

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.