Salisbury University
Exposure Control Plan

Prepared to comply with
OSHA Bloodborne Pathogens Standard 29 CFR 1910.1030

Original plan developed:	December 1999
Developed by:	Robert Shockley, Environmental Safety Manager
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Accepted by:	Dr. Joel Jones, Interim President
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I. FORMAL POLICY STATEMENT

Certain job activities at Salisbury University have the potential for employee and student exposure to human blood and/or body fluids. Human blood, other body fluids, and unfixed human tissues are potential sources of harmful and lethal diseases such as Hepatitis B, Hepatitis C, Creutzfeldt-Jakob disease and Acquired Immunodeficiency Syndrome (AIDS). Identification of infectious body fluids and human tissues requires considerable medical diagnostic efforts and are not 100% effective in detecting all infectious diseases. Therefore, to minimize the risk of occupational exposure to potentially contaminated blood and body fluids a combination of employee education, personal protective equipment (PPE), vaccinations, engineering controls, and application of recommended work practices will be used. The following Exposure Control Plan has been developed in accordance with the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogen Standard, 29 CFR 1910.1030. The plan will be consistent with the applicable Maryland and Federal laws of professional licensure, informed consent, and confidentiality of student and other personally identifiable records.

All employees of the institution share responsibility for all aspects of campus safety. Although this plan covers the entire campus as a general policy, it is necessary for each department to formulate detailed standard operating procedures that are unique to that unit. Supervision of this process and responsibility for administering the provisions of this plan includes, but is not limited to, the following individuals:

Title	Name	Phone
Environmental Safety Director	Wayne Shelton	x6-6485
University Police Chief	Edwin Lashley	x3-6007
Director of Human Resources	Marvin Pyles	x6-6213
Director of Student Health Services	Jennifer Berkman	x3-6262

Contract Service Provider	Name	Phone
Biohazard Licensed Waste Handler	Culver Enterprises	302-846-2542
Contaminated Laundry Contractor	Phillip's Cleaners	410-742-4231

When safety concerns arise, employees are urged to contact their immediate supervisor or the Environmental Safety Director. This policy covers all employees of Salisbury University who are identified under exposure determination, including full-time, part-time, temporary, contingent, and visiting personnel in any employment category.

At a minimum, the Environmental Safety Director will review this policy annually. In the event that there is a substantial change in the regulations or in standard operating procedures on campus, the plan will be revised accordingly. Revisions will reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens. In addition, the review process will document annual consideration and implementation of commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure. The review process will require input from non-managerial employees responsible for direct patient care

who are potentially exposed to injuries from contaminated sharps. The solicitation of input from employees will be documented in Student Health Services. That documentation will include, at a minimum, the names of employees involved and a description of the input process with regard to identification, evaluation, selection of controls. The input shall be documented including meeting minutes, and 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.

Salisbury University will record sharps injuries in the OSHA 300 and 301 forms and will include the type and brand of device involved on either the 300 or 301 form, and will maintain sharps injuries reports in a way that segregates sharps injuries from other types of work-related injuries or illnesses or allows sharps injuries to be easily separated as a log.

II. GLOSSARY

ACUTE: An adverse effect with symptoms of high severity coming quickly to a crisis.

AUTOCLAVE: A steam-sterilizing device designed to destroy all microbial life on objects with a combination of heat and pressure.

BIOSAFETY LEVEL (BSL) ASSOCIATED RISKS WITH MICROORGANISMS:

BSL1 - Minimal disease in healthy adults such as ***Bacillus subtilis***
BSL2 - Moderate risk associated with human diseases such as Hepatitis B Virus
BSL3 - Microorganisms that may cause serious diseases such as ***Mycobacterium tuberculosis***
BSL4 - Microorganisms that are high-risk and considered lethal such as Lassa fever virus

BLOODBORNE PATHOGENS - Microorganisms that are present in human blood, and that can cause disease in humans. These pathogens include, but are not limited to, Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV), and the infectious prion that causes Creutzfeldt-Jakob Disease.

BODY SUBSTANCE ISOLATION- a work practice in which contact with all body substances (blood, urine, tissue, etc.) is prevented

CHRONIC: An adverse effect with symptoms that develop slowly over a long period of time, or that frequently recur.

CJD - CREUTZFELDT-JAKOB DISEASE - Rare, fatal, encephalopathy; caused by unknown slow virus. Can be transmitted via objects contaminated with blood.

CONFIRMED SOURCE INDIVIDUAL - means a Source Individual known, as a result of pre-exposure or post-exposure testing, to be infected with a bloodborne pathogen.

CONTAMINATED - Marked by the presence, or the reasonably anticipated presence, of blood, other potentially infectious materials, radiation or chemicals on an item or surface.

CONTAMINATED LAUNDRY - Laundry that has been soiled with blood, other potentially infectious materials, radiation or chemicals.

CONTAMINATED SHARPS - Any contaminated object that can penetrate the skin; including, but not limited to, needles, scalpels, broken glass, capillary tubes, and exposed ends of dental wires.

DECONTAMINATION - The use of physical or chemical means to remove, inactivate, or destroy microorganisms in blood and other potentially infectious materials, radiation or

chemicals on a surface or item 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.

ENGINEERING CONTROLS - Devices or equipment for isolating or removing hazards from the workplace (e.g., safer medical devices, such as sharps with engineered sharps injury protections and needleless systems).

EXPOSURE INCIDENT - A specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from an employee performing his or her duties.

FOMITE - An object that is not inherently infectious, but is considered a biohazard because it has been exposed to, or in contact with, materials considered infectious. Example: Telephone handled with contaminated gloves becomes a biohazardous fomite

HAND WASHING FACILITIES - Locations that provide an adequate supply of running potable water, soap, and single-use towels or hot-air drying machines.

HBV - Hepatitis B Virus

HEPA FILTERS - High-efficiency particulate air filters

HIV - Human Immunodeficiency Virus

INFECTIOUS AGENTS: Sources that cause infections either by inhalation, ingestion, or direct contact with the host material.

LICENSED HEALTH-CARE PROFESSIONAL - A person whose legally permitted scope of practice allows him or her to independently perform the activities required for Hepatitis B vaccination and post-exposure evaluation and follow-up.

NEEDLELESS SYSTEMS – 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 medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

OCCUPATIONAL EXPOSURE - Reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood, other potentially infectious materials, radiation or chemicals that may result from employees performing their duties.

OTHER POTENTIALLY INFECTIOUS MATERIALS (OPIM) - 1) The following: blood, semen, vaginal secretions, sputum, saliva, nasal secretions, feces, urine, vomitus, tissues, cerebrospinal fluid, synovial fluid, vitreous fluid, wound exudates, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid. Generally sweat, breast milk and tears do not require special handling. 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-contaminated culture media or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

OSHA: Occupational Safety and Health Administration, the regulatory branch of the Department of Labor concerned with employee safety and health.

PARENTERAL - Exposure occurring as a result of piercing the skin barrier (e.g., subcutaneous, intramuscular, intravenous routes) through such events as needle sticks, bites, cuts, and abrasions.

PERSONAL PROTECTIVE EQUIPMENT (PPE)- Specialized clothing or equipment worn by an employee to protect against a hazard as well as prevent further contamination.

REGULATED WASTE - The EPA categorizes hazardous wastes as listed or characteristic wastes. The EPA and state/local jurisdictions publish lists of wastes which are considered hazardous and therefore are regulated. Characteristic wastes are regulated because they are ignitable, corrosive, reactive or toxic. Medical waste is regulated in the state of MD.

SHARPS - Any object that can penetrate the skin, including, but not limited to, needles, scalpels, and broken glass.

SHARPS WITH ENGINEERED SHARPS INJURY PROTECTIONS – 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.

SOP's - Standard operating procedures

SOURCE INDIVIDUAL - Any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients, clients in institutions for the developmentally disabled, trauma victims, clients of drug and alcohol treatment facilities, residents of hospices and nursing homes, human remains, and individuals who donate or sell blood or blood components.

STANDARD PRECAUTIONS: The new CDC recommendation for treating all blood and body fluids as potentially infectious. It combines the former Universal Precautions and Body Substance Isolation recommendations. Body fluids to be isolated include semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid and amniotic fluid.

STERILITY: 1) Infertility; changes made in male or female reproductive systems resulting in inability to reproduce. 2) Condition in which all microbial life is absent.

STERILIZE - To use a physical or chemical procedure to destroy all microbial life, including highly resistant material endospores.

TB - *Mycobacterium tuberculosis*

TRANSMISSION-BASED PRECAUTIONS- The new CDC term for isolation procedures above and beyond Standard Precautions which are based on the presence of a confirmed pathogen.

UNIVERSAL PRECAUTIONS - The CDC's previous approach to infection control in which all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens. (See new Standard Precautions and Transmission Based Precautions.)

WORK PRACTICE CONTROLS - Mandated procedures or policies that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., by prohibiting recapping of needles using a two-handed technique). Where occupational exposure remains after institution of these controls, personal protective equipment shall be utilized.

Any term used in this Policy which is defined in the paragraph (b) of the OSHA Standard shall have the meaning set forth in the OSHA Standard unless a different meaning is set forth in this part of the Policy.

II. EXPOSURE DETERMINATION/RISK ASSESSMENT

OSHA requires employers to perform an exposure determination concerning which employees may incur occupational exposure to blood or OPIM. The exposure determination is made without regard to the use of personal protective equipment (i.e., employees are considered to be exposed even if they wear personal protective equipment).

Non-Discrimination

Salisbury University shall make its facilities and services for health care services available to employees without regard to their status as Source Individuals or Confirmed Source Individuals. However, as medically appropriate, some Source Individuals or Confirmed Source Individuals may be referred to treatment in special settings or denied access to some programs in order to safeguard their welfare, the health of other patients or clients, and the safety of Salisbury University personnel.

Voluntary Disclosures: Confidentiality

Persons who are not or will not be engaged in invasive patient care activities are not required or encouraged to disclose infection with a bloodborne pathogen. **Prospective or current students, employees, or other Salisbury University personnel who are infected with**

a bloodborne pathogen, and whose work or academic program does or will include invasive procedures, are strongly encouraged but not required to disclose infection to the appropriate School involved. Any person's disclosure of infection will be maintained in confidence by the individual affiliated with Salisbury University to whom the disclosure was made unless other persons must be informed in order to implement this Policy. A statement encouraging disclosures by persons who may or will be involved in invasive procedures may be included in School and Unit bulletins that advertise or describe academic programs to prospective and current students. Information regarding Review Panels and disclosures may be provided at enrollment, or soon thereafter, and at employee orientations. By one of these means it is expected that all students, employees, and other Salisbury University personnel currently or prospectively involved in invasive procedures will be informed by their School or Unit that:

(a) voluntary disclosure is encouraged;

(b) the health status of a person who discloses infection will be held in confidence by Salisbury University, and only persons who have a need to know the status in order to implement this Policy will be made aware of the status and these persons will be required to sign a statement indicating their need to maintain complete confidentiality;

(c) voluntary and timely disclosure permits the School or Unit to assist in developing appropriate accommodations of maximum benefit to the disclosing individual (this includes instituting additional safety measures for the immunocompromised employee.); and

(d) disclosure itself cannot be the basis for academic dismissal or termination of employment, which would only follow careful consideration of a persons situation as discussed in this Policy.

Accommodations

When necessary and reasonable, appropriate accommodations, including modifications of activities, curriculum, and job responsibilities, may be made for infected students or employees who otherwise would be engaged in invasive procedures or exposed to medically unacceptable risks of opportunistic infection. Inquiries with respect to competencies of prior performances by such individuals may be made by a Review Panel, a Dean or a Unit head as an aid to designing appropriate accommodations. Curriculum modifications will be subject to decisions of the Schools advancement or curriculum committee (as determined by the School) and the Schools Dean.

Risk Assessment

Not all employees are reasonably expected to have exposure to human blood and body fluids as part of their general duties. The departments have therefore been broadly characterized as shown below as to their relative risk of exposure. It is up to the department heads in each area in which exposure can reasonably be expected to evaluate the actual expectation of exposure for

each job category and provide appropriate training and vaccination accordingly. See Appendix 2 for an outline of information required in each unit's exposure control plan.

Exposure Expected	Exposure Possible	Exposure Unlikely
Student Health Services	Campus Police	All other areas
Health Sciences Faculty	Biology Faculty	
Nursing Faculty	Campus Recreation	
Athletic Trainers	Intercollegiate Athletics	
Custodial	Physical Plant	
	Residence Hall Staff	
	Dining Services	

III. STANDARD OPERATING PROCEDURES

All departments are responsible for formulating standard operating procedures for that area as each unit has unique needs and duties. The following are minimal expectations in each unit.

General safety work practice controls

Work Practice Controls are procedures that reduce the risk of occupational exposure by altering the way a task is performed. The following general work practice controls are to be followed by all personnel when working with human blood or OPIM. All departments are responsible for formulating more detailed work practice controls (see Appendix 2).

General behavior: Serious and professional behavior is required at all times. Practical jokes or other behavior that might confuse, startle, or distract another worker are strictly forbidden. The work areas should be clean and uncluttered, with chemicals, biohazards and equipment properly labeled and stored. All users must clean up the work area on completion of an operation or at the end of the day. Supervisors have the right and responsibility to remove employees from duty for infractions of any safety rule.

Clothing: Appropriate dress is required at all times. Long hair and loose clothing must be confined. Shoes will be worn at all times, and sandals, perforated shoes, sneakers and any shoes made of canvas are generally not acceptable. Use of contact lenses should be avoided unless necessary; if they must be used, supervisors should be informed so special precautions can be taken. If contact lenses are worn, safety glasses are **NOT** adequate protection and safety goggles should be used.

Lab coats and other protective clothing are to be worn buttoned-up/zipped up while work is in progress and should be removed immediately upon significant contamination. Protective clothing should be laundered with bleach to minimize biohazardous material by the laundry contractor at no expense to the employee (see below).

Personal health and hygiene: Attention to these needs is strictly prohibited in potentially contaminated areas. Eating, drinking, smoking, gum chewing, applying cosmetics or lip balm,

and handling contact lenses are prohibited in work areas where there is a potential for occupational exposure. Employees should wash their hands and leave the area before conducting these activities.

Smoking: Smoking is prohibited in the work area/building.

Food and drink: No materials for human consumption are stored in refrigerators, freezers, cabinets, or on shelves, countertops, or bench tops where blood, other potentially infectious materials, radiation or chemicals are stored, or in other areas of possible contamination. Food and drink may only be stored in designated refrigerators. Sorting, handling, or consuming food or beverages in contaminated areas and use of refrigerators, glassware, or utensils for food and drink that are also used for operation are strictly forbidden.

Hand washing: Hand washing is required immediately (or as soon as possible) after removing gloves or other personal protective equipment and after hand contact with blood or other potentially infectious materials. If personnel incur exposure to their skin or mucous membranes then those areas shall be washed or flushed with water as soon as feasible following contact. Hands and any exposed skin are washed between all contacts; before eating, drinking, smoking, applying cosmetics, and changing contact lenses; and after using lavatory facilities. Facilities for hand washing are provided and are separate from those used for washing equipment or for waste disposal. Hands are washed with soap and water as soon as possible. Wearing gloves does **NOT** mean that hand washing is unnecessary!

Personal protective equipment: PPE is removed immediately after leaving the work area (or as soon as possible) or if overtly contaminated and placed in an appropriately designated area or container for storage, washing, decontamination, or disposal.

Unattended operations: Hazardous operations must not be left unattended.

Work surfaces: Work surfaces are made of impervious materials to facilitate disinfection and decontamination. The decontamination solution for a few areas of the University is 10% household bleach which is made fresh daily for each day of use. However, the University also uses a variety of disinfectants and sterilants that are included within EPA's A, B, C, and D list of "appropriate disinfectants".

Needles and Sharps: Contaminated needles and other contaminated sharps will not be bent, recapped, removed, sheared or purposely broken. OSHA allows an exception to this if the procedure would require that the contaminated needle be recapped or removed and no alternative is feasible and the action is required by the medical procedure. If such action is required then the recapping or removal of the needle must be done by the use of a mechanical device or a one handed "scoop" technique. Procedures that require recapping of needles are discouraged. During use, containers for contaminated sharps shall be easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found. To whatever extent reasonably possible, safety-engineered sharps devices will be incorporated into every procedure.

Licensed Waste Handler: Salisbury University will provide containers sufficient to contain regulated wastes capable of resisting punctures and labeled as a biohazard (as appropriate). These will be removed by a licensed waste handler.

Handling of Materials: Packages marked with the universal biohazard symbol or otherwise identified as containing potentially infectious materials are to be inspected for leaks immediately upon arrival at the facility.

All procedures are to be conducted in a manner that will minimize splashing, spraying, splattering, and generation of droplets of blood or OPIM. Specific methods include the use of protective clothing, gloves, chin length face shields, eye protection, and the use of work gloves to protect latex/nitrile gloves from abrasion and tearing when large items are handled. Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.

Handle sharp objects with safety awareness. Maintain eye contact with the item. Shield machines that splash and splatter. Use capped tubes and safety cups when vortexing and centrifuging. Wrap cotton or a gauze pad moistened with disinfectant around rubber stoppers or lyophilized containers when opening them. To the extent possible, perform all procedures that could aerosolize material in a biological safety cabinet.

Specimens of blood or OPIM are to be placed in a container that prevents leakage during the collection, handling, processing, storage, and transport of the specimens. The container used for this purpose will be labeled in accordance with the requirements of the OSHA standard. Supervisors shall ensure that all equipment has been decontaminated prior to servicing and shipping.

Any specimen container(s) shall be placed within a secondary container that is leak-proof and clamped to prevent spillage of infectious materials. The outer container shall have a biohazard label and content information. The outer container shall be decontaminated with 1:10 dilution of chlorine bleach or another appropriate disinfectant only if it is also contaminated.

Specimen collection: Refer to individual department policies with regard to collection of hazardous specimens.

Emergency phone numbers: All phones should have 911 for the county emergency system and x 36222 for Public Safety posted on them. The nature of the emergency and the location should be stated calmly and clearly.

Individual responsibility: All employees must be safety conscious. All should seek information and advice about hazards, plan appropriate protective procedures, and plan positioning of equipment before beginning any new operation. Unsafe conditions must be reported immediately, and work should not proceed until the conditions are adequately changed.

Standard (Universal) and Transmission-Based Precautions

The Centers for Disease Control (CDC) Standard Precautions (formerly known as Universal Precautions) will be observed at this facility in order to prevent contact with blood or other potentially infectious materials. All blood or OPIM will be considered infectious regardless of the perceived status of the source individual. Persons having occupational exposure potential must be trained in standard precautions, and these precautions must be used in exposure situations. These persons must also be informed of known biohazards and educated on all aspects of HIV infection, Acquired Immune Deficiency Syndrome, CJD and HBV and HCV infection appropriate to expected educational and job-related behaviors. The requirements of paragraph (g) of the OSHA standard shall be followed by all personnel. (Communication of hazards to employees.)

When it is known that a specific disease is present, employees will also use the Transmission-Based Precautions applicable to that disease. This recommendation applies primarily to employees in Student Health Services, as no other employees would typically be in the position of knowing an individual's medical diagnosis.

Biohazard Symbol

All containers of potentially infectious materials, objects contaminated with potentially infectious materials and areas handling potentially infectious materials must be labeled with the universal biohazard symbol (see right). The symbol should be black on an orange background.

Engineering Controls

Engineering and work practice controls will be utilized to eliminate or minimize exposure to employees at this facility. Engineering controls include all control measures that isolate or remove a hazard from the workplace, encompassing not only sharps with engineered sharps injury protection but also other medical devices designed to reduce the risk of percutaneous exposure to bloodborne pathogens. Where occupational exposure remains after institution of these controls, personal protective equipment shall also be utilized. At Salisbury University the following items are available:

Specimen Containers: Containers for specimens of blood or OPIM must be designed to prevent leakage during collection, handling, and storage. They are to be inspected for leakage prior to use and on a daily basis. Avoid contaminating the outside of the container. Be sure the lid is on tight. Decontaminate the outside of the container with 10% bleach solution or its equivalent disinfectant before transporting only if the outside is also contaminated. To make a 10% bleach solution, add one part commercial bleach (5.25% available chlorine) to nine parts water. All specimen containers must be clearly labeled as to contents, labeled with a biohazard label and then double containerized for transport.

Containers for Special Medical Waste: Special Medical Waste such as used disposable containers, gloves, etc., must be kept in closed containers that can hold all contents without leakage during handling, storage and transport. Waste containers must be clearly labeled with the biohazard symbol, indicating they contain biohazardous waste. Containers are to be inspected for leakage daily. If outside contamination of the primary container occurs, the primary container shall be placed within a secondary container which prevents leakage during the handling, processing, storage, transport, or shipping of specimen.

Sharps Containers: Sharps include syringes, needles, slides, scalpels, cover slips, glass pipettes, and broken glass that may be contaminated with infectious materials. Sharps containers should be leak-proof, puncture resistant, labeled with the universal biohazard symbol, and closeable. Full sharps containers must be sealed and placed in a properly lined biohazard burn box. Pick up and disposal must be done by a licensed waste handler. To whatever extent reasonably possible, safety-engineered sharps devices will be incorporated into every procedure.

Contaminated needles and other contaminated sharps will not be bent, recapped, removed, sheared or purposely broken. OSHA allows an exception to this if the procedure would require that the contaminated needle be recapped or removed and no alternative is feasible and the action is required by the medical procedure. If such action is required then the recapping or removal of the needle must be done by the use of a mechanical device or a one "scoop" handed technique. At this facility needle removal boxes will always be provided.

Splash shields: Clear plastic splash shielding will be made available for those procedures in which splashing or aerosols are unavoidable.

Biological safety cabinet (hood): Hoods will be made available for those procedures in which splashing or aerosols are unavoidable or for handling microorganisms for which this type of containment is necessary. The university will certify each hood semi-annually as to proper air flow and integrity of the HEPA filters.

IV. PERSONAL PROTECTIVE EQUIPMENT (PPE)

Personal protective equipment (PPE) used at this facility is provided without cost to personnel. PPE is chosen based on the anticipated exposure to blood or OPIM. Personal protective equipment will be considered appropriate only if it does not permit blood or OPIM to pass through or reach the individual's clothing, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used. Appropriate PPE shall be provided to employees at no cost and used in every circumstance warranted.

Supervisors shall ensure that appropriate PPE in the appropriate sizes is readily accessible at the work site or is issued without cost to employees. Hypoallergenic gloves, glove liners, powder free gloves, or other similar alternatives shall be readily accessible to those who are allergic to the gloves normally provided. **Protective Equipment should be removed before leaving the work site and either be stored or disposed of appropriately.**

Supervisors shall ensure that all PPE is removed when penetrated by blood and then double bagged for laundering. All PPE shall be removed prior to leaving the work area. When PPE is removed, it shall be placed in an appropriately designated container for storage, washing, decontamination or disposal. All repairs and replacements will be made by the employer at no cost to employees.

The following pieces of PPE shall be available and used when there is potential for exposure to bloodborne pathogens:

Gloves

Disposable, single-use latex or nitrile gloves shall be worn where it is reasonably anticipated that employees will have hand contact with blood or other potentially infectious materials, when collecting and processing human specimens and when handling or touching contaminated items or surfaces.

Disposable gloves used at this facility are not to be washed or decontaminated for reuse and are to be replaced as soon as practical when they become contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised. Utility gloves will be discarded if they are cracked, peeling, torn, punctured, or exhibits other signs of deterioration or when their ability to function as a barrier is compromised. Double gloving has been shown to provide more protection from punctures and abrasion that can occur during use than a single glove layer. Check gloves for leaks prior to wearing them. If gloves are damaged (torn or punctured) or become damaged or contaminated during a procedure, replace them. **Wash hands with soap and water for 30 to 60 seconds immediately after removing gloves.**

It is essential that workers wearing contaminated gloves avoid touching themselves and non-contaminated objects such as door knobs, telephones, computer key boards, pencils, etc. All fomites created in this manner must be decontaminated.

Clothing

Protective clothing must be worn when there is a risk of body fluids spattering or becoming aerosolized and contacting a workers skin or clothing. Protective clothing should be resistant to fluids, and may be disposable or reusable. Reusable clothing must be properly laundered by the laundry contractor prior to reuse at no charge to the employee.

Face Protection

Face shields are required for all procedures that may spray, spatter or aerosolize blood or other potentially infectious material. Masks in combination with eye protection devices, such as goggles or glasses with solid side shield, or chin length face shields, are required to be worn when splash, spray, or aerosolized blood or OPIM may contact eye, nose, mouth or mucous membranes. Eyeglasses alone are not effective against infectious material. **If eyes or mucous**

membranes are sprayed or splashed with potentially infectious materials, the affected areas should be flushed with tap water for 15 to 20 minutes. After flushing, the individual must be transported for medical attention. The Emergency Room of PRMC will provide medical evaluation and follow-up for this type of exposure.

Protective Footwear and Headwear

Disposable shoe covers and caps must be worn in situations where cross contamination is possible.

Additional PPE selections and such as use of CPR masks, headnets, smocks, foot covering and aprons may be necessary to ensure employee safety in regards to bloodborne pathogens in certain workplace situations. Examples include the use of masks for exposure to fungi and TB, insulated gloves for handling heated materials and splash aprons.

V. HOUSEKEEPING AND LAUNDRY

Routine Cleaning

All areas of the worksite must be maintained in a clean and sanitary condition. All tables, counters, lab surfaces, etc. must be disinfected with fresh 10% chlorine bleach solution (or its equivalent) at least daily and immediately following completion of procedures involving human blood and OPIM.

Contaminated Work Surfaces and Other Fomites

Work areas, surfaces and contaminated objects must be decontaminated with freshly prepared 10% bleach or its equivalent disinfectant solution after completion of procedures involving and/or immediately following any spill of blood or OPIM. Recommended contact time for effective decontamination is 20-30 minutes.

Broken Glass

Broken glass must never be picked up by hand. Recommended mechanical means of clean up include use of a brush and dustpan, tongs or forceps. Utensils must be cleaned and decontaminated immediately after use. The contaminated glass should be disposed of in a sharps container.

Contaminated Sharps

Sharps should be placed in a properly marked puncture-resistant sharps container and labeled with a biohazard symbol. Containers for contaminated sharps shall be easily accessible to personnel and located in each separate procedure area. The containers shall be maintained upright throughout their use and replaced as needed and shall not be overfilled. When moving containers of contaminated sharps from the area of use, the containers shall be closed

immediately prior to removal. The sharps container shall be placed in a plastic bag-lined biohazard burn box and removed by Salisbury University's contracted licensed waste handler.

Autoclaves (steam sterilizers)

Some departments are equipped with autoclave devices to sterilize their own biohazardous waste. These units are required to document that the sterilization process is effective by insuring that stock cultures of *Bacillus stearothermophilus* or its equivalent are routinely destroyed.

Laundry

Contaminated protective clothing is to be placed in labeled bags and sent to a commercial laundry service that has the capability to properly handle and launder potentially infectious material. Home laundry is not permitted. Laundry shall be cleaned and decontaminated by Salisbury University's laundry contractor.

Laundry contaminated with blood or other potentially infectious materials will be handled as little as possible. Such laundry will be placed in appropriately marked biohazard labeled bags at the location where it was used. Such laundry will not be sorted or rinsed in the area of use.

VI. ADMINISTRATIVE CONTROLS

The above controls will be examined and maintained on a regular schedule by the Environmental Safety Director and appropriate supervisory personnel. The effectiveness of the controls will be reviewed annually and updated as needed by the Environmental Safety Director and appropriate supervisory personnel. The Environmental Health & Safety Department Budget is responsible for providing for the financial resources to assure compliance with all safety requirements that are not already provided for in departmental budgets. This financial responsibility may include, but is not limited to, employee vaccination, medical care, personal protective equipment, waste removal, laundry and engineering controls.

To achieve the goals of this policy, supervisors and managers are required to develop Standard Operating Procedures (SOPs) for activities in which an employee may be exposed to bloodborne pathogens. Procedures must contain the following elements (also see Appendix 2):

- A clear and descriptive position description;
- The names and job classifications of all individuals that will participate in the bloodborne pathogen activities;
- Identification of the area where duties are performed and a description of the procedures to be used to prevent unauthorized personnel from being exposed to a potential hazard;
- A listing of the possible sources of exposure to bloodborne pathogens or other potentially infectious material in the specific task or procedure. (Note: All liquids or media that come into contact with blood, unfixed human tissue or human cell lines are to be considered

potentially infectious material until the source tissue has been disinfected.)

- A detailed description of the task or procedure including all of the applicable safety precautions, detailed in the Exposure Control Plan.
- Identification of the departmental point of contact for exposure incidents.

VII. HEPATITIS B VACCINATION PROGRAM

The University offers the HBV vaccination series to all personnel who have occupational exposure, and post-exposure follow-up to personnel who have had an exposure incident. All medical evaluations and procedures including the Hepatitis B vaccination series and post-exposure follow-up, including prophylaxis shall be available to the personnel at a reasonable time and place, performed by or under the supervision of a licensed physician or by or under the supervision of another licensed health care professional, and provided according to the recommendations of the U. S. Public Health Service.

Human Resources shall refer new and existing employees identified as being at risk to Salisbury University's Student Health Services for the Hepatitis B vaccination program. Student Health Services shall send a roster of those vaccinated to Human Resources so that the vaccination may be recorded in each employee's file. The HBV vaccination shall be offered by the University, at no cost, to all employees who have occupational exposure. Laboratory tests to establish antibody titer, if deemed necessary, shall be conducted by an accredited laboratory at no cost to the employee. Hepatitis B vaccination shall be made available:

- After personnel have received training in occupational exposure (see Information and Training);
- Within 10 working days of initial assignment;
    - To all personnel who have occupational exposure unless they have previously; received the complete Hepatitis B vaccination series, antibody testing has revealed that they are immune or the vaccine is contraindicated for medical reasons.

Participation in a pre-screening program shall not be a prerequisite for receiving Hepatitis B vaccination. If an individual initially declines Hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the vaccination shall then be made available. All employees who decline the Hepatitis B vaccination offered shall sign the OSHA required waiver indicating their refusal. All personnel may be vaccinated at the Student Health Services.

If a routine booster dose of Hepatitis B vaccine is recommended by the U. S. Public Health Service at a future date, such booster doses shall be made available.

Students and non-employees who have exposure and who ordinarily have access to Student Health Services shall be offered the HBV vaccine and vaccination at their own expense.

VIII. POST-EXPOSURE EVALUATION AND FOLLOW-UP

All exposure incidents shall be reported, investigated, and documented by Student Health Services. When an employee incurs an exposure incident, it shall be reported to the supervisor. Personnel with potential exposure shall report to the Student Health Services if the potential exposure occurred Monday through Thursday, 8:30 AM to 4:30 PM, and Fridays 9:00 AM to 4:30 PM. At all other times, individuals shall go to the PRMC Emergency Room for treatment, medical evaluation and follow-up, including at least the following elements:

- Documentation of the route of exposure, and the circumstances under which the exposure incident occurred;
- Identification and documentation of the source individual, unless it can be established that identification is infeasible or prohibited by state or local law;
- The source individual's blood shall be tested as soon as feasible after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the person responsible for the Hepatitis B vaccination program shall establish that legally required consent cannot be obtained. When the source individuals consent is not required by law, the source individuals blood, if available, shall be tested and the results documented;
- When the source individual is already known to be infected with HBV or HIV testing for the source individual's HBV or HIV status need not be repeated provided that appropriate documentation can be obtained;
- Results of the source individual's testing shall be made available to the exposed individual along with information on applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

Collection and testing of blood for HBV and HIV serological status will comply with the following:

- The exposed individual's blood shall be collected as soon as feasible and tested after consent is obtained;
- The exposed individual will be offered the option of having their blood collected for testing of HIV/HBV serological status. The blood sample will be preserved for up to 90 days to allow the person to decide if the blood should be tested for HIV serological status.

All university personnel who experience an exposure incident will be offered post-exposure evaluation and follow-ups in accordance with the OSHA standard and the CDC guidelines which are current at the time of the incident. The health care professional responsible for the persons Hepatitis B vaccination and post-exposure evaluation will be provided with the following by the Student Health Services:

- A copy of 29 CFR 1910. 1030;
- A written description of the exposed individuals duties as they relate to the exposure incident;
- Written documentation of the route of exposure and circumstances under which exposure occurred;
- Results of the source individuals blood testing, if available;
- All medical records relevant to the appropriate treatment of the person including vaccination status.

Student Health Services shall obtain and provide the individual with a copy of the evaluating health care professionals written opinion within 15 days of the completion of the evaluation. The health care professionals written opinion for HBV vaccination must be limited to whether HBV vaccination is indicated, and if the individual has received such vaccination. It will include a statement that the individual has been informed of the results of the evaluation and of any medical conditions resulting from exposure to blood or OPIM which require further evaluation or treatment. All other findings or diagnosis shall remain confidential and shall not be included in the written report.

IX. COMMUNICATION OF HAZARDS TO EMPLOYEES

Labels

Warning labels need to be affixed to containers of regulated waste, refrigerators, freezers, incubators or other containers that contain blood or OPIM. They also need to be placed on containers used to transport regulated materials, and are required for any equipment that can reasonably be expected to become contaminated during the course of its use.

The warning label must contain the word "Biohazard" along with the universal biohazard symbol and printed in fluorescent orange or orange-red color with lettering or symbols in a contrasting color.

Blood products that have been released for transfusion or other clinical use are exempted from these labeling requirements.

Signs

Signs will be posted at the entrance to work areas in which infectious and potentially infectious materials is used. Required signs will be fluorescent orange in a contrasting color and they must contain the following information:

- The universal biohazard symbol;
- The name of infectious agent;
- Special requirements for entering the area;
- Name and day/night time telephone numbers of the laboratory supervisor and/or other responsible person(s).

IX. INFORMATION AND TRAINING

Training shall be required for all personnel who may have exposure to bloodborne pathogens in the course of their employment. The Environmental Safety Officer shall ensure that bloodborne pathogens trainers are knowledgeable in the subject matter. Human Resources shall refer all new employees with a risk of exposure for training at the time of initial assignment. Training shall be repeated within twelve months of the previous training. Human Resources will also ensure that newly hired or transferred employees have an appointment for the HBV vaccine within 10 days of employment or reassignment or that they have signed the vaccine declination form.

Training shall be tailored to the education and language level of the personnel, provided at no cost to the personnel and during the normal work shift. The training will be interactive and

cover the following:

- The standard and its contents;
- The epidemiology and symptoms of bloodborne diseases;
- The modes of transmission of bloodborne pathogens;
- The Salisbury University Bloodborne Pathogen Exposure Control Plan, and a method for obtaining a copy;
- The recognition of tasks that may involve exposure;
- The use and limitations of methods to reduce exposure, for example engineering controls, work practices and PPE;
- The types, use, location, removal, handling, decontamination, and disposal of PPE
- The basis of selection of PPE;
- The Hepatitis B vaccination, including efficacy, safety, method of administration, benefits, and the cost, if any;
- The appropriate actions to take and persons to contact in an emergency involving blood or OPIM;
- The procedures to follow if an exposure incident occurs, including the method of reporting and medical follow-up;
- The evaluation and follow-up required after an exposure incident;
- The signs, labels, and color-coding systems used to identify potentially infectious materials.

Additional training shall be provided to the Salisbury University personnel when there are any changes of tasks or procedures affecting the risk of occupational exposure. Personnel who have received training on bloodborne pathogens in the 12 months preceding the effective date of this plan shall only receive training in provisions of the plan that were not covered.

X. RECORD KEEPING

The Environmental Safety Director will maintain training records in the Environmental Health and Safety Office. Environmental Health & Safety will identify employees that require a training session and notify both the supervisor/chairperson if an employee is in need of a session. Training records shall be maintained for three years from the date of training.

The following information shall be documented by the Environmental Safety Director:

- The dates of the training sessions;
- An outline describing the material presented;
- The names and qualifications of persons conducting the training; and
- The names and departments of all persons attending the training session.

Student Health Services is responsible for maintaining medical records as indicated below.

Medical records shall be maintained in accordance with OSHA Standard 29 CFR 1910. 20. These records shall be kept confidential, and must be maintained for at least the duration of employment, studies, or volunteer effort plus 30 years.

The records shall include the following:

- The name and Social Security number of the individual;
- A copy of individuals HBV vaccination status, including the dates of vaccination;
- A copy of all results of examinations, medical testing, and follow-up procedures;
- A copy of the information provided to the health care professional, including a description of the individuals duties as they relate to the exposure incident, and documentation of the routes of exposure and circumstances of the exposure.

Availability: Medical records shall be made available to an employee in accordance with 29 CFR 1910. 20. Medical records shall be made available to the Assistant Secretary of Labor for the Occupational Safety and Health Administration and the Director of the National Institute for Occupational Safety and Health upon request.

Transfer of Records: If this facility is closed or there is no successor employer to receive and retain the medical records for the prescribed period, the Director of the NIOSH shall be contacted for final disposition.

Evaluation and Review: This program and its effectiveness are reviewed every year and updated as needed by the Environmental Safety Officer.

XI. REFERENCES

29 CFR 1910.1030: Bloodborne Pathogens Standard

Centers for Disease Control

Appendix 1

DECLINATION/ACCEPTANCE FORM

HEPATITIS B VACCINATION

NO – I DO NOT WANT THE HBV VACCINATION

I, _____, understand owing to my occupational exposure to blood and other potentially infectious materials at Salisbury University, I may be at risk of acquiring Hepatitis B Virus (HBV) infection. I have been given the opportunity to be vaccinated with Hepatitis B Vaccine at no charge to me. However, I decline the Hepatitis B vaccine at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring Hepatitis B, a serious disease. If, in the future, I continue to have occupational exposure to human blood or other potentially infectious materials and I want to be vaccinated with Hepatitis vaccine, I can receive the vaccination series at no charge to me.

Employee Signature **Print Name** **Date**

Employee ID# **Department** **Office Phone**

(DO NOT CUT OR TEAR FORM)

YES - I WANT THE HBV VACCINATION

I, _____, would like to be scheduled for the Hepatitis B vaccine series. Please forward my name to Student Health Services for appointment scheduling. I understand that I am responsible to set an appointment for the first vaccine once my supervisor notifies me; Student Health Services will schedule the remaining two appointments during the first visit. If I am unable to make an appointment, I understand that it is my responsibility to re-schedule with Student Health Services.

Employee Signature **Print Name** **Date**

Employee ID# **Department** **Office Phone**

Appendix 2

Outline for Exposure Control Protocols for Each Unit

EXPOSURE CONTROL PROTOCOL OUTLINE

Each unit must develop its own protocols for safety as the plan for the entire campus deals in general work practices and cannot possibly cover all the pertinent requirements in each unit. The following is an outline to consider when writing safety protocols for a particular unit. These protocols may best be attached for the Salisbury University campus plan for each employee's reference.

Introduction- with reference to the Exposure Control Plan for the entire campus

Glossary - terms unique to the unit not covered in the campus plan, if necessary

Risk Assessment- A clear and descriptive position description for all job categories in the unit must be listed and classified as to potential exposure to blood and body fluids

Standard Operating Procedures – all procedures unique to a unit not covered in the campus plan to include:

A. Identification of the area where duties are performed and a description of the procedures to be used to prevent unauthorized personnel from being exposed to a potential hazard
B. A listing of the possible sources of exposure to bloodborne pathogens or other potentially infectious material in the specific task or procedure
C. Work practices and clothing policies - detailed descriptions of tasks or procedures including all of the applicable safety precautions.
D. Engineering controls, protective equipment and personal protective equipment
E. Waste labeling and handling
F. Contaminated laundry labeling and handling

Administrative Controls – a clear description of responsibilities within the unit and identification of the departmental point of contact for exposure incidents.

Vaccination and Medical Treatment- protocols not covered by the campus's plan

Information and Training Protocols – General safety training will be in place for the campus, but units are still responsible for instruction in unit-specific protocols and documentation of such training on an annual basis.

Appendix 3

OSHA
Bloodborne Pathogens Standard

Regulations (Standards - 29 CFR) Bloodborne Pathogens. - 1910.1030

- **Standard Number:** 1910.1030
- **Standard Title:** Bloodborne pathogens.
- **SubPart Number:** Z
- **SubPart Title:** Toxic and Hazardous Substances

(a) Scope and Application. This section applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b) of this section.

(b) Definitions. For purposes of this section, the following shall apply:

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

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

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

Clinical Laboratory means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

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

Contaminated Laundry means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.

Contaminated Sharps means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

Decontamination means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item 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.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

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.

Exposure Incident means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

Handwashing Facilities means a facility providing an adequate supply of running potable water, soap and single use towels or hot air drying machines.

Licensed Healthcare Professional is a person whose legally permitted scope of practice allows him or her to independently perform the activities required by paragraph (f) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up.

HBV means hepatitis B virus.

HIV means human immunodeficiency virus.

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.

Occupational Exposure means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

Other Potentially Infectious Materials means (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); and (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.

Parenteral means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

Personal Protective Equipment is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

Production Facility means a facility engaged in industrial-scale, large-volume or high concentration production of HIV or HBV.

Regulated Waste means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials 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 materials.

Research Laboratory means a laboratory producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in production facilities.

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.

Source Individual means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

Sterilize means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.

Universal Precautions is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

Work Practice Controls means controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

(c) **Exposure Control --**
(c)(1)

Exposure Control Plan.

(c)(1)(i)

Each employer having an employee(s) with occupational exposure as defined by paragraph (b) of this section shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure.

(c)(1)(ii)

The Exposure Control Plan shall contain at least the following elements:

(c)(1)(ii)(A)

The exposure determination required by paragraph (c)(2),

..1910.1030(c)(1)(ii)(B)

(c)(1)(ii)(B)

The schedule and method of implementation for paragraphs (d) Methods of Compliance, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, (g) Communication of Hazards to Employees, and (h) Recordkeeping, of this standard, and

(c)(1)(ii)(C)

The procedure for the evaluation of circumstances surrounding exposure incidents as required by paragraph (f)(3)(i) of this standard.

(c)(1)(iii)

Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.1020(e).

(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:

(c)(1)(iv)(A)

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

(c)(1)(iv)(B)

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

(c)(1)(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.

(c)(2)

Exposure Determination.

(c)(2)(i)

Each employer who has an employee(s) with occupational exposure as defined by paragraph (b) of this section shall prepare an exposure determination. This exposure determination shall contain the following:

(c)(2)(i)(A)

A list of all job classifications in which all employees in those job classifications have occupational exposure;

..1910.1030(c)(2)(i)(B)

(c)(2)(i)(B)

A list of job classifications in which some employees have occupational exposure, and

(c)(2)(i)(C)

A list of all tasks and procedures or groups of closely related task and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in accordance with the provisions of paragraph (c)(2)(i)(B) of this standard.

(c)(2)(ii)

This exposure determination shall be made without regard to the use of personal protective equipment.

(d)

Methods of Compliance --

(d)(1)

General. Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.

(d)(2)

Engineering and Work Practice Controls.

(d)(2)(i)

Engineering and work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after institution of these controls, personal protective equipment shall also be used.

..1910.1030(d)(2)(ii)

(d)(2)(ii)

Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.

(d)(2)(iii)

Employers shall provide handwashing facilities which are readily accessible to employees.

(d)(2)(iv)

When provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible.

(d)(2)(v)

Employers shall ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.

(d)(2)(vi)

Employers shall ensure that employees wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials.

(d)(2)(vii)

Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B) below. Shearing or breaking of contaminated needles is prohibited.

..1910.1030(d)(2)(vii)(A)

(d)(2)(vii)(A)

Contaminated needles and other contaminated sharps shall not be bent, recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure.

(d)(2)(vii)(B)

Such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.

(d)(2)(viii)

Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be:

(d)(2)(viii)(A)

Puncture resistant;

(d)(2)(viii)(B)

Labeled or color-coded in accordance with this standard;

(d)(2)(viii)(C)

Leakproof on the sides and bottom; and

(d)(2)(viii)(D)

In accordance with the requirements set forth in paragraph (d)(4)(ii)(E) for reusable sharps.

(d)(2)(ix)

Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure.

(d)(2)(x)

Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials are present.

..1910.1030(d)(2)(xi)

(d)(2)(xi)

All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.

(d)(2)(xii)

Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.

(d)(2)(xiii)

Specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping.

(d)(2)(xiii)(A)

The container for storage, transport, or shipping shall be labeled or color-coded according to paragraph (g)(1)(i) and closed prior to being stored, transported, or shipped. When a facility utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary provided containers are recognizable as containing specimens. This exemption only applies while such specimens/containers remain within the facility. Labeling or color-coding in accordance with paragraph (g)(1)(i) is required when such specimens/containers leave the facility.

(d)(2)(xiii)(B)

If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of this standard.

..1910.1030(d)(2)(xiii)(C)

(d)(2)(xiii)(C)

If the specimen could puncture the primary container, the primary container shall be placed within a secondary container which is puncture-resistant in addition to the above characteristics.

(d)(2)(xiv)

Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible.

(d)(2)(xiv)(A)

A readily observable label in accordance with paragraph (g)(1)(i)(H) shall be attached to the equipment stating which portions remain contaminated.

(d)(2)(xiv)(B)

The employer shall ensure that this information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken.

(d)(3)

Personal Protective Equipment --

(d)(3)(i)

Provision. When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Personal protective equipment will be considered "appropriate" only if it does not permit blood or other potentially infectious materials to pass through to 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 will be used.

(d)(3)(ii)

Use. The employer shall ensure that the employee uses appropriate personal protective equipment unless the employer shows that the employee temporarily and briefly declined to use personal protective equipment when, under rare and extraordinary circumstances, it was the employee's professional judgment that in the specific instance its use would have prevented the delivery of health care or public safety services or would have posed an increased hazard to the safety of the worker or co-worker. When the employee makes this judgement, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future.

(d)(3)(iii)

Accessibility. The employer shall ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the worksite or is issued to employees. Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.

(d)(3)(iv)

Cleaning, Laundering, and Disposal. The employer shall clean, launder, and dispose of personal protective equipment required by paragraphs (d) and (e) of this standard, at no cost to the employee.

..1910.1030(d)(3)(v)

(d)(3)(v)

Repair and Replacement. The employer shall repair or replace personal protective equipment as needed to maintain its effectiveness, at no cost to the employee.

(d)(3)(vi)

If a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible.

(d)(3)(vii)

All personal protective equipment shall be removed prior to leaving the work area.

(d)(3)(viii)

When personal protective equipment is removed it shall be placed in an appropriately designated area or container for storage, washing, decontamination or disposal.

(d)(3)(ix)

Gloves. Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin; when performing vascular access procedures except as specified in paragraph (d)(3)(ix)(D); and when handling or touching contaminated items or surfaces.

(d)(3)(ix)(A)

Disposable (single use) gloves such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.

..1910.1030(d)(3)(ix)(B)

(d)(3)(ix)(B)

Disposable (single use) gloves shall not be washed or decontaminated for re-use.

(d)(3)(ix)(C)

Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.

(d)(3)(ix)(D)

If an employer in a volunteer blood donation center judges that routine gloving for all phlebotomies is not necessary then the employer shall:

(d)(3)(ix)(D)(1)

Periodically reevaluate this policy;

(d)(3)(ix)(D)(2)

Make gloves available to all employees who wish to use them for phlebotomy;

(d)(3)(ix)(D)(3)

Not discourage the use of gloves for phlebotomy; and

(d)(3)(ix)(D)(4)

Require that gloves be used for phlebotomy in the following circumstances:

(d)(3)(ix)(D)(4)(i)

When the employee has cuts, scratches, or other breaks in his or her skin;

(d)(3)(ix)(D)(4)(ii)

When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and

(d)(3)(ix)(D)(4)(iii)

When the employee is receiving training in phlebotomy.

..1910.1030(d)(3)(x)

(d)(3)(x)

Masks, Eye Protection, and Face Shields. Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

(d)(3)(xi)

Gowns, Aprons, and Other Protective Body Clothing. Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments shall be worn in occupational exposure situations. The type and characteristics will depend upon the task and degree of exposure anticipated.

(d)(3)(xii)

Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (e.g., autopsies, orthopaedic surgery).

(d)(4)

Housekeeping --

(d)(4)(i)

General. Employers shall ensure that the worksite is maintained in a clean and sanitary condition. The employer shall determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area.

(d)(4)(ii)

All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials.

..1910.1030(d)(4)(ii)(A)

(d)(4)(ii)(A)

Contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning.

(d)(4)(ii)(B)

Protective coverings, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the workshift if they may have become contaminated during the shift.

(d)(4)(ii)(C)

All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination.

(d)(4)(ii)(D)

Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dust pan, tongs, or forceps.

(d)(4)(ii)(E)

Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed.

(d)(4)(iii)

Regulated Waste --

..1910.1030(d)(4)(iii)(A)

(d)(4)(iii)(A)

Contaminated Sharps Discarding and Containment.

(d)(4)(iii)(A)(1)

Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:

(d)(4)(iii)(A)(1)(i)

Closable;

(d)(4)(iii)(A)(1)(ii)

Puncture resistant;

(d)(4)(iii)(A)(1)(iii)

Leakproof on sides and bottom; and

(d)(4)(iii)(A)(1)(iv)

Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard.

(d)(4)(iii)(A)(2)

During use, containers for contaminated sharps shall be:

(d)(4)(iii)(A)(2)(i)

Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries);

(d)(4)(iii)(A)(2)(ii)

Maintained upright throughout use; and

(d)(4)(iii)(A)(2)(iii)

Replaced routinely and not be allowed to overfill.

(d)(4)(iii)(A)(3)

When moving containers of contaminated sharps from the area of use, the containers shall be:

(d)(4)(iii)(A)(3)(i)

Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping;

(d)(4)(iii)(A)(3)(ii)

Placed in a secondary container if leakage is possible. The second container shall be:

(d)(4)(iii)(A)(3)(ii)(A)

Closable;

(d)(4)(iii)(A)(3)(ii)(B)

Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and

(d)(4)(iii)(A)(3)(ii)(C)

Labeled or color-coded according to paragraph (g)(1)(i) of this standard.

(d)(4)(iii)(A)(4)

Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.

(d)(4)(iii)(B)

Other Regulated Waste Containment --

(d)(4)(iii)(B)(1)

Regulated waste shall be placed in containers which are:

(d)(4)(iii)(B)(1)(i)

Closable;

(d)(4)(iii)(B)(1)(ii)

Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;

(d)(4)(iii)(B)(1)(iii)

Labeled or color-coded in accordance with paragraph (g)(1)(i) this standard; and

(d)(4)(iii)(B)(1)(iv)

Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

(d)(4)(iii)(B)(2)

If outside contamination of the regulated waste container occurs, it shall be placed in a second container. The second container shall be:

(d)(4)(iii)(B)(2)(i)

Closable;

(d)(4)(iii)(B)(2)(ii)

Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;

(d)(4)(iii)(B)(2)(iii)

Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and

(d)(4)(iii)(B)(2)(iv)

Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

(d)(4)(iii)(C)

Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.

..1910.1030(d)(4)(iv)

(d)(4)(iv)

Laundry.

(d)(4)(iv)(A)

Contaminated laundry shall be handled as little as possible with a minimum of agitation.

(d)(4)(iv)(A)(1)

Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.

(d)(4)(iv)(A)(2)

Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.

(d)(4)(iv)(A)(3)

Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through of or leakage from the bag or container, the laundry shall be placed and transported in bags or containers which prevent soak-through and/or leakage of fluids to the exterior.

(d)(4)(iv)(B)

The employer shall ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment.

..1910.1030(d)(4)(iv)(C)

(d)(4)(iv)(C)

When a facility ships contaminated laundry off-site to a second facility which does not utilize Universal Precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded in accordance with paragraph (g)(1)(i).

(e)

HIV and HBV Research Laboratories and Production Facilities.

(e)(1)

This paragraph applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. It does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. These requirements apply in addition to the other requirements of the standard.

(e)(2)

Research laboratories and production facilities shall meet the following criteria:

(e)(2)(i)

Standard Microbiological Practices. All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

(e)(2)(ii)

Special Practices.

(e)(2)(ii)(A)

Laboratory doors shall be kept closed when work involving HIV or HBV is in progress.

..1910.1030(e)(2)(ii)(B)

(e)(2)(ii)(B)

Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leakproof, labeled or color-coded container that is closed before being removed from the work area.

(e)(2)(ii)(C)

Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms.

(e)(2)(ii)(D)

When other potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The hazard warning sign shall comply with paragraph (g)(1)(ii) of this standard.

(e)(2)(ii)(E)

All activities involving other potentially infectious materials shall be conducted in biological safety cabinets or other physical-containment devices within the containment module. No work with these other potentially infectious materials shall be conducted on the open bench.

(e)(2)(ii)(F)

Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area and shall be decontaminated before being laundered.

..1910.1030(e)(2)(ii)(G)

(e)(2)(ii)(G)

Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with other potentially infectious materials is unavoidable.

(e)(2)(ii)(H)

Before disposal all waste from work areas and from animal rooms shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

(e)(2)(ii)(I)

Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency and which are checked routinely and maintained or replaced as necessary.

(e)(2)(ii)(J)

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 (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of other potentially infectious materials. Extreme caution shall be used when handling needles and syringes. A needle shall not be bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture-resistant container and autoclaved or decontaminated before reuse or disposal.

(e)(2)(ii)(K)

All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.

..1910.1030(e)(2)(ii)(L)

(e)(2)(ii)(L)

A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or other responsible person.

(e)(2)(ii)(M)

A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

(e)(2)(iii)

Containment Equipment.

(e)(2)(iii)(A)

Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and 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.

(e)(2)(iii)(B)

Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually.

(e)(3)

HIV and HBV research laboratories shall meet the following criteria:

..1910.1030(e)(3)(i)

(e)(3)(i)

Each laboratory shall contain a facility for hand washing and an eye wash facility which is readily available within the work area.

(e)(3)(ii)

An autoclave for decontamination of regulated waste shall be available.

(e)(4)

HIV and HBV production facilities shall meet the following criteria:

(e)(4)(i)

The work areas shall be separated from areas that are 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.

(e)(4)(ii)

The surfaces of doors, walls, floors and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.

..1910.1030(e)(4)(iii)

(e)(4)(iii)

Each work area shall contain a sink for washing hands and a readily available eye wash facility. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.

(e)(4)(iv)

Access doors to the work area or containment module shall be self-closing.

(e)(4)(v)

An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.

(e)(4)(vi)

A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The 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. The proper direction of the airflow shall be verified (i.e., into the work area).

(e)(5)

Training Requirements. Additional training requirements for employees in HIV and HBV research laboratories and HIV and HBV production facilities are specified in paragraph (g)(2)(ix).

(f)

Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up --

..1910.1030(f)(1)

(f)(1)

General.

(f)(1)(i)

The employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident.

(f)(1)(ii)

The employer shall ensure that all medical evaluations and procedures including the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are:

(f)(1)(ii)(A)

Made available at no cost to the employee;

(f)(1)(ii)(B)

Made available to the employee at a reasonable time and place;

(f)(1)(ii)(C)

Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and

(f)(1)(ii)(D)

Provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place, except as specified by this paragraph (f).

(f)(1)(iii)

The employer shall ensure that all laboratory tests are conducted by an accredited laboratory at no cost to the employee.

..1910.1030(f)(2)

(f)(2)

Hepatitis B Vaccination.

(f)(2)(i)

Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii)(I) and within 10 working days of initial assignment to all employees who have occupational exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.

(f)(2)(ii)

The employer shall not make participation in a prescreening program a prerequisite for receiving hepatitis B vaccination.

(f)(2)(iii)

If the employee initially declines hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time.

(f)(2)(iv)

The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the statement in Appendix A.

(f)(2)(v)

If a routine booster dose(s) of hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii).

(f)(3)

Post-exposure Evaluation and Follow-up. Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements:

(f)(3)(i)

Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred;

..1910.1030(f)(3)(ii)

(f)(3)(ii)

Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;

(f)(3)(ii)(A)

The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.

(f)(3)(ii)(B)

When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.

(f)(3)(ii)(C)

Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

(f)(3)(iii)

Collection and testing of blood for HBV and HIV serological status;

(f)(3)(iii)(A)

The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

..1910.1030(f)(3)(iii)(B)

(f)(3)(iii)(B)

If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

(f)(3)(iv)

Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;

(f)(3)(v)

Counseling; and

(f)(3)(vi)

Evaluation of reported illnesses.

(f)(4)

Information Provided to the Healthcare Professional.

(f)(4)(i)

The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

(f)(4)(ii)

The employer shall ensure that the healthcare professional evaluating an employee after an exposure incident is provided the following information:

(f)(4)(ii)(A)

A copy of this regulation;

(f)(4)(ii)(B)

A description of the exposed employee's duties as they relate to the exposure incident;

(f)(4)(ii)(C)

Documentation of the route(s) of exposure and circumstances under which exposure occurred;

..1910.1030(f)(4)(ii)(D)

(f)(4)(ii)(D)

Results of the source individual's blood testing, if available; and

(f)(4)(ii)(E)

All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer's responsibility to maintain.

(f)(5)

Healthcare Professional's Written Opinion. The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.

(f)(5)(i)

The healthcare professional's written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.

(f)(5)(ii)

The healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information:

(f)(5)(ii)(A)

That the employee has been informed of the results of the evaluation; and

(f)(5)(ii)(B)

That the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.

..1910.1030(f)(5)(iii)

(f)(5)(iii)

All other findings or diagnoses shall remain confidential and shall not be included in the written report.

(f)(6)

Medical Recordkeeping. Medical records required by this standard shall be maintained in accordance with paragraph (h)(1) of this section.

(g)

Communication of Hazards to Employees --

(g)(1)

Labels and Signs --

(g)(1)(i)

Labels.

(g)(1)(i)(A)

Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F) and (G).

(g)(1)(i)(B)

Labels required by this section shall include the following legend:

(g)(1)(i)(C)

These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color.

(g)(1)(i)(D)

Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

..1910.1030(g)(1)(i)(E)

(g)(1)(i)(E)

Red bags or red containers may be substituted for labels.

(g)(1)(i)(F)

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 of paragraph (g).

(g)(1)(i)(G)

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

(g)(1)(i)(H)

Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated.

(g)(1)(i)(I)

Regulated waste that has been decontaminated need not be labeled or color-coded.

(g)(1)(ii)

Signs.

(g)(1)(ii)(A)

The employer shall post signs at the entrance to work areas specified in paragraph (e), HIV and HBV Research Laboratory and Production Facilities, which shall bear the following legend:

(Name of the Infectious Agent)
(Special requirements for entering the area)
(Name, telephone number of the laboratory director or other responsible person.)

..1910.1030(g)(1)(ii)(B)

(g)(1)(ii)(B)

These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color.

(g)(2)

Information and Training.

(g)(2)(i)

Employers shall ensure that all employees with occupational exposure participate in a training program which must be provided at no cost to the employee and during working hours.

(g)(2)(ii)

Training shall be provided as follows:

(g)(2)(ii)(A)

At the time of initial assignment to tasks where occupational exposure may take place;

(g)(2)(ii)(B)

Within 90 days after the effective date of the standard; and

(g)(2)(ii)(C)

At least annually thereafter.

(g)(2)(iii)

For employees who have received training on bloodborne pathogens in the year preceding the effective date of the standard, only training with respect to the provisions of the standard which were not included need be provided.

(g)(2)(iv)

Annual training for all employees shall be provided within one year of their previous training.

..1910.1030(g)(2)(v)

(g)(2)(v)

Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

(g)(2)(vi)

Material appropriate in content and vocabulary to educational level, literacy, and language of employees shall be used.

(g)(2)(vii)

The training program shall contain at a minimum the following elements:

(g)(2)(vii)(A)

An accessible copy of the regulatory text of this standard and an explanation of its contents;

(g)(2)(vii)(B)

A general explanation of the epidemiology and symptoms of bloodborne diseases;

(g)(2)(vii)(C)

An explanation of the modes of transmission of bloodborne pathogens;

(g)(2)(vii)(D)

An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan;

(g)(2)(vii)(E)

An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;

..1910.1030(g)(2)(vii)(F)

(g)(2)(vii)(F)

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;

(g)(2)(vii)(G)

Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment;

(g)(2)(vii)(H)

An explanation of the basis for selection of personal protective equipment;

(g)(2)(vii)(I)

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 will be offered free of charge;

(g)(2)(vii)(J)

Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;

(g)(2)(vii)(K)

An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available;

(g)(2)(vii)(L)

Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;

..1910.1030(g)(2)(vii)(M)

(g)(2)(vii)(M)

An explanation of the signs and labels and/or color coding required by paragraph (g)(1); and

(g)(2)(vii)(N)

An opportunity for interactive questions and answers with the person conducting the training session.

(g)(2)(viii)

The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.

(g)(2)(ix)

Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements.

(g)(2)(ix)(A)

The employer shall assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.

(g)(2)(ix)(B)

The employer shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.

..1910.1030(g)(2)(ix)(C)

(g)(2)(ix)(C)

The employer shall provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The employer shall assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.

(h)

Recordkeeping --

(h)(1)

Medical Records.

(h)(1)(i)

The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020.

(h)(1)(ii)

This record shall include:

(h)(1)(ii)(A)

The name and social security number of the employee;

(h)(1)(ii)(B)

A copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination as required by paragraph (f)(2);

(h)(1)(ii)(C)

A copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3);

(h)(1)(ii)(D)

The employer's copy of the healthcare professional's written opinion as required by paragraph (f)(5); and

..1910.1030(h)(1)(ii)(E)

(h)(1)(ii)(E)

A copy of the information provided to the healthcare professional as required by paragraphs (f)(4)(ii)(B)(C) and (D).

(h)(1)(iii)

Confidentiality. The employer shall ensure that employee medical records required by paragraph (h)(1) are:

(h)(1)(iii)(A)

Kept confidential; and

(h)(1)(iii)(B)

Not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by this section or as may be required by law.

(h)(1)(iv)

The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020.

(h)(2)

Training Records.

(h)(2)(i)

Training records shall include the following information:

(h)(2)(i)(A)

The dates of the training sessions;

(h)(2)(i)(B)

The contents or a summary of the training sessions;

(h)(2)(i)(C)

The names and qualifications of persons conducting the training; and

..1910.1030(h)(2)(i)(D)

(h)(2)(i)(D)

The names and job titles of all persons attending the training sessions.

(h)(2)(ii)

Training records shall be maintained for 3 years from the date on which the training occurred.

(h)(3)

Availability.

(h)(3)(i)

The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

(h)(3)(ii)

Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee representatives, to the Director, and to the Assistant Secretary.

(h)(3)(iii)

Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.1020.

..1910.1030(h)(4)

(h)(4)

Transfer of Records.

(h)(4)(i)

The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h).

(h)(4)(ii)

If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director, at least three months prior to their disposal and transmit them to the Director, if required by the Director to do so, within that three month period.

(h)(5)

Sharps injury log.

(h)(5)(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:

(h)(5)(i)(A)

The type and brand of device involved in the incident,

(h)(5)(i)(B)

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

(h)(5)(i)(C)

An explanation of how the incident occurred.

(h)(5)(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.

(h)(5)(iii)

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

(i)

Dates --

(i)(1)

Effective Date. The standard shall become effective on March 6, 1992.

(i)(2)

The Exposure Control Plan required by paragraph (c) of this section shall be completed on or before May 5, 1992.

(i)(3)

Paragraph (g)(2) Information and Training and (h) Recordkeeping shall take effect on or before June 4, 1992.

(i)(4)

Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, and (g)(1) Labels and Signs, shall take effect July 6, 1992.

[56 FR 64004, Dec. 06, 1991, as amended at 57 FR 12717, April 13, 1992; 57 FR 29206, July 1, 1992; 61 FR 5507, Feb. 13, 1996; 66 FR 5325 Jan., 18, 2001]

Appendix 4

OSHA 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-AS85

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 S4004, 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:

1. 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, 3274C). 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 Bloodbome 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 postexposure 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 re-presents 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 nonconfidential 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 requirements specified in the standard, and the confidentiality of the injured employee is protected.

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

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

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

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

IV. Economic Analysis

Incremental Costs of the Mandated Revisions to the Standard

OSHA has determined that the total cost of this action is $33,814,991 per year, and thus, that it is not an economically significant regulatory action within the meaning of Executive Order 12866. However, the rule is

defined as a significant rule under the Executive Order, and has been reviewed by the Office of Management and Budget. This amendment to the final standard does not involve any new engineering requirements to protect workers from sharps injuries, but it does include two new recordkeeping requirements: First, the amended standard requires employers to "establish and maintain a sharps injury log for the recording of percutaneous injuries* * * "However, for recordable needlestick incidents, OSHA already requires employers to collect much of the information needed for developing such a log under other rules, the Recording and Reporting Occupational Injuries and Illnesses regulation (29 CFR 1904) in particular. Moreover, OSHA has recently published revisions to 29 CFR 1904 that would cover the remaining, previously nonrecordable needlestick injuries. Second, the current action requires any employer "who is required to establish an Exposure Control Plan" to "solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan." The methodology OSHA has used for computing costs for each requirement of the amended standard is presented in the next two sections.

Cost of Establishing and Maintaining a Sharps Injury Log

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

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

(590,164 cases) x (0.08 hours/case) x ($26.32/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 'Ire-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, 803s 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 stablishments 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 filnge 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 establishments) x (0.25 hours/establishment) X ($33.22/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 employees) x (33% response rate) x (0.25 hours/employee) x ($25.90/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 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 establishments) x (0.25 hours/establishment) x ($33.22/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(Q) 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 ONO 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 an 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 bloodbome 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 OMM control number is displayed (§ 1320.5 (b)(2)(i)). OSHA will publish the ON3 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 ICR12180180(2000) in the OSHA Docket Office, U.S. Department of Labor, Room N2625, 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).
OAM 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 l0th 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 Z3 also issued under 5 U.S.C. 553, Section 1910.1000 Tables Z-1, Z-2, and Z-3 not issued under 29 CFR part 1911 except for the arsenic (organic compounds), benzene, and cotton dust listings.

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

Section 1910.1002 not issued under 29 U.S.C. 655 or 29 CFR part 1911; also issued under 5 U.S.C. 553.
Sections 1910.1018, 1910.1029 and 1910.1200 are also issued under 29 U.S.C. 653.
Section 1910.1030 is also issued under Pub. L. 106-430, 114 Stat. 1901.

* * * * *

2. Section 1910.1030 is amended as follows:
A. In § 1910.1030, paragraph (b) the definition for "Engineering Controls" is revised and definitions are added in alphabetical order to read as set, forth below:
B. Paragraph (c)(1)(iv) is revised to read as set forth below:
C. Paragraph (c)(1)(v) is redesignated paragraph (c)(1)(vi), and a new paragraph (c)(1)(v) is added *to* read as set forth below:
D. A new paragraph (h)(5) is added to read as set forth below:

§ **1910.1030 Bloodborne pathogens.**
* * * * *
(b) * * *
Engineering controls means controls (e.g., sharps disposal containers, selfsheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodbome 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 bloodbome 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 bloodbome 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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Appendix 5

Sample Document for Solicitation of Input

Salisbury University

Student Health Services

Safety Sharps Evaluation

Name: _____ Job Title: _____

Today's Date: _____ Product: _____

Period of Time Used/_____ Estimation of Times Used _____

Please **circle** the most appropriate answer for each question.

	AGREE				DISAGREE	
1. I can activate the safety feature with one hand.	1	2	3	4	5	N/A
2. I can see the tip of the sharp when I need to (even when the safety feature is activated).	1	2	3	4	5	N/A
3. It is impossible NOT to use the safety feature.	1	2	3	4	5	N/A
4. This product can be used as quickly as I expected.	1	2	3	4	5	N/A
5. This product is easy to handle when gloved.	1	2	3	4	5	N/A
6. The device offers a good view of any aspirated fluid.	1	2	3	4	5	N/A
7. There is a distinct signal when the safety feature is activated (audible or visible).	1	2	3	4	5	N/A
8. The safety feature operates reliably. Indicate approximate number of failures in this period_____	1	2	3	4	5	N/A
9. The exposed sharp is permanently covered after use.	1	2	3	4	5	N/A
10. The device is just as easy to process after use than non-safety engineered devices I have used.	1	2	3	4	5	N/A
11. This product is easy to learn and understand.	1	2	3	4	5	N/A
12. The design of the product suggests proper use.	1	2	3	4	5	N/A
13. It is almost impossible to skip a crucial step in proper use of this device.	1	2	3	4	5	N/A
14. I prefer using this device to non-safety engineered devices.	1	2	3	4	5	N/A
15. I prefer trying another safety-engineered product.	1	2	3	4	5	N/A

Comments/Concerns: _____

_____

_____

_____

Reviewed by: _____ Title: _____

Date of Review: _____