

Safety & Health Fact Sheet



July 1999

Cal/OSHA Consultation Service
California Department of Industrial Relations
P. O. Box 420603 ■ San Francisco, CA 94142-0603

Safety Needles & Needleless Systems Bloodborne Pathogens Regulation Changes

New Cal/OSHA requirements intended to reduce needlesticks and other "sharps" injuries that can cause exposure to bloodborne pathogens took full effect on July 1, 1999. **An easy-to-read version of the revised regulation is available from the Cal/OSHA Consultation Service.**

Why was the regulation changed?

The recent changes to Section 5193 came about in response to:

- Continuing high numbers of needlestick and other sharps injuries in health care settings.
- Recognition of hepatitis C as a bloodborne pathogen of serious concern.
- Emerging technologies for needleless systems, and needles and other sharps devices with "engineered sharps injury protection" (e.s.i.p.).

Major elements of the revisions:

- New requirements for use of needleless systems and sharps devices with e.s.i.p., subject to four exceptions.
- New requirements for a program to evaluate and select needleless systems and sharps devices with e.s.i.p. appropriate for procedures conducted, with active involvement of frontline health care providers.
- Maintenance of a Sharps Injury Log.
- Addition of hepatitis C as a specifically named bloodborne pathogen.
- Reorganization of existing requirements for greater clarity, and a number of other changes.

Employers affected by these changes:

Health care providers continue to be the primary focus of Section 5193. The new requirements focus on employees conducting the following medical procedures:

- Withdrawal of body fluids.
- Accessing a vein or artery.
- Administration of medications or fluids.
- Any other procedure with potential for a sharps injury exposure incident.

Other employers who remain covered by the regulation include emergency and public safety services, correctional and custodial care facilities, and providers of services to any of these covered employers—such as plumbers and laundry—whose employees could be exposed to bloodborne pathogens. Employers whose employees may be reasonably anticipated to have occupational exposure to bloodborne pathogens are also covered, as are employees providing first aid.

What if safer devices are not available or could compromise patient care?

The goal of the new requirements is to protect employees without compromising patient safety or care. Practicing medical professionals helped draft the revisions. To address availability, patient care and other issues, there are four exceptions to the new requirements:

- Employer shows that no needleless systems or sharps devices with e.s.i.p. are available in the marketplace for their procedure.
- A licensed health care professional directly involved with a patient's care determines that available needleless systems or sharps devices with e.s.i.p. would compromise the patient's care or safety.
- Employer shows that available needleless systems and sharps devices with e.s.i.p. are not more effective in preventing exposure to bloodborne pathogens than the alternative they are using.
- Employer shows that sufficient information is not available on the safety performance of needleless systems or sharps devices with e.s.i.p. available in the marketplace, and the employer is actively evaluating such devices.

Where do we start?

Employers who have not yet begun converting to needleless systems and sharps devices with e.s.i.p. should focus **immediately** on coming into compliance by:

- Evaluating records of sharps injuries, talking with employees, and addressing areas where the frequency and consequences of exposure are greatest.
- Evaluating and selecting devices for the highest risk areas, then establishing the program—including maintenance of the required Sharps Injury Log—for all covered procedures.
- Documenting the above activities.

Cal/OSHA Consultation Service Offices

For telephone assistance and to request a no-cost consultation at your worksite:

Sacramento 916-263-0704

Oakland 510-622-2891

Van Nuys 818-901-5754

San Diego/San Bernardino/Anaheim 714-935-2750

Or toll-free **1-800-963-9424**

Questions asked frequently

Q. What does “engineered sharps injury protection” (e.s.i.p.) mean?

A. As defined in the regulation, e.s.i.p. is a physical attribute that is built into a needle or other sharps device which effectively reduces the risk of a blood-borne pathogens exposure incident. Examples: devices which blunt, sheath, or withdraw the sharp.

Q. Would devices that facilitate safer recapping or disposal of sharps qualify as engineered sharps injury protection?

A. No. To qualify as e.s.i.p. the attribute must be an integral part of the sharps device. The ultimate intention, where any sharps device is used, is that it be guarded before—or as soon as possible after—removal from the patient or other source of blood or infectious material.

Q. Can I choose between a needleless system and a sharps device with e.s.i.p. if both are available for a particular procedure?

A. No. Where this choice is available, the needleless system must be used. Devices with e.s.i.p. are acceptable only where no satisfactory needleless system is available.

Q. Is a needleless system or sharps device with e.s.i.p. now required even when a doctor or nurse determines that it could compromise patient care or safety?

A. No. This is one of the exceptions to the new requirements. However, this exception is allowed only where a licensed health care professional directly involved in the patient’s care has made and documented the determination, as required in the regulation.

Q. Can we use up our supply of traditional sharps devices?

A. Yes, but **only** where the required safer alternatives are not available, or one of the exceptions applies.

Q. We have completed our evaluation and selection process, including active involvement of affected employees, and have decided on the needleless system and sharps devices with e.s.i.p. that we want to use. However, our vendor has told us that several of the devices are temporarily out of stock. What do we do now?

A. Cal/OSHA recognizes that these major new requirements may cause temporary shortages of some devices, and will take this into account in enforcement actions. If the vendor delay is likely to be lengthy, alternative suppliers should be used. Just as with any device critical to continued patient care and employee safety, alternative devices and suppliers should be evaluated, selected and maintained as a back-up source.

Q. Is a device with engineered sharps injury protection that has been activated still required to be disposed of as sharps waste?

A. Yes. Because some devices can be defeated or deactivated, sharps with activated safety devices must still be disposed of as sharps waste.

Q. Do the new requirements apply to sharps other than needles?

A. Yes. The revised regulation contains a new definition of sharps in general, and requires that non-needle sharps be used which incorporate engineered sharps injury protection, subject to the four exceptions.

Q. Where can I get additional help with understanding the new requirements?

A. A number of Internet resources are listed below. You can also obtain free assistance from the Cal/OSHA Consultation Service without the concern of receiving an inspection or citations. You can request assistance by telephone, come into one of the offices around the state, or have a consultant come to your worksite.

Resources for information and assistance

Up-to-date information is key to keeping up with the requirements of Section 5193:

■ At the Cal/OSHA website you can access a regulatory update which links to the new regulation:

www.dir.ca.gov/dosh

■ At the California Department of Health Services Sharps Program website—www.ohb.org/sharps.htm—you can see a list of needleless systems and sharps devices with e.s.i.p. and their manufacturers, and download a sample Sharps Injury Log.

■ The federal OSHA website—www.osha.gov—has links to a wide variety of needlestick prevention resource materials.

■ At the CDC website—www.cdc.gov—you can subscribe to Morbidity and Mortality Weekly Report by e-mail, and automatically receive recommendations of CDC, including for post-exposure procedures that are referenced by subsection (f) of Section 5193.

■ The International Health Care Worker Safety Center (EPINet) website—

www.med.virginia.edu/medcntr/centers/epinet/

—has a wealth of information and resources, including a list of needleless systems and sharps devices with e.s.i.p., as well as detailed aggregate data on needlestick injuries recorded by the 70 institutions cooperating in its reporting network.

■ The TDICT website—www.tdict.org—contains safety feature evaluation forms and other information to help with the process of evaluating and selecting safer devices.

■ The Medical Waste Management Program in the California Department of Health Services has information on California requirements for management of medical waste. You can phone them at 916-327-6904.

OSHA[®] FactSheet

OSHA's Bloodborne Pathogens Standard

Bloodborne pathogens are infectious microorganisms present in blood that 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), the virus that causes AIDS. Workers exposed to bloodborne pathogens are at risk for serious or life-threatening illnesses.

Protections Provided by OSHA's Bloodborne Pathogens Standard

All of the requirements of OSHA's Bloodborne Pathogens standard can be found in Title 29 of the Code of Federal Regulations at 29 CFR 1910.1030. The standard's requirements state what employers must do to protect workers who are occupationally exposed to blood or other potentially infectious materials (OPIM), as defined in the standard. That is, the standard protects workers who can reasonably be anticipated to come into contact with blood or OPIM as a result of doing their job duties.

In general, the standard requires employers to:

- **Establish an exposure control plan.** This is a written plan to eliminate or minimize occupational exposures. The employer must prepare an exposure determination that contains a list of job classifications in which all workers have occupational exposure and a list of job classifications in which some workers have occupational exposure, along with a list of the tasks and procedures performed by those workers that result in their exposure.
- **Employers must update the plan annually** to reflect changes in tasks, procedures, and positions that affect occupational exposure, and also technological changes that eliminate or reduce occupational exposure. In addition, employers must annually document in the plan that they have considered and begun using appropriate, commercially-available effective safer medical devices designed to eliminate or minimize occupational exposure. Employers must also document that they have solicited input from frontline workers in identifying, evaluating, and selecting effective engineering and work practice controls.
- **Implement the use of universal precautions** (treating all human blood and OPIM as if known to be infectious for bloodborne pathogens).
- **Identify and use engineering controls.** These are devices that isolate or remove the bloodborne pathogens hazard from the workplace. They include sharps disposal containers, self-sheathing needles, and safer medical devices, such as sharps with engineered sharps-injury protection and needleless systems.
- **Identify and ensure the use of work practice controls.** These are practices that reduce the possibility of exposure by changing the way a task is performed, such as appropriate practices for handling and disposing of contaminated sharps, handling specimens, handling laundry, and cleaning contaminated surfaces and items.
- **Provide personal protective equipment (PPE), such as gloves, gowns, eye protection, and masks.** Employers must clean, repair, and replace this equipment as needed. Provision, maintenance, repair and replacement are at no cost to the worker.
- **Make available hepatitis B vaccinations to all workers with occupational exposure.** This vaccination must be offered after the worker has received the required bloodborne pathogens training and within 10 days of initial assignment to a job with occupational exposure.
- **Make available post-exposure evaluation and follow-up to any occupationally exposed worker who experiences an exposure incident.** An exposure incident is a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or OPIM. This evaluation and follow-up must be at no cost to the worker and includes documenting the route(s) of exposure and the circumstances

under which the exposure incident occurred; identifying and testing the source individual for HBV and HIV infectivity, if the source individual consents or the law does not require consent; collecting and testing the exposed worker's blood, if the worker consents; offering post-exposure prophylaxis; offering counseling; and evaluating reported illnesses. The healthcare professional will provide a limited written opinion to the employer and all diagnoses must remain confidential.

- **Use labels and signs to communicate hazards.** Warning labels must be affixed to containers of regulated waste; containers of contaminated reusable sharps; refrigerators and freezers containing blood or OPIM; other containers used to store, transport, or ship blood or OPIM; contaminated equipment that is being shipped or serviced; and bags or containers of contaminated laundry, except as provided in the standard. Facilities may use red bags or red containers instead of labels. In HIV and HBV research laboratories and production facilities, signs must be posted at all access doors when OPIM or infected animals are present in the work area or containment module.
- **Provide information and training to workers.** Employers must ensure that their workers receive regular training that covers all elements of the standard including, but not limited to: information on bloodborne pathogens and diseases, methods used to control occupational

exposure, hepatitis B vaccine, and medical evaluation and post-exposure follow-up procedures. Employers must offer this training on initial assignment, at least annually thereafter, and when new or modified tasks or procedures affect a worker's occupational exposure. Also, HIV and HBV laboratory and production facility workers must receive specialized initial training, in addition to the training provided to all workers with occupational exposure. Workers must have the opportunity to ask the trainer questions. Also, training must be presented at an educational level and in a language that workers understand.

- **Maintain worker medical and training records.** The employer also must maintain a sharps injury log, unless it is exempt under Part 1904 -- Recording and Reporting Occupational Injuries and Illnesses, in Title 29 of the Code of Federal Regulations.

Additional Information

For more information, go to OSHA's Bloodborne Pathogens and Needlestick Prevention Safety and Health Topics web page at: <https://www.osha.gov/SLTC/bloodbornepathogens/index.html>.

To file a complaint by phone, report an emergency, or get OSHA advice, assistance, or products, contact your nearest OSHA office under the "U.S. Department of Labor" listing in your phone book, or call us toll-free at **(800) 321-OSHA (6742)**.

This is one in a series of informational fact sheets highlighting OSHA programs, policies or standards. It does not impose any new compliance requirements. For a comprehensive list of compliance requirements of OSHA standards or regulations, refer to Title 29 of the Code of Federal Regulations. This information will be made available to sensory-impaired individuals upon request. The voice phone is (202) 693-1999; the teletypewriter (TTY) number is (877) 889-5627.

For assistance, contact us. We can help. It's confidential.



Cleaning Spills of Blood and Body Substances

- Wear protective gloves and use appropriate PPE (e.g., use forceps to pick up any sharps and discard in sharps container)
- If the spill contains large amounts of blood or body fluids (e.g., >10 mL), clean the visible matter with disposable absorbent material and discard in appropriate containers for biohazardous waste
- Decontaminate the area using an EPA-registered disinfectant with specific label claims for bloodborne pathogens (e.g., HIV, HBV, HCV) or a freshly diluted bleach-based product (preferably EPA-registered), in accordance with manufacturer's instructions, and allow the surface to dry
- If a bleach-based product is used:
 - Use a 1:100 dilution to decontaminate nonporous surfaces
 - If the spill involves large amounts of blood or body fluids, use a 1:10 dilution for first application of germicide *before cleaning*, then followed by cleaning and subsequent decontamination with 1:100 dilution application

Post-Exposure Evaluation and Management

Employers are required to establish exposure control plans that include post-exposure follow up for their employees and to comply with incident reporting requirements mandated by the 1992 OSHA bloodborne pathogen standard. Access to clinicians who can provide post-exposure care should be available during all working hours, including nights and weekends. HBIG, hepatitis B vaccine, and antiretroviral agents for HIV post-exposure prophylaxis (PEP) should be available for timely administration, either by providing access on site or by creating linkages with other facilities or providers to make them available off-site (CDC, 2001).

The following are recommendation by the Centers for Disease Control (DHHS, 2003) for immediate activity after exposure.

Provide immediate care to the exposure site.

- Wash wounds and skin with soap and water.
- Flush mucous membranes with water.
- Irrigate eyes with clean water, saline or sterile irrigants.

No scientific evidence shows that using antiseptics or squeezing the wound will reduce the risk of transmission of a bloodborne pathogen. Using a caustic agent such as bleach is not recommended.

Report the exposure to the government agency responsible for managing exposures. Reporting is necessary because PEP treatment may be recommended.

Spill Kit: Spray bottle with 10% bleach and water (1:10 solution). Label bottle with contents. Change bleach solution every 24 hours.

Zip Log Bag:

- 1 face mask
- 1 pair of goggles
- 1 pair of gloves
- 1 protective gown
- 1 copy of protocol

DECONTAMINATION PROCEDURES BLOOD/BODY FLUID SPILLS

"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.

Policy: To ensure the appropriate cleaning disinfecting of equipment and the patient care area to prevent the spread of infections.

Procedures:

1. All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials as soon as possible.
2. OSHA requires that work surfaces be cleaned with an "appropriate disinfectant." Appropriate disinfectants include a diluted bleach solution and EPA-registered antimicrobial products such as tuberculocides (List B), sterilants (List A), products registered against HIV/HBV (List E), and [Sterilants/ High Level Disinfectants](#) for equipment sterilization.
 - Fresh solutions of diluted household bleach made up every 24 hours are also considered appropriate for disinfection of environmental surfaces and for decontamination of sites. Contact time for bleach is generally considered to be the time it takes the product to air dry.
3. Employees must wear gloves when hand contact with blood, mucous membranes, OPIM, or non-intact skin is anticipated, and when performing vascular access procedures, or when handling contaminated items or surfaces [\[29 CFR 1910.1030\(d\)\(3\)\(ix\)\]](#).
4. Immediately clean-up of blood/body fluid spills as soon as possible after the spill occurs.
5. If the spill contains broken glass or other objects, these should be removed and discarded without contact with the hands. Use a device such as dustpan and broom to pick up sharp objects. Rigid sheets of cardboard may be used to handle such objects and discarded with the objects into an appropriate biohazard container.
6. Disinfect the spill site using an appropriate intermediate to high-level hospital disinfectant, such as a 10% dilution of household bleach. Flood the spill site or wipe down the spill site with disposable towels soaked in disinfectant to make the site. The disinfectant should be allowed to remain on the spill site for the period of time recommended by the manufacturer.
7. Wash hands as soon as possible after contamination and after removing gloves
8. If you get blood on you:
 - Wash it off as soon as possible with soap and water
 - Immediately flush your eyes with running water at a sink or eyewash station
 - Report the incident to your supervisor
 - Wear protective gloves
 - Disinfectant:
 - Solution of ¼ cup bleach per gallon of water
 - Commercially purchased disinfectant

CA Code of Regulations, Title 8, Sec. 5193

[http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051#1910.1030\(d\)\(4\)\(ii\)](http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051#1910.1030(d)(4)(ii))