or semi-liquid blood or OPIM or objects that are caked with dried blood or OPIM and are capable of releasing these materials when handled or compressed or contaminated sharps. Regulated waste, not consisting of sharps, shall be disposed of in containers which are closable, constructed to contain all contents and prevent leakage during handling, storage, transport or shipping, must be labeled and color-coded.

V. HEPATITIS B VACCINATION

Employees with potential exposure to blood or OPIM based on identified job classification, tasks, hazard evaluation and/or exposure history will be offered the Hepatitis B vaccine at no cost to the employee within 10 working days of initial assignment unless the employee:

A. Has already completed the Hepatitis B vaccination series
B. Has proof of immunity to Hepatitis B or is HbsAg+
C. Vaccine is contraindicated for medical reasons

All employees with potential exposure to bloodborne pathogens, working for the County at the time this program is implemented will be offered the vaccination. Employees must have received training concerning the Hepatitis B vaccination prior to receiving the vaccination. Employees must acknowledge in writing if they choose to decline the vaccine with the understanding that they will be given the vaccination at a later date upon their request.

All new employees who have an occupational exposure will be offered the Hepatitis B vaccination at the time of reporting and must acknowledge in writing if they decline, understanding the vaccination will be given should they request it at a later date, if they continue to have occupational exposure to Bloodborne Pathogens.

Post-vaccination testing is important for the overall effectiveness of a hepatitis B vaccination program and for the protection of individual employees. All employees who have received the hepatitis B vaccinations must be offered and encouraged to receive testing to assure the development of protective antibodies to hepatitis B.

Post-vaccination testing and follow-up should be conducted as detailed in the latest recommendations of the CDC. The December 26, 1997 document provides the latest recommendations and states:

One to two months after completion of the 3-dose vaccination series, employees with occupational exposure to blood or OPIM should be tested for antibody to Hepatitis B Surface Antigen (HbsAb). Persons who do not respond to the primary vaccine series should complete a second 3-dose vaccine series or be evaluated to determine if they are HbsAg+. Re-vaccinated persons should be retested at the completion of the second vaccine series.

Periodic serologic testing to monitor antibody concentrations after completion of the vaccine series is not recommended.

VI. SHARPS INJURY LOG

The employer shall establish and maintain a Sharps Injury Log, which is a record of each exposure incident involving a sharp. The exposure incident shall be recorded on the log within 14 working days of the date the incident is reported to the employer.

Each log entry should include:

Date and time of the exposure incident
Type and brand of sharp involved in the exposure incident
Description of the exposure incident
Job classification of the exposed employee
Department or work area where the exposure incident occurred
Procedure that the exposed employee was performing at the time of the incident
How the incident occurred
Part of body involved in the exposure incident

If the sharp had engineered sharps injury protection (ESIP), whether the protective mechanism was activated, whether the injury occurred before the protective mechanism was activated, during activation of the mechanism or after activation of the mechanism

If the sharp had no ESIP, the injured employee's opinion as to whether and how such a mechanism could have prevented the injury and employee's opinion about whether any other engineering, administrative or work practice control could have prevented the injury.

The information in the Sharps Injury Log shall be recorded and maintained in such a manner as to protect the confidentiality of the injured employee.

Sharps Injury Log must be kept five (5) years from the date the exposure incident occurred.

Periodically, information collected from the Sharps Injury Log will be evaluated to determine frequency of use of the types and brands of sharps involved in the exposure incidents documented on the Sharps Injury Log as well as currently available engineering controls and work practices for procedures performed by employees in their respective work areas.

Input will be solicited from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps for identification, evaluation and selection of effective engineering and work practice controls.

VII. 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:

A. Documented routes of exposure and circumstances under which the exposure incident occurred
B. Identity of source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law

The employer shall pay for the collection and testing of the employee's blood for HBV, HCV and HIV status. Additional collection and testing shall be made available as recommended by the CDC.

VII. POST-EXPOSURE EVALUATION AND FOLLOW-UP

The employer shall provide and pay for counseling and evaluation of reported illnesses.

The employer shall ensure that the healthcare professional responsible for treating the employee is provided (1) a copy of this regulation, (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 occurred, (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.

The heathcare professional's written opinion for post-exposure evaluation and following-up shall be limited to the following information: (1) that the employee has been informed of the results of the evaluation and (2) that the employee has been told about any medical conditions resulting from exposure to blood or OPIM which require further evaluation or treatment.

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

The exposed employee shall be provided with a copy of the evaluating physician's written opinion within 15 working days of completion of the evaluation.

VIII. INFORMATION AND TRAINING

A. All employees with potential exposure to blood or OPIM must receive initial training within 10 working days of initial assignment and at least annually thereafter. Additional training shall be provided when changes such as introduction of new engineering, administrative or work practice controls, modification of tasks or procedures or institution of new tasks of procedures affect the employee's occupational exposure.

B. The training program shall contain:

1. A copy and explanation of CCR, Title 8, Section 5193

2. A general explanation of the epidemiology and symptoms of bloodborne pathogens

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

4. Explanation of the Department's exposure control plan and how to obtain a written copy of the plan

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

6. An explanation of the use and limitations of methods to prevent/reduce exposure including appropriate engineering controls, administrative or work practice controls and personal protection equipment.

7. Information on 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.

VIII. INFORMATION AND TRAINING - continued

9. Information on the Hepatitis B vaccine, its efficacy, safety, method of administration, benefits of being vaccinated and that the vaccine & 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 OPIM.

11. An explanation of the procedure to follow if an exposure incident occurs, including method of reporting the incident, the medical follow-up that will be made available and the procedure for recording the incident on the Sharps Injury Log.

12. Information on the post-exposure 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.

C. The training must be conducted by a person who is 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.

D. The employees must be offered an opportunity for interactive questions and answers with the person conducting the training session.

E. Training records shall include the following information:

1. Dates of training session;

2. Contents of summary of training sessions, including training tools used

3. Names of persons conducting the training;

4. Names of all persons attending training sessions, and

5. Post-tests taken by employees to demonstrate the effectiveness of the training session.

F. These records shall be maintained by individual departments for 3 years.

IX. MEDICAL RECORDS

Record maintenance will be as follows:

Medical records must be kept for duration of employment plus thirty (30) years.

A. The Department shall establish and maintain an accurate record for each employee with occupational exposure.

IX. MEDICAL RECORDS - continued

B. This record shall include the name and social security number of the employee, a copy of the employee's hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination, a copy of all results of examinations, medical testing and follow-up procedures, the employer's copy of the healthcare professional's written opinion, a copy of the information provided to the healthcare professional.

C. The employer shall ensure that employee medical records are kept confidential, not disclosed or reported without the employee's written consent.

X. RECORD KEEPING

A. Organization managers will maintain hazard evaluation review of job classification (work activity review), engineering/administrative and protective equipment control and program recommendations and supervise BPECP information/training

B. Organization Managers and Supervisors will maintain an active roster of those employees who are identified by risk, job classifications in the BPECP, work activity, protective equipment and/or controls, hazard evaluation dates and any reports initiated or received concerning these activities

C. Specific Identified Risk Classification exposure determination or hazard evaluation reports and Occupational First Report of Injury are to be maintained for at least the duration of employment plus 30 years.

XI PROGRAM EVALUATION

A. The Safety Office will monitor annually the effectiveness of the overall program and review organization BPECP.

B. Organizations will annually evaluate the effectiveness of their program and audit records to ensure documentation of training and exposure incidents.

C. Human Resources/Health Services will audit annually medical records to ensure BPECP documentation and follow-up is complete.

D. Managers/Supervisors will monitor quarterly the effectiveness of their program. If necessary, consultation will be made with the Safety Office.

APPENDIX A
DEFINITIONS

APPENDIX A: DEFINITIONS

Blood: Human blood, human blood components and products made from human blood

Bloodborne Pathogens: 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), hepatitis C virus (HCV) and human immunodeficiency virus (HIV).

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

Contaminated: The presence or the reasonably anticipated presence of blood or other potentially infectious materials on a surface or in or on an item.

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

Decontamination: 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. Decontamination includes procedures regulated by Health and Safety Code Section 118275.

Engineering Controls: Controls (e.g., sharps disposal containers, needleless systems and sharps with engineered sharps injury protection) that isolate or remove the bloodborne pathogens hazard from the workplace

Engineered Sharps Injury Protection: Means either (1) a physical attribute built into a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, which effectively reduces the risk of an exposure incident by a mechanism such as barrier creation, blunting, encapsulation, withdrawal or other effective mechanisms or (2) a physical attribute built into any other type of needle device, or into a non-needle sharp, which effectively reduces the risk of an exposure incident.

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

Hand washing Facilities: A facility providing an adequate supply of running potable water, soap and single use towels or hot air drying machines.

HBV: Hepatitis B virus

HCV: Hepatitis C virus

HIV: Human Immunodeficiency Virus

Licensed Healthcare Professional: A person whose licensed scope of practice includes an activity which this section requires to be performed (e.g., Hepatitis B vaccination, post-vaccination antibody testing, post-exposure evaluation and follow-up).

Needle or Needle Device: A needle of any type, including, but not limited to, solid and hollow-bore needles.

Needleless System: A device that does not utilize needles for (1) the withdrawal of body fluids after initial venous or arterial access is established (2) the administration of medication of fluids and (3) any other procedure involving the potential for an exposure incident.

Occupational Exposure: 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.

OPIM: Other potentially infectious materials which includes (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 other body fluid that is visibly contaminated with blood such as saliva or vomitus, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids such as emergency response, (2) any unfixed tissue or organ (other than intact skin) from a human (living or dead) and (3) any of the following, if known or reasonably likely to contain or be infected with HIV, HBV or HCV: cell, tissue or organ cultures from human or experimental animals, blood, organs or other tissues from experimental animals or culture medium or other solutions

Parenteral Contact: Piercing mucous membranes or the skin barrier through such events as needle sticks, human bites, cuts, and abrasions

Personal Protective Equipment: Specialized clothing or equipment worn or used by an employee for protection against a hazard.

Regulated Waste: Waste that is any of the following (1) liquid or semi-liquid blood or OPIM (2) contaminated items that contain liquid or semi-liquid blood, or are caked with dried blood or OPIM and are capable of releasing these materials when handled or compressed, (3) contaminated sharps (4) pathological and microbiological wastes containing blood or OPIM, and (5) medical waste regulated by Health and Safety Code Sections 117600 – 118360

Sharp: Any object used or encountered that can be reasonably anticipated to penetrate the skin or any other part of the body, and to result in an exposure incident, including, but not limited to, needle devices, scalpels, lancets, broken glass, broken capillary tubes, exposed ends of dental wires and dental knives, drills and burs

Sharps Injury: Any injury caused by a sharp, including, but not limited to, cuts, abrasions or needle sticks

Sharps Injury Log: A written or electronic record satisfying the requirements of subsection ((C)(2)

Source Individual: Any individual, living or dead, whose blood or OPIM may be a source of occupational exposure to the employee.

Universal Precautions: An approach to infection control which considers all human blood and certain human body fluids as if known to be infectious for HIV, HBV and HCV and other bloodborne pathogens

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

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APPENDIX B

UPDATED U.S. PUBLIC HEALTH SERVICE GUIDELINES FOR THE MANAGEMENT OF OCCUPATIONAL EXPOSURES TO HBV, HCT & HIV AND RECOMMENDATIONS FOR POST EXPOSURE PROPHYLAXIS (MMWR 6/29/01/50 (PRII): 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*).

Definition of Health-Care Personnel and Exposure

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*).

Risk for Occupational Transmission of HBV - continued

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*).

Efficacy of PEP for HBV - continued

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 toinfants, 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*).

Risk for Occupational Transmission of HCV - continued

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.

Postexposure Management for HCV - continued

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*).

Risk for Occupational Transmission of HIV- continued

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

Efficacy of Antiretrovirals for PEP in Animal Studies - continued

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

Reports of Failure of PEP - continued

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.

Antiretroviral Agents for PEP - continued

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.

Toxicity and Drug Interactions of Antiretroviral Agents - continued

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 Antiretroviral Agents - continued

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).

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

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.

Evaluation of the Exposure Source - continued

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).

Management of Exposures to HBV - continued

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.

Management of Exposures to HCV - continued

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.

Use of PEP When HIV Infection Status of Source Person is Unknown - continued

- 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.

Monitoring and Management of PEP Toxicity - continued

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*).

Counseling and Education - continued

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

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

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

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

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-Negative**
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 warranted
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 warranted

* HIV-Positive, Class 1 — asymptomatic HIV infection or known low viral load (e.g., <1,500 RNA copies/mL). HIV-Positive, Class 2 — symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of postexposure prophylaxis (PEP) should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation 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 between the 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 vein).

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

	Infection status of source				
Exposure type	HIV-Positive Class 1†	HIV-Positive Class 2†	Source of unknown HIV status§	Unknown source¶	HIV-Negative
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 warranted
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 warranted

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

† HIV-Positive, Class 1 — asymptomatic HIV infection or known low viral load (e.g., <1,500 RNA copies/mL). HIV-Positive, Class 2 — symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of postexposure prophylaxis (PEP) should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation 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 between the 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

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]).

Table 5

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>

APPENDIX C

EMPLOYEE TRAINING DOCUMENTATION

BLOODBORNE PATHOGEN EXPOSURE CONTROL GUIDELINES
DOCUMENT NUMBER: 2011

INDIVIDUAL EMPLOYEE TRAINING DOCUMENTATION

NAME OF TRAINER/INSTRUCTOR: _____

TRAINING SUBJECT: Bloodborne Pathogen Exposure Control Plan

TRAINING MATERIALS USED: _____

NAME OF EMPLOYEE: _____

DATE OF HIRE/ASSIGNMENT: _____

I, _____, hereby certify that I have received training as described above in the following areas:
A copy and explanation of the Bloodborne Pathogen Standard
Epidemiology and Symptoms
Mode of Transmission
Employer's Exposure Control Plan
Risk Identification
Methods of compliance
Decontamination and Disposal
Personal protective Equipment
Hepatitis B vaccination
Emergency action for bloodborne pathogen exposure
Exposure Incident
Post-Exposure Evaluation and follow-up
Signs and labels
An opportunity for interactive questions and answers with the person conducting the training session.

I fully understand this training, agree to comply with the instructions received, and the BPECP.

_____ _____
Employee Signature Date

_____ _____
Trainer/Instructor Signature Date

APPENDIX D
SAMPLE EXPOSURE CONTROL PLAN

BLOODBORNE PATHOGEN EXPOSURE CONTROL GUIDELINES
DOCUMENT NUMBER: 2011

+BLOODBORNE PATHOGENS EXPOSURE CONTROL PLAN

Department:
Division/Location:
Date of Preparation:

In accordance with the Riverside County Bloodborne Pathogen Program, the _____Department has developed the following Exposure Control Plan (ECP) in compliance with GISO 5193, Cal/OSHA's Bloodborne Pathogen Standard

PURPOSE

The _____ Department provides a safe and healthful workplace for all employees. Our Department's policy is to establish, implement and maintain an effective Exposure Control Plan as required by the Bloodborne Pathogens Regulation in California Code of Regulations, Title 8 (8 CCR), Section 5193.

The written plan is designed to prevent or minimize employees' occupational exposure to blood and other potentially infectious materials (OPIM). This plan is consistent with the requirements of the Cal/OSHA Injury and Illness Prevention Program (8CCR 3203).

GENERAL REQUIREMENTS

This plan applies to all personnel employed by the Riverside County _____ Department.

All personnel will follow good personal hygiene, which includes clean clothes appropriate for dress codes and uniform regulations in area of assignment. All employees will also be responsible for adhering to all components of the Exposure Control Plan.

For positions or tasks that may place employees at high risk of exposure, managers/supervisors may develop specific site procedures that supplement this Exposure Control Plan.

ACCESSIBILITY

A copy of the Department's Exposure Control Plan will be maintained and located at each facility in the **(which?)** office. This written plan will be readily accessible to all employees. The employees are advised of this availability during the initial and all subsequent Bloodborne Pathogen Training Sessions.

Our exposure control plan is made available upon request, for examination and copying, to our employees, the Chief of Cal/OSHA, and NIOSH (or their respective designees) in accord with 8 CCR 3204, "Access to Employee Exposure and Medical Records."

BLOODBORNE PATHOGEN EXPOSURE CONTROL GUIDELINES
DOCUMENT NUMBER: 2011

RESPONSIBILITIES

The Exposure Control Officer **(name/job title**) with the assistance of **(name of committee/job titles)** is responsible for the overall management and support of the department's Bloodborne Pathogen Compliance Program. Responsibilities include:

Implementation of the Exposure Control Plan

Review and update the ECP at least annually or as necessary (1) to reflect new or modified tasks and procedures which affect occupational exposure; (2) to reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens, (3) to include new and revised employee positions with occupational exposure;(4) to review and evaluate the exposure incidents which occurred since the previous update, (5) and to review and respond to information indicating that the ECP is deficient in any area.

Conduct periodic audits to monitor and ensure compliance.

Ensure that input is solicited from non-managerial employees responsible for direct patient contact who are potentially exposed to injuries for the identification, evaluation and selection of effective engineering and work practice controls and shall document the solicitation in the ECP

OUTLINE OF EXPOSURE CONTROL PLAN

The _____ Department's written exposure control plan contains the following elements:

I. Exposure determinations
II. Methods of Compliance
    - Engineering controls
    - Work practices
    - Personal protective equipment
    - Housekeeping & decontamination procedures
    - Handling of regulated waste
III. Hepatitis B vaccination
IV. Post-exposure evaluation and follow-up
V. Communication of hazards to employees
    - Labels and Signs
    - Training

VI. Record keeping

I. EXPOSURE DETERMINATION

Many employees in the _____ Department have occupational exposure to bloodborne pathogens. Occupational exposure means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious material (OPIM) that may result from the performance of an employee's duties. Parenteral contact means piercing mucous membranes or the skin barrier through such events as needle sticks, human bites, cuts and abrasions. OPIM includes various contaminated human body fluids, unfixed human tissues or organs (other than skin), and other materials known or reasonably likely to be infected with human immunodeficiency virus (HIV), hepatitis B virus (HBV) or hepatitis C virus (HCV) through cells, tissues, blood, organs, culture mediums, or solutions.

OUTLINE OF EXPOSURE CONTROL PLAN - continued

Our policy is to conduct exposure determinations throughout the facilities by analyzing job tasks and procedures for each classification in order to identify employees who can be reasonably anticipated to have contact with blood or other infectious materials. Exposure determinations are made without regard to the use of personal protective equipment (PPE).

_____ Department employees, identified as being at risk of occupational exposure to bloodborne pathogens, are identified below, in the following manner:

List #1 Job classifications in which all employees have potential occupational exposure

List #2 Job classifications in which some employees have exposures, and all tasks and procedures associated with potential exposure.

List #1

Job Classifications in which **all** employees have occupational exposure include the following:
(list classifications where all employees have occupational exposure)

Such tasks include, but are not limited to:

List tasks that place employees at risk of exposure

List #2

Job Classifications in which **Some Employees** Have Occupational Exposure include:

Job Classification **Tasks/Procedures in These jobs that have Occupational Exposure**

List classifications where only some of the employees have occupational risk and describe what task places them at occupational risk of exposure.

II. METHODS OF COMPLIANCE

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

Utilizing Universal Precautions, _____ Department employees shall consider the following fluids/tissues as potentially infectious materials:

Blood
Semen
Vaginal Secretions
Cerebrospinal Fluid
Pleural Fluid
Pericardial Fluid
Peritoneal Fluid
Amniotic Fluid
Saliva in Dental Procedures
Any other body fluid that is visibly contaminated with blood such as saliva or vomitus
Any and all body fluids in situations where it is difficult or impossible to differentiate between body fluids such as in an emergency response

OUTLINE OF EXPOSURE CONTROL PLAN - continued

The _____ Department's policy is to select appropriate and effective engineering and work practice controls to reduce or eliminate exposure incidents.

Engineering controls means controls that isolate or remove the bloodborne pathogens hazard from the workplace.

Work Practice Controls means controls that reduce the likelihood of exposure by defining the manner in which a task is performed. All employees are responsible for implementing and enforcing safe work practices which will reduce the risk of exposures during all procedures or tasks that involve contact with blood or OPIM. The safe work practices include handling and processing of evidence and repair of contaminated equipment.

Both types of controls are updated concurrently because engineering controls alone cannot provide protection to an employee unless they are used with appropriate work practice controls. The _____ Department's policy is to perform all procedures involving blood or OPIM in a manner so that splashing, spraying, spattering, and generation of droplets are kept at a minimum.

The _____ Department has developed a schedule and method of implementation for the applicable subsections (d) through (h) of 8 CCR 5193. We have determined which subsections are applicable to the Department and documented the pertinent information as follows:

(Name/Job Title) shall ensure that engineering controls be examined and maintained or replaced **(how often)** to ensure their effectiveness.

(Name/Job Title) shall evaluate and update work practice controls **(how often)** to ensure their effectiveness. **(Name/Job Title)** will seek the participation of employees whose job duties involve occupational exposure to bloodborne pathogens and whose contributions of expertise and experience is significant. This committee, whose members include **(list of job classifications/names)** will meet **(how often)** to discuss these issues. To assess the effectiveness of our engineering and work practice controls, we will use information gathered from the Sharps Injury Log, Cal/OSHA's Log 300 and employee interviews.

Where occupational exposure remains after institution of these controls, personal protective equipment shall also be utilized

Engineering and Work Practice Controls

The following engineering and work practice controls are used throughout the _____Department.

Hand washing facilities are available to employees who may be exposed to blood or OPIM. These facilities are readily accessible in all work places. If handwashing facilities are not available (such as in the case of field exposures), employees must use an antiseptic cleanser, instant hand sanitizer or antiseptic towelette in conjunction with clean paper towels. If these alternatives are used, hands are to be washed with soap and running water as soon as feasible**. (Person/Job Title)** shall ensure that employees receive training on the importance of hand washing after removal of personal protective gloves and other personal protective equipment and that employees wash hands and any other potentially contaminated skin area immediately or as soon as feasible with soap and water.

Needleless Systems, Needle Devices and Non-needle Sharps shall be used for (1) withdrawal of body fluids after initial venous or arterial access is established (2) administration of medications or fluids and (3) any other procedure involving the potential for an exposure incident for which a needleless system is available as an alternative to the use of needle devices.

When needleless systems are not used, needles with engineered sharps injury protection shall be used for (1) withdrawal of body fluids (2) administration of medications or fluids (3) accessing a vein or artery and (4) any other procedure involving the potential for an exposure incident for which a needle device with engineered sharps injury protection is available. If sharps, other than needle devices are used (e.g., finger stick devices), these items shall include engineered sharps injury protection.

The only exceptions applying to the engineering controls is as follows:

-if it is not available in the marketplace

-if a licensed healthcare professional directly involved in a patient's care determines, in the reasonable exercise of clinical judgment, that use of the engineering control will jeopardize the patient's safety or the success of a medical, dental or nursing procedure involving the patient. The determination must be documented according to the procedure required by (c) (1) (B) 7.

-if the employer can demonstrate by means of objective product evaluation criteria that the engineering control is not more effective in preventing exposure incidents than the alternative used by the employer

-if the employer can demonstrate that reasonably specific and reliable information is not available on the safety performance of the engineering control for the employer's procedures, and that the employer is actively determining by means of objective product evaluation criteria whether use of the engineering control will reduce the risk of exposure incidents occurring in the employer's workplace.

Handling and Disposal of Sharps

Sharps are defined as "any object used or encountered in the industries covered by subsection (a) that can be reasonably anticipated to penetrate the skin or any other part of the body, and to result in an exposure incident, including, but not limited to, needle devices, scalpels, lancets, broken glass, broken capillary tubes, exposed ends of dental wires and dental knives, drills and burs." All contaminated sharp objects shall be handled in an approved manner to provide employee protection.

All procedures involving the use of sharps shall be performed using effective techniques and methods designed to minimize the risk of sharps injury.

Handling and Disposal of Sharps - continued

Disposable sharps shall not be reused and shall be placed immediately, as soon as possible, into containers that are closable, puncture resistant and leak-proof on the sides and bottom in conjunction with proper evidence handling procedures and policy.

Shearing or breaking of contaminated needles and other contaminated sharps is prohibited.

Contaminated sharps shall not be bent, recapped or removed from devices

Sharps that are contaminated with blood or OPIM shall not be stored or processed in a manner that requires employees to reach by hand into the containers which these sharps have been placed

Sharps containers shall not be opened, emptied or cleaned manually or in any other manner which would expose employees to the risk of sharps injury.

The contents of sharps container shall not be accessed unless properly reprocessed or decontaminated.

The employee using or coming into contact with and/or having possession of the sharps is responsible for placing it in the appropriate container.

Contaminated needles and sharps that are reusable are to be placed immediately after use into appropriate containers that are puncture resistant, labeled with a biohazard label and are leakproof**. (list where reusable sharps containers are located, who has responsibility for removing sharps from containers, manner of removal and how often the containers will be checked to remove the sharps)**

At all times, during the use of sharps, containers for contaminated sharps shall be:

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 including field units

Maintained upright throughout use

Replaced as necessary to avoid overfilling

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

The _____ Department shall provide the required sharps disposal and transport containers

Handling and Disposal of Sharps

If contaminated items are stored, transported, shipped, or packaged, proper labeling is required.

Specimens of blood or OPIM are to be placed in a container which prevents leakage during collection, handling, processing, storage, transport or shipping of the specimens. The container used for this purpose shall be properly labeled or color-coded and closed prior to storage, transport or shipping.

Handling and Disposal of Sharps - continued

Any specimen which could puncture a primary container will be placed within a secondary container which is puncture resistant. If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage and is properly labeled as containing biohazardous materials.

Double bagging of contaminated evidence is not required unless the primary container is contaminated or leaks.

If contaminated evidence could puncture the primary container, a secondary puncture-resistant container is required.

All equipment that may be contaminated must be decontaminated prior to servicing. Should complete decontamination be impossible, the parts that are contaminated must be labeled with a biohazard sign.

Equipment items contaminated with blood or OPIM should be cleaned with disinfectant in the appropriate manner.

All laundry and linen that is contaminated with known or suspected body fluids that will be washed, processed or handled by employees, will be identified for special handling by placing the items into red bags with a biohazard symbol.

Uniform items and other clothing that has become contaminated with blood of OPIM should be removed as soon as feasible. Contaminated uniform items and other clothing should be laundered in the manner prescribed by the manufacturer. Normal washing with regular detergents is sufficient to decontaminate clothing items. Dry cleaning is also sufficient to decontaminate clothing items.

Contaminated gloves shall be removed prior to driving or operating any vehicle or equipment and disposed of in the proper manner.

Contaminated county vehicles shall be cleaned and disinfected by the operator prior to re-use. In the case of gross contamination the employee will contact a supervisor to determine the course of action.

A mechanical device (BVM or pocket mask with one-way valve or Microshield Mouth to Mouth Resuscitation Barrier) will be used for all respiratory assistance or resuscitation.

Prohibited Work Practices include the following:

Mouth pipetting/suctioning of blood or OPIM is prohibited.

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

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

Personal Protective Equipment (PPE)

Personal protective equipment is the employee's last line of defense against bloodborne pathogens.

(Name/Job Title) is responsible for ensuring that the following provisions are met.

Personal Protective Equipment (PPE) - continued

The selection of the type of protective clothing includes an assessment of the possibility of exposure resulting from splashing, spraying, or soaking of clothing, while performing a task.

All personal protective equipment used at The _____ Department is provided without cost to the employees. All PPE is repaired and replaced as necessary by the department. Personal protective equipment is considered appropriate only if it does not permit blood or OPIM to pass through or to reach the employees' clothing, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which protective equipment will be used **(Indicate how PPE will be provided to employees, e.g., who has responsibility for distribution.) (List which procedures require protective clothing and the type of protection required).**

(examples)

TASKS	**PPE REQUIRED**
Contact with active arterial bleeding	**goggles, glasses, face masks, gowns, gloves**
Assisting with childbirth	**goggles, glasses, face masks, gowns, gloves**
Autopsies	**caps, gowns, shoe covers, gloves, face masks, eye protection**

The selection of the type of protective clothing includes an assessment of the possibility of exposure during a task resulting from splashing, spraying, or soaking of clothing with blood or OPIM.

Protective clothing can be disposable or reusable and made from various fabrics with a broad range of capability to resist penetration of liquids or repel a liquid challenge

The employees are trained regarding the use of the appropriate personal protective equipment for their job classifications and tasks/procedures they perform. Initial training about personal protective equipment is completed in the department before an employee starts a new position. Additional training is provided, when necessary, if an employee takes a new position or new job functions are added to their current position.

Interference with proper performance of a procedure, improper fit, or creation of a warm environment for the employee are not acceptable reasons to disregard use of PPE. PPE shall be worn without exception.

All personal protective equipment is visually inspected periodically **(how often)** for defects and repaired or replaced as needed to maintain its effectiveness.

(Name/Job Title) is responsible for ensuring that all department work areas have appropriate personal protective equipment available to the employees.

Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives are available to those employees who are allergic to gloves normally provided.

Personal protective equipment will be cleaned, laundered and/or disposed of by the _____ Department at no cost to the employees.

Personal Protective Equipment (PPE) - continued

Reusable or disposable cover gowns, which will not generally prevent gross liquid contamination from soaking through to the skin, are considered adequate protection for common evidence processing procedures where gross liquid/blood contamination is not likely.

All protective garments which are penetrated by blood shall be removed immediately or as soon as feasible. All PPE will be removed prior to leaving the work area or location which requires the equipment.

When PPE is removed, it is to be placed in an appropriately designated area or container for storage, washing, decontamination or disposal.

Gloves must be worn when there is reasonable likelihood of contact with:

- Blood
- Body fluids
- Mucous membranes
- Non-intact skin
- When performing vascular access procedures
- When handling contaminated items or surfaces

Disposable gloves are not to be washed or decontaminated for reuse and are to be replaced when they become contaminated, if they are torn/punctured, or when their ability to function as a barrier is compromised. Utility gloves may be decontaminated for reuse provided that the integrity of the glove is not compromised. Utility gloves are to 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.

Contaminated disposable gloves should be disposed of after use in an appropriately labeled, color-coded red bag.

Disposable gloves should be removed by pulling the gloves off, inside out. Employees should never touch personal items or their face while wearing gloves.

Employees must wash their hands after removing gloves.

Employees wearing other types of gloves (e.g., cotton, leather) should wear disposable gloves under the outer glove.

Disposable gloves should be carried by personnel while on duty and should be worn whenever an employee anticipates contact with body fluid or any time the employee has open cuts or breaks in the skin on the hands.

Masks in combination with eye protection devices, such as goggles or glasses with solid side shield, or chin length face shields, are required to be worn whenever splashes, spray splatter, or droplets of blood or OPIM are generated and eye, nose or mouth contamination can be reasonably anticipated. Personal eye glasses do not provide a sufficient level of protection. If eye glasses are worn, goggles which completely cover the glasses must also be worn to prevent exposure through the eyes.

Additional protective clothing such as lab coats, gowns, aprons, shoe covers, boots, clinic jackets, or similar outer garments shall be worn in instances where gross contamination can be reasonably anticipated. The following situations require that such protective clothing be utilized.

Personal Protective Equipment (PPE) - continued

Employees, observers, trainees, etc., attending autopsies shall wear protective clothing to include caps, gowns, shoe covers, gloves, face masks and eye protection. PPE will be provided by the Coroner's bureau.

If the employee's own clothing or department owned apparel becomes contaminated with blood or OPIM, during work, the department will be responsible for laundering at no cost to the employee. Grossly contaminated clothing shall be disposed of in accordance with BioHazard procedures.

Protective clothing must be removed prior to leaving the work area or when it becomes permeated by blood or OPIM and placed in Biohazard containers.

Housekeeping & Decontamination Procedures

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 it can be demonstrated that the decontamination of such equipment or portions of such equipment is not feasible. **(Name/Job Title)** shall ensure that information pertaining to the contamination status of a piece of equipment 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.

(Job Title/Name) shall ensure that the worksite is maintained in a clean and sanitary condition.

(Job Title/Name) 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.

Employees performing decontamination procedures must wear personal protective equipment including, but not limited to, full length apron, disposable gloves, protective goggles and face mask.

Decontamination will be accomplished by utilizing the following method/materials:

Wash equipment thoroughly with a fresh 1:10 bleach/water solution or other hospital-strength disinfectant with a sponge or brush (Note: when using other than 1:10 bleach/water solution, disinfectant should be verified with_____ for appropriateness of use. Allow the disinfectant to remain on the surface for two minutes or the manufacturer's recommendation. Rinse thoroughly with clean water. Dry the equipment with a disposable towel or allow to air dry before returning equipment to service.

The facility is cleaned and decontaminated according to the following schedule:
(individualize for each facility)

Area	Schedule	Procedure and Cleaner Used
_____	_____	_____
_____	_____	_____

All contaminated work surfaces are to be decontaminated after completion of procedures and immediately after any spill of blood or OPIM as well as at the end of the work shift if the surface has become contaminated since the last cleaning.

Housekeeping & Decontamination Procedures - continued

All equipment shall be cleaned and decontaminated after contact with blood or OPIM.

Protective coverings 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 been contaminated during the shift.

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

Laundry contaminated with blood or OPIM will be handled as little as possible and with a minimum of agitation. Such laundry will be placed and transported in appropriate labeled and color-coded container. Such laundry will not be sorted or rinsed in the area of use**. (Job Title/Name)** shall ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment.

Blood spills shall be cleaned up promptly with a disinfectant solution such as a fresh 1:10 dilution (1 part bleach to 10 parts water) of liquid chlorine bleach (5.25% sodium hypo chlorite), or a hospital strength disinfectant. Studies have shown that HIV is inactivated rapidly after being exposed to commonly used chemical germicides. Germicides vary in their activity against infectious agents and in the time needed for disinfection. Manufacturer's guidelines shall be followed.

Disposable towels, used to clean up spills of blood or OPIM, should be disposed of in red bags with biohazard symbol.

Mops used to clean up spills of body fluids should be soaked in a cleaning solution for at least one hour after use to ensure decontamination.

Regulated Waste Disposal

OSHA uses the terms "regulated waste", "medical waste," and "infectious waste," or "biohazardous waste," (all terms that may be used in the state of California). Riverside County _____ Department uses the term BIOHAZARDOUS WASTE which is synonymous with all the above listed terms for Department purposes

Regulated Waste (biohazardous waste) as defined by OSHA includes:

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

Pathological and microbiological waste containing blood or other potentially infectious material.

Regulated Waste Disposal - continued

Handling, storage, treatment and disposal of all biohazardous waste shall be in accordance with Health and Safety Code, Chapter 6, Section 117600 through 118360 and other applicable federal, state and local regulations.

The _____ Department shall contract for the removal of BioHazardous Waste at each facility. Each organization will have a California licensed medical waste disposal company provide the disposal of all biohazardous waste. The company will provide an appropriately labeled container with closable lid. The disposal company will remove all bio-hazard waste at least once a week, or sooner as needed for disposing contaminated biohazardous waste only. Nothing is to be placed into the biohazardous waste container unless it is first sealed in a red bag with the biohazard symbol. Sharps containers that are ready for removal by the contracted agency must be sealed and placed with the disposal container for pick up.

If the container becomes full before the next scheduled pick-up, arrangements will be made for a sooner pick-up. As an added precaution, the containers should only be handled while wearing gloves.

Containers used for temporarily storing biohazardous waste or contaminated items shall be labeled with a biohazard symbol and lined with a red bag bearing a biohazard symbol. All items placed into these containers shall be sealed in red bags with a biohazard symbol. These containers must be cleaned and decontaminated regularly, even if plastic liners are used. At the time of emptying, these containers with plastic liners must be inspected and cleaned if visibly contaminated. This process will be done by the contract vendor.

When moving containers of contaminated sharps from the area of use, the containers are to be closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport or shipping.

Other regulated waste shall be placed in containers which are closable, constructed to contain all contents and prevent leakage of fluids during handling, transport or shipping.

A waste bag and container must be color-coded and closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport or shipping.

Compliance Monitoring

Compliance monitoring is performed at the direction of _____. _____ is responsible for ensuring that the employees follow the protective measures.

The responsibility of the manager/supervisor for monitoring compliance, reporting non-compliance, and the action taken in response to non-compliance is clearly defined and communicated to the employees.

The _____ or designees are responsible for documenting that appropriate training has been given and that necessary protective equipment has been provided. **(Attachment C)**

When monitoring reveals repeated failure to follow recommended practices after additional supplies, education and/or retraining, and counseling have been provided, disciplinary action may be taken according to the disciplinary procedures of the Department.

Compliance Monitoring - continued

Riverside County _____ Department is responsible for the provision of a work place free from recognized hazards. This includes workers on-site from other organizations, employed by another agency, volunteers, and students from all programs.

III. HEPATITIS B VACCINATIONS

The _____ Department offers the Hepatitis B vaccination series to all employees who have occupational exposure to bloodborne pathogens. We strongly encourage our employees to be vaccinated and recognize that all employees with occupational exposure to blood or OPIM are at risk of contracting hepatitis B.

The hepatitis B vaccination is made available to employees after they receive training about the vaccination and within ten working days of their initial work assignment. The vaccinations shall be offered at no cost to the employee, made available at a reasonable time and place and performed by or under the supervision of a licensed physician. The _____ Department follows the most current recommendations of the Centers for Disease Control and Prevention's Morbidity and Mortality Report for the immunization of employees.

The series is made available unless:

The employee previously received the complete hepatitis B vaccination series, or
Antibody testing has revealed the employee is immune, or
The vaccination series is contraindicated for medical reasons.

An important component of our hepatitis vaccination program is post-vaccination serological testing. This test is provided at no cost to our employees approximately 6 weeks following completion of the three-dose hepatitis vaccination series. This is done to ensure that protective antibodies to hepatitis B surface antigen have developed. In the absence of an adequate antibody response, employees are strongly encouraged to complete a second three-dose vaccine series followed by serological retesting or an evaluation for positive HbsAg. Employees who still do not have adequate antibody responses following the second 3-dose vaccine series and are HbsAg negative, are informed that they may be considered susceptible to HBV infection. They are counseled on the precautions needed to prevent HBV infection and the need for prophylactic administration of hepatitis B immune globulin within 24 hours of an occupational exposure.

Our organization does not make accepting the hepatitis B vaccination series or post-vaccine serology a condition of employment.

All employees who decline the Hepatitis B vaccinations shall sign a waiver indicating their refusal. If an employee initially declines the vaccinations, but at a later date, while still covered under this program, decides to accept the vaccinations, the vaccinations shall then be made available.

Vaccination/Post-Serology Testing Procedure

The _____ Department considers accurate record keeping to be of the utmost importance. Its importance and the need for confidentiality cannot be expressed strongly enough. It is the responsibility of all levels of employees involved in the process to make certain the documenting paperwork is processed properly. Vaccinations are performed under the supervision of a licensed physician or other health care professional. The Department elected to use the services of the Riverside County Public Health Department to perform the Hepatitis B vaccinations and post-serology testing. The employee must provide documentation when vaccination/labwork is administered, regardless where administered.

Vaccination/Post-Serology Testing Procedure - continued

Employees will be notified of the location of the clinic nearest their place of employment.

_____will track each employee's series of vaccinations/date of lab work and insure proper documentation occurs. It is the responsibility of the employee to insure that he/she keeps the appointment. Employees will be released during work hours to receive their shots if the appointment time is during work hours.

Employees must notify _____ each time they have received their vaccination/labwork.

_____ shall record the date of the present vaccination and the date for the next vaccination or antibody test.

Upon completion of the Hepatitis B vaccinations, the _____shall insure that documentation is placed in the employee's _____ file.

Employees who decline to have the vaccinations shall complete a declination form. The coordinator shall insure the declination form (copy) is placed in the employee's _____ file.

IV. POST-EXPOSURE EVALUATION

When an employee has an exposure incident (specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or OPIM that results from the performance of an employee's duties), after appropriate first aid procedures have been followed, the employee shall immediately report the incident to the supervisor.
.
Occupational exposure to blood or OPIM requires timely and appropriate post-exposure intervention.

(Job Title/Name) ensures that immediately following an exposure incident, the exposed employee receives the following:

- Confidential medical evaluations with qualified physicians
- Lab tests conducted by an accredited laboratories
- Treatment and PEP drugs when appropriate Counseling

The Post-exposure evaluation is :

- Made available at no cost to our employees, at a reasonable time and place
- Performed by or under the supervision of a licensed physician or another licensed health care professional
- Kept current according to the recommendations of the MMWR

Upon report of an exposure incident, the _____ Department will refer the employee to the nearest county approved worker's compensation medical provider and will provide the healthcare provider responsible for post-exposure follow-up treatment with the following information:

- A description of the exposed employee's duties as they relate to the exposed incident
- Documentation of the routes of exposure and circumstances under which the exposure occurred
- Results of the source individual's blood testing, if available
- A copy of 8 CCR 5193

IV. POST-EXPOSURE EVALUATION - continued

All medical records relevant to the appropriate treatment of the exposed employee,
Including:
Hepatitis B series vaccination status and all vaccination dates
Medical records regarding the employee's ability to receive the vaccination (e.g., information on whether the complete hepatitis B vaccination series was already administered, antibody testing revealed immunity, or the vaccination was contraindicated for medical reasons)

The Department shall identify and document the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law. (The _____ Department shall take necessary actions to obtain the source person's blood tested to confirm the presence of bloodborne pathogens.

If pre-exposure samples of blood or OPIM are available from an unidentified source individual, the department will test those available samples for HBV, HCV and HIV infectivity.

Testing for the source individual's blood for HBV, HCV and HIV infectivity is performed as soon as feasible and after his/her consent is obtained. For HIV infectivity testing, our department obtains consent from the source individual in the form of a "Voluntary Informed Written Consent." If the source individual is known to be already infected with HBV, HCV or HIV, testing to determine his/her infectivity status is not repeated.

Results of the source individual's testing are made available to the exposed employee.

A source individual may refuse to give consent and no pre-exposure samples may be available. In such situations, the department documents that legally required consent could not be obtained and no samples are tested.

If consent cannot be obtained (and is not required by law) and pre-exposure samples of blood or OPIM are available, the department tests those samples for HBV, HCV and HIV infectivity.

The healthcare provider, during the post-exposure evaluation, collects and tests the exposed employee's blood for HBV, HCV and HIV serological status as soon as feasible and after his or her consent is obtained. If the exposed employee consents to baseline blood collection but does not give consent at that time for HIV serological testing, the sample is preserved for at least 90 days. If the employee decides, within 90 days of the exposure incident, to have the baseline sample tested for HIV serological status, the testing is conducted as soon as is feasible. Additional samples of blood will be collected and tested, and the provisions for PEP when medically indicated are made available as recommended by the U.S. Public Health Service.

To comply with 8 CCR 5193, medical information about the employee is restricted and not discussed or revealed to supervisors, Human Resources representatives or other health care professionals who do not need the information

The department will obtain a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the medical evaluation. A copy of this written opinion is provided to the employee involved in the exposure incident. The healthcare professional's written opinion is limited to: Whether the hepatitis B vaccination series is indicated and the exposed employee has already received such vaccinations

IV. POST-EXPOSURE EVALUATION - continued

Post-exposure evaluation and follow-up (i.e., inform the employee about the results of the evaluation and any medical conditions resulting from the exposure to blood or OPIM requiring further evaluation or treatment).

Employee Responsibilities:

- Report exposure to immediate supervisor
- Complete a written memo detailing the exposure
- Assist in the completion of the worker's compensation paperwork

Supervisor responsibilities:

- Complete a supervisor's memo detailing the incident
- Assure that the employee is transported to the nearest available county approved worker's compensation provider for urgent care, along with proper paperwork for post-Exposure

All other findings or diagnoses remain confidential and are not included in the written opinion

Exposure Incident Evaluation

Every exposure incident will be evaluated by the _____ Department to identify and correct problems, with the goal of preventing reoccurrence.

All exposures will be documented in a timely manner. The events surrounding each incident are reviewed by **(who and when),** with appropriate corrective action taken and documented.

_____ shall review any exposure to ascertain if policies and procedures were complied with and sufficient to protect the employee.

Sharps Injury Log

The _____ Department's policy is to evaluate the circumstances (including the routes of exposure) under which all occupational exposure incidents occur. This evaluation is conducted as soon as possible after a report of an exposure incident is submitted. For each reported sharps injury exposure incident, we gather and evaluate, if possible, the following information which is maintained in the Sharps Injury Log:

Date and time of the exposure incident

Type and brand of sharp involved in the exposure incident

A description of the exposure incident which shall include:

- -Job classification of the exposed employee
- -Department or work area where the exposure incident occurred
- -The procedure that the exposed employee was performing at the time of the incident
- -How the incident occurred
- -The body part involved in the exposure incident
- -If the sharp had engineered sharps injury protection, whether the protective mechanism was activated, and whether the injury occurred before the protective mechanism was activated, during activation of the mechanism or after activation of the mechanism, if applicable

IV. POST-EXPOSURE EVALUATION - continued

-If the sharp had no engineered sharps injury protection, the injured employee's opinion as to whether and how such a mechanism could have prevented the injury
-The employee's opinion about whether any engineering, administrative or work practice control could have prevented the injury

Each exposure incident shall be recorded on the Sharps Injury Log within 14 working days of the date the incident is reported to the employer and shall be maintained in such a manner as to protect the confidentiality of the injured employee.

Each organization shall maintain a Sharps Injury Log.

The sharps Injury Log shall be kept confidential and located in the administrative section of the organization.

VI. COMMUNICATION OF HAZARDS TO EMPLOYEES

Labels and Signs

Specific labeling (with biohazard symbol or the use of red bags or container) is required to warn employees of potential hazards.

Warning labels are affixed to containers of regulated waste, refrigerators and freezers containing blood or OPIM and other containers used to store, transport, or ship blood or OPIM. The warning labels are either an integral part of the containers or are affixed as close as is feasible to the containers by string, wire, or adhesive (or other methods) to prevent their loss or unintentional removal. Warning labels are (1) predominantly fluorescent orange or orange-red (2) have lettering and symbols in contrasting colors; and (3) have the following words:

BIOHAZARD
(with biohazard symbol)

Or in the case of regulated waste

BIOHAZARDOUS WASTE OR SHARPS WASTE

Information and Training

All employees with occupational exposure in our department will participate in a training program that is provided at no cost during working hours and at a location reasonably accessible to the employee. The training materials used are appropriate in content and vocabulary in the educational and literacy levels and are conveyed in the language of our employees. The training materials clearly state the objectives of the training.

Trainers are knowledgeable in the subject matter covered by the training program as it relates to our workplace. All employees have an opportunity for interactive questions and answers with the persons conducting the training.

The training program includes information and explanations of at least the following:

Epidemiology, symptoms and modes of transmission of bloodborne diseases

Exposure control plans we have implemented and how to obtain a copy of the written plan

Appropriate methods for recognizing tasks and activities that may involve exposure to blood or OPIM

Use and limitations of methods that will prevent or reduce exposures, including appropriate engineering, administrative or work practice controls and personal protective equipment

The basis for selection of PPE

Types, proper use, location, removal, handling, decontamination and disposal of PPE

Hepatitis B vaccination series, including its efficacy, safety, method of administration, benefits and the fact that the vaccination be offered to employees free of charge

Appropriate actions to take and persons to contact in an emergency involving blood or OPIM

Procedure to follow if an exposure incident occurs including:
- Method of reporting the incident
- Medical follow-up that will be made available
- Procedure for recording the incident in the sharps injury log

Post-exposure evaluation and follow-up that will be made available to employees

Signs, labels and/or color codings that are used

In addition to the above-mentioned information, we will provide to all employees a copy of 8 CCR 5193 “Bloodborne Pathogens” and an explanation of its content.

Training is provided at the time of employees’ initial assignment (to tasks in which occupational exposure may occur) and at least annually thereafter. Additional training, limited to addressing the new exposures created, is provided to the employee whose occupational exposure is affected by:

- Introduction of new engineering, administrative or work practice controls
- Changes or modifications in existing tasks or procedures
- Institution of new tasks or procedures.

VII. RECORDKEEPING

The _____ Department establishes and maintains an accurate record of each employee with occupational exposure, including medical records, training records and a sharps injury log.

All training records shall be maintained at _____.

Medical Records

Employee medical records are kept confidential and are not disclosed or reported to any person within or outside our workplace unless the subject employee has given his or her express written consent

Medical records include the employee's name, social security number and a copy of the employee's:

- Hepatitis B series vaccination status and all vaccination dates
- Reports of serological testing
- Documentation regarding the ability to receive the hepatitis B vaccination series, including whether:
  - The complete hepatitis B vaccination series was given; or
  - Antibody testing revealed immunity; or
  - The vaccination was contraindicated for medical reasons
- Results from examinations, medical testing and follow-up procedures
- Information provided to the healthcare professional following an exposure incident
- The healthcare professional's written post-exposure evaluation

Medical records are maintained for at least the duration of the individual's employment plus 30 years.

Training Records

Training records include the employee's name and job title and:

- Date of training sessions
- A summary of the training sessions
- Names and qualifications of persons conducting the training

Training records are maintained for three years from the date on which the training began

Sharps Injury Log Records

The Sharps Injury Log contains the information specified earlier in the plan. The log is maintained for five years from the date that the exposure incident occurred

APPENDIX E

SHARPS INJURY LOG

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DOCU

Sharps Injury Log

The following information, if known or reasonably available, is documented within 14 working days of the date on which each exposure incident was reported.

1. Date and time of the exposure incident: _____
2. Date of exposure incident report: _____ Report written by: _____
3. Type and brand of sharp involved: _____
4. Description of exposure incident:
   - Job classification of exposed employee: _____
   - Department or work area where the incident occurred: _____
   - Procedure being performed by the exposed employee at the time of the incident: _____
     _____
   - How the incident occurred: _____
   - Body part(s) involved: _____
   - Did the device involved have engineered sharps injury protection? Yes (✓) _____ No (✓) _____
   - Was engineered sharps injury protection on the sharp involved? Yes (✓) _____ No (✓) _____

If Yes	If No
A. Was the protective mechanism activated at the time of the exposure incident? Yes ____No ____ B. Did the injury occur before, during, or after the mechanism was activated? _____ Comments: _____ _____	A. Does the injured employee believe that a protective mechanism could have prevented the injury? Yes ____No ____

   - Does the exposed employee believe that any controls (e.g., engineering, administrative, or work practice) could have prevented the injury? Yes (✓) _____ No (✓) _____
     Employee's opinion:
     _____
     _____
5. Comments on the exposure incident (e.g., additional relevant factors involved):
   _____
   _____
   _____
6. Employee interview summary:
   _____
   _____
   _____
7. Picture(s) of the sharp(s) involved (please attach if available).

Make copies as needed

APPENDIX F

BLOODBORNE PATHOGEN STANDARD
GISO 5193

§5193. Bloodborne Pathogens.

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

Exception: This regulation does not apply to the construction industry.

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

"Biological Cabinet" means a device enclosed except for necessary exhaust purposes on three sides and top and bottom, designed to draw air inward by means of mechanical ventilation, operated with insertion of only the hands and arms of the user, and in which virulent pathogens are used. Biological cabinets are classified as:

(1) Class I: A ventilated cabinet for personnel protection with an unrecirculated inward airflow away from the operator and high-efficiency particulate air (HEPA) filtered exhaust air for environmental protection.

(2) Class II: A ventilated cabinet for personnel, product, and environmental protection having an open front with inward airflow for personnel protection, HEPA filtered laminar airflow for product protection, and HEPA filtered exhaust air for environmental protection.

(3) Class III: A total enclosed, ventilated cabinet of gas-tight construction. Operations in the cabinet are conducted through attached protective gloves.

"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), hepatitis C virus (HCV) and human immunodeficiency virus (HIV).

"Chief" means the Chief of the Division of Occupational Safety and Health of the California Department of Industrial Relations or designated representative.

"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 a surface or in or on an item.

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

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"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. Decontamination includes procedures regulated by Health and Safety Code Section 118275.

"Engineering Controls" means controls (e.g., sharps disposal containers, needlelesss systems and sharps with engineered sharps injury protection) that isolate or remove the bloodborne pathogens hazard from the workplace.

"Engineered Sharps Injury Protection" means either:

(1) A physical attribute built into a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, which effectively reduces the risk of an exposure incident by a mechanism such as barrier creation, blunting, encapsulation, withdrawal or other effective mechanisms; or

(2) A physical attribute built into any other type of needle device, or into a non-needle sharp, which effectively reduces the risk of an exposure incident.

"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.

"HCV" means hepatitis C virus.

"HIV" means human immunodeficiency virus.

"Licensed Healthcare Professional" is a person whose licensed scope of practice includes an activity which this section requires to be performed by a licensed healthcare professional.

"Needle" or "Needle Device" means a needle of any type, including, but not limited to, solid and hollow-bore needles.

"Needleless System" means a device that does not utilize needles for:

(1) The withdrawal of body fluids after initial venous or arterial access is established;

(2) The administration of medication or fluids; and

(3) Any other procedure involving the potential for an exposure incident.

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

"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.

"One-Hand Technique" means a procedure wherein the needle of a reusable syringe is capped in a sterile manner during use. The technique employed shall require the use of only the hand holding the syringe so that the free hand is not exposed to the uncapped needle.

"OPIM" means other potentially infectious materials.

"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 other body fluid that is visibly contaminated with blood such as saliva or vomitus, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids such as emergency response;

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

(3) Any of the following, if known or reasonably likely to contain or be infected with HIV, HBV, or HCV:

(A) Cell, tissue, or organ cultures from humans or experimental animals;

(B) Blood, organs, or other tissues from experimental animals; or

(C) Culture medium or other solutions.

"Parenteral Contact" 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 or used 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, HBV or HCV.

"Regulated Waste" means waste that is any of the following:

(1) Liquid or semi-liquid blood or OPIM;

(2) Contaminated items that:

(A) Contain liquid or semi-liquid blood, or are caked with dried blood or OPIM; and

(B) Are capable of releasing these materials when handled or compressed.

(3) Contaminated sharps.

(4) Pathological and microbiological wastes containing blood or OPIM.

(5) Regulated Waste includes "medical waste" regulated by Health and Safety Code Sections 117600 through 118360.

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

"Sharp" means any object used or encountered in the industries covered by subsection (a) that can be reasonably anticipated to penetrate the skin or any other part of the body, and to result in an exposure incident, including, but not limited to, needle devices, scalpels, lancets, broken glass, broken capillary tubes, exposed ends of dental wires and dental knives, drills and burs.

"Sharps Injury" means any injury caused by a sharp, including, but not limited to, cuts, abrasions, or needlesticks.

"Sharps Injury Log" means a written or electronic record satisfying the requirements of subsection (c)(2).

"Source Individual" means any individual, living or dead, whose blood or OPIM may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinical 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.

"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, HCV, and other bloodborne pathogens.

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

(c) Exposure Response, Prevention and Control.

(1) Exposure Control Plan.

(A) Each employer having an employee(s) with occupational exposure as defined by subsection (b) of this section shall establish, implement and maintain an effective Exposure Control Plan which is designed to eliminate or minimize employee exposure and which is also consistent with Section 3203.

(B) The Exposure Control Plan shall be in writing and shall contain at least the following elements:

1. The exposure determination required by subsection (c)(3);

2. The schedule and method of implementation for each of the applicable subsections: (d) Methods of Compliance, (e) HIV, HBV and HCV 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;

3. The procedure for the evaluation of circumstances surrounding exposure incidents as required by subsection (f)(3)(A).

4. An effective procedure for gathering the information required by the Sharps Injury Log.

5. An effective procedure for periodic determination of the frequency of use of the types and brands of sharps involved in the exposure incidents documented on the Sharps Injury Log;

Note: Frequency of use may be approximated by any reasonable and effective method.

6. An effective procedure for identifying currently available engineering controls, and selecting such controls, where appropriate, for the procedures performed by employees in their respective work areas or departments;

7. An effective procedure for documenting patient safety determinations made pursuant to Exception 2. of subsection (d)(3)(A); and

8. An effective procedure for obtaining the active involvement of employees in reviewing and updating the exposure control plan with respect to the procedures performed by employees in their respective work areas or departments.

(C) Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with Section 3204(e).

(D) The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary as follows:

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

2.a. To reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and

b. To document consideration and implementation of appropriate commercially available needleless systems and needle devices and sharps with engineered sharps injury protection;

3. To include new or revised employee positions with occupational exposure;

4. To review and evaluate the exposure incidents which occurred since the previous update; and

5. To review and respond to information indicating that the Exposure Control Plan is deficient in any area.

(E) Employees responsible for direct patient care. In addition to complying with subsections (c)(1)(B)6. and (c)(1)(B)8., the employer 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.

(F) The Exposure Control Plan shall be made available to the Chief or NIOSH or their respective designee upon request for examination and copying.

(2) Sharps Injury Log.

The employer shall establish and maintain a Sharps Injury Log, which is a record of each exposure incident involving a sharp. The information recorded shall include the following information, if known or reasonably available:

(A) Date and time of the exposure incident;

(B) Type and brand of sharp involved in the exposure incident;

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(C) A description of the exposure incident which shall include:

1. Job classification of the exposed employee;

2. Department or work area where the exposure incident occurred;

3. The procedure that the exposed employee was performing at the time of the incident;

4. How the incident occurred;

5. The body part involved in the exposure incident;

6. If the sharp had engineered sharps injury protection, whether the protective mechanism was activated, and whether the injury occurred before the protective mechanism was activated, during activation of the mechanism or after activation of the mechanism, if applicable;

7. If the sharp had no engineered sharps injury protection, the injured employee's opinion as to whether and how such a mechanism could have prevented the injury; and

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

(D) Each exposure incident shall be recorded on the Sharps Injury Log within 14 working days of the date the incident is reported to the employer.

(E) The information in the Sharps Injury Log shall be recorded and maintained in such a manner as to protect the confidentiality of the injured employee.

(3) Exposure Determination.

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

1. A list of all job classifications in which all employees in those job classifications have occupational exposure;

2. A list of job classifications in which some employees have occupational exposure; and

3. 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 subsection (c)(3)(A)2. of this standard

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

(d) Methods of Compliance.

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

(2) Engineering and Work Practice Controls--General Requirements.

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(A) Engineering and work practice controls shall be used to eliminate or minimize employee exposure.

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

(C) Work practice controls shall be evaluated and updated on a regular schedule to ensure their effectiveness.

(D) All procedures involving blood or OPIM shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.

(3) Engineering and Work Practice Controls--Specific Requirements.

(A) Needleless Systems, Needle Devices and non-Needle Sharps.

1. Needleless Systems. Needleless systems shall be used for:

a. Withdrawal of body fluids after initial venous or arterial access is established;

b. Administration of medications or fluids; and

c. Any other procedure involving the potential for an exposure incident for which a needleless system is available as an alternative to the use of needle devices.

2. Needle Devices. If needleless systems are not used, needles with engineered sharps injury protection shall be used for:

a. Withdrawal of body fluids;

b. Accessing a vein or artery;

c. Administration of medications or fluids; and

d. Any other procedure involving the potential for an exposure incident for which a needle device with engineered sharps injury protection is available.

a. Withdrawal of body fluids;

b. Accessing a vein or artery;

c. Administration of medications or fluids; and

d. Any other procedure involving the potential for an exposure incident for which a needle device with engineered sharps injury protection is available.

3. Non-Needle Sharps. If sharps other than needle devices are used, these items shall include engineered sharps injury protection.

4. Exceptions. The following exceptions apply to the engineering controls required by subsections (d)(3)(A)1.-3.:

a. Market Availability. The engineering control is not required if it is not available in the marketplace.

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b. Patient Safety. The engineering control is not required if a licensed healthcare professional directly involved in a patient's care determines, in the reasonable exercise of clinical judgement, that use of the engineering control will

jeopardize the patient's safety or the success of a medical, dental or nursing procedure involving the patient. The determination shall be documented according to the procedure required by (c)(1)(B)7.

c. Safety Performance. The engineering control is not required if the employer can demonstrate by means of objective product evaluation criteria that the engineering control is not more effective in preventing exposure incidents than the alternative used by the employer.

d. Availability of Safety Performance Information. The engineering control is not required if the employer can demonstrate that reasonably specific and reliable information is not available on the safety performance of the engineering control for the employer's procedures, and that the employer is actively determining by means of objective product evaluation criteria whether use of the engineering control will reduce the risk of exposure incidents occurring in the employer's workplace.

(B) Prohibited Practices.

1. Shearing or breaking of contaminated needles and other contaminated sharps is prohibited.

2. Contaminated sharps shall not be bent, recapped, or removed from devices.

Exception: Contaminated sharps may be bent, recapped or removed from devices if:

a. The employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure; and

The procedure is performed using a mechanical device or a one-handed technique.

3. Sharps that are contaminated with blood or OPIM 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.

4. Disposable sharps shall not be reused.

5. Broken Glassware. 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.

6. The contents of sharps containers shall not be accessed unless properly reprocessed or decontaminated.

7. Sharps containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of sharps injury.

8. Mouth pipetting/suctioning of blood or OPIM is prohibited.

9. 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.

10. Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or OPIM are present.

(C) Requirements for Handling Contaminated Sharps.

1. All procedures involving the use of sharps in connection with patient care, such as withdrawing body fluids, accessing a vein or artery, or administering vaccines, medications or fluids, shall be performed using effective patient-handling techniques and other methods designed to minimize the risk of a sharps injury.

2. Immediately or as soon as possible after use, contaminated sharps shall be placed in containers meeting the requirements of subsection (d)(3)(D) as applicable.

3. At all time during the use of sharps, containers for contaminated sharps shall be:

a. 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);

b. Maintained upright throughout use, where feasible; and

c. Replaced as necessary to avoid overfilling.

(D) Sharps Containers for Contaminated Sharps.

1. All sharps containers for contaminated sharps shall be:

a. Rigid;

b. Puncture resistant;

c. Leakproof on the sides and bottom;

d. Portable, if portability is necessary to ensure easy access by the user as required by subsection (d)(3)(C)3.a.; and

e. Labeled in accordance with subsection (g)(1)(A)(2).

2. If discarded sharps are not to be reused, the sharps container shall also be closeable and sealable so that when sealed, the container is leak resistant and incapable of being reopened without great difficulty.

(E) Regulated Waste.

1. General.

Handling, storage, treatment and disposal of all regulated waste shall be in accordance with Health and Safety Code Chapter 6.1, Sections 117600 through 118360, and other applicable regulations of the United States, the State, and political subdivisions of the State.

2. Disposal of Sharps Containers.

When any container of contaminated sharps is moved from the area of use for the purpose of disposal, the container shall be:

a. Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping; and

b. Placed in a secondary container if leakage is possible. The second container shall be:

i. Closable;

ii. Constructed to contain all contents and prevent leakage dur8ing handling, storage, transport, or shipping; and

iii. Labeled according to subsection (g)(1)(A) of this section.

3. Disposal of Other Regulated Waste. Regulated waste not consisting of sharps shall be disposed of in containers which are:

a. Closable;

b. Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping;

c. Labeled and color-coded in accordance with subsection (g)(1)(A) of this section; and

d. Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

4. Outside Contamination. If outside contamination of a container of regulated waste occurs, it shall be placed in a second container. The second container shall be:

a. Closable.

b. Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;

c. Labeled and color-coded in accordance with subsection (g)(1)(A) of this section; and

d. Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

(F) Handling Specimens of Blood or OPIM. Specimens of blood or OPIM shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping.

1. The container for storage, transport, or shipping shall be labeled or color-coded according to subsection (g)(1)(A), and closed prior to being stored, transported, or shipped. When a ffacility 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 subsection (g)(1)(A) is required when such specimens/ containers leave the facility.

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

3. 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.

(G) Servicing or Shipping Contaminated Equipment.

Equipment which may become contaminated with blood or OPIM 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 or will interfere with a manufacturer's ability to evaluate failure of the device.

1. A readily observable label in accordance with subsection (g)(1)(A)8. shall be attached to the equipment stating which portions remain contaminated.

2. Information concerning all remaining contamination shall be 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.

(H) Cleaning and Decontamination of the Worksite.

1. General Requirements.

a. Employers shall ensure that the worksite is maintained in a clean and sanitary condition.

b. Employers shall determine and implement appropriate written methods and schedules for cleaning and decontamination of the worksite.

c. The method of cleaning or decontamination used shall be effective and shall be appropriate for the:

i. Location within the facility;

ii. Type of surface or equipment to be treated;

iii. Type of soil or contamination present; and

iv. Tasks or procedures being performed in the area.

d. All equipment and environmental and work surfaces shall be cleaned and decontaminated after contact with blood or OPIM no later than at the end of the shift. Cleaning and decontamination of equipment and work surfaces is required more often as specified below.

2. Specific Requirements.

a. Contaminated Work Surfaces. Contaminated work surfaces shall be cleaned and decontaminated with an appropriate disinfectant immediately or as soon as feasible when:

i. Surfaces become overtly contaminated;

ii. There is a spill of blood or OPIM;

iii. Procedures are completed; and

iv. At the end of the work shift if the surface may have become contaminated since the last cleaning.

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

c. Protective Coverings. 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.

(I) Hygiene.

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

2. 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.

3. Employers shall ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment. 4. 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 OPIM.

(J) Laundry.

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

a. 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.

b. Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with subsection (g)(1)(A) 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.

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

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

3. 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 subsection (g)(1)(A).

(4) Personal Protective Equipment.

(A) Provision. Where occupational exposure remains after institution of engineering and work practice controls, 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 OPIM 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.

Note: For fire fighters, these requirements are in addition to those specified in Sections 3401-3411, and are intended to be consistent with those requirements.

(B) 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 judgment, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent such occurences in the future. The employer shall encourage employees to report all such instances without fear of reprisal in accordance with Section 3203.

(C) 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.

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

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

1. If a garment(s) is penetrated by blood or OPIM, the garment(s) shall be removed immediately or as soon as feasible.

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

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

(G) Gloves. Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, OPIM, mucous membranes, and non-intact skin; when performing vascular access procedures except as specified in subsection (d)(4)(G)4.; and when handling or touching contaminated items or surfaces. These requirements are in addition to the provisions of Section 3384.

1. 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.

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

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3. 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.

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

a. Periodically reevaluate this policy;

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

c. Not discourage the use of gloves for phlebotomy; and

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

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

ii. When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and iii. When the employee is receiving training in phlebotomy.

(H) Masks, Eye Protection, Face Shields, and Respirators.

1. 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 OPIM may be generated and eye, nose, or mouth contamination can be reasonably anticipated. These requirements are in addition to the provisions of Section 3382.

2. Where respiratory protection is used, the provisions of Sections 5144 and 5147 are required as applicable.

Note: Surgical masks are not respirators.

(I) Gowns, Aprons, and Other Protective Body Clothing.

1. 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. These requirements are in addition to the provisions of Section 3383.

2. 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). These requirements are in addition to the provisions of Section 3383.

(e) HIV, HBV and HCV Research Laboratories and Production Facilities.

(1) General.

This subsection applies in addition to the other requirements of this section to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV, HBV and HCV.

Exception: This subsection does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs.

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

(A) Standard Microbiological Practices. All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens. Such methods are further specified in Health and Safety Code Section 118215.

(B) Special Practices.

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

2. 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.

3. 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.

4. When OPIM 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 subsection (g)(1)(B) of this standard.

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

6. 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.

7. Special care shall be taken to avoid skin contact with OPIM. Gloves shall be worn when handling infected animals and when making hand contact with OPIM is unavoidable.

8. 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.

9. Vacuum lines shall be protected with liquid disinfectant traps and HEPA filters or filters of equivalent or superior efficiency and which are checked routinely and maintained or replaced as necessary.

10. 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 OPIM. 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.

11. 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.

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

13. Written biosafety procedures shall be prepared and adopted into the Exposure Control Plan of subsection (c)(1). Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

(C) Containment Equipment.

1. 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 OPIM that pose a threat of exposure to droplets, splashes, spills, or aerosols.

2. Biological safety cabinets shall be certified by the employer that they meet manufacturers' specifications when installed, whenever they are moved and at least annually.

(3) HIV, HBV and HCV research laboratories shall meet the following criteria:

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

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

Note: Treatment of medical waste should meet the requirements of Health and Safety Code Section 118215.

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

(A) 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.

(B) 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.

(C) 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.

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

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

Note: Treatment of medical waste should meet the requirements of Health and Safety Code Section 118215.

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(F) 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). The ventilation system shall conform to the requirements of Article 107.

(5) Training Requirements.

Training requirements for employees in HIV, HBV and HCV research laboratories and HIV, HBV and HCV production facilities are specified in subsection (g)(2) and they shall receive in addition the following initial training:

(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, HBV or HCV.

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

(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.

(f) Hepatitis B Vaccination and Bloodborne Pathogen Post-exposure Evaluation and Follow-up.

(1) General.

(A) 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 for bloodborne pathogens exposure to all employees who have had an exposure incident. When an employer is also acting as the evaluating health care professional, the employer shall advise an employee following an exposure incident that the employee may refuse to consent to post-exposure evaluation and follow-up from the employer-healthcare professional. When consent is refused, the employer shall make immediately available to exposed employees a confidential medical evaluation and follow-up from a healthcare professional other than the exposed employee's employer.

Exception: Designated first aid providers who have occupational exposure are not required to be offered pre-exposure hepatitis B vaccine if the following conditions exist:

1. The primary job assignment of such designated first aid providers is not the rendering of first aid.

a. Any first aid rendered by such persons is rendered only as a collateral duty responding solely to injuries resulting from workplace incidents, generally at the location where the incident occurred.

b. This exception does not apply to designated first aid providers who render assistance on a regular basis, for example, at a first aid station, clinic, dispensary, or other location where injured employees routinely go for such assistance, and emergency or public safety personnel who are expected to render first aid in the course of their work.

2. The employer's Exposure Control Plan, subsection (c)(1), shall specifically address the provision of hepatitis B vaccine to all unvaccinated first aid providers who have rendered assistance in any situation involving the presence of blood or OPIM (regardless of whether an actual exposure incident, as defined by subsection (b), occurred) and the provision of appropriate post-exposure evaluation, prophylaxis and follow-ups for those employees who experience an exposure incident as defined in subsection (b), including:

a. Provisions for a reporting procedure that ensures that all first aid incidents involving the presence of blood or OPIM shall be reported to the employer before the end of work shift during which the first aid incident occurred.

i. The report must include the names of all first aid providers who rendered assistance, regardless of whether personal protective equipment was used and must describe the first aid incident, including time and date.

A. The description must include a determination of whether or not, in addition to the presence of blood or OPIM, an exposure incident, as defined in subsection (b), occurred.

B. This determination is necessary in order to ensure that the proper post-exposure evaluation, prophylaxis and follow-up procedures required by subsection (f)(3) are made available immediately if there has been an exposure incident, as defined in subsection (b).

ii. The report shall be recorded on a list of such first aid incidents. It shall be readily available to all employees and shall be provided to the Chief upon request.

b. Provision for the bloodborne pathogens training program, required by subsection (g)(2), for designated first aiders to include the specifics of the reporting requirements of subsection (f)(3) and of this exception.

c. Provision for the full hepatitis B vaccination series to be made available as soon as possible, but in no event later than 24 hours, to all unvaccinated first aid providers who have rendered assistance in any situation involving the presence of blood or OPIM regardless of whether or not a specific exposure incident, as defined by subsection (b), has occurred.

3. The employer must implement a procedure to ensure that all of the provisions of subsection 2. of this exception are complied with if pre-exposure hepatitis B vaccine is not to be offered to employees meeting the conditions of subsection 1. of this exception.

(B) 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:

1. Made available at no cost to the employee;

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

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

4. 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 subsection (f).

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

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(2) Hepatitis B Vaccination.

(A) Hepatitis B vaccination shall be made available after the employee has received the training required in subsection (g)(2)(G)9. 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.

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

(C) 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.

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

(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:

(A) The employer shall document the route(s) of exposure, and the circumstances under which the exposure incident occurred;

(B) The employer shall identify and document the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;

1. The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV, HCV 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.

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

3. 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.

(C) The employer shall provide for collection and testing of the employee's blood for HBV, HCV and HIV serological status;

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

2. 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.

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3. Additional collection and testing shall be made available as recommended by the U.S. Public Health Service.

(D) The employer shall provide for post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;

(E) The employer shall provide for counseling and evaluation of reported illnesses.

(4) Information Provided to the Healthcare Professional.

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

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

1. A copy of this regulation;

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

3. Documentation of the route(s) of exposure and circumstances under which exposure occurred, as required by subsection (f)(3)(A);

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 which are the employer's responsibility to maintain, as required by subsection (h)(1)(B)2.

(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.

(A) 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.

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

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

2. That the employee has been told about any medical conditions resulting from exposure to blood or OPIM which require further evaluation or treatment.

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

(6) Medical Recordkeeping.

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

(g) Communication of Hazards to Employees.

§5193. Bloodborne Pathogens - continued

(1) Labels and Signs.

(A) Labels.

1. Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or OPIM; and other containers used to store, transport or ship blood or OPIM, except as provided in subsection (g)(1)(A)5., 6. and 7.

Note: Other labeling provisions, such as Health and Safety Code Sections 118275 through 118320 may be applicable.

2. Labels required by this section shall include either the following legend as required by Section 3341:

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Or in the case of regulated waste the legend:

BIOHAZARDOUS WASTE or SHARPS WASTE

as described in Health and Safety Code Sections 118275 through 118320.

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

4. Labels required by subsection (g)(1)(A) shall either be an integral part of the container or shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

5. Red bags or red containers may be substituted for labels except for sharp containers or regulated waste red bags. Bags used to contain regulated waste shall be color-coded red and shall be labeled in accordance with subsection (g)(1)(A)2. Labels on red bags or red containers do not need to be color-coded in accordance with subsection (g)(1)(A)3.

6. 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 subsection (g). 7. Individual containers of blood or OPIM that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.

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

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

(B) Signs.

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

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(Name of the Infectious Agent)

(Special requirements for entering the area)

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

2. These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color, and meet the requirements of Section 3340.

(2) Information and Training.

(A) 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.

(B) Training shall be provided as follows:

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

2. At least annually thereafter.

(C) 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.

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

(E) Employers shall provide additional training when changes, such as introduction of new engineering, administrative or work practice controls, modification of tasks or procedures or insitituion of new tasks or procedures, affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

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

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

1. Copy and Explanation of Standard. An accessible copy of the regulatory text of this standard and an explanation of its contents;

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

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

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

5. Risk Identification. An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and OPIM;

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6. Methods of Compliance. An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, administrative or work practice controls and personal protective equipment;

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

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

9. Hepatitis B Vaccination. 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;

10. Emergency. Information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM; 11. Exposure Incident. An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident, the medical follow-up that will be made available and the procedure for recording the incident on the Sharps Injury Log;

12. Post-Exposure Evaluation and Follow-Up. Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;

13. Signs and Labels. An explanation of the signs and labels and/or color coding required by subsection (g)(1); and

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

Note: Additional training is required for employees of HIV, HBV, and HCV Research Laboratories and Production Facilities, as described in subsection (e)(5).

(H) 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.

(h) Recordkeeping.

(1) Medical Records.

(A) The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with Section 3204.

(B) This record shall include:

1. The name and social security number of the employee;

2. 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 subsection (f)(2);

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

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

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5. A copy of the information provided to the healthcare professional as required by subsections (f)(4)(B)2., 3. and 4.
(C) Confidentiality. The employer shall ensure that employee medical records required by subsection (h)(1) are:

1. Kept confidential; and

2. 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.

(D) The employer shall maintain the records required by subsection (h)(1) for at least the duration of employment plus 30 years in accordance with Section 3204.

(2) Training Records.

(A) Training records shall include the following information:

1. The dates of the training sessions;

2. The contents or a summary of the training sessions;

3. The names and qualifications of persons conducting the training; and

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

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

(3) Sharps Injury Log.

The Sharps Injury Log shall be maintained 5 years from the date the exposure incident occurred.

(4) Availability.

(A) The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Chief and NIOSH for examination and copying. (B) Employee training records required by this subsection shall be provided upon request for examination and copying to employees, to employee representatives, to the Chief, and to NIOSH.

(C) Employee medical records required by this subsection shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Chief, and to NIOSH in accordance with Section 3204.

(D) The Sharps Injury Log required by subsection (c)(2) shall be provided upon request for examination and copying to employees, to employee representatives, to the Chief, to the Department of Health Services, and to NIOSH.

(5) Transfer of Records.

(A) The employer shall comply with the requirements involving transfer of records set forth in Section 3204.

(B) 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 NIOSH, at least three months prior to their disposal and transmit them to the NIOSH, if required by the NIOSH to do so, within that three month period.

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(i) Appendix.

Appendix A to this section is incorporated as a part of this section and the provision is mandatory.

Appendix A--Hepatitis B Vaccine Declination

(MANDATORY)

The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the following statement as required by subsection (f)(2)(D):

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

NOTE

Authority cited: Sections 142.3 and 144.7, Labor Code. Reference: Sections 142.3 and 144.7, Labor Code; Sections 117600 through 118360, Health and Safety Code.

HISTORY 1. New section filed 12-9-92; operative 1-11-93 (Register 92, No. 50).

2. Editorial correction of printing errors in subsections (c)(1)(A) and (d)(2)(C) (Register 93, No. 32).

3. Amendment of subsections (g)(1)(A)2. and (g)(1)(B)2. filed 2-5-97; operative 3-7-97 (Register 97, No. 6).

4. Amendment filed 1-22-99 as an emergency; effective 1-22-99 (Register 99, No. 4). The emergency regulation filed 1-22-99 shall remain in effect until the nonemergency regulation becomes operative or until August 1, 1999, whichever first occurs pursuant to Labor Code section 144.7(a).

5. Permanent adoption of 1-22-99 amendments, including further amendments, filed 7-30-99 pursuant to Labor Code section 144.7(a); operative 7-30-99 pursuant to Government Code section 11343.4(d) (Register 99, No. 31).

6. Repealer of subsection (c)(1)(D)2., new subsections (c)(1)(D)2.a.-b. and (c)(1)(E), subsection relettering, amendment of subsection (c)(2), new subsections (c)(2)(D)-(E) and amendment of subsections (d)(3)(B)2.Exception, (d)(3)(E)3.b., (d)(3)(H)1.b. and (d)(3)(H)2.a. filed 8-3-2001; operative 8-3-2001. Submitted to OAL for printing only. Exempt from OAL review pursuant to Labor Code section 142.3 (Register 2001, No. 31).

Appendix.

to this section is incorporated as a part of this section and the provision is mandatory.

Appendix A

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