

# Overview: Regulations and Legislation in the U.S. for Preventing Occupational Exposures to Bloodborne Pathogens

*By Jane Perry, M.A., and Janine Jagger, M.P.H., Ph.D.*

## The 1991 Bloodborne Pathogens Standard

The BPS was issued by OSHA in December 1991, after a lengthy rulemaking process (240). It required healthcare facilities to develop an exposure control plan for each area of their institutions; use engineering and work practice controls to eliminate or minimize employee exposures to bloodborne pathogens; provide puncture- and leak-resistant sharps disposal containers; train HCWs in safe work practices and universal precautions; provide follow-up and treatment, as appropriate, when an employee sustained a blood exposure; and maintain records of reported exposures.

Methods of compliance with the BPS included universal precautions, engineering controls, work practice controls (such as handwashing and not recapping needles), use of personal protective equipment (such as gloves and masks), and appropriate housekeeping and waste handling procedures.

The definition of “engineering controls” in the 1991 BPS included only two examples of engineering controls: sharps disposal containers and self-sheathing needles. At that time, safety-engineered sharps technology was still relatively new and untested; little emphasis was placed on safety-engineered sharp devices as a means of preventing blood exposures. During the 1990s, however, there was increasing pressure by

HCW groups to emphasize safety-engineered sharp devices as a primary engineering control. In September 1998, OSHA issued a Request for Information (RFI) specifically on “engineering and work practice controls used to eliminate or minimize the risk of occupational exposure to bloodborne pathogens due to PIs from contaminated sharps” (266). OSHA received almost 400 comments from healthcare facilities, including nursing homes, clinics, acute care facilities, and rehabilitation and pediatric hospitals, and published an executive summary in May 1999 (267). One of the key findings was that “safer medical devices are an effective and feasible method of hazard control.” According to OSHA, “nearly every healthcare facility responding to the RFI noted that a reduction in injuries had occurred after the introduction of a safer medical device.” The responses also indicated that training and education regarding the proper use of safer devices were key to their acceptance, that safer devices in general did not adversely affect patient care, and that the higher cost of these devices was offset by savings from reduced post-exposure testing and treatment.

On the basis of these findings, OSHA issued a revised compliance directive for the BPS in November 1999 (241); compliance directives provide instruction to OSHA field officers on interpretation and enforcement of OSHA standards. The revised

BPS directive placed explicit emphasis on the use of safety-engineered devices to prevent occupational blood exposures. The directive noted that since the BPS was issued in 1991, there had been “a substantial increase in the number and assortment of effective engineering controls,” and directed employers to continuously evaluate new safety devices as they came on the market.

## FDA and NIOSH Safety Alerts

Along with the BPS, there were several other significant federal actions during the 1990s related to the prevention of sharps injuries. In 1992, the Food and Drug Administration (FDA) issued a safety alert advising healthcare facilities to stop using needles to connect intravenous lines or access intravenous ports (268). EPINet data showed that needles used for this purpose were responsible for a large proportion of needlestick injuries in the U.S., and in 1992 there were already more than a dozen needleless or shielded-needle products available to eliminate this risk. The FDA alert had a significant impact in reducing sharps injuries, as reflected in the EPINet data. In 1993, shortly after the alert was issued, 30% of needlesticks from hollow-bore needles were caused by needles used to access intravenous ports; by 1998, with a significant increase in the adoption of needleless and recessed-needle intravenous (IV) systems, the fraction was reduced to 13%

## Legislating Safety:

# U.S. State and Federal Government Actions to Prevent Occupational Exposures to Bloodborne Pathogens

<b>1987</b>	<b>Centers for Disease Control and Prevention (CDC) issues Universal Precautions</b> for prevention of HIV transmission in healthcare settings
<b>1987-1989</b>	Occupational Safety and Health Administration (OSHA) initiates rulemaking process and holds hearings on proposed Bloodborne Pathogens Standard
<b>1991</b>	<b>Dec. 1991: OSHA issues the Bloodborne Pathogens Standard (BPS)</b> to “protect approximately 5.6 million workers in health care and related occupations from the risk of exposure to bloodborne pathogens.” Standard requires engineering and work practice controls, personal protective equipment, training, surveillance, hepatitis B vaccination, and other actions to minimize risk of bloodborne disease transmission.
<b>1992</b>	Feb. 1992: Congress holds hearings on healthcare worker safety and needlestick injuries; healthcare workers, including a nursing assistant who was occupationally infected with HIV from a needlestick injury, give testimony about the need for safer needle devices. March 1992: OSHA issues compliance directive for BPS (directive provides guidance for OSHA field officers on how to enforce the standard when they conduct inspections). <b>April 1992: Food and Drug Administration (FDA) issues safety alert on needlestick risk from needles used for piggyback connections and to access IV lines.</b>
<b>1997</b>	<b>Jan. 1997: CDC publishes two studies evaluating efficacy of safety devices</b> in reducing percutaneous injuries (one study evaluates safety phlebotomy devices, the other a blunt suture needle). <b>Oct. 1997: First federal needle safety bill introduced in U.S. House of Representatives, “Health Care Worker Protection Act”</b> (sponsored by Rep. Pete Stark [D-CA]) (bill did not move forward).
<b>1998</b>	<b>Sept. 1998: California passes first state needle safety law, A.B. 1208;</b> this precedent-setting legislation sets the stage for other states to enact similar laws.* Sept. 1998: OSHA issues a Request for Information (RFI) on “Occupational Exposure to Bloodborne Pathogens”, soliciting input from healthcare facilities on effectiveness of safety devices.
<b>1999</b>	May 1999: A second federal bill, “Health Care Worker Needlestick Prevention Act,” introduced by Rep. Pete Stark in Congress (once again, bill went nowhere). Feb. 1999: FDA issues a safety advisory warning about injury/infection risk from use of glass capillary tubes. <b>Nov. 1999: OSHA issues revised compliance directive for the BPS,</b> based on responses to its RFI; <b>for the first time, OSHA makes it clear that healthcare facilities are required to use safety devices</b> Nov. 1999: National Institute for Occupational Safety and Health (part of the CDC) issues a guideline, “Preventing Needlestick Injuries in Health Care Settings.”
<b>2000</b>	Sept. 2000: Needlestick Safety and Prevention Act introduced in U.S. House of Representatives by Rep. Cass Ballenger (R-NC); bill passed unanimously. <b>Nov. 6, 2000: President Clinton signs the Needlestick Safety and Prevention Act into law.</b>
<b>2001</b>	<b>Jan. 2001: OSHA issues revised BPS, as mandated by the Needlestick Safety and Prevention Act.</b> April 2001: Revised BPS becomes effective. Nov. 2001: OSHA issues updated compliance directive for BPS, reflecting new requirements in the revised standard.
<b>2002</b>	From April 2001 to May 2002, OSHA issues 132 citations for failure to use engineering controls (safety devices)— <i>four</i> times more than all citations issued over the previous decade. Fines total over \$1 million. OSHA also issues several letters of interpretation on the BPS that make it clear there are <i>no</i> exemptions to the requirement to use safety devices.

\* By the end of 2001, an additional 20 states had passed laws related to needlestick prevention.

in EPINet network hospitals, and continues to decline.

In 1999, the FDA, in conjunction with OSHA and the CDC, issued a second sharps-related warning, this one regarding potential bloodborne pathogen exposures from glass capillary tubes (264). The advisory urged healthcare facilities to choose safer alternatives (plastic or mylar-wrapped glass capillary tubes), in order to reduce high-risk injuries from blood-contaminated glass in the healthcare setting.

In November 1999, a third federal agency—the National Institute of Occupational Safety and Health (NIOSH) of the CDC—took action on sharps safety. NIOSH issued an alert (“Preventing Needlestick Injuries in Health Care Settings”) that urged healthcare employers to use safety-engineered sharps devices and establish comprehensive programs to reduce needlestick injuries (269). While it did not have the force of law, the alert was significant in that the CDC explicitly supported the use of safety devices as a primary means of preventing needlestick injuries.

### State Legislation

While the U.S. federal government took significant steps in promoting sharps injury prevention during the 1990s, states were the first to introduce and pass needle safety legislation. In September 1998, California enacted groundbreaking legislation, A.B. 1208, which mandated that needles and other sharp devices have engineered sharps injury protection, that is, built-in protective features. The bill mandated that the state’s bloodborne pathogens standard be revised to reflect these new requirements. (California, along with about half of U.S. states, operates its own state OSHA program).

From 1999 through 2001, 20

additional states passed legislation related to needle safety. Because the bills varied widely in their requirements and scope, there was increasing pressure for federal needle safety legislation that would bring national uniformity to requirements for safety-engineered sharp devices.

### The Needlestick Safety and Prevention Act and 2001 Revised Bloodborne Pathogens Standard

In June 2000, the congressional Subcommittee on Workforce Protections convened a hearing to discuss the impact of the 1999 compliance directive and determine whether additional federal action was needed. The hearing was chaired by Rep. Cass Ballenger (R-NC), who subsequently introduced the Needlestick Safety and Prevention Act (H.R. 5178) in September 2000. With widespread support from the healthcare industry and medical device manufacturers, the legislation passed both houses of Congress unanimously and was signed into law by President Clinton on November 6, 2000 (270). The first law of its kind in the world, it provided U.S. HCWs with an unprecedented level of protection, and set a global standard for both employee and patient safety.

The Needlestick Safety Act mandated that the bloodborne pathogens standard be revised in several key areas to improve needle safety and strengthen exposure prevention programs; OSHA published the revised standard on January 18, 2001, and it became effective April 18, 2001 (271). The revised standard mandated that employers include non-managerial, frontline healthcare employees who provide direct patient care in the process of evaluating and selecting safer devices. Employers were also required to document in their expo-

sure control plan that they had evaluated and implemented safer medical devices designed to reduce the risk of blood exposures, and update the plans at least annually to reflect changes in sharps prevention technology. Finally, employers were required to maintain a sharps injury log, with information on the type and brand of device causing injury, the department or work area where the injury occurred, and an explanation of how it occurred. The intent of this requirement was to enable healthcare facilities to evaluate exposure risk and device effectiveness. OSHA did not specify the format for the log, as long as it met the minimum requirements for data collection and the confidentiality of employees was protected. Employers with 10 or fewer employees were exempt from this requirement, but not from the other requirements of the revised BPS.

The revised standard included a new term, “sharps with engineered sharps injury protections,” defined as “a nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.” This definition delineates the kinds of procedures for which safety devices must be used. Safety devices are not needed for tasks that do not involve potential exposure to patients’ body fluids, such as preparing medications in pharmacies.

With the revised BPS of 2001, OSHA made it clear that use of safety devices was not optional—it was the law.

### References

1. Occupational Safety and Health Administration. Occupational exposure to bloodborne pathogens; final rule (29 CFR Part 1910.1030). *Fed-*

*eral Register*, 1991;56(235):64004-64182.

2. Occupational Safety and Health Administration. Occupational exposure to bloodborne pathogens: Request for information. *Federal Register*, 1998;63:48250-48252.

3. Occupational Safety and Health Administration. Record summary of the request for information on occupational exposure to bloodborne pathogens due to percutaneous injury. *Executive Summary*, 1999; [www.osha-slc.gov/html/ndlreport052099.html](http://www.osha-slc.gov/html/ndlreport052099.html).

4. Occupational Safety and Health Administration. OSHA Instruction: Enforcement procedures for the Occupational Exposure to

Bloodborne Pathogens. Directives number CPL 2-2.44D. Washington, DC: U.S. Department of Labor, November 5, 1999.

5. Benson JS, Food and Drug Administration. FDA safety alert: Needlestick and other risks from hypodermic needles on secondary I.V. administration sets - piggyback and intermittent I.V. Rockville, MD: U.S. Department of Health and Human Services; April 16, 1992.

6. Food and Drug Administration, National Institute for Occupational Safety and Health, and Occupational Safety and Health Administration. Glass capillary tubes: Joint safety advisory about

potential risks. Rockville, MD: FDA, 1999.

7. National Institute for Occupational Safety and Health. NIOSH Alert: Preventing needlestick injuries in health care settings. DHHS (NIOSH) Publication No. 2000-108. November 1999.

8. Needlestick Safety and Prevention Act of 2000, Pub. L. No. 106-430, 114 Stat. 1901, November 6, 2000.

9. Occupational Safety and Health Administration. Occupational exposure to bloodborne pathogens; needle-sticks and other sharps injuries; final rule (29 CFR Part 1910.1030). *Federal Register*, 2001;66(12):5318-5325.

---

---