



## ***The Needlestick Safety and Prevention Act (PL 106-430)***

### ***– A Summary –***

The main elements of the Federal Law governing the selection and use of syringes in the healthcare workplace that reduce or eliminate needlestick injuries (NSIs) can be summarized as follows:

#### ***Employers must:***

- Establish a NSI Exposure Control Plan, which must be assessed and updated at least annually, particularly, to reflect changes in technologies that reduce or eliminate NSIs
- Evaluate each new safety syringe that becomes commercially available
- Choose the best commercially available device and must document their decision-making for the selection of any safety syringe, without regard to cost
- Solicit input from users (non-managerial) in identifying, evaluating and selecting safety syringes for use in their institution, and must document such solicitation
- ***Provide “self-sheathing needles”***
- Provide post-exposure evaluation and follow-up for any NSI incident, including tests for bloodborne pathogens, such as HIV and Hepatitis B and Hepatitis C, for both the source individual (patient) and victim of the NSI
- Maintain past and current records, e.g., sharps injury logs, documenting all incidents and pertinent facts relating to the route of exposure and circumstances of each reported NSI, including the results of blood tests on the source individual and the victim of the NSI, such log being subject to annual inspection by OSHA personnel, as an overall measure of device efficacy



## **The Needlestick Safety and Prevention Act** **-- The Self-Sheathing Protectus Safety Syringe --**

From inception, Protectus Medical Devices, Inc., set forth a firm list of criteria that **any** safety syringe development program should consider and incorporate in any final design and, on that basis, created the revolutionary **Protectus Safety Syringe**. Within this list of “Criteria for Development and Acceptance,” the elements specifically intended by The Occupational Safety & Health Administration (OSHA) within the stated definition of “**Engineering Controls**” are:

- “An **engineering control** is the use of available technology and devices to isolate or remove hazards from the worker.”
- “Examples of **engineering controls** include, but are not limited to, puncture-resistant sharps containers, splash guards, mechanical pipetting, and **self-sheathing needles**<sup>1</sup>.”
- “**Engineering Controls** shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness<sup>2,3</sup>.”

The **Protectus Safety Syringe** primary design and function patents specify that a fixed barrier (sheath) shall automatically cover the needle if intentional control of the device is lost at any time during its use, thus making the device “**self-sheathing**.”

The OSHA “Guideline” was first entered into the Federal Register as a mandate in 1991<sup>3</sup> and, in a subsequent Federal Register (2001), was specifically restated as the current mandate (see Occupational Exposure to Bloodborne Pathogens; Needlestick and Other Injuries; Final Rule 66:5317-5325). The Final Rule amended the “**Engineering Controls**” definition to:

- “**Engineering Controls** means controls (e.g., sharps disposal containers, **self-sheathing needles**, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace<sup>5</sup>.”

The revisions also clarified the important need for employers to select safer needle devices as they become available and to involve employees in identifying and choosing safer devices. Specifically, the revised OSHA Bloodborne Pathogens Standard obligates employers to consider safer needle devices when they conduct their annual review of their exposure control plan. These rules/regulations are the exact language used to write both federal (see PL106 430) and state legislation. To date, nearly all fifty states have also passed such legislation.

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<sup>1</sup> Compliance Assistance Guideline for February 27, 1990 OSHA Instruction CPL 2-2.44B Enforcement Procedures for Occupational Exposure to Hepatitis B Virus and Human Immunodeficiency Virus

<sup>2</sup> Federal Register/Vol. 56 No. 235/ Friday, December 6, 1991/Rules and Regulations

<sup>3</sup> OSHA 29 CFR Part 1910.1030 Bloodborne Pathogens

<sup>4</sup> Ibid.

<sup>5</sup> Ibid.

# OSHA<sup>®</sup> 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/bloodborne pathogens/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.**

