

INDIANA UNIVERSITY



BLOODBORNE PATHOGENS EXPOSURE CONTROL PLAN

**BIOSAFETY COMMITTEE
OFFICE OF THE VICE PRESIDENT FOR RESEARCH ADMINISTRATION
OFFICE OF ENVIRONMENTAL HEALTH AND SAFETY MANAGEMENT**

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- A. Occupational Exposure to Bloodborne Pathogens - The OSHA Standard (29 CFR 1910.1030)
- B. Hepatitis B Vaccination Acceptance/Declination Policy and Form
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- E. Department/Sub-Unit Exposure Determination List
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1.0 INTRODUCTION

1.1 OSHA Regulation

On December 6, 1991, the Occupational Safety and Health Administration (OSHA) promulgated a final rule entitled "Occupational Exposure to Bloodborne Pathogens" (see Appendix A). The purpose of this standard is to eliminate or minimize occupational exposure to the Hepatitis B virus (HBV), Human immunodeficiency virus (HIV), and other bloodborne pathogens. The schedule for implementation of the program elements is given in paragraph (i) (1-4) of the standard.

It has been well documented that employees with occupational exposure to blood and other potentially infectious materials containing bloodborne pathogens face a significant health risk. This risk can be minimized or eliminated using a combination of engineering and work practice controls, administrative controls, personal protective clothing and equipment, training, medical surveillance, Hepatitis B vaccination, warning signs or labels, and other provisions described in this plan.

1.2 Definitions

Blood - human blood, human blood components, and products made from human blood.

Bloodborne Pathogens - pathogenic microorganisms that are present in human blood and can cause disease in humans. These include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).

Contaminated - the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

Contaminated Sharps - any contaminated object that is sharp or has the potential to be a sharp that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

Decontamination - the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on an item or surface to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

HBV - Hepatitis B Virus.

HCV - Hepatitis C Virus.

HIV - Human Immunodeficiency Virus.

Occupational Exposure - any reasonably anticipated skin, eye, mucous membrane, or parenteral contact (i.e. piercing through the skin or splashing of mucous membrane) with blood or other potentially infectious materials (see below) that may result from the performance of an employee's duties.

OPIM - Other Potentially Infectious Material.

Other Potentially Infectious Material (OPIM) - materials other than blood, which pose a potential health risk including:

- 1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;
- 2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead);
- 3) HIV-containing cell or tissue cultures, organ cultures, and HIV-or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV;
- 4) Blood or body fluids of animals that have been intentionally or are suspected of having been exposed to human bloodborne pathogens in research, in production of biologicals, in the in vivo testing of pharmaceuticals, or other procedures.

PPE - Personal Protective Equipment. Specialized clothing or equipment worn by an employee for protection against a hazard.

Regulated Waste - liquid or semi-liquid blood or other potentially infectious material; contaminated items that would release blood or other potentially infectious material in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious material.

Sterilize - the use of a physical or chemical procedure to destroy all microbial life.

Universal Precautions - An approach to infection control, which treats all blood and other potentially infectious materials as if known to be infectious for HIV, HBV, and other bloodborne pathogens. This approach includes the use of barrier precautions by employees to prevent direct skin, parenteral, or mucus membrane contact with blood or other body fluids that are visibly contaminated with blood.

1.3 Bloodborne Pathogens of Concern in Occupational Exposure

Hepatitis B virus and human immunodeficiency virus are the two bloodborne pathogens of greatest concern for occupational exposure. The elements of this exposure control plan shall also provide protection against other bloodborne diseases such as hepatitis C, syphilis, malaria, babesiosis, brucellosis, leptospirosis, arboviral infections, relapsing fever, Creutzfeldt-Jakob disease, human T-lymphotropic virus type I, and viral hemorrhagic fever.

1.3.1 Hepatitis B and C Viruses (HBV, HCV)

Hepatitis B virus infection is the major bloodborne occupational hazard to health care workers. Symptoms of the acute form of the disease may range from none, to mild flu-like symptoms, or to more severe symptoms including jaundice, extreme fatigue, anorexia, nausea, and abdominal pain. Outcomes of acute forms of the infection may include hospitalization, weeks to months of work loss, and, in severe cases, death.

An estimated 6% to 10% of adults infected with hepatitis B virus become chronic HBV carriers, capable of infecting other individuals. HBV carriers are at high risk of developing chronic persistent hepatitis, chronic active hepatitis, cirrhosis of the liver and primary liver cancer.

Hepatitis C virus infection is a disease which affects the liver. There is no vaccine for HCV although there are some antiviral medications available that may help reduce the risk of developing liver disease if exposure occurs.

There are several ways in which the viruses can be transmitted. The most efficient and common means of occupational transmission is parenteral, or the direct inoculation of infectious material by piercing through the skin barrier. In the workplace this might occur as a result of needlestick or other accidental injury with a sharp, contaminated object which is capable of penetrating the skin. Direct inoculation is also possible when preexisting lesions on hands from other injuries or from dermatitis provide a route of entry for the virus to enter the body.

A second mode of transmission is for infected blood to contact mucous membranes of the eye, nose, or mouth. Therefore, a splash of blood or serum into an individual's unprotected eyes or mouth poses a risk of transmission of infection. Hepatitis B can also be transmitted sexually, and perinatally (from infected mother to newborn infant). Hepatitis C is primarily transmitted parenterally. These modes of transfer indicate that occupational exposure to this pathogen can also have serious implications for the spouses, sexual partners, and families of infected individuals.

1.3.2 Human Immunodeficiency Virus (HIV)

HIV affects the immune system, leading to a wide range of clinical disorders, including AIDS, which usually lead to the death of the HIV infected patient. HIV is known to be

transmitted through blood, semen, vaginal secretions and breast milk. Documented modes of transmission include:

- Engaging in sexual intercourse with an infected person
- Using contaminated needles
- Having parenteral, mucous membrane or non-intact skin contact with HIV-infected blood, blood components or blood products
- Receiving transplants of HIV-infected organs or tissues.
- Through blood transfusions
- Through semen used for artificial insemination
- Perinatal transmission

Exposure to HIV may occur through the physical contact described above with an infected individual or with specimens from infected individuals, from parenteral exposure (accidents involving a needle, scalpel, or other sharp instrument or object which has been contaminated with blood or body fluids from an HIV-infected individual), or by splashes of infected blood or other body fluids to the mucous membranes of the mouth, nose, or eyes.

HIV is not transmitted by casual contact such as: shaking hands, talking, sharing of food, eating utensils, plates, drinking glasses, or towels, sharing the same household facilities, hugging, or casual kissing on the cheek or lips.

1.4 Applicability

The Bloodborne Pathogens Exposure Control Plan applies to all employees, including part-time, temporary, probationary, and employed students, who may as part of their jobs come into contact with persons, unconditioned primate animals, or items which are infectious or potentially infectious for bloodborne pathogens on a daily or near daily basis.

Health care and laboratory employees whose work may involve the risk of exposure to blood or other potentially infectious materials may include, but are not limited to the following: physicians, surgeons, nurses, nurses aides, physician's assistants, pathologists, phlebotomists, medical technologists, medical assistants, therapists, therapy assistants, paramedics, emergency medical technicians, dentists, dental hygienists, dental assistants, dental lab technicians, laboratory and blood bank technologists, research laboratory personnel, research scientists, medical and dental teaching faculty, graduate students, associate instructors and animal laboratory personnel.

Others whose positions may include some occupational exposure tasks include workers in: law enforcement, daycare facilities, sterilization services, janitorial/housekeeping services, laundry services, maintenance, central supply, equipment technicians, transportation service workers, or couriers involved in delivery and transport of potentially infectious materials.

2.0 *EXPOSURE CONTROL PLAN RESPONSIBILITIES*

2.1 **Human Fluids and Tissue Biosafety Subcommittee**

- Members of the Human Fluids and Tissue Biosafety Subcommittee will include the Institutional Biosafety Committee (IBC) Chair, the Biosafety Officer, and representatives from the IU Health Center, the Office of Environmental Health and Safety Management (EH&S), and the Office of Risk Management.
- Provide overall administrative guidance and supervision for the Exposure Control Plan for Biosafety Level 2 (BSL 2) and Biosafety Level 3 (BSL 3) laboratories.
- Review and update the campus Exposure Control Plan annually and as new information becomes available (see Appendix L).

2.2 **Biosafety Officer**

- Aid BSL 2 and BSL 3 laboratories in determining those employment positions or tasks that qualify for reasonable anticipation of exposure to bloodborne pathogens.
- Provide training to all staff employees in BSL 2 and BSL 3 laboratories who have potential occupational exposure to bloodborne pathogens.
- Aid BSL 2 and BSL 3 laboratories in determining appropriate personal protective equipment, work practices, engineering controls, and housekeeping schedules.
- Ensure that records are maintained for BSL 2 and BSL 3 laboratories whose employees have been trained or vaccinated for Hepatitis B in this program.

2.3 **Office of Environmental Health and Safety Management**

- Review and update the campus Exposure Control Plan annually and as new information becomes available (see Appendix L).
- Provide overall administrative guidance and supervision for the Exposure Control Plan for all laboratories and workplaces except BSL 2 and BSL 3 laboratories.
- Aid these departments or sub-units in determining those employment positions or tasks that qualify for reasonable anticipation of exposure to bloodborne pathogens.
- Provide training to all those staff who have potential occupational exposure to bloodborne pathogens and whose departments or sub-units do not provide training internally.

- Aid these departments or sub-units in determining appropriate personal protective equipment, work practices, engineering controls, and housekeeping schedules.
- Ensure that records are maintained for those employees trained and Hepatitis B vaccinated in this program.

2.4 Indiana University Health Center

- Provide hepatitis B vaccination campus wide to eligible employees.
- Maintain employee records relative to hepatitis B vaccination.
- Evaluate employees and students reporting exposure incidents and provide appropriate diagnostic tests, treatment, and follow-up evaluation and counseling.
- Maintain employee records relative to post-exposure incidents and treatment.

2.5 Promptcare East

- Evaluate employees reporting exposure incidents and provide appropriate diagnostic tests, treatment, and follow-up evaluation and counseling.
- Maintain employee records relative to post-exposure incidents and treatment.

2.6 Department Heads, Managers, and Supervisors

- Identify those employment positions within each department or appropriate sub-unit, which fit the definition of "occupational exposure" described in Section 1.2 and specify those tasks or procedures in which occupational exposure is likely to occur.
- Customize the Exposure Control Plan for specific areas by adding appropriate information for each department or sub-unit in Appendices E, F, G, H, and I of this document.
- Enforce all elements of the Exposure Control Plan within the work setting and initiate progressive disciplinary proceedings when necessary as outlined by Human Resources Administration.
- Ensure that all existing and new employees are informed and trained in all elements of the Exposure Control Plan.

- Provide ongoing evaluation of the elements provided in Appendices E-I and update or modify them as needed to reflect current knowledge on effective infection control procedures, work practice controls, personal protective equipment and engineering controls which are likely to reduce the frequency of exposure incidents.

2.7 Employees

- Attend annual, required training sessions on controlling exposure to bloodborne pathogens in the workplace.
- Comply with all elements of the Exposure Control Plan, which apply to work-related tasks and procedures with potential exposure, including the use of personal protective equipment and appropriate work practice controls.
- Report all exposure incidents to the work supervisor or other responsible individual immediately, or as soon as feasible, after they occur.

3.0 EXPOSURE DETERMINATION

The Exposure Control Plan applies to all employees with potential occupational exposure to bloodborne pathogens. Each department shall list employment positions and tasks that create potential exposure (see Appendix E). Each department shall then identify their staff members who are a part of the employment positions listed or are required to complete any listed tasks. Staff members identified in this manner are a part of this Bloodborne Pathogens Program and must comply with all aspects of the Exposure Control Plan. This exposure determination shall be made without regard to the use of personal protective equipment. All employees must be notified concerning their occupational exposure status.

4.0 PROCEDURES AND EQUIPMENT FOR REDUCING EXPOSURE RISKS

4.1 Universal Precautions

Universal precautions refer to approaches to infection control in which all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, HCV, or other bloodborne pathogens. These approaches recognize that there is no practical way to determine the health status of all persons who may be sources of bloodborne pathogens.

Using this assumption when dealing with infectious materials eliminates the need for decision-making to determine the extent of actual or potential disease hazards and establishes minimum standards for contamination control, which will effectively control bloodborne pathogens if they are present.

Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. In situations where differentiation between body fluid types is difficult or impossible (e.g. poor lighting, uncontrolled or emergency situations), all body fluids shall be considered potentially infectious materials.

4.2 Engineering Controls

Engineering controls include all measures designed to reduce the potential for contact between workers and potentially infectious materials by either removing the hazard or isolating the worker from exposure. Examples of engineering controls include puncture resistant sharps containers, plexiglass splash shields, mechanical pipettes, self-sheathing needles, biological safety cabinets, and use of disposable barrier materials to cover and prevent contamination of environmental surfaces and equipment.

Appropriate engineering controls shall be provided by each department and should be used in preference to other control methods in order to limit occupational exposure. (see Appendix F) Provision of these controls is the joint responsibility of the supervisor and the department head.

Engineering control mechanisms shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness. Each department or appropriate sub-unit shall be responsible for evaluation and maintenance of engineering controls in their area and is the joint responsibility of the supervisor and the department head. (see Appendix F) These responsibilities shall include:

- Scheduling of inspections. [Biological safety cabinets are to be certified at least annually according to the National Sanitation Foundation.]
- Written documentation of the following: inspection dates, evaluations, maintenance performed, and persons responsible.

4.3 Work Practice Controls

Work practice controls are those measures, which reduce the likelihood of exposure by altering the manner in which a task is performed. Specific work practices required in addition to those listed below should be specified for each department or sub-unit in Appendix G of their Exposure Control Plan. The following work practice controls shall be instituted for employees with occupational exposure on a daily or near daily basis to blood and other potentially infectious material.

4.3.1 Hand Washing

- Readily accessible hand washing facilities, shall be provided for employees whenever possible.
- When hand-washing facilities are not available, employees shall be provided with antiseptic towelettes or an antiseptic hand cleanser and clean cloth/paper towels. When these alternatives are used, employees shall wash their hands with soap and water as soon as feasible.
- Hands and any other exposed skin surfaces must be washed with soap and running water and mucous membranes should be flushed with water as soon as possible after contact with blood or other potentially infectious material.
- Hands must be washed as follows:
 - a) Whenever there is visible contamination with blood or body fluids;
 - b) After completion of work;
 - c) After removing gloves and between glove changes;
 - d) Before leaving the work area;
 - e) Before eating, drinking, smoking, applying cosmetics or lip balm, changing contact lenses;
 - f) When using lavatory facilities;
 - g) Before all other activities which entail hand contact with mucous membranes, eyes or breaks in the skin.

4.3.2 Handling Contaminated Sharps

Any object, which is contaminated with blood or OPIM and is capable of penetrating the skin, is considered a contaminated sharp. Breakable equipment or supplies are potential sharps if they can create surfaces capable of penetrating the skin. Examples of sharps include needles, scalpels, broken capillary tubes, certain dental instruments, and exposed ends of dental wires. Needlesticks are an efficient means of transmitting bloodborne diseases. Because of their high potential for transmitting bloodborne pathogens to employees, contaminated sharps should be handled as follows:

- Contaminated needles and other contaminated sharps or potential sharps shall not be recapped, removed or bent unless no alternative is feasible or unless required by a specific medical procedure (e.g. procedures such as blood gas analysis, inoculation of a blood culture bottle, or administration of incremental doses of medication to a single patient).

- In situations where recapping or needle removal is required, it shall be accomplished only by means of a mechanical device or a one-handed technique.
- All contaminated sharps shall be transferred to rigid, puncture-resistant, labeled, leak-proof containers immediately or as soon as possible after use; they may not be stored or handled prior to decontamination in such a way as to require employees to reach their hands into the container to retrieve the item.

4.3.3 Other Work Practice Controls

- All procedures involving direct handling of blood or other potentially infectious material should be accomplished in a manner, which minimizes splashing, spraying, spattering, or aerosol production of other potentially infectious material.
- Mouth pipetting/suction of other potentially infectious material and all other material is prohibited.
- Specimens of blood or other potentially infectious material must be placed in labeled containers, which prevent leakage and are of sufficient strength to prevent expulsion during collection, handling, processing, storage, transport, or shipping, and must comply with IATA regulations. The following container requirements must be met:
 - a) These containers must be closed prior to storage, transport or shipping.
 - b) Biohazard labeling or color-coding is required on each container, which leaves the University.
 - c) The specimen must be placed in a second container, which meets the same provisions as above if the outside of the primary container becomes contaminated or if the specimen could puncture the primary container.

For detailed shipping and labeling instructions of biohazardous materials contact the Biosafety Officer, 856-3638.

- Contaminated equipment must be decontaminated, if feasible, using approved methods prior to servicing or shipment. When such decontamination is not feasible, the equipment must be clearly labeled as a biohazard (see section 8.0) to alert employees, as well as transportation and service personnel of the need to use universal precautions in transporting items for disposal.
- Eating, drinking, smoking, applying cosmetics, and handling contact lenses are prohibited in work areas where blood or OPIM are used or stored.
- Food or drink storage is prohibited in work areas (e.g. refrigerators, freezers, shelves, cabinets, counter tops, bench tops) where blood or OPIM are used or stored.

- Refrigerators or freezers used for storage of blood or specimens may not be used for storage of food or drink.

4.4 Personal Protective Equipment (PPE)

Personal protective equipment includes any item, which the employee wears or uses on his/her person to provide barrier protection of the skin or mucous membranes from contamination by blood or other potentially infectious material. Examples include: gloves, gowns, lab coats, face shields, masks, eye protection, mouthpieces, resuscitation bags, pocket masks, and other ventilation devices.

The use of appropriate PPE is required as supplementary protection in all situations where occupational exposure remains after institution of both engineering controls and work practice controls. The use of appropriate PPE is required for all employees when engaged in tasks involving contact with blood, body fluids, or any potentially infectious material for whom occupational exposure is reasonably anticipated.

The only exception to this requirement shall be those rare and extraordinary occasions when, in the professional judgment of the employee, wearing of required PPE would have prevented delivery of health or public safety services or would have posed an increased hazard to the employee or coworkers. Such situations must be investigated and documented to determine whether such occurrences can be prevented.

4.4.1 Provision and Use of PPE

Each department or appropriate sub-unit shall determine appropriate types of PPE necessary to provide barrier protection for their employees (see Appendix H). Appropriate PPE shall be readily accessible to all employees for whom it is required and shall be provided in appropriate sizes.

The determination of the exact types of PPE is dependent on the procedure(s) being performed by each employee and the type and amount of exposure which is anticipated. PPE shall be judged as appropriate only if it does not permit blood or other potentially infectious materials to pass through or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment shall be used.

Departments shall provide clean, laundered and/or disposable PPE at no cost to the employee. Only those items of clothing intended to protect the employee's person, work clothes, or street clothes against contact with blood or OPIM are considered to be PPE in this context.

4.4.2 Gloves

Gloves must be worn by all employees when performing tasks involving contact with blood, certain body fluids, OPIM, or when handling or touching contaminated items or surfaces.

- **Glove Selection**

The type of gloves (e.g. sterile surgical, non-sterile examination, or utility gloves) selected should be impervious to liquids and strong enough to withstand the rigors of the task to be performed. Use of vinyl or latex gloves is intended to cover defects in the skin on the hands and is not intended to provide protection from wounds caused by sharps.

The following guidelines are recommended by the Centers for Disease Control (Morbidity and Mortality Weekly Report, Vol. 24, 6/24/88):

- a) Sterile gloves should be used for procedures involving contact with normally sterile areas of the body.
- b) Examination gloves should be used for procedures involving contact with mucous membranes, unless otherwise indicated, and for other patient care or diagnostic procedures that do not require the use of sterile gloves.
- c) Surgical and examination gloves may not be re-used. Washing gloves with soap or detergents may cause enhanced penetration of liquids through undetected holes in the glove. Disinfecting agents may cause deterioration.
- d) Use general-purpose utility gloves (e.g. rubber household gloves) for housekeeping chores involving potential blood contact and for instrument cleaning and decontamination procedures. Utility gloves may be decontaminated and reused but should be discarded if they are peeling, cracked, discolored, punctured, torn, or if there is other evidence of deterioration.

- **Changing Gloves**

Gloves shall be changed under the following circumstances:

- a) Between patient contacts.
- b) If visibly contaminated with blood or body fluids (although certain repetitive tasks in laboratory settings may be completed before gloves are changed, i.e. wiping the probe on a whole blood analyzer).
- c) When physical damage to the integrity of the glove is observed (e.g. tearing, surface defects).

- Contaminated disposable gloves should be discarded into a biohazard container immediately after removal.
- Employees with known minor skin defects (e.g. cuts, abrasions, burns, dermatitis, or exudative lesions) on arms, hands, face or neck must cover these areas with a water-resistant occlusive bandage in addition to the use of personal protective equipment.
- Employees with weeping or exudative lesions or dermatitis, which cannot be securely covered, shall refrain from direct patient care and handling clean or soiled patient equipment. (Indiana State Board of Health 410 IAC 1-4-8 Precautions).

4.4.3 Masks, Eye Protection, and Face Shields

These barrier devices are intended to protect the eyes, nose and mouth from coming into contact with blood or body fluid droplets. Examples are disposable facemasks, plastic or disposable face shields, protective eyeglasses with non-permeable side vents, and goggles.

Employees shall wear protective face shields or masks, and eye protection whenever splashes, spray, spatter or droplets of blood or OPIM may be generated and eye, nose or mouth contamination can be reasonably anticipated. Plexiglas splash shields, either bench mounted or hung from the ceiling or from a ring stand, may be used in place of facial personal protective equipment. These protective devices shall be used while uncapping all blood or body fluid samples when the risk of droplet formation and spattering is present (e.g. when uncapping sample tubes).

Employees shall remove masks, eye protection, and face shields when leaving the work area. All disposable masks and shields shall be discarded in an infectious waste container when visibly contaminated or penetrated by blood or OPIM. Reusable eye wear and shields, which are visibly contaminated, should be washed with soap and water using gloved hands.

4.4.4 Protective Body Clothing

Protective body clothing, such as gowns, lab coats, lab jackets, or aprons, shall be provided when needed to cover and protect work clothing and exposed skin from contamination with potentially infectious blood or body fluids. Use of protective clothing may be required during patient treatment, when handling contaminated materials, or during decontamination procedures.

Protective gowns or laboratory coats may be made of cloth or of disposable impervious material depending on the degree and type of contamination, which is anticipated. Protective clothing items should be long-sleeved and kept buttoned or fastened at all times to maximize protection of exposed skin and work clothes.

All protective clothing items shall be removed before leaving the laboratory or work area; contaminated or soiled gowns or coats may not be worn in public areas. Public areas include, but are not limited to, employee break rooms, lounges, eating areas, storage areas, and rest rooms. Protective clothing shall be changed immediately, or as soon as possible, after becoming visibly contaminated with blood or body fluids.

Contaminated gowns or coats shall be laundered or disposed of according to Biosafety Committee policy for infectious waste or contaminated linen. Disposable gowns shall be discarded in biohazard containers or bags. Protective clothing may not be taken home to be washed or discarded.

4.4.5 Cardiopulmonary Resuscitation Masks

Employees whose tasks include participation in cardiopulmonary resuscitation (CPR) shall use a one-way mask when performing mouth-to-mouth resuscitation. Masks shall be provided and made readily available wherever the need for CPR may be reasonably expected to occur (Source: Indiana Department of Health 410 IAC 1-4-8).

4.5 Housekeeping

All work areas shall be maintained in a clean and sanitary condition. To ensure this, each department or sub-unit shall establish and implement a written schedule for specific cleaning and methods of decontamination for affected work areas (see Appendix I). Frequency and methods of decontamination should be based on the location within the facility, the type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the work area. These schedules and instructions must be responsive to the following elements:

- All equipment and working surfaces must be cleaned, then decontaminated after contact with blood or OPIM.
- Contaminated work surfaces must be decontaminated with an appropriate disinfectant at the following times:
 - a) After completion of procedures;
 - b) Immediately, or as soon as possible, after surfaces are overtly contaminated or after any spill of blood or OPIM; and
 - c) At the end of the work shift if the surface may have become contaminated since the last cleaning.

- Solutions which are acceptable disinfectants include, but are not limited to the following:
 - a) Sodium hypochlorite, five-tenths percent (0.5%) concentration, by volume (common household bleach should be diluted 1 part bleach to 10 parts water). The solution shall be dated and shall not be used if it is more than 24 hours old.
 - b) Isopropyl alcohol (rubbing alcohol) at a seventy percent (70%) concentration by volume (Indiana State Board of Health; 410 IAC 1-4-8 Precautions, Oct. 6, 1989).
 - c) Other chemical agents, which have an Environmental Protection Agency (EPA) registration number and that, meet hospital level disinfection standards.
 - d) Only chemical agents that have an EPA registration number and a TB kill claim as required by CDC may be used in the Health Center.
- The use of protective barrier coverings such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper is useful in covering work surfaces or for covering equipment or items which may be difficult to clean and decontaminate effectively. When such barrier coverings are used, they must be removed and replaced as soon as they become overtly contaminated or at the end of the shift if they have become contaminated during the shift.
- All bins, pails, cans, or other receptacles which are re-used and which may become contaminated must be inspected and decontaminated on a regularly scheduled basis. These receptacles should also be cleaned and decontaminated immediately or as soon as possible once visible contamination is detected.
- Broken glassware, which might be potentially contaminated, should never be picked up with unprotected hands. Mechanical means such as a brush and dustpan, tongs, or forceps should be used. These items should then be disposed of in a puncture-resistant container, as for contaminated sharps.
- Reusable sharps, which are contaminated, should not be stored or processed in such a way that employees are required to reach by hand into containers where these sharps have been placed.

4.6 Containing and Handling Regulated Waste

4.6.1 Contaminated Sharps Containers

- All contaminated sharps and potential sharps must be discarded immediately after use, or as soon as possible into containers which meet the following requirements:
 - a) Closable and not able to be opened except by use of tools.
 - b) Puncture-resistant.

- c) Leak-proof on bottom and sides to prevent leakage of contaminated liquids.
 - d) Labeled using the universal biohazard symbol and the word "biohazard".
- Sharps containers must be easily accessible for use, maintained in an upright position during use, and replaced routinely so that they are not overfilled.
 - When moving containers of contaminated sharps, the containers must be closed so that their contents do not spill or protrude.
 - If leakage of the primary container is possible, it must be placed into a second container, which is closable, labeled, and shall safely contain all contents without leaking.
 - Reusable containers should not be opened, emptied, or cleaned manually or in any manner, which would expose employees to the risk of injury.

4.6.2 Other Regulated Waste Containers

- Regulated waste shall be placed in containers, which are closable and labeled using the universal biohazard symbol and the word "biohazard". Containers must be constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping. Containers must be closed prior to being handled, stored, or transported.
- If outside contamination of a regulated waste container occurs, it must be placed in a second container, which meets the requirements stated above.

4.7 Waste Treatment and Disposal

4.7.1 Health Center Procedures

Infectious waste generated in the Health Center is removed by a licensed vendor and disposed of in accordance with OSHA standard 1910.1030.

4.7.2 Non-Health Center Procedures

Infectious waste generated on campus at other than the Health Center may be autoclaved on site or collected and transported for treatment. If waste is autoclaved, the container must be labeled as "treated" prior to disposal with general refuse with the exception of syringes and sharps, which in addition to autoclaving must be incinerated. Note: any waste that contains human tissues or fluids must be disposed of as regulated waste, which will be collected by EHS and disposed of in accordance with OSHA standard 1910.1030.

If an autoclave is unavailable for treatment on site, collection and transportation must be handled by the originating department and prior arrangements made for disposal with the Office of Environmental Health and Safety Management.

4.8 Laundry

All employees who have contact with contaminated laundry must wear protective gloves and other appropriate personal protective equipment. All contaminated laundry shall be handled as little as possible with minimum agitation during handling. All contaminated laundry shall be bagged or put into containers at the location where it is used. It should not be sorted or rinsed prior to being placed in bags or containers. Bags or containers for contaminated laundry shall be clearly labeled or color-coded as containing potentially infectious material. When contaminated laundry is wet or when it is determined that there is a reasonable likelihood of leakage from the bag or container, it must be placed and transported in bags or containers which shall prevent liquids from soaking through or leaking to the exterior.

5.0 HIV/HBV RESEARCH LABORATORIES

5.1 Laboratory Inclusions and Exclusions

Any research laboratories or production facilities which are involved in the culture, production, concentration, experimentation, or manipulation of HIV or HBV must comply with the following OSHA special regulations affecting its activities in addition to the other requirements set forth in this plan. These regulations do not apply to clinical or diagnostic labs, which are engaged solely in the analysis of blood, tissues, or organs.

5.2 Safety Requirements for Both HIV, HBV, and HCV Research and Production Facilities

5.2.1 Standard Microbiological Practices

These facilities shall comply with standard microbiological practices as set forth by the CDC for Biosafety Level 2 (BL2). All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving, which is known to destroy bloodborne pathogens.

5.2.2 Special Practices

The following special practices shall also be instituted:

- Laboratory doors shall be kept closed when work involving HIV, HBV, or HCV is in progress.
- Contaminated materials, which leave the site, must be placed in durable, leak-proof, labeled containers that are closed before leaving the work area.
- Access to the work area shall be limited to authorized persons. Written entry and exit procedures and policies shall be established and implemented.

- Warning signs containing the universal biohazard symbol shall be posted on all access doors whenever potentially infectious materials or infected animals are present in the work area or containment module.
- All activities involving OPIM shall be conducted in biological safety cabinets or other physical-containment devices. No work with these OPIM shall be conducted on the open bench.
- Appropriate PPE must be used in the work area and animal rooms. PPE may not be worn outside the work area and must be decontaminated before being laundered.
- Gloves are required when handling infected animals or making hand contact with OPIM.
- Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters (or filters of equivalent or superior efficiency). Filters shall be checked routinely and maintained or replaced as needed.
- Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (those in which the needle is integral to the syringe), and preferably self-sheathing syringes shall be used for the injection or aspiration of other potentially infectious materials. Needles and syringes shall be handled with extreme caution at all times. Needles may not be bent, sheared, replaced in the sheath or guard, (unless resheathed by a one-handed method) or removed from the syringe after use. The needle and syringe shall be promptly placed in a puncture-resistant container and autoclaved or otherwise decontaminated before incineration.
- All spills shall be contained immediately and cleaned up by appropriate professional staff or by others who have been properly trained and equipped to work with concentrated potentially infectious materials.
- All spills or accidents, which result in an exposure incident, shall be reported immediately to the laboratory director, departmental chair, manager or supervisor.
- A biosafety manual shall be prepared or adopted and reviewed and updated at least annually. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures and shall be required to follow them.

5.2.3 Safety Equipment

Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices (e.g. special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, containment caging for animals) shall be used for all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols. Biological safety cabinets shall be certified when installed or when moved, and at least annually.

Each laboratory shall contain: readily available facilities for hand washing, an eye wash station, and an autoclave for decontamination of regulated waste.

5.3 Safety Requirements for HIV, HBV, and HCV Production Facilities

The following criteria shall apply to all HIV/HBV/HCV Production Facilities:

- Work areas shall be separated from areas open to unrestricted traffic flow within the building. Passage through two sets of doors shall be the basic requirement for entry into the work area from access corridors or other contiguous areas. Physical separation of the high-containment work area from access corridors or other areas or activities may also be provided by a double-doored clothes-change room (showers may be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area.
- Surfaces of doors, walls, floors and ceilings in the work area shall be water resistant and easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.
- Each work area shall contain a sink for washing hands and a readily available eye wash station. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.
- Access doors to the work area or containment module shall be self-closing.
- An autoclave for decontamination of regulated waste shall be available within, or as near as possible, to the work area.
- A ducted exhaust-air ventilation system shall be provided which creates directional airflow that draws air into the work area through the entry area. Exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes.

5.4 Training Requirements

Employees in HIV/HBV/HCV Laboratories and Production Facilities are required to meet the following training criteria in addition to the training requirements of Section 8.3:

- Demonstrated proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility must be established before employees are allowed to work with HIV or HBV.
- Employees must have had prior experience in handling human pathogens or tissue cultures before working with HIV, HBV or HCV.
- Employees who have had no prior experience handling human pathogens shall be provided with a training program. Initial work experience shall not include handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. Employees shall not be allowed to participate in work activities involving infectious agents until after proficiency with such agents have been demonstrated.

6.0 HEPATITIS B VACCINATION/SCREENING

The hepatitis B vaccine shall be made available to all employees who are identified as having potential occupational exposure on a daily or near daily basis to bloodborne pathogens. The IU Health Center shall provide HBV vaccinations for all employees in positions with the potential for occupational exposure. The Office of Risk Management will pay the vaccination expense.

Vaccinations shall be available to all existing employees with occupational exposure after receiving training regarding the risk of exposure to bloodborne pathogens and within 10 working days of initial assignment to jobs with occupational exposure. Vaccination is not indicated for employees who have already had the HBV series, who have had antibody testing documenting immunity to HBV, or who have medical contraindications to the vaccine. Pre-screening is not a prerequisite for receiving the vaccination.

Prior to receiving the vaccinations each employee must review and sign the “Hepatitis B Vaccination Policy” waiver found in Appendix B and online at:

<http://www.ehs.indiana.edu/publications.html>

Employees that accept the vaccinations must fill out an “Authorization for Treatment/Testing (Non-Injury/Illness)” form at:

<https://rmweb.indiana.edu/ORM/secure/OccHealthAuthEntry.cfm>

Any employee who initially declines the recommended vaccination may elect to accept it at a later date if still employed in a position with potential occupational exposure.

7.0 *POST-EXPOSURE EVALUATION AND FOLLOW-UP*

7.1 **Medical Examination After Exposure**

Exposure incidents are defined as any specific occupational incident involving eye, mouth, other mucous membrane, skin, or parenteral contact with blood or other potentially infectious materials. Employees are required to immediately report all exposure incidents to their work supervisor.

7.1.1 Biosafety Level 2 (BSL 2) or Biosafety Level 3 (BSL3) Laboratories and Animal Bites

Following a report of an exposure incident, the IU Health Center shall provide a confidential medical evaluation and follow-up to the employee and the Risk Officer for the Biosafety Committee for laboratory workers and any support staff entering these facilities or those with animal bites.

Exposure incidents must be documented on an Occupational Injury-Illness Report form available in each department or on-line at:

<https://rmweb.indiana.edu/ORM/secure/WCAuthEntry.cfm>

This completed form shall be provided to the IU Health Center with a copy to the Risk Officer for the Biosafety Committee at the time of medical evaluation and shall include the following information:

- The route(s) of exposure.
- The circumstances under which the exposure incident occurred.
- Identification and documentation of the source individual if possible; whenever possible, and with consent of the individual, the source should be tested to determine HIV, HBV, and HCV status unless it is already known. The results of these tests shall be disclosed to the exposed employee but may not be otherwise disclosed to preserve the confidentiality of the source individual.

7.1.2 All Laboratories and Workplaces except Biosafety Level 2 (BSL 2) and Biosafety Level 3 (BSL 3) Laboratories and Animal Bites

Promptcare East shall provide a confidential medical evaluation and follow-up to the employee and the the Office of Environmental Health and Safety Management (EHS) for workers and any support staff entering all laboratories and workplaces other than BSL 2 or BSL 3 laboratories or those with animal bites.

Exposure incidents must be documented on an “Occupational Injury/Illness Report Form” available in each department or on-line at:

<http://rmweb.indiana.edu/orm/SiteMap2.cfm> (click on “Work Comp” for the form)

This completed form shall be provided to Promptcare East with a copy to the Office of Environmental Health and Safety Management (EHS) for workers at the time of medical evaluation and shall include the following information:

- The route(s) of exposure.
- The circumstances under which the exposure incident occurred.
- Identification and documentation of the source individual if possible; whenever possible, and with consent of the individual, the source should be tested to determine HIV, HBV, and HCV status unless it is already known. The results of these tests shall be disclosed to the exposed employee but may not be otherwise disclosed to preserve the confidentiality of the source individual.

7.2 Collection and Testing of Blood for HIV/HBV/HCV Status

The testing of the exposed employee's blood shall be done as soon as feasible after obtaining consent. If the employee consents to baseline blood testing, but not to HIV testing, the samples must be stored and preserved for 90 days. If within that time the employee consents to further testing, it shall be done as soon as possible.

7.3 Post-Exposure Prophylaxis and Follow-Up

7.3.1 Biosafety Level 2 (BSL 2) or Biosafety Level 3 (BSL3) Laboratories and Animal Bites

The I.U. Health Center shall provide counseling to students, researchers, and all support staff and employees entering BSL 2 or BSL 3 laboratories or those with animal bites.

When post-exposure prophylaxis is medically indicated, the I.U. Health Center protocols for post-exposure prophylaxis to HBV or HIV shall be followed (see Appendix C) for students, researchers, and all other support staff and employees entering these work places.

A written evaluation of the exposure incident shall be provided to the student/employee within 15 days of the completion of evaluation (see Appendix D).

7.3.2 All Laboratories and Workplaces except Biosafety Level 2 (BSL 2) or Biosafety Level 3 (BSL 3) Laboratories and Animal Bites

Promptcare East shall provide counseling to students, researchers, and all support staff and employees from all laboratories or workplaces with exposure injuries other than BSL 2 and BSL 3 laboratories or those with animal bites.

When post-exposure prophylaxis is medically indicated, the Promptcare East protocols for post-exposure prophylaxis to HBV or HIV shall be followed for employees.

A written evaluation of the exposure incident shall be provided to the student/employee within 15 days of the completion of evaluation (see Appendix D).

8.0 *BIOHAZARD COMMUNICATION*

8.1 **Labels**

Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material. Labeling also applies to other outer containers used to store, transport or ship blood or other potentially infectious materials. Labels are also required for equipment to be serviced or transported that has parts that are unable to be decontaminated. These labels must identify which portions of the equipment remain contaminated.

These labels must meet the following criteria:

- Include the Biohazard legend depicted below:



- Have a fluorescent orange or orange-red colored background with lettering or symbols in a contrasting color.
- Be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

The following are exceptions to the labeling requirements:

- Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements.

- Individual containers of blood or OPIM that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.

8.2 Signs

Signs which are fluorescent orange or orange-red, with lettering or symbols in a contrasting color, and bearing the biohazard legend (see Section 8.1) shall be posted at the entrance to work areas for HIV and HBV research laboratories and production facilities.

8.3 Information and Training

All employees with occupational exposure to bloodborne pathogens shall participate in a training program, which shall be provided during working hours and at no cost to the employee. Training shall be provided to all existing employees falling under these regulations and at least annually. Supervisors must request training for all new employees at the time of initial assignment to tasks where occupational exposure may take place. Additional training shall be provided when changes occur which affect the employee's occupational exposure. These include the modification of tasks or procedures or the institution of new tasks or procedures.

The training program shall be designed so that content and vocabulary are appropriate for the educational level, literacy, and language of employees. Training shall be conducted by an individual who is knowledgeable in the subject matter covered in the content of the training program. The content of the training program shall contain at a minimum the following elements:

- A copy of the standard and explanation of its contents.
- A general explanation of the epidemiology and symptoms of bloodborne diseases.
- An explanation of the modes of transmission of bloodborne pathogens.
- An explanation of the Exposure Control Plan and the means by which employees can access a copy of the written plan.
- An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials.
- An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices and personal protective equipment.
- Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment.

- An explanation of the basis for selection of personal protective equipment.
- Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination shall be offered free of charge.
- Information on the appropriate actions to take and persons to contact regarding a personal exposure involving blood or other potentially infectious materials.
- Information on the post-exposure evaluation and follow up that IU is required to provide for the employee following an exposure incident.
- An explanation of the signs and labels required by the Exposure Control Plan.
- Opportunities for interactive questions and answers between the trainer and the employees.

9.0 *RECORDKEEPING*

Appropriate records shall be kept for all employees with occupational exposure documenting HBV vaccination, exposure incidents, and training relative to occupational exposure to bloodborne pathogens in the Risk Office for the Biosafety Committee.

9.1 **Medical Records**

The Risk Office for the Biosafety Committee shall establish and maintain records for staff with occupational exposure in Biosafety Level 2 (BSL 2) or Biosafety Level 3 (BSL 3) for the duration of employment and 30 years after termination of employment.

The Office of Environmental Health and Safety Management shall establish and maintain records for staff in all other laboratories and workplaces with occupational exposure at for the duration of employment and 30 years after termination of employment.

9.1.1 **Contents**

All medical records of employees with occupational exposure to bloodborne pathogens shall include the following elements:

- The employee's name and identification number.
- Hepatitis B vaccination status.
- Copies of results of all exams, tests, and follow up related to reported exposure incidents.
- Written medical opinion of post-exposure incidents.

9.1.2 Confidentiality

- All employee medical records shall be kept confidential.
- Medical records shall not be disclosed or reported without the employee's written consent to any person within or outside the workplace except as required by this plan or by law.

9.2 Training Records

The Risk Office for the Biosafety Committee and each affected department shall maintain records for the staff working in Biosafety Level 2 (BSL 2) or Biosafety Level 3 (BSL 3) trained in this program.

The Office of Environmental Health and Safety Management and each affected department shall maintain records of staff in all other laboratories and workplaces trained in this program.

All training records shall be kept for three (3) years from the date of training, and shall include the following information:

- Dates of training sessions
- Names, and positions of employees attending each session
- Contents or summary of training sessions
- Names and qualifications of trainers

9.3 Availability of Records

All employee medical and training records shall be provided upon request for examination and copying to the subject employee, to employee representatives, to representatives of accrediting agencies, to the Director or Assistant Secretary of OSHA in accordance with 29 CFR 1910.20 or to the Indiana State Department of Health in accordance with 410 IAC 1-3-23.

APPENDICES

APPENDIX A

Occupational Exposure to Bloodborne Pathogens

The OSHA Standard

29 CFR 1910.1030

Federal Registers

Occupational exposure to Bloodborne Pathogens; Needlestick and Other Sharps Injuries; Final Rule. - 66:5317-5325

Federal Registers - Table of Contents

- Publication Date: 01/18/2001
- Publication Type: Final Rules
- Fed Register #: 66:5317-5325
- Standard Number: 1904; 1904.6; 1910; 1910 Subpart Z; 1910.1000; 1910.1001; 1910.1002; 1910.1018; 1910.1029; 1910.1030; 1910.1200; 1911; 1915.1030
- Title: Occupational Exposure to Bloodborne Pathogens; Needlestick 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 needled syringe 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 were 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 (Sec. 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 Sec. 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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BILLING CODE 4510-26-P

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Occupational Safety & Health Administration
200 Constitution Avenue, NW
Washington, DC 20210

APPENDIX B

INDIANA UNIVERSITY

**Hepatitis B Vaccination Acceptance/Declination
Policy and Form**

APPENDIX C

**Protocols for Needle or Other Contaminated Injuries and
Exposures to Hepatitis or HIV**

Protocols for Needle or Other Contaminated Injuries and Exposures to Hepatitis or HIV for Biosafety Level 2 (BSL 2) and Biosafety Level 3 (BSL 3) Laboratories

The following procedures are to be followed by workers in all laboratories rated at BSL2 or BSL 3. The procedures apply to all incidents that occur in these laboratories and any animal bites. Personnel should report to the IU Health Center according to the instructions below. After hour emergencies should report to Bloomington Hospital Emergency Department.

PROCEDURE

1. Make site bleed.
2. Wash the area thoroughly.
3. Notify supervisor/department head of the accident.
4. If puncture from needle or instrument associated with known patient who has:
 - A. No history of hepatitis or syphilis: Tetanus booster indicated if not current. The supervisor should fill out the Indiana University Occupational Injury-Illness Report:

<https://rmweb.indiana.edu/ORM/secure/WCAuthEntry.cfm>

and forward a copy to the I.U. Health Center, and the Risk Officer for the Biosafety Committee (Office of the Vice President for Research Administration). The employee and students should go to IU Health Center during facility hours with a copy of the report.
 - B. History or possibility of hepatitis: Promptly bring the incident report to the I.U. Health Center, for consideration of prophylaxis with Immune Serum Globulin (ISG) or Hepatitis B Immune Globulin (HBIG) and for hepatitis B vaccine. The incident report should contain pertinent information. The I.U. Health Center will assist in collection of this information and will forward a copy to the Risk Officer.
 - C. History or possibility of syphilis: If the patient has a positive VDRL, with or without primary or secondary syphilis, the supervisor should follow 4.A by filling out the incident report and having the exposed student/employee report as soon as possible to the I.U. Health Center. After 90 days, a VDRL will be repeated on the exposed employee.
 - D. History or possibility of (+) HIV: If the patient has a positive HIV or is in a high-risk group, the supervisor should follow 4. A by filling out the incident report and having the exposed student/employee report within 30-60 minutes to the I.U. Health Center for evaluation. If the incident occurs after Health Center hours and it is a possible exposure to HIV infection, the employee is to report to the Emergency Room at Bloomington Hospital within 30-60 minutes. The supervisor is to notify the Health Center and the Risk Officer as soon as possible.

5. If the puncture wound is not associated with known patient (i.e., item found in linen or trash):
 - A. Do as in 4A ISG 3cc is given and hepatitis B vaccine series initiated.
6. If questions arise concerning the proper procedure to follow, the I.U. Health Center (5-2850) should be consulted.
7. If the patient is known to be HBsAg positive:
 - A. It will be determined if the exposed employee has started and/or completed the hepatitis B vaccine series. If yes, see below:
 - B. If the exposed employee has not been vaccinated, serum will be drawn and tested for HBsAg and HBsAb and they should receive prophylaxis with hepatitis B Immune Globulin (HBIG) and started on hepatitis B vaccine. This should be instituted within 24-48 hours.
 - C. If it is determined that the exposed person is HBsAb negative, the hepatitis B vaccine will be given again in one month and six months according to the standard recommendations.
 - D. If the exposed person is HBsAb positive, no further injections of HBIG will be needed.
8. If the source's hepatitis status is not known, the exposed employee will have serum drawn and tested for HBsAg and HBsAb and receive prophylaxis with ISG until results of the patient's hepatitis screening is available.
9. If the patient is HBsAg negative and HBsAb positive and has clinical evidence of active hepatitis, a GI or Infectious Disease consultation should be considered, if needed, to determine the risk of transmissibility. The risk of transmission of hepatitis virus to the fetus in the case of pregnancy will be explained.
10. Persons who have been immunized with hepatitis B vaccine must still report an exposure and be seen by the I.U. Health Center.
 - A. If an exposed employee has received one dose of the HB vaccine, HBsAb will be drawn and prophylaxis with HBIG will be given.

IF THE SOURCE PATIENT HAS AIDS OR OTHER EVIDENCE OF HIV INFECTION, DECLINES TESTING, OR HAS A POSITIVE TEST, THE EMPLOYEE SHOULD BE EVALUATED CLINICALLY AND SEROLOGICALLY FOR EVIDENCE OF HIV INFECTION AS SOON AS POSSIBLE AFTER THE EXPOSURE, AND, IF SERONEGATIVE, RETESTED AFTER 6 WEEKS AND ON A PERIODIC BASIS THEREAFTER (e.g. 3, 6, AND 12 MONTHS) FOLLOWING EXPOSURE, TO DETERMINE IF TRANSMISSION HAS OCCURED.

The employee will be informed of prophylactic AZT therapy as a treatment option. If the employee desires AZT, this will be administered in consultation with the I.U. Health Center. During this follow-up period, especially the first 6-12 weeks, when most infected persons are expected to seroconvert, exposed employees should receive counseling about the risk for infection and to help them follow U.S. Public Health Service (PHS) recommendations for preventing transmission of HIV. If the source patient is seronegative and has no other evidence of HIV infection, no further follow-up of the employee is necessary. If the source patient cannot be identified, decisions regarding appropriate follow-up should be individualized based on the type of exposure and the likelihood that the patient was infected.

Since these patients are also often in high-risk groups for syphilis and hepatitis B, it would seem prudent to follow existing recommendations for hepatitis B and possibly syphilis prophylaxis. *The recommended post-exposure prophylaxis for acute percutaneous exposure to hepatitis B virus is found in the Indiana University Health Center Policy for control of hepatitis and through communication with the I.U. Health Center.*

Protocols for Needle or Other Contaminated Injuries and Exposures to Hepatitis or HIV for All Laboratories and Workplaces Except Biosafety Level 2 (BSL 2) and Biosafety Level 3 (BSL 3) Laboratories and Animal Bites

The following procedures are to be followed by workers in all laboratories and work areas other than Biosafety Level 2 (BSL 2) or Biosafety Level 3 (BSL 3) laboratories and animal bites. Personnel should report to the Promptcare East according to the instructions below. After hour emergencies should report to Bloomington Hospital Emergency Department.

PROCEDURE

1. Make site bleed.
2. Wash the area thoroughly.
3. Notify supervisor/department head of the accident.
4. If puncture from needle or instrument associated with known patient who has:
 - A. A. No history of hepatitis or syphilis: Tetanus booster indicated if not current. The supervisor should fill out the Indiana University Occupational Injury-Illness :

<https://rmweb.indiana.edu/ORM/secure/WCAuthEntry.cfm>

and forward a copy to the Prompt Care East, and the Office of Environmental Health and Safety Management (EHS). The employee and student workers should go to Promptcare East during facility hours with a copy of the report.
 - B. History or possibility of hepatitis: Promptly bring the incident report to Promptcare East, for consideration of prophylaxis with Immune Serum Globulin (ISG) or Hepatitis B Immune Globulin (HBIG) and for hepatitis B vaccine. The incident report should contain pertinent information. Promptcare East will assist in collection of this information and will forward a copy to the EHS.
 - C. History or possibility of syphilis: If the patient has a positive VDRL, with or without primary or secondary syphilis, the supervisor should follow 4.A by filling out the incident report and having the exposed student/employee report as soon as possible to Promptcare East. After 90 days, a VDRL will be repeated on the exposed employee.
 - D. History or possibility of (+) HIV: If the patient has a positive HIV or is in a high-risk group, the supervisor should follow 4. A by filling out the incident report and having the exposed student/employee report within 30-60 minutes to Promptcare East for evaluation. If the incident occurs after hours and it is a possible exposure to HIV infection, the employee is to report to the Emergency Room at Bloomington Hospital within 30-60 minutes. The supervisor is to notify Promptcare East and EHS as soon as possible.

5. If the puncture wound is not associated with known patient (i.e., item found in linen or trash):
 - A. Do as in 4A ISG 3cc is given and hepatitis B vaccine series initiated.
6. If questions arise concerning the proper procedure to follow, the Promptcare East (353-6888) should be consulted.
7. If the patient is known to be HBsAg positive:
 - A. It will be determined if the exposed employee has started and/or completed the hepatitis B vaccine series. If yes, see below:
 - B. If the exposed employee has not been vaccinated, serum will be drawn and tested for HBsAg and HBsAb and they should receive prophylaxis with hepatitis B Immune Globulin (HBIG) and started on hepatitis B vaccine. This should be instituted within 24-48 hours.
 - C. If it is determined that the exposed person is HBsAb negative, the hepatitis B vaccine will be given again in one month and six months according to the standard recommendations.
 - D. If the exposed person is HBsAb positive, no further injections of HBIG will be needed.
8. If the source's hepatitis status is not known, the exposed employee will have serum drawn and tested for HBsAg and HBsAb and receive prophylaxis with ISG until results of the patient's hepatitis screening is available.
9. If the patient is HBsAg negative and HBsAb positive and has clinical evidence of active hepatitis, a GI or Infectious Disease consultation should be considered, if needed, to determine the risk of transmissibility. The risk of transmission of hepatitis virus to the fetus in the case of pregnancy will be explained.
10. Persons who have been immunized with hepatitis B vaccine must still report an exposure and be seen by Promptcare East.
 - A. If an exposed employee has received one dose of the HB vaccine, HBsAb will be drawn and prophylaxis with HBIG will be given.

IF THE SOURCE PATIENT HAS AIDS OR OTHER EVIDENCE OF HIV INFECTION, DECLINES TESTING, OR HAS A POSITIVE TEST, THE EMPLOYEE SHOULD BE EVALUATED CLINICALLY AND SEROLOGICALLY FOR EVIDENCE OF HIV INFECTION AS SOON AS POSSIBLE AFTER THE EXPOSURE, AND, IF SERONEGATIVE, RETESTED AFTER 6 WEEKS AND ON A PERIODIC BASIS THEREAFTER (e.g. 3, 6, AND 12 MONTHS) FOLLOWING EXPOSURE, TO DETERMINE IF TRANSMISSION HAS OCCURED.

The employee will be informed of prophylactic AZT therapy as a treatment option. If the employee desires AZT, this will be administered in consultation with the Promptcare East. During this follow-up period, especially the first 6-12 weeks, when most infected persons are expected to seroconvert, exposed employees should receive counseling about the risk for infection and to help them follow U.S. Public Health Service (PHS) recommendations for preventing transmission of HIV. If the source patient is seronegative and has no other evidence of HIV infection, no further follow-up of the employee is necessary. If the source patient cannot be identified, decisions regarding appropriate follow-up should be individualized based on the type of exposure and the likelihood that the patient was infected.

Since these patients are also often in high-risk groups for syphilis and hepatitis B, it would seem prudent to follow existing recommendations for hepatitis B and possibly syphilis prophylaxis. *The recommended post-exposure prophylaxis for acute percutaneous exposure to hepatitis B virus is found in the Indiana University Health Center Policy for control of hepatitis and through communication with the I.U. Health Center.*

APPENDIX D

Physician's Evaluation of Bloodborne Injury

Physician's Evaluation of Bloodborne Injury

Information and Consent Form for HIV Post-Exposure Treatment

Following a potential non-sexual exposure to the human immunodeficiency virus (HIV), a limited amount of scientific evidence suggests that the prompt use of anti-HIV medication(s) can slow or actually prevent the development of HIV infection in humans. After reading the following information, discuss these points and your situation with your health care provider before proceeding with treatment. Make sure all of your questions have been answered to your satisfaction.

Current (June, 1996) U.S. Public Health Service recommendations for HIV post-exposure drug treatment include the use of one, two or three drugs. Zidovudine, Lamivudine and Indinavir (or equivalent medications) may be used singly or in combination for post-exposure treatment, depending upon the likelihood of a person actually having been exposed to HIV and other factors. You have the right to decline any or all of the recommended drugs at any time, before or after treatment begins.

The best scientific evidence currently available suggests that post-exposure treatment for possible HIV infection is best started within one to two hours after exposure, and continued for four weeks. If you are unsure that you wish to commit to a four week course of treatment, you might consider at least starting the medications now so that you have a bit more time to consider your options. At this time, it is unknown just how long starting treatment can be delayed yet still offer some benefit. Beginning the treatment beyond one to two hours after exposure may slow but not prevent the establishment of HIV infection in the body.

Possible side effects of the medications noted above are as follows:

Zidovudine: Gastrointestinal Symptoms, headache, fatigue

Indinavir: Gastrointestinal symptoms, abnormalities of liver function, kidney stones

Lamivudine: Gastrointestinal symptoms, inflammation of the pancreas

With Indinavir and Lamivudine the listed side effects have been observed only with HIV-infected persons, and may or may not apply to persons without active HIV infection. Further, there is no information regarding the long-term or delayed effects of treatment with any of these drugs in HIV-free individuals. During the latter 2/3 of pregnancy, limited trials of treatment with Zidovudine suggest that this drug is not associated with serious or harmful effects in mothers or infants. The possible effect of any of these medications when given during the first three months of pregnancy is unknown. Potential side effects of Lamivudine and Indinavir when given at any time during pregnancy are unknown.

4. Hepatitis B vaccine series (0-1-6 months) started Reason(s) for Hepatitis B vaccine:
5. Hepatitis B vaccine booster; Date:
6. Recommended HIV follow-up: baseline, 6 weeks, 3-6-12 months
7. HIV counseling: yes no
8. AZT treatment: AZT 200 mg q4h x 2 weeks Then AZT 100 mg q4h x 4 weeks
With baseline CBC, Chem-12, creatine kinase - all repeated every 2 weeks

Started Date Time

Physician Date

NOTE: Under Indiana Code 16-1-9-5-7, it is unlawful for any person to disclose medical information involving a communicable disease without a release. Therefore, when consent is sought from a source individual, the source individual must be informed that the result will be released only to the exposed employee and the healthcare professional evaluating the employee after exposure. Positive HIV must be reported to ISBH.

If you did not give consent for HIV testing at that time your blood will be preserved for 90 days.

Reference: Federal register/Vol. 56, No. 235/Friday, December 6, 1991

APPENDIX E

Department/Sub-Unit Exposure Determination List

Department/Sub-Unit Exposure Determination List

Employment Positions

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.
- 9.
- 10.

Tasks with Potential Exposure

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.

APPENDIX F

Department/Sub-Unit Engineering Controls

APPENDIX G

Department/Sub-Unit Work Practice Controls

APPENDIX H

Department/Sub-Unit Personal Protective Equipment

APPENDIX I

**Department/Sub-Unit Housekeeping Schedule and
Decontamination Procedures**

APPENDIX J

Safety Needle/Sharps Evaluation Form

Safety Needle/Sharps Evaluation Form

Evaluator's Name:	Job Title:
Department:	Date:
Supervisor's Name:	Telephone #:
Name of Device:	
Name of Manufacturer:	
Applications of Device:	
Number of Times Used:	

Please circle the most appropriate answer for each question. A rating of one (1) indicates the highest level of agreement with the statement, five (5) the lowest. Not applicable (NA) may be used if the question does not apply to this product.

Please explain all problems with the device in the comments section.

- | | Agree.....Disagree |
|--|--------------------|
| 1. The safety feature can be activated using a one-handed technique. | 1 2 3 4 5 NA |
| 2. The user's hands remain behind the needle/sharp until activation of the safety mechanism is complete. | 1 2 3 4 5 NA |
| 3. The safety feature does not interfere with normal use of this product. | 1 2 3 4 5 NA |
| 4. Use of this product requires you to use the safety feature. | 1 2 3 4 5 NA |
| 5. A clear and unmistakable change (either audible or visible) occurs when the safety feature is activated. | 1 2 3 4 5 NA |
| 6. The device is easy to handle while wearing gloves. | 1 2 3 4 5 NA |
| 7. The device is easy to handle when wet. | 1 2 3 4 5 NA |
| 8. The device does not require more time to use than a non-safety device. | 1 2 3 4 5 NA |
| 9. The safety feature operates reliably. | 1 2 3 4 5 NA |
| 10. The exposed sharp is blunted or covered after use and prior to disposal. | 1 2 3 4 5 NA |
| 11. The safety feature works well with a wide variety of hand sizes and with a left-handed person as easily as with a right-handed person. | 1 2 3 4 5 NA |
| 12. Use of this product does not increase the number of sticks to the patient. | 1 2 3 4 5 NA |
| 13. Sterilization (if applicable) of this device is as easy as a standard device. | 1 2 3 4 5 NA |
| 14. The product does not require extensive training to be operated correctly. | 1 2 3 4 5 NA |
| 15. The device can be used without causing more patient discomfort than a conventional device. | 1 2 3 4 5 NA |

Would you recommend using this device? Yes No

Comments:

APPENDIX K

Sharps Injury Log

Sharps Injury Log

Please complete a log for each employee exposure incident involving a sharp.

Name of Injured:	University ID No.:
Name of Supervisor:	Telephone:
Date of Birth:	Male Female
Department:	Building and area of injury:
Date of Injury:	Time of Injury:

Fill in the square corresponding to the most appropriate answer.

Procedure:

Draw venous blood	Draw arterial blood
Injection, through skin	Cutting
Suturing	Unknown/Not applicable
Other (please specify):	

Exposure incident occurred:

During the use of sharp	Between steps of a multi-step procedure
After use and before disposal of sharp	While putting sharp into disposal container
Disassembling	
Sharp left, inappropriate place (table, chair, bed, etc.)	
Other (please specify):	

Body part(s) involved (check all that apply):

Finger	Face/head	Hand
Torso	Arm	Leg
Other (please specify):		

Identify sharp involved (if known):

Type:
 Brand:
 Model:
 (e.g. 18g needle/ABC Medical/"no stick" syringe)

Engineered Sharps Injury Protection:

Did the device being used have engineered sharps injury protection?		
Yes	No	Don't Know
Was the protective mechanism activated?		
Yes-fully	Yes-partially	No
Did the exposure incident occur		
Before,	During, or	After activation?

Exposed employee: If sharp had no engineered sharps injury protection, do you have an opinion that such a mechanism could have prevented the injury? Yes No

Explain:

Exposed employee: Do you have an opinion that any other engineering administrative or work practice control could have prevented the injury? Yes No

Explain:

APPENDIX L

Record of Exposure Control Plan (ECP) Review/Changes

Record of ECP Review/Changes

<u>Date</u>	<u>Pages Changed</u>	<u>Reviewer</u>
5/1992 Plan established		
8/1994		
6/18/2007	Pgs ii, 1, 3, 6, 7, 17, 19, 20, 21, 46	OVPRA
6/21/2007	Title, i, ii, iii, 5, 6, 7, 17, 21, 24, 25 44, 45, 49, 50, 51, 53, 54, 65, 67	EHS
4/28/2008	Title, ii, iii, 5, 6, 7, 20, 21, 22, 25, 26 44, 45, 46, 49, 52, 54, 65, 67	EHS