8. **INFECTION CONTROL**

A. **Infection Control**

**APPLIES TO:**

A. This policy applies to all IEHP Medi-Cal Members.

**POLICY:**

A. IEHP delegates responsibility for Infection Control monitoring oversight of Primary Care Physicians (PCPs) to contracted IPAs.

B. IPAs must have infection control policies and procedures that meet IEHP standards.

C. IEHP monitors infection control policies and practices through the PCP Site Review Surveys.

**PROCEDURES:**

**Infection Control Standards**

A. IEHP infection control standards follow the Federal Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Directives and universal precaution regulations (See Attachment, “Federal OSHA Bloodborne Pathogen Directive” in Section 8).

1. Universal precautions must be observed to prevent contact with blood or other potentially infectious materials.

2. Contaminated sharps are discarded immediately. Sharps containers are located close to the immediate area where sharps are used, and are inaccessible to unauthorized persons. Contaminated needles and other contaminated sharps must not be bent, recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure. Such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.

3. Needleless systems, needles with Engineered Sharps Injury Protection (ESIP) and non-needle sharps are used unless exemptions have been approved by Cal/OSHA (8 CCR, Section 5193).

4. Contaminated needles or sharps (any device capable of cutting or piercing) must be placed in appropriate containers. These containers must be puncture resistant, labeled or color-coded, and leak-proof on the sides and bottom. Needles, sharps, and containers must not be accessible to Members. Containers are not to be overfilled past manufacturer’s designated fill line, or more than ¾ full. The supply of containers on hand must be adequate to ensure routine change-out when filled.

5. Food and drink must not be kept in refrigerators, freezers, shelves, cabinets, or on countertops or bench tops where blood or other potentially infectious materials are present. Medications and vaccines must also be stored separately from
specimens.

6. Specimens of blood, other body fluids or other potentially infectious materials must be placed in an appropriate container that prevents leakage during collection, handling, processing, storage, transport or shipping of the specimens.

7. Protective equipment must be supplied by practitioners and be readily available to staff. Such equipment must include, but not be limited to, gloves, gowns, face shields or masks and eye protection.

8. Gloves must be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin, and when handling or touching contaminated items or surfaces.

9. Masks in combination with face shields or eye protection must be worn when it is reasonably anticipated that eye, nose, or mouth contamination could result from splashes, spray, splatter or droplets of blood, other body fluids and other potentially infectious materials. Additional protective clothing, such as lab coats, gowns, or aprons must be worn in instances when possible contamination can reasonably be anticipated, such as during surgery.

10. Medical Office must provide readily accessible hand washing facilities for all staff members who may incur exposure to blood, other body fluids or other potentially infectious materials. Staff must be required to wash hands and other potentially contaminated skin areas immediately or as soon as feasible after removing personal protective gloves or other equipment.

11. Medical Office must have sinks with a standard faucet, foot-operated pedals, 4-6-inch wing-type handle, automatic shut-off systems or other types of water flow control mechanisms.

12. Staff must be able to demonstrate infection control “barrier” methods used on site to prevent contamination of faucet handle, door handles, and other surfaces until hand washing can be performed. On occasions when running water is not readily available, an antiseptic hand cleanser, alcohol-based hand rub or antiseptic towelettes are acceptable until running water is available.

13. Medical Office must maintain the work site in a clean and sanitary condition. There are designated (clearly labeled) clean and soiled work areas, which are used and maintained appropriately.

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

15. Contaminated work surfaces must be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other
8. INFECTION CONTROL

A. Infection Control

potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning.

16. Disinfectant solutions used on site must be:
   a. Approved by the Environmental Protection Agency (EPA);
   b. Effective in killing HIV/HB and TB; and
   c. Used according to the product label for desired effect.

17. Vision Office contact lenses used in trial fitting should be disinfected before each fitting as follows:
   a. Hard Contact Lenses (PMMA)
      1) 3% Hydrogen Peroxide
   b. Soft Contact Lenses
      1) 3% Hydrogen Peroxide
      2) Heat disinfection (78°-80°C or 172°-176°F for 10 min, if approved for heat.

18. Medical Office must maintain written “housekeeping” schedules which have been established and are followed for regular routine daily cleaning. Staff is able to identify frequency for routine cleaning of surfaces and equipment, the disinfectant used and responsible personnel.

19. Contaminated laundry [soiled with blood/Other Potentially Infectious Material (OPIM)] must be placed in bags, or containers with a lid, and labeled or color-coded. Contaminated laundry must be laundered by a contracted “commercial laundry service” or a washer and dryer on site.

20. Any of the following methods for sterilization of instruments and supplies are acceptable: steam sterilization, cold sterilization, or autoclave. Autoclaves and sterilizers must be operated by trained personnel and maintained according to manufacturer(s) instructions.
   a. Cold sterilization must be performed using effective solutions, which kill HIV, TB, and HBV as specified by the Center for Disease Control and Prevention (CDC). Manufacturers’ recommendations must be followed for length of soaking and time frame for effectiveness of solution.
   b. Autoclave use must include documentation of date, time, duration of run cycle, temperature, steam pressure, operator of each run, results of each run, and recording of sterilizer calibration. Spore testing or Killit testing must be performed at least monthly and results documented. Autoclave must be maintained according to manufacturer’s instructions.

21. Sterilized packages must be stored in a clean, dry area. Labels for sterilized items
include date of sterilization, load run identifications, information and general contents (e.g. suture set) of package. Each item in a sterile package need not be listed on the label if a master list of package contents is available elsewhere on site. Sterilized items are considered sterile until use, except if packaging is opened, wet/moist, discolored or damaged. These items are not considered sterile and should not be kept in storage area with sterile packages.

22. There must be a process/procedure in place for routine evaluation of sterilized packages.

23. All biohazardous waste must be stored in a rigid, leak-proof container with a tight fitting lid and labeled “biohazardous waste”. The storage area must be marked with a “biohazardous waste” sign and be inaccessible to unauthorized persons. If storage is outside the facility, it must be locked, with posted warning signs in English and Spanish that are visible at a distance of twenty (25) feet.

24. Contaminated waste (e.g. dental drapes, band aids, sanitary napkins, soiled disposal diapers) are disposed of in regular solid waste (trash) containers, and are maintained to prevent potential contamination of patient/staff areas and/or unsafe access by infants/children. Closed containers are not required for regular, solid waste trash containers.

25. Biohazardous waste must be properly removed from the facility by a contracted medical waste hauler or personnel authorized to transport such waste to another site for disposal by a contracted medical waste hauler. Authorized personnel must have an approved limited quantity hauling exemption granted by the California DHCS Waste Management Division if hauling more than 35.2 pounds.

26. IPA or Medical Office must ensure that all staff with potential for office exposure participates in an infection control-training program that addresses OSHA Bloodborne Pathogen Regulations and Universal Precaution Regulations. This training must be done annually.

27. The Medical Office must have a method in place to document sharps injuries. Date, time, description of exposure incident, sharp type/brand and follow-up care is documented within fourteen (14) days of the injury incident.

28. IPA or Medical Office must maintain Isolation Precautions and Procedures and ensure that all staff is appropriately trained to minimize Member and staff exposure to disease risk factors. Staff must demonstrate knowledge of disease pathways; techniques for protection from respiratory, contact, and bloodborne pathogens.

29. The Medical Office must be able to demonstrate or verbally explain the procedure used on site to isolate patients with potentially contagious conditions from other patients.

B. IEHP Infection Control Standards are distributed to contracted Providers as a part of the
8. INFECTION CONTROL

A. Infection Control

IEHP Provider Manual. The Bloodborne Pathogen “Sample” Exposure Control Plan is attached (See Attachment, “Exposure Control Plan for Bloodborne Pathogens” in Section 8).

C. IPAs must have infection control policies and procedures that comply with IEHP requirements noted above and that at a minimum meet the following standards:

1. Compliance with all Federal and State OSHA requirements for:
   a. Body substance isolation and control;
   b. Hepatitis B vaccination of at-risk employees; and
   c. CDC recommendations for post-exposure treatment, prophylaxis and follow-up.

2. Compliance with all Federal, State or local requirements for the handling of biohazardous waste;

3. Specific policies outlining available protective equipment including type, location and appropriate use; and

4. Specific policies outlining training requirements for applicable staff, including methods for documenting attendance.

D. IPAs must ensure that all of their practitioners have the training, equipment and procedures noted below:

1. Infection control training for all staff;

2. Application of total body substance isolation procedures and universal precautions;

3. Application of Member isolation precautions for communicable diseases;

4. Appropriate immunization of employees at risk of exposure (Hepatitis B, Rubella);

5. Adequate infection control equipment (gloves, masks, gown, etc.) and training in proper use;

6. Policies regarding sharps disposal and adequate equipment for same;

7. Proper techniques for sterilization of equipment including appropriate methods, proper autoclave use, maintenance and spore testing and time frames for storage of sterilized instruments;

8. Proper cleaning of surfaces including proper use of disinfectants and frequency;

9. Procedures in the event of body fluid exposure (needle sticks, blood splashes, etc.); and

10. Proper biohazardous waste disposal.
8. INFECTION CONTROL

A. Infection Control

E. All IPA medical staff and Providers that become aware of Members with reportable diseases are required to report these cases to Public Health authorities as specified by State regulations. Please refer to Policy 10K, “Reporting Communicable Diseases to Public Health Authorities.”

REFERENCE:

A. 8 California Code of Regulations § 5193
## 8. INFECTION CONTROL

Attachments

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>POLICY CROSS REFERENCE</th>
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<tbody>
<tr>
<td>Exposure Control Plan For Bloodborne Pathogens</td>
<td>8A</td>
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<tr>
<td>Federal OSHA Bloodborne Pathogen Directive</td>
<td>8A</td>
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Exposure Control Plan for Bloodborne Pathogens
Supplement

This is a supplement to the Cal/OSHA booklet entitled "Exposure Control Plan for Bloodborne Pathogens". This supplement, its companion booklet entitled "A Best Practices Approach for Reducing Bloodborne Pathogens Exposure", and the bloodborne pathogens standard should be used to develop your Exposure Control Plan.

Please follow these instructions at the following pages in the Exposure Control Plan for Bloodborne Pathogens booklet:

♦ Page 2, Exposure Determinations

It is recommended that you identify in the spaces provided in the form the name of the person or group that is responsible for making exposure determinations.

♦ Pages 5-6, Schedules and Methods of Implementation

To properly develop this aspect of your Exposure Control Plan, you must first determine which elements of subsections 5193(d), (f), (g) and (h) apply to your workplace. You can do this by reviewing these subsections in the bloodborne pathogens standard and by reviewing the information and forms on pages 28-75 of the companion Cal/OSHA booklet "A Best Practices Approach for Reducing Bloodborne Pathogens Exposure".

NOTE: Some elements of the above listed subsections are applicable primarily to healthcare environments and laboratories, e.g., (d)(3)(A)--Needleless Systems, Needle devices, and non-Needle Sharps. Other elements, such as (d)(3)(I)-Hygiene, and subsection (f)--Hepatitis B Vaccination and Bloodborne Pathogen Post-Exposure Evaluation and Follow-up, apply equally to virtually all workplaces subject to the bloodborne pathogens standard.

Once you have determined which subsections are applicable to your workplace, you should determine and describe in your Exposure Control Plan how you will comply with the requirement. One example of how this can be done is to identify the person(s) or group(s) responsible for implementing these requirements, and defining their responsibilities, e.g., gathering information, making decisions, and identifying sources from which equipment will be purchased.

♦ Page 7, Provisions for the Initial Reporting of Exposure Incidents

Remember that an exposure incident is an emergency to be responded to as soon as possible.

The purpose of the form provided on this page is to provide and gather information related to exposure incidents. However, the form mentions the term "first aid incident", which is any incident in which an employee provides first aid and in which blood or OPIM is involved. A first aid incident may or may not be an exposure incident, depending on whether the employee was actually exposed to blood or OPIM while providing first aid.

Normally, employers need not record a first aid incident if it is not an exposure incident. However, if an employer has opted not to provide pre-exposure Hepatitis B vaccinations to designated first aid providers, as allowed by the exception to subsection (f)(1)(A), then the employer must record all first aid incidents, whether or not they are exposure incidents, and may use this form to do so.

♦ Page 15, Sharps Injury Log

If you marked “Yes” in the box titled "If No" located in the middle of the Sharps Injury Log, then you must record the employees opinion on how a protective mechanism could have prevented the injury.

The question at the eighth red bullet of Item No. 4 in the Sharps Injury Log asks whether the employee believes that "…any controls (e.g., engineering controls, administrative or work practice) could have prevented the injury." The question to be asked the employee is whether any control measure other than the protective mechanism referred to in the "If No" box could have prevented the injury.
Exposure Control Plan for Bloodborne Pathogens
Publishing Information

The Exposure Control Plan for Bloodborne Pathogens was developed by the Education Unit, Cal/OSHA Consultation Service, California Department of Industrial Relations. The document was prepared for publication by the staff of CDE Press, California Department of Education. It was distributed under the provisions of the Library Distribution Act and Government Code Section 11096.

Published 2001 by the California Department of Industrial Relations

This booklet is not meant to be a substitute for or a legal interpretation of the occupational safety and health standards. Please see California Code of Regulations, Title 8, or the Labor Code for detailed and exact information, specifications, and exceptions.

Photo Credits

Cal/OSHA gratefully acknowledges Richard Munn, M.D., Department of Pathology, University of California Davis Medical School, for the slides used as photographs in this booklet.
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About This Booklet

This booklet was developed to help employers and employees design an effective exposure control plan in accord with California Code of Regulations, Title 8, Section 5193. Cal/OSHA acknowledges that the needs and resources of organizations with employees who have occupational exposure to blood or other potentially infectious materials (OPIM) vary widely. Therefore, a basic bloodborne pathogens exposure control plan has been designed to provide streamlined implementation procedures. The plan promotes the use of safer engineering controls and more effective work practices in hospitals, nursing homes, medical and dental offices, and other workplace settings where occupational exposure to blood or OPIM is likely to occur.

The exposure control plan consists of the following sections:

- “Policy and Elements of the Plan” establishes a policy statement and identifies the required elements.
- “Exposure Determinations” defines important terms and provides worksheets to list job classifications, tasks, or procedures in which employees may have occupational exposures.
- “Schedules and Methods of Implementation” contains forms to describe various procedures that may be required by 8 CCR 5193.
- “Provisions for the Initial Reporting of Exposure Incidents” provides a structure for reporting exposure incidents.
- “Hepatitis B Vaccination Series for Unvaccinated Employees” establishes a policy statement and provides a form to describe the relevant procedure.
- “Post-Exposure Evaluation and Follow-up” contains a worksheet to document the provision of post-exposure evaluation and follow-up to exposed employees.
- “Effective Procedures” provides worksheets to document various procedures, including evaluating the circumstances surrounding exposure incidents and gathering information for the Sharps Injury Log.

For More Help

A companion booklet, A Best Practices Approach for Reducing Bloodborne Pathogens Exposure, is also available from Cal/OSHA. It provides a practical, step-by-step approach to addressing occupational bloodborne pathogens exposure. This booklet can help with:

- Identifying and Selecting Appropriate and Effective Engineering Controls
- Assessing Engineering Controls and Work Practices
- Handling Regulated Wastes
- Cleaning and Decontaminating the Worksite
- Providing Post-Exposure Evaluation and Follow-up
- Training Employees
- Labeling
- Recordkeeping
- Obtaining Additional Information and Resources
We provide a safe and healthful workplace for employees. Our organization’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. This written plan is designed to prevent or minimize employees’ occupational exposure to blood and other potentially infectious materials (OPIM). The plan is consistent with the requirements of the Cal/OSHA Injury and Illness Prevention Program (8 CCR 3203).

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.”

Our organization’s written exposure control plan contains at least the following elements:

- Exposure determinations
- The schedule and method of implementation for each of the applicable subsections of the bloodborne pathogens regulation (8 CCR 5193), which include:
  - Methods of compliance
  - Hepatitis B vaccination and post-exposure evaluation and follow-up
  - Communication of hazards to employees
  - Recordkeeping
  - Provisions for the initial reporting of exposure incidents
  - Hepatitis B vaccination series for unvaccinated employees
  - Effective procedures for:
    - Evaluating the circumstances surrounding exposure incidents
    - Work practice controls—exception to prohibited practices
    - Gathering sharps injury log information
    - Making periodic determinations of the frequency of use and the types and the brands of sharps involved in exposure incidents
    - Identifying and selecting appropriate and currently available engineering control devices
    - Engineering controls—exception 2 (Patient Safety Determinations)
  - Actively involving employees in the review and update of the exposure control plan for the procedures they perform

The information-gathering and documentation procedures serve as a basis for making decisions about the use of needleless systems and sharps with engineered sharps injury protection.
Exposure Determinations

Employees in our organization 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 needlesticks, 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. See A Best Practices Approach for Reducing Bloodborne Pathogens for a more detailed definition of OPIM.

Our policy is to conduct exposure determinations throughout the facility without regard to the use of personal protective equipment (PPE). We have committees, workgroups, lead person(s), or other individuals who conduct, evaluate, and periodically review exposure determinations. This process involves identifying all the job classifications, tasks, or procedures in which our employees may have occupational exposure to blood or OPIM. Our approach is to consider (check one):

- [ ] all our job classifications at once
- [ ] selected job classifications on a staggered schedule

Other methods or procedures we use to conduct exposure determinations are specified below:

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Make copies as needed
Job Classifications in Which All Employees Have Occupational Exposure

All individuals in each job classification listed below have occupational exposure.

1. ________________ 6. ________________ 11. ________________
2. ________________ 7. ________________ 12. ________________
3. ________________ 8. ________________ 13. ________________
4. ________________ 9. ________________ 14. ________________
5. ________________ 10. ________________ 15. ________________

Examples include Anesthesia Technicians, Anesthesiologists, Central Processing Unit (CPU) Staff, Certified Nursing Assistants, Dental Assistants, Dental Hygienists, Dentists, EMT Personnel, Evidence Technicians, Firefighters, I.V. Therapists, Labor and Delivery Technicians, Laboratory Staff, Medical Technologists, Licensed Vocational Nurses, Lifeguards, Nurse Practitioners, Nursing Assistants, Pathologists, Pathology Assistants, Perfusionists, Phlebotomists, Physicians, Police Officers, Registered Nurses, Surgeons, and Surgical Technicians.
Job Classifications in Which Some Employees Have Occupational Exposure

The only individuals who have occupational exposure in the job classifications listed below are those who perform the tasks/procedures noted.

<table>
<thead>
<tr>
<th>Job Classification</th>
<th>Tasks/Procedures in These Jobs That Have Occupational Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. ____________________</td>
<td></td>
</tr>
<tr>
<td>2. ____________________</td>
<td></td>
</tr>
<tr>
<td>3. ____________________</td>
<td></td>
</tr>
<tr>
<td>4. ____________________</td>
<td></td>
</tr>
</tbody>
</table>

Examples may include:

<table>
<thead>
<tr>
<th>Job Classification</th>
<th>Tasks/Procedures in These Jobs That Have Occupational Exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dietary Employees</td>
<td>Handling food contaminated with vomitis, blood, or OPIM</td>
</tr>
<tr>
<td>Field Service Technicians</td>
<td>Doing maintenance/repairs on medical equipment contaminated with blood or OPIM</td>
</tr>
<tr>
<td>Housekeepers</td>
<td>Handling regulated waste, cleaning up spills or equipment</td>
</tr>
<tr>
<td>Medical Assistants</td>
<td>Administering injections, cleaning rooms, disinfecting equipment</td>
</tr>
<tr>
<td>Patient Escort/Transport Personnel</td>
<td>Transporting patients, responding to incidents</td>
</tr>
<tr>
<td>Physical Therapists</td>
<td>Conducting exams, providing patient therapy</td>
</tr>
<tr>
<td>Plant Operations Engineers</td>
<td>Doing maintenance/repairs on systems or equipment contaminated with blood, OPIM, or containing used sharps</td>
</tr>
<tr>
<td>Playground Supervisors</td>
<td>Providing first aid</td>
</tr>
<tr>
<td>School Bus Drivers</td>
<td>Providing first aid</td>
</tr>
<tr>
<td>Schoolteachers</td>
<td>Providing first aid</td>
</tr>
<tr>
<td>Security Services</td>
<td>Responding to incidents or emergencies</td>
</tr>
<tr>
<td>Technicians – EEG/EKG</td>
<td>Patient contact activities: exams, taking vital signs</td>
</tr>
<tr>
<td>Mammography/Nuclear Medicine</td>
<td>Attaching/handling/cleaning diagnostic equipment</td>
</tr>
<tr>
<td>Radioimaging/Ultrasound</td>
<td>Attaching/handling/cleaning diagnostic equipment</td>
</tr>
</tbody>
</table>

Make copies as needed
Schedules and Methods of Implementation

For additional assistance in addressing the requirements of subsections (d) through (h) of 8 CCR 5193, obtain a copy of A Best Practices Approach for Reducing Bloodborne Pathogens Exposure.

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

**Subsection (d) Methods of Compliance**

Schedule and methods of implementation:

________________________________________________________________________________________

________________________________________________________________________________________

Comments:________________________________________________________________________________

________________________________________________________________________________________

This subsection does not apply for the following reasons:

________________________________________________________________________________________

**Subsection (f) Hepatitis B Vaccination, Post-Exposure Evaluation, and Follow-up**

Schedule and methods of implementation:

________________________________________________________________________________________

________________________________________________________________________________________

Comments:________________________________________________________________________________

________________________________________________________________________________________

This subsection does not apply for the following reasons:

________________________________________________________________________________________
Subsection (g) Communication of Hazards to Employees

| Applicable (√) | yes ☐ no ☐ (Specify reasons below) |

Schedule and methods of implementation:
________________________________________________________________________________________________________________________________________________________
________________________________________________________________________________________________________________________________________________________

Comments: ____________________________________________________________________________
________________________________________________________________________________________________________________________________________________________

This subsection does not apply for the following reasons:
________________________________________________________________________________________________________________________________________________________
________________________________________________________________________________________________________________________________________________________

Subsection (h) Recordkeeping

| Applicable (√) | yes ☐ no ☐ (Specify reasons below) |

Schedule and methods of implementation:
________________________________________________________________________________________________________________________________________________________

Location of records (e.g., sharps injury log, employees’ medical records, training records):
________________________________________________________________________________________________________________________________________________________
________________________________________________________________________________________________________________________________________________________

Comments: ____________________________________________________________________________
________________________________________________________________________________________________________________________________________________________

This subsection does not apply for the following reasons:
________________________________________________________________________________________________________________________________________________________
________________________________________________________________________________________________________________________________________________________

☐ Make copies as needed
Our organization reports all exposure incidents as soon as possible (and in no case later than the end of the work shift during which they occurred) regardless of whether first aid was rendered. An exposure incident means 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. Parenteral means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions. All employees (including designated first-aid providers who provide first aid regularly and those who render first aid only as a collateral duty) receive training about our policy.

The following individual(s) are designated by our organization to receive reports of exposure incidents:

- Contact person(s): ___________________________ Telephone/pager number: ________________
- Contact person(s): ___________________________ Telephone/pager number: ________________
- After-hours contact person: ____________________ Telephone/pager number: ________________

The exposure incident report includes at least the following:

- The names of all employees involved in the exposure incident (including all first-aid providers who have rendered assistance regardless of whether personal protective equipment was used).
- A description of the exposure or first-aid incident, including:
  - The time and date
  - A determination of whether an exposure incident occurred. This determination is necessary to ensure that the proper post-exposure evaluation is conducted and prophylaxis and follow-up are made available immediately if an exposure incident has occurred.

Person receiving the report: ____________________ Telephone/pager number: ________________

The exposure incident report is recorded on a list of first-aid incidents (when the rendering of first aid is involved). If the exposure incident involves a sharp, the Sharps Injury Log (see page 15) will also be completed. The exposure incident report is provided to the Chief of Cal/OSHA upon request.

Note: The following forms are separate documents with their own requirements: (1) Provisions for the Initial Reporting of Exposure Incidents, (2) the Sharps Injury Log, (3) the Doctor’s First Report of Injury and Illness (5021), and (4) the Federal OSHA Log 200.

Make copies as needed
Our organization strongly encourages hepatitis B vaccination and makes the vaccination series available to all employees who have occupational exposure to blood or OPIM. Included are collateral first-aid providers who have rendered assistance in any situation involving the presence of blood or OPIM regardless of whether an actual exposure incident has occurred. The vaccination series is provided to collateral first-aid providers as soon as possible but no later than 24 hours after the employee has rendered assistance. Our procedure to ensure that the hepatitis B vaccination series is made available to all unvaccinated employees is described below.

Description of procedure:

_____________________________________________________________________________________

_____________________________________________________________________________________

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Make copies as needed
For additional assistance with post-exposure evaluation and follow-up, obtain a copy of the booklet *A Best Practices Approach for Reducing Bloodborne Pathogens Exposure*.

Our organization has made prearrangements for appropriate post-exposure evaluation and follow-up for all employees involved in an exposure incident. An *exposure incident* means 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 an exposure incident is reported, we make *immediately* available to the exposed employee a confidential medical evaluation and follow-up. Follow-up may include post-exposure prophylaxis (when medically indicated), counseling, and evaluation of a reported illness, if appropriate. For each exposure incident, we document the route(s) of exposure and the circumstances under which the exposure incident occurred.

### Personnel Designated to Provide Post-Exposure Evaluation and Follow-up

<table>
<thead>
<tr>
<th>Name of In-house Health Care Professional(s):</th>
<th>Telephone/Pager Number:</th>
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<tr>
<th>Name of Alternate Health Care Provider(s):</th>
<th>Telephone/Pager Number:</th>
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### Description of Procedures

1. Appropriate Post-Exposure Evaluation
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   ____________________________________________
   ____________________________________________

2. Post-Exposure Prophylaxis
   ____________________________________________
   ____________________________________________
   ____________________________________________

3. Follow-up
   ____________________________________________
   ____________________________________________
   ____________________________________________

4. Additional Services
   ____________________________________________
   ____________________________________________
   ____________________________________________

☐ Make copies as needed
For additional assistance, obtain a copy of *A Best Practices Approach for Reducing Bloodborne Pathogens Exposure*.

Our policy is to evaluate the circumstances (including the route(s) 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 exposure incident, we gather and evaluate, if possible, the following information:

**Date and location (department, unit, floor, dental operatory, etc.) of exposure incident:**

________________________________________________________________________

**Employee(s) job classification:**

________________________________________________________________________

________________________________________________________________________

**Tasks and procedure(s) performed:**

________________________________________________________________________

________________________________________________________________________

**Routes of exposure (e.g., eye, intact skin, non-intact skin, mouth, other mucous membranes, parenteral contact, etc.):**

________________________________________________________________________

________________________________________________________________________

**Description of sharp(s) or other device(s) involved (including type and brand):**

________________________________________________________________________

**Personal protective equipment worn:**

________________________________________________________________________

**Other pertinent information:**

________________________________________________________________________

________________________________________________________________________

**Date of evaluation:** ____________________________

**Evaluator(s) name(s):**

________________________________________________________________________

Telephone/pager number: ____________________________

________________________________________________________________________

Telephone/pager number: ____________________________

[Make copies as needed]
Work Practice Controls
Exception to Prohibited Practices

Our organization prohibits the bending, recapping, or removal of contaminated sharps from devices except when:

• It can be demonstrated that there is no feasible alternative to this action or that a specific medical or dental procedure requires such action, and
• That action is performed by using a mechanical device or a one-handed technique.*

For each device and the associated task and procedure, describe the reason(s) for the bending, recapping, or removal of contaminated sharps:

________________________________________________________________________
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The name of the supervisor making the decision to bend, recap, or remove contaminated sharps:
________________________________________________________________________

Date: __________________

*One-handed technique refers to a procedure in which the needle of a reusable syringe is capped in a sterile manner during use. The technique employed requires the use of only the hand holding the syringe so that the free hand is not exposed to the uncapped needle.

[ ] Make copies as needed
A sharp is any object used or encountered that can be reasonably anticipated to penetrate the skin or any other part of the body, resulting in an exposure incident. Sharps include, but are not limited to, needle devices, scalpels, lancets, broken glass and capillary tubes, exposed ends of dental wires and knives, drills, and burs. An exposure incident means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious material that results from the performance of an employee’s duties.

A sharps injury means any injury caused by a sharp, including but not limited to cuts, abrasions, or needlesticks. A Sharps Injury Log has been established and maintained as a record (in either written or electronic form) of each exposure incident involving a sharp. Our policy is to maximize the utility of the Sharps Injury Log by filling out the information as completely as possible in easy-to-understand language. The log documents our organization’s sharps injury history in sufficient detail to support the development of effective exposure-control strategies.

Effective Procedures
Gathering Sharps Injury Log Information
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 (✓) _____

<table>
<thead>
<tr>
<th>If Yes</th>
<th>If No</th>
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<tbody>
<tr>
<td>A. Was the protective mechanism activated at the time of the exposure</td>
<td>A. Does the injured employee believe that</td>
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<td>incident? Yes ____No ____</td>
<td>a protective mechanism could have</td>
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<td>B. Did the injury occur before, during, or after the mechanism was</td>
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<td>activated?</td>
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<td>Comments: ___________________________________________________________</td>
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- 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).
Periodic determinations are made on the frequency of use and the types, models, or brands of sharps involved in the exposure incidents documented on our Sharps Injury Log. We make these determinations (which include a review of our Sharps Injury Log) ____________ (e.g., monthly, quarterly, semiannually, annually).

The Use of Sharps Involved in Exposure Incidents

<table>
<thead>
<tr>
<th>Area/Location or Unit</th>
<th>Type/Model/Brand of Sharp</th>
<th>Task or Procedure Performed</th>
<th>Date and Description of Exposure Incident</th>
<th>Frequency of Use of Sharps*</th>
<th>Supervisor Making the Determination</th>
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* Reasonable and effective methods are employed to approximate the frequency of use of sharps involved in exposure incidents (e.g., looking at purchase records or in-house tracking records, statistical sampling, combinations of these or other methods). The methods employed by our organization include the following:

_____________________________________________________________________________________________________
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Comments: ____________________________________________________________
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Make copies as needed
Identifying and Selecting Appropriate and Currently Available Engineering Control Devices

For additional assistance with identifying and selecting engineering controls, obtain a copy of *A Best Practices Approach for Reducing Bloodborne Pathogens Exposure*.

Our policy is to select appropriate and effective engineering controls to prevent or minimize exposure incidents. Engineering controls means 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.

We first evaluate products that eliminate the use of sharps (e.g., needleless systems), if available. If these devices are not selected, we then evaluate devices equipped with engineered sharps injury protection (ESIP). ESIP 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.

We establish and maintain procedures for identifying and selecting appropriate and effective engineering controls, which may include the following steps:

1. Set up a Process ✔
2. Define Needs ✔
3. Gather Information ✔
4. Test and Select Products ✔
5. Use New Products ✔
6. Conduct Follow-up ✔

We modify the steps outlined above to fit our requirements as follows:

I. Set up a Process

We use a systematic process to identify and select appropriate and effective engineering controls. The process may include committees, subcommittees, working groups, a lead person, or other responsible employees. The same groups or individuals are responsible for all the steps in the process of identifying and selecting engineering controls. In our organization the setup is:

---

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We actively involve managers and employees from departments, units, floors, or dental operatories where engineering controls are (or will be) used. We choose individuals with expertise and experience in particular professions or specialties to evaluate new products that will be used in their area(s) of practice. Individuals involved in our process include:

2. Define Needs

We address each potential exposure of the tasks and procedures performed in various departments, units, floors, or dental operatories. We solicit input from frontline employees, supervisors, and managers. We also collect occupational exposure and injury data. We then identify our needs and establish our priorities on the basis of an analysis of all the available information.

<table>
<thead>
<tr>
<th>Priority</th>
<th>Potential Exposures to Be Addressed</th>
<th>Work Area</th>
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3. Gather Information

We gather information on currently available engineering controls that are designed to reduce occupational exposure to blood or OPIM. Because new technology is continually entering the marketplace, we also periodically search for information on new products.

4. Test and Select Products

Each potential exposure is addressed by applying screening criteria to the engineering controls under consideration. When available, multiple devices are screened for each potential exposure being addressed. This helps ensure that more than one product is selected for testing for a given task or procedure.

Screening criteria are applied to products in order to eliminate those with readily identifiable problems (e.g., ineffective devices, safety issues, visual obstructions). Only devices meeting an acceptable number of screening criteria are then tested in actual patient or product trials. For each exposure being addressed, we document the new products that meet an acceptable number of screening criteria and will be included in the testing.

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<table>
<thead>
<tr>
<th>Department/Unit/Floor/ Dental Operatory</th>
<th>Potential Exposure to Be Addressed</th>
<th>New Products Chosen to Test for This Exposure</th>
<th>Catalog No.</th>
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**Testing Products**

Testing can help evaluate whether products are actually effective at reducing or eliminating workplace exposure incidents. Frontline employees who perform the tasks and procedures associated with the exposures being addressed are involved in the testing. If available, multiple products from a single category of devices are tested for each potential exposure being addressed. The testing of new products is suspended immediately if there is any evidence that a device is causing injuries to employees or patients.

To help ensure that devices are handled safely and evaluations are objective, we provide training on the safe and proper use of devices before testing begins. This training is given to the groups or individuals responsible for product selection, all participants involved in the testing, and their supervisors. Participants in the testing are also given the opportunity to practice using the new devices. These practice sessions simulate, as closely as possible, the tasks and procedures involved under “real-life” conditions. Representatives of manufacturers and distributors are requested to demonstrate the intended use of their products, answer questions, and train employees in the safe operation of each device.

**“Tools”**

Checklists, evaluation forms, or other types of standardized “tools” are used in the testing of new products. The tools are tailored to the specific category of product under consideration. To provide a standard basis for comparison among products, we use the same checklist or evaluation form when testing multiple products within a given type or category of device.

**Protocols**

We may use protocols in our testing process to make the evaluation of new products more systematic. Protocols also help us document the details of each item involved in our testing process.

**Selecting Products**

After the testing is completed, all the information, including checklists and evaluation forms, is reviewed. Input from frontline employees involved in the testing is documented and considered when it is time to select products for purchase. Based on the analysis of all the available information,
consensual decisions are made regarding whether to purchase particular products. If two or more products are found to be satisfactory in a given category, we consider purchasing them. We document how devices ranked and which products we have decided to purchase. We provide feedback to employees on the ranking and selection of products.

5. Use New Products

We may introduce new products on a limited basis in a pilot implementation or trial phase. During this trial period, issues associated with the day-to-day use of the new products may arise. Employees may need time to develop new skills, establish new work practices, and break old habits. Employees are strongly encouraged to report any problems to their supervisors during the trial period. If problems appear to be serious or widespread, they are reported to the decision makers. Problems with new products are addressed as they arise and are resolved before the new product is used throughout our organization.

All staff members (and supervisors) using the new products or devices are thoroughly trained. This training is a mix of the knowledge and skills needed to work safely. For each new device, representatives of manufacturers and distributors are requested to:

- Demonstrate its proper use and application
- Provide training on its safe operation
- Answer questions
- Provide follow-up

Training also includes practice sessions to simulate the tasks and procedures that individuals will be performing with the new devices. Multiple devices may have been selected for a given task or procedure. If this is the case, individuals are trained on all the selected devices.

6. Conduct Follow-up

Follow-up helps ensure that new products are effective and appropriate and are replaced over time by newer, more effective technology. As newer products become available, they are screened, tested, and selected according to the process described previously.

Our follow-up process systematically reevaluates devices and incorporates the input of frontline employees who have been using the products. Decisions on the appropriateness and effectiveness of new devices are not made until employees have had enough time to adjust to using the products. Follow-up evaluations of products and the associated work practices are conducted six months after the implementation and quarterly, semiannually, or annually thereafter. Findings are used to improve product selection and training.

Staff members receive periodic feedback on how new products are working and what other products have become available. Follow-up training is provided if problems are discovered with work practices or currently used devices. If newer devices are selected to replace those currently being used, all individuals (and their supervisors) using the newer devices are thoroughly trained.
Additional information on Exceptions 1, 3, and 4 to using engineering controls may be found in *A Best Practices Approach for Reducing Bloodborne Pathogens Exposure*.

The use of engineering controls (e.g., needleless systems, needle devices, and non-needle sharps) is *not* required if a licensed health care professional:

- Is directly involved in the patient’s care
- Determines that the control will jeopardize the patient’s safety or the success of a medical, dental, or nursing procedure
- Exercises reasonable clinical judgment

If this exception applies, the form below (or equivalent information) should be submitted to the exposure control plan administrator.

### Patient Safety Determinations for Exceptions to Using Engineering Controls

<table>
<thead>
<tr>
<th>Type of Control Under Consideration and Procedure(s) or Tasks(s) Involved</th>
<th>Name of Licensed Health Care Professional Making the Determination</th>
<th>Date of Determination</th>
<th>Reason(s) for the Exception</th>
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Comments:

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[Make copies as needed]
Actively Involving Employees in the Review and Update of the Exposure Control Plan

Our exposure control plan is reviewed and updated at least annually (and whenever necessary) to include:

- New or modified tasks or procedures that affect occupational exposure
- Progress in implementing the use of needleless systems and sharps with engineered sharps injury protection
- New or revised job position(s) that involve occupational exposure
- Reviews and evaluations of exposure incidents that have occurred since the previous update
- Reviews and responses to information indicating that the existing exposure control plan is deficient in any area

All employees are encouraged to provide suggestions on improving the procedures they perform in their departments, units, floors, or dental operatories. Employees contribute to the review and update of the exposure control plan by:

- Participating as members of committees (e.g., safety and health, labor-management, infection control, product evaluation and selection, purchasing of equipment)
- Attending meetings to discuss safety and health issues and improvements
- Reporting issues or potential problems to supervisors
- Providing ideas, recommendations, or suggestions
- Filling out reports, questionnaires, or other documents
- Participating in other procedures as described below

The process for actively involving employees in the review and update of the plan is as follows:

__________________________________________________________________________________
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We Want to Hear from You

Cal/OSHA values and welcomes your comments about our booklet. We want to provide the best service possible to employers and employees in California. To give Cal/OSHA feedback about this booklet, please fax this form to the Education Unit at (916) 574-2532, e-mail us at Dosheducation@hq.dir.ca.gov, or mail your comments to:

Education Unit
Cal/OSHA Consultation Service
2211 Park Towne Circle, Suite 4
Sacramento, CA 95825

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<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Comments</th>
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<tbody>
<tr>
<td>1. Has the information contained in this booklet encouraged you to develop, evaluate, or improve an exposure control plan for bloodborne pathogens at your workplace?</td>
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<td>• Which worksheets are the most helpful? (For each worksheet, please indicate the title, why the worksheet was helpful, and page number[s].)</td>
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<td>• Which worksheets need improvement? (Please indicate the title and page number[s] of the worksheet and specific suggestions.)</td>
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<tr>
<td>2. Has the information contained in this booklet effected any other changes in your workplace regarding bloodborne pathogens issues?</td>
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<td>3. Are any parts of the booklet unclear or confusing? What improvements do you recommend? (Please provide the page numbers of the booklet and the specific topics.)</td>
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<td>4. What important issues were not addressed? (Please describe in detail.)</td>
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<tr>
<td>5. Do you have any other comments? (When referring to specific text or sections, please indicate the page numbers.)</td>
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<td>6. Do you have a bloodborne pathogens success story to share with us? (If so, please provide your name and telephone number.)</td>
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</table>

Thank you for your participation.

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Acknowledgments

Writers and Editors

Zin Cheung and Mario Feletto, Cal/OSHA Consultation Service, Education Unit, Sacramento, California

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Michael Alvarez, Regional Manager, Cal/OSHA Consultation Service, Sacramento, California

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On-site Development and Research

University of California Davis Medical Center, Sacramento, California

Carl Foreman, Acting Director, Environmental Health and Safety, University of California, Davis, Health Systems, Sacramento, California

Gilda L. Gaerlan-Acosta, EH & S Specialist I, Environmental Health and Safety, University of California, Davis, Health Systems, Sacramento, California

Layout and Design

Paul Lee, Graphic Designer III, CDE Press, California Department of Education, Sacramento, California

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Venetec International, Inc., San Diego, California

Note: The titles and locations of the persons included in this list were current at the time this booklet was developed.
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Your call will in no way trigger an inspection by Cal/OSHA enforcement.

- **Voluntary Protection Program**
  San Francisco, CA 94142
  (415) 703-5272

- **Education Unit**
  Sacramento, CA 95825
  (916) 574-2528
Subchapter 7. General Industry Safety Orders  
Group 16. Control of Hazardous Substances  
Article 109. Hazardous Substances and Processes

§ 5193. Bloodborne Pathogens.

Exposure Control Plan for Bloodborne Pathogens  
A Best Practices Approach for Reducing Bloodborne Pathogens Exposure  
Safe needle fact sheet

(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.

“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, 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” 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.

“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;
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;

(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.

(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.

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

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 b. 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 during 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
(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 facility utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary provided containers are recognizable as containing specimens. This exemption only applies while such specimens/containers remain within the facility. Labeling or color-coding in accordance with 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), 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 occurrences 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.

   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.

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 (shower 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.

(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.

(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.

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.


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.

(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:
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.
California Code of Regulations, Title 8, Section 5193. Bloodborne Pathogens.

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:

(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 institution 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;

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
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.

(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).


7. Change without regulatory effect providing more legible illustrations for biohazard symbols filed 3-2-2009 pursuant to section 100, title 1, California Code of Regulations (Register 2009, No. 10).