

Subchapter 7. General Industry Safety Orders
Group 16. Control of Hazardous Substances
Article 109. Hazardous Substances and Processes

§5193. Bloodborne Pathogens.

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

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

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

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

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

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

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

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

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

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

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

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

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

"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 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 any of the following:

- (1) Liquid or semi-liquid blood or OPIM;
- (2) Contaminated items that:
 - (A) Contain liquid or semi-liquid blood, or are caked with dried blood or OPIM; and
 - (B) Are capable of releasing these materials when handled or compressed.
- (3) Contaminated sharps.
- (4) Pathological and microbiological wastes containing blood or OPIM.
- (5) Regulated Waste includes "medical waste" regulated by Health and Safety Code Sections 117600 through 118360.

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

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

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

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

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

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

By July 1, 1999, the Exposure Control Plan shall additionally contain the following elements required by subsections (c)(1)(B) 4. through 8.:

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

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

6. An effective procedure for identifying currently available engineering controls, and selecting such controls, where appropriate, for the procedures performed by employees in their respective work areas or departments;
7. An effective procedure for documenting patient safety determinations made pursuant to Exception 2. of subsection (d)(3)(A); and
8. An effective procedure for obtaining the active involvement of employees in reviewing and updating the exposure control plan with respect to the procedures performed by employees in their respective work areas or departments.

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

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

1. To reflect new or modified tasks and procedures which affect occupational exposure;
2. By July 1, 1999, if sharps are used in the employer's place of employment, to reflect progress in implementing the use of needleless systems 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) 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 exposure incident shall be recorded on the log within 14 working days of the date the incident is reported to the employer. 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) By July 1, 1999, 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 other engineering, administrative or work practice control could have prevented the injury.

(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. By July 1, 1999, the employer shall comply with the following requirements:

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 injury protection.

EXCEPTIONS: The following exceptions apply to the engineering controls required by subsection (d)(3) (A):

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

2. 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)6.

3. 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.

4. 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 the procedure is performed using a mechanical device or a one-handed technique, and the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure.

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;
 - c. Labeled and color-coded in accordance with subsection (g)(1)(A) of this section; and
 - d. Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.
4. Outside Contamination. If outside contamination of a container of regulated waste occurs, it shall be placed in a second container. The second container shall be:
 - a. Closable;
 - b. Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;
 - c. Labeled and color-coded in accordance with subsection (g)(1)(A) of this section; and
 - d. Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

(F) Handling Specimens of Blood or OPIM.

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

1. The container for storage, transport, or shipping shall be labeled or color-coded according to subsection (g)(1)(A), and closed prior to being stored, transported, or shipped. When a 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 according 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.

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

2. Information concerning all remaining contamination shall be conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken.

(H) Cleaning and Decontamination of the Worksite.

1. General Requirements.

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

b. Employers shall determine and implement an appropriate written schedule 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 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 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 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 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 (showers may be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area.

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

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

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

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

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

(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 HVC research laboratories and HIV, HBV and HVC 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 or HBV.

(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 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 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 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.

(5) Healthcare Professional's Written Opinion.

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

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

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

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

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

(6) Medical Recordkeeping.

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

(g) Communication of Hazards to Employees.

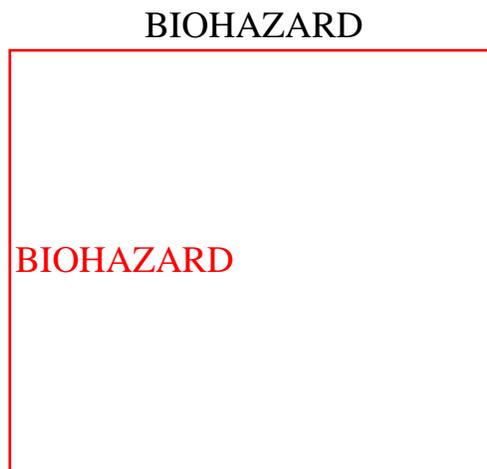
(1) Labels and Signs.

(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 any of the following legends 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.
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:

BIOHAZARD



(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 Plans. 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. Method 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 OPIIm;
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.

Appendix.

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

The above information is provided free of charge by the Department of Industrial Relations from its web site at <http://www.dir.ca.gov/>.