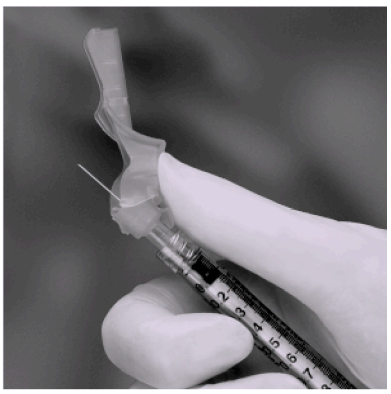
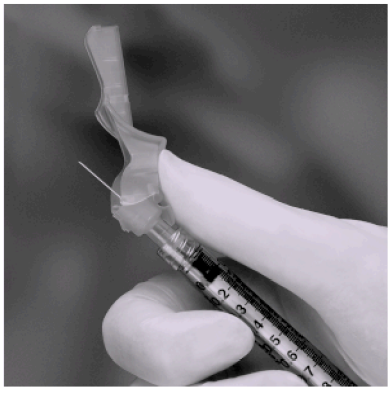
The Needlestick Safety and Prevention Act sets forth in greater detail requirements for employers to identify, evaluate, and implement safety-engineered medical devices.

If you have not already made safety medical devices available, you should do so now to ensure compliance and to protect your staff.





HEALTH INDUSTRY DISTRIBUTORS ASSOCIATION

Serving Medical Products Distributors Since 1902

THE NEEDLESTICK SAFETY AND PREVENTION ACT

Overview and Enforcement Fact Sheet

The Needlestick Safety and Prevention Act mandates the evalutation and use of safety-engineered medical devices, the maintenance of a sharps injury log, and the involvement of non-managerial employees in evaluating/choosing safety devices. Under the law, medical practices should already be using safety devices, or those where the safety feature is integral to the device. The law requires ALL employers to use safety-engineered devices, regardless of the size of the practice, the added expense of such products, or the type of facility.

OSHA enforces the Needlestick Safety and Prevention Act by conducting on-site inspections and issuing citations and fines when facilities are deemed out of compliance. Each OSHA citation can lead to a fine up to $7,000, and blatant violations can lead to fines as high as $70,000. Failure to use a safety product, like a safety hypodermic needle and syringe, can lead to multiple citations. To shed light on OSHA enforcement, below are overviews of three recent OSHA inspections, illustrating how OSHA is enforcing the new standard across different types of healthcare facilities.

NURSING HOME: In a recent 12 month period, 1,543 nursing homes were inspected by OSHA, resulting in 944 citations on the Bloodborne Pathogen Standard (BPS), many involving the non-use of safety devices for skin injection. A review of one citation recently issued to a group of three nursing homes shows how fines were issued even though the nursing homes had conducted an evaluation of safety devices for skin injection. However, the facility hadn't actually implemented the new devices, demonstrating the importance of implementation as well as evaluation of safety devices.

FAMILY MEDICAL PRACTICE: A recent OSHA inspection of a family practice was the result of a complaint filed by a patient claiming that nurses were not wearing gloves. The OSHA inspector determined gloves were being properly used, but did find the facility failed to follow guidelines in the updated Bloodborne Pathogen Standard. The practice was cited and fined for:

- Failure to update the Exposure Control Plan annually
- Failure to use "engineered sharps protection;" specifically, failure to use safety needles/ syringes for skin injections.

SURGERY CENTER: A recent facility-wide inspection at a freestanding surgery center led to citations and fines for a number of violations, including:

- Failure to document consideration and implementation of appropriate engineering controls that have existed for more than one year.
- Failure to use engineering controls when administering IM and SubQ injections, when drawing blood, and when starting IV's.
- Failure to train employees annually on the requirements of the BPS.
- Failure to maintain a sharps injury log.

Your Distributor Can Help You!

- Product training and demonstrations
- Product samples
- Information for product evaluation
- Education about compliance requirements

YOUR CUSTOMERS' MOST FREQUENTLY ASKED QUESTIONS

Does the "Needlestick Act" apply to me?

The Act applies to all employers who have employees with reasonably anticipated occupational exposure to blood or other potentially infectious materials (OPIM). This includes physician offices, medical clinics, nursing homes, home care facilities, surgery centers, and hospitals. As long as there is an employee in the practice who has the potential of incurring an exposure to blood or OPIM, even if they are not the one using the device, the practice must be in full compliance.

How does the law's revision affect states that operate their own federally-approved occupational safety and health programs?

States with state OSHA programs were required to adopt the revised standard by October 18, 2001. States may choose to implement their own, more stringent standards independently of the Needlestick Act.

Does OSHA have a list of available safer medical devices?

No. OSHA does not approve or endorse any product.

What if a safety-engineered option is not available for the medical device that I use?

If there is no safety-engineered device available for a certain procedure, you are not required to use anything new. However, employers must implement work practice controls and, if exposure risks remain, must provide protective gear. Employers also must inquire as to the availability of safety devices each year, and document that fact in the Exposure Control Plan. If a safer device is available, but back ordered or delayed, this must be documented in the Exposure Control Plan. You must implement the device(s) as soon as it becomes available, and then document that fact.

We have tried safety-engineered devices, and we don't believe they are safer than what we use today. Do we still need to convert to safety products?

This judgment is likely to be challenged, since OSHA has already collected data from across the country demonstrating that safety-engineered devices do effectively reduce needlesticks. Deciding not to use safety devices needs to be based on clinical justifications that are clearly documented in the Exposure Control Plan. In the absence of such clinical evidence, employers are expected to adopt safety devices.

We feel safety-engineered devices cost too much. Is it acceptable if we delay conversion until the price comes down?

No. Before passing the Needlestick Act, OSHA conducted an industry-wide cost/benefit analysis and concluded that the use of safety medical devices was beneficial due to the reduction in the expenses associated with testing and treating injured healthcare workers. For example, it can cost upwards of $500,000 to $1,000,000 to treat a worker who contracts hepatitis C or HIV.

Is the use of a needle destroyer/pulverizer considered an acceptable alternative to using safety-engineered devices?

No. Needle destroyers / pulverizers as well as sharps collectors facilitate the safe disposal of used needles, but they do not provide any protection from the risk of a needlestick during product use, which is when most needlesticks occur.

We have placed a box of safety product on the shelf to use for select, high-risk situations. Does this make us compliant with the new safety legislation?

No. The legislation requires employees to use safety devices in all cases where safer medical devices are available.

What if we have never had anyone on our staff experience a needlestick injury, must we still convert to safety devices?

Yes. OSHA standards are intended to prevent occupational injuries and illnesses.

Does the Needlestick Safety and Prevention Act apply to medical or dental offices that have fewer than 10 employees?

Yes, the Needlestick Safety and Prevention Act applies to all employers with employees who have occupational exposures, regardless of how many workers are employed. However, workplaces with 10 or fewer employees are exempt from recording and maintaining a Sharps Inquiry Log. All other applicable provisions of the Bloodborne Pathogens Standard still apply.

What information do I need to include in my written Exposure Control Plan? How often do I need to update it?

In addition to what is already required by the 1991 standard, the revised standard requires the documentation of annual consideration and implementation of appropriate engineering controls, and solicitation of non-managerial workers in evaluating/choosing safety devices. The plan must be reviewed and updated every year.

What is the position of key healthcare professional organizations on this safety legislation?

The American Medical Association supports the updated Bloodborne Pathogen Standard and the need to prevent needlestick injuries. Further, on April 1, 2002, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) will require full compliance with the new Bloodborne Pathogen Standard, including the use of safety devices, in order to receive accreditation.

Further information on the Bloodborne Pathogens Standard and the enforcement procedures for the Occupational Exposure to Bloodborne Pathogens can be obtained at **www.osha.gov** or by phone at **1-800-321-OSHA**. The National Institute for Occupational Safety and Health (NIOSH) and the Centers for Disease Control and Prevention (CDC) also have documents related to the prevention of occupational exposure to blood and OPIM.