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**29 CFR Part 1910
Occupational Exposure to Bloodborne
Pathogens; Needlesticks and Other Sharps
Injuries; Final Rule**

DEPARTMENT OF LABOR**Occupational Safety and Health Administration****29 CFR Part 1910**

[Docket No. H370A]

RIN 1218-AB85

Occupational Exposure to Bloodborne Pathogens; Needlestick and Other Sharps Injuries; Final Rule

AGENCY: Occupational Safety and Health Administration (OSHA), Department of Labor

ACTION: Final Rule; Request for Comment on the Information Collection (Paperwork) Requirements

SUMMARY: The Occupational Safety and Health Administration is revising the Bloodborne Pathogens standard in conformance with the requirements of the Needlestick Safety and Prevention Act. This Act directs OSHA to revise the Bloodborne Pathogens standard to include new examples in the definition of engineering controls along with two new definitions; to require that Exposure Control Plans reflect how employers implement new developments in control technology; to require employers to solicit input from employees responsible for direct patient care in the identification, evaluation, and selection of engineering and work practice controls; and to require certain employers to establish and maintain a log of percutaneous injuries from contaminated sharps.

DATES: Effective Date: The effective date is April 18, 2001. Written comments: Written comments on the Information Collection Requirements must be submitted on or before March 19, 2001.

ADDRESSES: Copies of materials in the docket may be obtained from the OSHA Docket Office, Room N-2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, Telephone (202) 693-2350. Referenced documents are included in Docket H370A and are identified by the exhibit number indicated.

Submit written comments on the Information Collection Requirements to the Docket Office, Docket No. ICR-0180 (2001), OSHA, U.S. Department of Labor, Room N-2625, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693-2350. Commenters may transmit written comments of 10 pages or less in length by facsimile to (202) 693-1648.

In compliance with 28 U.S.C. 2112(a), the Agency designates the Associate Solicitor for Occupational Safety and

Health, Office of the Solicitor, Room S-4004, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, as the recipient of petitions for review of the standard.

FOR FURTHER INFORMATION CONTACT:

Bonnie Friedman, Director, OSHA Office of Public Affairs, Room N-3647, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Telephone: (202) 693-1999.

SUPPLEMENTARY INFORMATION:**I. Events Leading to the Amended Final Rule**

Blood and other potentially infectious materials have long been recognized as a potential threat to the health of employees who are exposed to these materials by percutaneous contact (penetration of the skin). Injuries from contaminated needles and other sharps have been associated with an increased risk of disease from more than 20 infectious agents (Exs. 3-172GG, 3-274C). The primary agents of concern in current occupational settings are the human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV).

To reduce the health risk to workers whose duties involve exposure to blood or other potentially infectious materials, OSHA promulgated the Bloodborne Pathogens (BBP) standard (29 CFR 1910.1030) on December 6, 1991 (56 FR 64004). The provisions of the standard were based on the Agency's determination that a combination of engineering and work practice controls, personal protective equipment, training, medical surveillance, hepatitis B vaccination, signs and labels, and other requirements would minimize the risk of disease transmission.

Needlesticks and other percutaneous injuries resulting in exposure to blood or other potentially infectious materials continue to be of concern due to the high frequency of their occurrence and the severity of the health effects associated with exposure. The Centers for Disease Control and Prevention has estimated that healthcare workers in hospital settings sustain 384,325 percutaneous injuries involving contaminated sharps annually (Ex. 5-4). When non-hospital healthcare workers are included, the best estimate of the number of percutaneous injuries involving contaminated sharps is 590,164 per year (Ex. 3-172V). When these injuries involve exposure to infectious agents, the affected workers are at risk of contracting disease. Workers may also suffer from adverse side effects of drugs used for post-exposure prophylaxis and from

psychological stress due to the threat of infection following an exposure incident.

Since publication of the BBP standard, a wide variety of medical devices have been developed to reduce the risk of needlesticks and other sharps injuries. These "safer medical devices" replace sharps with non-needle devices or incorporate safety features designed to reduce the likelihood of injury. In a September 9, 1998, Request for Information (RFI), OSHA solicited information on occupational exposure to bloodborne pathogens due to percutaneous injury (63 FR 48250). Based in part on the responses to the RFI, the Agency has pursued an approach to minimize the risk of occupational exposure to bloodborne pathogens that involves three components. First, the Agency proposed that the revised Recordkeeping standard (29 CFR 1904) include a requirement that all percutaneous injuries from contaminated needles and other sharps be recorded on OSHA logs (61 FR 4030). Second, OSHA issued a revised compliance directive for the BBP standard on November 5, 1999, to reflect advances made in medical technology and treatment. The directive guides OSHA's compliance officers in enforcing the standard and ensures that consistent inspection procedures are followed. Third, the Agency placed amendment of the bloodborne pathogens standard on its regulatory agenda to more effectively address sharps injuries.

Congress was prompted to take action in response to growing concern over bloodborne pathogen exposures from sharps injuries and in response to recent technological developments that increase employee protection. On November 6, 2000, the Needlestick Safety and Prevention Act was signed into law. The Act directs OSHA to revise the BBP standard in accordance with specific language included in the Act.

II. Statutory Authority

On November 6, 2000, President Clinton signed the Needlestick Safety and Prevention Act, Pub. L. 106-430. The Act requires OSHA to revise the BBP standard within six months of the Act's enactment. To facilitate expeditious completion of this directive, Congress explicitly exempted OSHA from procedural requirements generally attending rulemaking under OSH Act 6(b) and from the procedural requirements of the Administrative Procedure Act (5 U.S.C. 500 *et seq.*).

III. Summary and Explanation

The revisions to OSHA's BBP standard required under the Needlestick Safety and Prevention Act can be broadly categorized into four areas: modification of definitions relating to engineering controls; revision and updating of the Exposure Control Plan; solicitation of employee input; and recordkeeping.

The revised standard adds two additional terms to the definition section found in paragraph (b) and alters the definition of one other term. It adds "Sharps with Engineered Sharps Injury Protections" and defines this term 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 term encompasses a broad array of devices that make injury involving a contaminated sharp less likely, and includes, but is not limited to, syringes with a sliding sheath that shields the attached needle after use; needles that retract into a syringe after use; shielded or retracting catheters used to access the bloodstream for intravenous administration of medication or fluids; and intravenous medication delivery systems that administer medication or fluids through a catheter port or connector site using a needle that is housed in a protective covering.

The revised standard also adds the term "Needleless Systems," which is defined as "a device that does not use needles for: (A) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (B) the administration of medication or fluids; or (C) any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps." "Needleless Systems" provide an alternative to needles for the specified procedures, thereby reducing the risk of percutaneous injury involving contaminated sharps. Examples of needleless systems include, but are not limited to, intravenous medication delivery systems that administer medication or fluids through a catheter port or connector site using a blunt cannula or other non-needle connection, and jet injection systems that deliver subcutaneous or intramuscular injections of liquid medication through the skin without use of a needle.

The definition of "Engineering Controls" has been modified to include as examples "safer medical devices,

such as sharps with engineered sharps injury protections and needleless systems." This change clarifies that safer medical devices are considered to be engineering controls under the standard. The term "Engineering Controls" includes all control measures that isolate or remove a hazard from the workplace, encompassing not only sharps with engineered sharps injury protections and needleless systems but also other medical devices designed to reduce the risk of percutaneous exposure to bloodborne pathogens. Examples include blunt suture needles and plastic or mylar-wrapped glass capillary tubes, as well as controls that are not medical devices, such as sharps disposal containers and biosafety cabinets.

The expanded definitions reflect the intent of Congress to have OSHA amend the BBP standard to clarify

* * * the direction already provided by OSHA in its Compliance Directive; namely, that employers who have employees with occupational exposure to bloodborne pathogens must consider and, where appropriate, use effective engineering controls, including safer medical devices, in order to reduce the risk of injury from needlesticks and from other sharp medical instruments * * * (Ex. 5-3).

Thus, the revised definitions do not reflect any new requirements being placed on employers with regard to protecting workers from sharps injuries, but are meant only to clarify the original standard, and to reflect the development of new safer medical devices since that time.

Paragraph (c)(1)(iv) of the standard is revised to add new requirements to the annual review and update of the Exposure Control Plan. The review and update of the plan is now required to "(A) reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and (B) document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure." Thus, the additional provisions require that employers, in their written Exposure Control Plans, account for innovations in procedure and technological developments that reduce the risk of exposure incidents. This would include, but would not be limited to, newly available medical devices designed to reduce the risk of percutaneous exposure to bloodborne pathogens. Consideration and implementation of safer medical devices could be documented in the Exposure Control Plan by describing the safer devices identified as candidates for

adoption; the method or methods used to evaluate devices and the results of evaluations; and justification for selection decisions. This information must be updated at least annually.

The revised Exposure Control Plan requirements make clear that employers must implement the safer medical devices that are appropriate, commercially available, and effective. No one medical device is appropriate in all circumstances of use. For purposes of this standard, an "appropriate" safer medical device includes only devices whose use, based on reasonable judgment in individual cases, will not jeopardize patient or employee safety or be medically contraindicated. Although new devices are being continually introduced, OSHA recognizes that a safer device may not be available for every situation. If a safer device is not available in the marketplace, the employer is not required to develop any such device. Furthermore, the revised requirements are limited to the safer medical devices that are considered to be "effective." For purposes of this standard, an "effective" safer medical device is a device that, based on reasonable judgment, will make an exposure incident involving a contaminated sharp less likely to occur in the application in which it is used.

Paragraph (c)(1)(v) of the revised standard now requires that "An employer, who is required to establish an Exposure Control Plan shall solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan." This change represents a new requirement, which is performance-oriented. No specific procedures for obtaining employee input are prescribed. This provides the employer with flexibility to solicit employee input in any manner appropriate to the circumstances of the workplace. A dental office employing two hygienists, for example, may choose to conduct periodic conversations to discuss identification, evaluation, and selection of controls. A large hospital, on the other hand, would likely find that an effective process for soliciting employee input requires the implementation of more formal procedures. The solicitation of input required by the standard requires employers to take reasonable steps to obtain employee input in the identification, evaluation, and selection of controls. Methods for soliciting employee input may include

involvement in informal problem-solving groups; participation in safety audits, worksite inspections, or exposure incident investigations; participation in analysis of exposure incident data or in job or process hazard analysis; participation in the evaluation of devices through pilot testing; and involvement in a safety and health committee properly constituted and operated in conformance with the National Labor Relations Act.

Employee input can serve to assist the employer in overcoming obstacles to the successful implementation of control measures. A number of respondents to the RFI indicated that they encountered some resistance when new devices required staff members to adopt new techniques, or when staff members perceived that use of the device might have an adverse effect on the patient (e.g., Exs. 3-50, 3-79, 3-99, 3-133). As a way of addressing this resistance, staff involvement in the selection process can play an important role in the acceptance and proper use of safer medical devices (e.g., Exs. 3-18, 3-42, 3-56, 3-88, 3-324, 3-355). According to their experience, the participation of frontline workers can help to overcome the following barriers:

- Safer medical devices often require adjustments in technique, and a number of respondents noted that staff members are often reluctant to revise practices to which they have become accustomed.
- Equipment compatibility problems. With the broad array of devices being used in healthcare settings, it is critical to ensure that devices will work together when necessary.
- The need for continued evaluation of devices and the allotment of sufficient time for adequate device evaluation. After initial use by employees, some facilities found it necessary to replace the device originally selected with a more suitable device.

The Community Health Network (CHN) of San Francisco provides an example of a safety and health committee with responsibility for sharps injury prevention (Ex. 5-5). Representatives of both labor and management serve on the committee, and are provided with access to non-confidential information regarding bloodborne pathogen exposure incidents at CHN facilities. The committee is responsible for establishing criteria for safer devices; overseeing device evaluation by representative groups of device users; and selecting preferred devices for purchase. The committee is also responsible for developing safer

alternatives to work practices that are associated with exposure incidents.

The concept of involving a team in sharps injury prevention programs is supported by the American Hospital Association (AHA) in guidelines to assist hospitals and health systems in developing such programs (Ex. 5-1). According to AHA, a successful program revolves around communication, education, training, and collaboration. Among the specific steps recommended are assembling a multidisciplinary team that includes representation of frontline workers and departments using devices; selecting targeted devices for evaluation; pilot-testing of devices; and collecting data after a device is adopted to evaluate its impact.

The standard requires that employers seek input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps. Employees involved in administering treatment or performing any procedure in the presence of an individual receiving care are considered to be involved in direct patient care. For example, an employee who uses a needlestick to collect blood from patients in a nursing home, or an employee who administers flu vaccinations in a factory employee health unit, would both be considered to be involved in direct patient care and engaged in activities that put them at risk of direct exposure due to needlestick injuries. Employers may also choose to include other employees in the request for input, such as lab technicians, housekeeping staff, maintenance workers, and management-level personnel who may be at risk of injury involving contaminated sharps. An employer who is otherwise required to establish an Exposure Control Plan under the standard, but does not have any non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps, is not required to solicit employee input with respect to this provision.

The revised standard does not require employers to request input from all potentially exposed employees involved in direct patient care; however, the employees involved by the employer should represent the range of exposure situations encountered in the workplace. Input from employees covered by a collective-bargaining agreement may also be requested through their authorized bargaining agent.

The revised standard requires that solicitation of input from employees be

documented in the Exposure Control Plan. Employers can meet this obligation by identifying the employees who were involved and describing the process by which input was requested. Employers should also describe the input obtained with regard to identification, evaluation, and selection of controls. Evidence that employee input has been sought can include, for example, meeting minutes, copies of documents used to request employee participation, or records of responses received from employees such as reports evaluating the effectiveness of a safer medical device in trial applications.

The requirement for solicitation of input from employees has been designated as paragraph (c)(1)(v) in the revised standard. The requirement that the Exposure Control Plan be made available to the Assistant Secretary of Labor for Occupational Safety and Health and the Director of the National Institute for Occupational Safety and Health upon request, previously designated as paragraph (c)(1)(v), has been moved and is now paragraph (c)(1)(vi) in the revised standard.

The recordkeeping requirements of the standard at paragraph (h) have been amended by adding paragraph (h)(5) to require that employers maintain a sharps injury log to serve as a tool for identifying high risk areas and evaluating devices. Paragraph (h)(5)(i) now states, "The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum: (A) The type and brand of device involved in the incident, (B) the department or work area where the exposure incident occurred, and (C) an explanation of how the incident occurred." The sharps injury log must be maintained for the period required by 29 CFR 1904. The requirement to establish and maintain the log only applies to employers who are otherwise required to maintain a log of occupational injuries and illnesses under 29 CFR 1904 (OSHA's Recordkeeping rule).

The sharps injury log must include the specified minimum information regarding the device involved (if known), the location of the incident, and the description of the events that resulted in the injury. The level of detail presented should be sufficient to allow ready identification of the device, location, and circumstances surrounding an exposure incident (e.g.,

the procedure being performed, the body part affected, objects or substances involved and how they were involved) so that the intended evaluation of risk and device effectiveness can be accomplished.

Information in the sharps injury log must be recorded and maintained in a manner that protects the privacy of the injured employee. If data from the log are made available to other parties, any information that directly identifies an employee (e.g., name, address, social security number, payroll number) or information that could reasonably be used to identify indirectly a specific employee (e.g., exact age, date of initial employment) must be withheld.

The format of the sharps injury log is not specified. The employer is permitted to determine the format in which the log is maintained (e.g., paper or electronic), and may include information in addition to that required by the standard, so long as the privacy of injured workers is protected. The Agency recognizes that many employers already compile reports of percutaneous exposure incidents in a variety of ways. Existing mechanisms for collecting these reports will be considered sufficient to meet the requirements of the standard for maintaining a sharps injury log, provided that the information gathered meets the minimum requirements specified in the standard, and the confidentiality of the injured employee is protected.

Under newly published revisions to OSHA's Recordkeeping rule (29 CFR 1904), employers are required to record sharps injuries involving contaminated objects on the OSHA 300 Log of Work-Related Injuries and Illnesses and the OSHA 301 Injury and Illness Incident Report (the new forms replace the current 200 and 101 forms). When the revisions become effective, employers may elect to use the OSHA 300 and 301 forms to meet the sharps injury log requirements, provided two conditions are met. First, the employer must enter the type and brand of the device on either the 300 or 301 form. Second, the employer must maintain the records in a way that segregates sharps injuries from other types of work-related injuries and illnesses, or allows sharps injuries to be easily separated. For example, if OSHA 300 and 301 records are maintained on a computer, the employer must ensure that the computer is able to produce a record of sharps injuries that does not include other

types of work-related injuries and illnesses (i.e., through using a program that allows for sorting of entries by injury type). If records are kept on paper forms, the employer would need to use a separate page of the 300 Log for sharps injuries.

The revisions to the Recordkeeping rule will not become effective until January 1, 2002, at the earliest, and until then many sharps injuries involving contaminated objects will not be recordable on the OSHA log. Therefore, employers must keep a separate sharps log from the effective date of this rule until the revised Recordkeeping rule becomes effective.

These revisions to the BBP standard become effective April 18, 2001. Exposure Control Plans that are reviewed and updated on or after this effective date must reflect the requirements of the revised standard. Percutaneous exposure incidents that occur on or after this effective date must be recorded on the sharps injury log.

OSHA's BBP standard, including the amendments herein promulgated, is applicable to general industry and shipyard employment (as referenced in 29 CFR 1915.1030).

IV. Economic Analysis

Incremental Costs of the Mandated Revisions to the Standard

OSHA has determined that the total cost of this action is \$33,814,991 per year, and thus, that it is not an economically significant regulatory action within the meaning of Executive Order 12866. However, the rule is defined as a significant rule under the Executive Order, and has been reviewed by the Office of Management and Budget. This amendment to the final standard does not involve any new engineering requirements to protect workers from sharps injuries, but it does include two new recordkeeping requirements: First, the amended standard requires employers to "establish and maintain a sharps injury log for the recording of percutaneous injuries * * *" However, for recordable needlestick incidents, OSHA already requires employers to collect much of the information needed for developing such a log under other rules, the Recording and Reporting Occupational Injuries and Illnesses regulation (29 CFR 1904) in particular. Moreover, OSHA has recently published revisions to 29 CFR 1904 that would cover the remaining, previously nonrecordable

needlestick injuries. Second, the current action requires any employer "who is required to establish an Exposure Control Plan" to "solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan." The methodology OSHA has used for computing costs for each requirement of the amended standard is presented in the next two sections.

Cost of Establishing and Maintaining a Sharps Injury Log

The rule requires employers to maintain a log for all needlestick and sharps injuries. At a minimum, the sharps injury log must contain: "(A) The type and brand of device involved in the incident, (B) the department or work area where the exposure incident occurred, and (C) an explanation of how the incident occurred." The costs attributable to the log correspond directly to the number of needlestick and sharps injuries. The International Health Care Worker Safety Center (IHCWSC) provides the best available estimate of the number of needlestick injuries (Ex. 3-172V). IHCWSC has computed that 590,164 needlestick and sharps injuries occur annually.

Needlestick and sharps injury cases will require an effort pertaining to collection of data on the type and brand of device, the department or work area where the incident occurred, and an explanation of how the incident occurred. Because the amount of information required to be collected is limited, OSHA estimates that it will require an average of five minutes per case (0.08 hours) to collect the data and enter it onto the separate log. Assuming that the task of collecting information related to the incident and entry onto the log will be conducted by an individual with the skill level of a Personnel Training and Labor Relations Specialist, an hourly wage of \$26.32 is used to compute cost. (The hourly wage for Personnel Training and Labor Relations Specialist as reported in the Bureau of Labor Statistics Occupational Employment Statistics Survey is \$19.03; benefits are computed at 38.3 percent of the hourly wage.) Thus, the incremental annual cost of the separate sharps injury log is:

$$(590,164 \text{ cases}) \times (0.08 \text{ hours/case}) \times (\$26.32/\text{hour}) = \$1,294,352.$$

In summary, OSHA estimates that the total annual cost of maintaining a sharps injury log will be \$1,294,352. This estimate is likely to overstate true costs for at least three reasons. First, for already recordable incidents, the data needed to maintain a separate sharps injury log are already collected and entered into a log format for other purposes, namely for the requirements set forth by 29 CFR Part 1904. It is unlikely that the data will need to be "re-entered." Instead, businesses are likely to develop procedures for automating the process or for organizing log information, thereby significantly reducing the incremental costs associated with this incremental action. For nonrecordable cases, the data collection required by the Needlestick Safety and Prevention Act and this revision to the BBP standard will be required under 29 CFR Part 1904 (once revisions to Part 1904 become effective), so that the incremental costs associated with the separate sharps injury log are short-term in nature. Finally, and perhaps most importantly, the above

cost estimate significantly overstates costs because it includes costs for all establishments in SIC 80. Under revisions to 29 CFR Part 1904, SICs 801, 802, 803, 804, 807, and 809 are exempted from recordkeeping requirements under Part 1904 and will thus not be required by this amendment to the BBP standard to keep a needlestick and sharps injury log. This is potentially significant because SICs 801, 802, 803, 804, 807, and 809 constitute 31 percent of employment for SIC 80, though not necessarily 31 percent of sharps injuries.

Cost of Solicitation of Employee Input

The cost associated with solicitation of employee input is comprised of three components: (1) The initial solicitation, conducted by a manager; (2) the employee response; and (3) documentation of the solicitation in the Exposure Control Plan.

The cost of the initial solicitation is likely to vary with establishment size, number of incidents, and employee interest. The establishments that will be

affected are those that are: (1) Required to develop an Exposure Control Plan, and (2) have employees who are involved in direct patient care and who are potentially exposed to needlestick injuries. The overwhelming majority of such establishments are in SIC 80, Health Services. County Business Patterns reports that in 1997 (1997 data are used as the most recent year for which data are available using the SIC reporting system), there were 502,724 establishments in SIC 80. OSHA estimates that the initial solicitation or call for employee input will require an average of 15 minutes (0.25 hours) of managerial time. The wage rate of a Medicine and Health Care Manager is \$33.22 per hour, including fringe benefits. (The hourly wage for a Medicine and Health Care Manager reported in the Bureau of Labor Statistics Occupational Employment Statistics Survey is \$24.02; benefits are computed at 38.3 percent of the hourly wage.) The estimated cost of the initial solicitation is:

$$(502,724 \text{ establishments}) \times (0.25 \text{ hours/establishment}) \times (\$33.22/\text{hour}) = \$4,175,080.$$

The cost associated with the employee response varies with the number of employees and the response rate to the initial solicitation. According to County Business Patterns, there were 11,348,141 individuals employed in SIC 80 in 1997. OSHA estimates that it will

require 15 minutes (0.25 hours) of employee time to respond to the solicitation and that approximately 33 percent of employees will respond. Using a wage rate of \$25.90 (which is the total hourly compensation in 1998 for professional specialty and technical

employees in Health Services reported in the Bureau of Labor Statistics publication *Employer Costs for Employee Compensation, 1986-1988*), the estimated costs associated with employee response are:

$$(11,348,141 \text{ employees}) \times (33\% \text{ response rate}) \times (0.25 \text{ hours/employee}) \times (\$25.90/\text{hour}) = \$24,248,140.$$

Note that it is implicitly assumed that input is solicited from *all* employees. This assumption will result in an overstatement of costs because the standard requires that input be solicited only from the fraction of employees who are involved in direct patient care and

who are potentially exposed to needlestick injuries.

Finally, the revised standard requires that the employer document the solicitation in the Exposure Control Plan. Because the affected employers are already required to establish a Plan, the incremental effort associated with this

documentation will be small. OSHA estimates that it will require only 15 minutes (0.25 hours) of managerial time. Thus, the total annual cost of documenting the solicitation in the Exposure Control Plan is estimated to be:

$$(502,724 \text{ establishments}) \times (0.25 \text{ hours/establishment}) \times (\$33.22/\text{hour}) = \$4,175,080.$$

In summary, OSHA has estimated the total cost of the solicitation to be \$32,598,300 (\$4,175,080 + \$24,248,140 + \$4,175,080). This estimate is likely to overstate the cost because employers have several avenues for achieving this requirement of the standard, many of which will reduce costs. For example, employers are not required to solicit input from all employees and could meet the requirement by, for example, consulting a properly constituted safety committee consisting of a subset of employees. In fact, recent state

legislation has mandated sharps safety committees in a number of states. In these situations, the only incremental cost associated with the solicitation mandated by this amendment to the BBP standard will be documentation of the solicitation in the Exposure Control Plan.

Total Cost and Cost Per Establishment

According to the above analysis, the maximum total annual cost of this action is \$33,892,653, consisting of \$1,294,352 associated with maintaining

a sharps injury log and \$32,598,300 associated with soliciting and documenting employee input into the Exposure Control Plan. This amounts to \$67 per establishment, per year, which will not cause significant economic impact on either large or small affected establishments.

V. Unfunded Mandates

OSHA has determined that, for the purposes of section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532), this rule does not include any

federal mandate that may result in increased expenditures by state, local, or tribal governments in the aggregate of more than \$100 million, or increased expenditures by the private sector of more than \$100 million. Moreover, the Agency has determined that for purposes of section 203 of the Act, this rule does not significantly or uniquely affect these entities.

Background

The Unfunded Mandates Reform Act was enacted in 1995. While much of the Act is designed to assist the Congress in determining whether its actions will impose costly new mandates on state, local, and tribal governments, the Act also includes requirements to assist federal agencies to make this same determination with respect to regulatory actions.

Analysis

As discussed in Section IV, Economic Analysis, this rule will have incremental costs of \$34 million per year, all of which are associated with maintaining the sharps injury log and soliciting and documenting employee information. These total costs represent an average cost of \$67 per year per affected establishment. OSHA does not anticipate any disproportionate budgetary effects upon any particular region of the nation, or particular state, local or tribal governments, or urban or rural communities.

VI. Environmental Impacts

The National Environmental Policy Act requires that "major Federal actions significantly affecting the quality of the human environment" be accompanied by a statement addressing the environmental impact of the proposed action. (42 U.S.C. 4332(C)) Department of Labor regulations establish a criteria for determining when an environmental impact statement is required in a rulemaking proceeding:

Preparation of an environmental impact statement will always be required for proposals for promulgation, modification or revocation of health standards which will significantly affect air, water or soil quality, plant or animal life, the use of land or other aspects of the human environment.

29 CFR 11.10 (a)(3)

OSHA has concluded that no significant environmental impacts would result from this rulemaking. This final standard expands the universe of engineering controls permissible for reducing occupational exposure to bloodborne pathogens. It also widens the scope of Exposure Control Plan review, requires maintenance of a sharps injury log, and mandates the

solicitation of input from employees on the identification, evaluation, and selection of effective engineering and work practice controls. The Agency has not identified any impacts of these requirements on the environment.

VII. Federalism

This standard has been reviewed in accordance with the Executive Order on Federalism (Executive Order 13132, 64 FR 43255, Aug. 10, 1999). The order requires that agencies, to the extent possible, refrain from limiting state policy options; consult with states prior to taking actions that would restrict state policy options; and take such action only when there is clear constitutional authority and the presence of a problem of national scope. Executive Order 13132 also provides that agencies shall not promulgate regulations that have significant Federalism implications and impose substantial direct compliance costs on state or local governments, unless the agency consults with state and local officials early in the process of developing the proposed regulation and provides a summary Federalism impact statement in the preamble of the final rule. Finally, the Order provides for preemption of state law only if there is a clear Congressional intent for the agency to do so, and provides that any such preemption is to be limited to the extent possible.

Under Section 6(b) of the Executive Order, an agency is exempt from state consultation requirements if it is promulgating a regulation that is required by statute. The amendments to OSHA's BBP standard codified in this rule were explicitly written by Congress and enacted as Public Law 106-430. Moreover, Congress clearly intended the revised BBP standard to have the same legal effect as other standards issued under 6(b) of the Occupational Safety and Health Act of 1970. Nonetheless, OSHA has consulted extensively with those 25 States and territories that operate OSHA-approved State plans with regard to OSHA policy on safe needle devices and the requirements of the subject legislation.

Section 18 of the OSH Act expresses Congress' intent to preempt state laws relating to issues on which Federal OSHA has promulgated occupational safety and health standards. Under the OSH Act, a state can avoid preemption only if it submits, and receives Federal approval for, a State plan for the development and enforcement of standards. OSHA-approved State plans operate under authority of State law and must adopt occupational safety and health standards which, among other

things, must be at least as effective in providing safe and healthful employment and places of employment as Federal standards.

In *Gade v. National Solid Wastes Management Assoc.*, the U.S. Supreme Court reaffirmed the view that Section 18 of the OSH Act effectively preempts states without approved plans from adopting or enforcing any laws that directly, substantially, and specifically regulate occupational safety and health. 505 U.S. 88, 107 (1992). However, needlestick laws in states without an OSHA-approved State plan would not be affected to the extent to which they regulate the occupational safety and health conditions of state or local government employees (see Section 3(5) of the OSH Act).

VIII. State Plan States

The 23 states and 2 territories that operate their own federally approved occupational safety and health plans must adopt a comparable amended standard within six months of the publication date of a final Federal OSHA standard. The States and territories with this obligation include: Alaska, Arizona, California, Connecticut (for State and local government employees only), Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York (for State and local government employees only), North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming. Until such time as state and territorial standards are amended, Federal OSHA will provide interim enforcement assistance, as appropriate.

IX. Paperwork Reduction Act

This final rule contains new collection of information (paperwork) requirements in revisions to the Bloodborne Pathogen Standard (1910.1030 and 1915.1030) made as a result of the Needlestick Safety and Prevention Act (Pub. L. 106-430). These new paperwork requirements are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA 95), 44 U.S.C. 3501 *et seq.*, and its regulation at 5 CFR Part 1320. OSHA solicits public comments concerning its estimate of the burden hours and costs for the revised paperwork requirements. The Agency will summarize the comments received and include a summary of them in its request to OMB to approve the information collection requirements; they will also become a matter of public record. OSHA seeks this information as part of its continuing effort to reduce

paperwork and respondent burden. The information helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed.

The Needlestick Safety and Prevention Act requires employers, who have exposure control plans in accordance with § 1910.1030 (c)(1)(iv), "to review and update such plans to reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens." The exposure control plan must also "document consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure." Employers required to have exposure control plans must also "solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan."

The Needlestick Safety and Prevention Act also requires employers, who currently maintain a log of occupational injuries and illnesses under 29 CFR 1904, to "establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps." The information in the sharps injury log must be recorded and maintained so that the confidentiality of the injured worker is protected. The log must contain at least the following information: "(A) the type and brand of device involved in the incident; (B) the department or work area where the exposure incident occurred; and (C) an explanation of how the incident occurred."

Respondents are not required to comply with collection of information (paperwork) requirements unless a currently valid OMB control number is displayed (§ 1320.5 (b)(2)(i)). OSHA will publish the OMB control number as soon as it receives approval on its ICR for the revised collections. A copy of the Agency's revised ICR for the BBP standard is available for inspection and copying as part of Docket ICR1218-0180(2000) in the OSHA Docket Office, U.S. Department of Labor, Room N-2625, 200 Constitution Avenue, NW., Washington, DC 20210, or you may request a mailed copy by telephoning Todd Owen at (202) 693-2444.

Comments on the ICR should be submitted to the Docket Office, Docket Number ICR-0180 (2001), OSHA, U.S. Department of Labor, Room N-2625, 200 Constitution Avenue, NW., Washington, DC 20210, telephone: (202) 693-2350. Commenters may transmit written comments of 10 pages or less in length by facsimile to (202) 693-1648.

The Department and OMB are particularly interested in comments that

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Title: Bloodborne Pathogens standard (29 CFR 1910.1030).

OMB Number: 1218-0180 (Revision).

Frequency: Employers must: annually review their exposure control plans; initially establish and maintain a sharps injury log; as necessary, make injury recordings in the log; and solicit input from non-managerial employees.

Affected Public: The respondents are those employers that must maintain an exposure control plan, and employers who are required to maintain a log of occupational injuries and illnesses under 29 CFR part 1904.

Total Respondents: 502,724 establishments.

Average time per response: Three to five minutes for employers to record needlestick incidents; fifteen minutes for employers to solicit non-managerial employees on effective engineering and work practice controls; fifteen minutes for employers to modify their existing exposure control plans.

Estimated Burden Hours: 49,180 hours for employers to log needlestick incidents; 125,681 hours for employers to solicit non-managerial employees; and 125,681 hours for employers to update existing exposure control plans.

Estimated Cost (Operation and Maintenance): 0.

X. Authority and Signature

This document was prepared under the direction of Charles N. Jeffress, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Accordingly, pursuant to sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657) and the Needlestick Safety and Prevention Act (Pub. L. 106-430, 114 Stat. 1901, November 6, 2000); and Secretary of Labor's Order No. 3-2000 (65 FR 50017), 29 CFR part 1910 is amended as set forth below.

List of Subjects in 29 CFR Part 1910

Blood, Blood diseases, Health, Healthcare, Hepatitis B virus, Hepatitis C virus, Hospitals, Human immunodeficiency virus, Needlestick, Occupational safety and health, Sharps injury.

Signed at Washington, DC, this 10th day of January 2001.

Charles N. Jeffress,

Assistant Secretary of Labor for Occupational Safety and Health.

XI. Amended Final Rule and Appendix

The Occupational Safety and Health Administration is amending part 1910 of title 29 of the Code of Federal Regulations as follows:

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

1. The authority citation for 29 CFR part 1910, subpart Z, is revised to read as follows:

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12-71 (36 FR 8754), 8-76 (41 FR 25059), 9-83 (48 FR 35736), 1-90 (55 FR 9033), 6-96 (62 FR 111), or 3-2000 (65 FR 50017), as applicable; and 29 CFR part 1911.

All of subpart Z issued under Sec. 6(b) of the Occupational Safety and Health Act, except those substances that have exposure limits listed in Tables Z-1, Z-2, and Z-3 of 29 CFR 1910.1000. The latter were issued under Sec. 6(a) (29 U.S.C. 655(a)).

Section 1910.1000, Tables Z-1, Z-2 and Z-3 also issued under 5 U.S.C. 553, Section 1910.1000 Tables Z-1, Z-2, and Z-3 not issued under 29 CFR part 1911 except for the arsenic (organic compounds), benzene, and cotton dust listings.

Section 1910.1001 also issued under section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 333) and 5 U.S.C. 553.

Section 1910.1002 not issued under 29 U.S.C. 655 or 29 CFR part 1911; also issued under 5 U.S.C. 553.

Sections 1910.1018, 1910.1029 and 1910.1200 are also issued under 29 U.S.C. 653.

Section 1910.1030 is also issued under Pub. L. 106-430, 114 Stat. 1901.

* * * * *

2. Section 1910.1030 is amended as follows:

A. In § 1910.1030, paragraph (b), the definition for "Engineering Controls" is revised and definitions are added in alphabetical order to read as set forth below:

B. Paragraph (c)(1)(iv) is revised to read as set forth below:

C. Paragraph (c)(1)(v) is redesignated paragraph (c)(1)(vi), and a new paragraph (c)(1)(v) is added to read as set forth below:

D. A new paragraph (h)(5) is added to read as set forth below:

§ 1910.1030 Bloodborne pathogens.

* * * * *

(b) * * *

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.

* * * * *

Needleless systems means a device that does not use needles for:

(1) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established;

(2) The administration of medication or fluids; or

(3) Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

* * * * *

Sharps with engineered sharps injury protections means 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.

* * * * *

(c) * * *

(1) * * *

(iv) The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure. The review and update of such plans shall also:

(A) Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and

(B) Document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.

(v) An employer, who is required to establish an Exposure Control Plan shall solicit input from non-managerial employees responsible for direct patient

care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan.

* * * * *

(h) * * *

(5) *Sharps injury log.* (i) The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum:

(A) The type and brand of device involved in the incident,

(B) The department or work area where the exposure incident occurred, and

(C) An explanation of how the incident occurred.

(ii) The requirement to establish and maintain a sharps injury log shall apply to any employer who is required to maintain a log of occupational injuries and illnesses under 29 CFR 1904.

(iii) The sharps injury log shall be maintained for the period required by 29 CFR 1904.6.

* * * * *

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