Exposure Control Plan for Bloodborne Pathogens

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Bloodborne Pathogen Policy and Procedures
Exposure Control Plan

Section 1  Introduction

Yale University is committed to eliminating or minimizing occupational exposure of employees to bloodborne pathogens and other potentially infectious materials. This policy has been written to meet these goals as well as to comply with OSHA's Bloodborne Pathogen Standard (29 CFR 1910.1030). The standard can be found in Appendix 1. The most current version can be accessed on the web at the electronic code of federal regulations website.

As specified in OSHA's Bloodborne Pathogens Standard, a written exposure control plan outlines how the employer will: (1) identify occupationally exposed employees; (2) reduce or eliminate potential exposure through engineering and work practice controls, personal protective equipment and housekeeping; (3) provide the information on bloodborne pathogen hazards that must be communicated to all potentially exposed employees; (4) meet the special training and work practice requirements in HIV and HBV research laboratories and production facilities; (5) make available Hepatitis B vaccination to all potentially exposed employees and provide post-exposure follow-up to employees exposed during incidents and (6) meet the recordkeeping requirements.

This document serves as Yale University's Exposure Control Plan. Individual departments may, at their discretion, write department-specific plans or sections which fulfill all the requirements of this document and the OSHA Standard. Department-specific plans or section modifications must be in writing, maintained with a copy of this manual within the department and approved by the Yale Biological Safety Committee or its designee.

An official copy of Yale's Exposure Control Plan is available at the following locations to ensure employee access to this document:

- Chemistry Department Instrument Room
- Sterling Chemistry Laboratory
- 225 Prospect Street
- Center for Science and Social Science Information
- Kline Biology Tower
- 219 Prospect Street
- Law School Library
- 127 Wall Street
- Environmental Health & Safety
- 135 College Street, Suite 100
- Divinity School Library
- 409 Prospect Street
- Medical School Library
- 333 Cedar Street
- Yale Health Center
- Acute Care
- 55 Lock Street

Copies are also available from Yale Environmental Health and Safety, Departmental Business Offices and can be retrieved on the World Wide Web on the Environmental Health and Safety homepage, http://ehs.yale.edu/.

It is important to update the Exposure Control Plan. To ensure this, the plan will be reviewed and updated under the following circumstances: (1) annually; (2) when new or modified tasks or procedures are implemented that have potential for occupational exposure; (3) when employees' jobs are revised...
such that a new potential for occupational exposure may exist and (4) when new positions are established that may involve exposure to bloodborne pathogens.

Section 2 Definitions

Blood: human blood, human blood components, and products made from human blood

Bloodborne Pathogen: 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).

Covered Department: a department having one or more employees who have occupational exposure to blood or other potentially infectious material

Covered Employee: an employee who has occupational exposure to blood or other potentially infectious material (Categories I and IIA, see section 4)

Engineering Controls: 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 Determination: an evaluation of each position (individual employee) to determine occupational exposure (Categories I, IIA, IIB, see section 4)

HBV: Hepatitis B virus

HIV: Human immunodeficiency virus

HIV and HBV Research Laboratory: a research laboratory engaged in the culture, production, concentration, experimentation, and manipulation of HIV or HBV; does not refer to a clinical or diagnostic laboratory engaged solely in the analysis of blood, tissues, or organs

Occupational Exposure: 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 Material: (1) the following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) any unfixed tissue or organ (other than intact skin) from a human (living or dead); (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture media or other solutions: blood, organs, or other tissues from experimental animals infected with HIV or HBV; (4) any primary or continuous human cell or tissue culture cell line and (5) non-human primates or blood, body fluids, tissues or other unfixed specimens from non-human primates

Regulated Waste: 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 can
release these materials during handling; contaminated sharps and pathological and microbiological wastes containing blood or other potentially infectious materials

Standard: refers to OSHA’s Bloodborne Pathogen Standard (29 CFR Part 1910.1030) which can be found in Appendix 1

Universal Precautions: an 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

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

Section 3 Responsibilities

Responsibility for controlling exposures to bloodborne pathogens rests at all levels including:

3.1 Yale Biological Safety Committee

The Yale Biological Safety Committee, which reviews and recommends policies that provide for the safe conduct of work involving infectious agents, will review this plan annually and establish the criteria to be used in categorizing employees with respect to exposure. The committee will also approve department specific variations of this plan.

3.2 Environmental Health and Safety (EHS)

EHS and specifically the Biological Safety Officer will:

- have overall responsibility for coordinating the implementation of the Exposure Control Plan for the entire university.
- work with the Yale Biological Safety Committee, Department Heads, other administrators and employees to develop and administer any additional bloodborne pathogens-related policies and practices needed to support the effective implementation of this plan.
- keep abreast of current legal requirements concerning bloodborne pathogens.
- provide technical assistance for compliance with the Exposure Control Plan and answer biological safety questions for employees.
- routinely inspect areas where covered employees work to ensure that activities are conducted in accordance with the provisions set forth in this policy and the Standard.
- provide departments where covered employees work with copies of the Standard, this policy and training by a competent individual if the department is unable to perform its own training.
- review training provided by departments to ensure that this training meets the criteria set forth in the Standard.
- investigate all exposure or potential exposure incidents to infectious materials to determine the cause and recommend procedures as necessary to prevent future incidents; engineering controls in
use at the time of the incident will be reviewed to determine if a safe sharps device could have prevented the exposure

- review and update this policy annually as required by the Standard.
- EHS Section of Environmental Affairs will inspect all regulated waste containers to ensure proper packaging and labeling prior to shipment.

3.3 Yale Employee Health

Yale Employee Health will:

- provide covered employees with the opportunity to receive the HBV vaccination series as outlined in Section 7.1.
- upon notification of an exposure incident by a department, arrange for a medical evaluation of the exposed individual. The medical evaluation will include all the elements that appear in the Standard.

3.4 Department Directors, Department Heads, Principal Investigators and Immediate Supervisors

- Covered departments' Directors, Principal Investigators or Department Heads must ensure, through their supervisory personnel, compliance with Section 5 and 6 of this policy, which outlines exposure control methods.
- All covered departments must assist EHS by conducting an exposure determination for each position (individual employee) and submit their findings (when requested) to EHS. The exposure determination will be made using guidelines provided by EHS.
- All bloodborne pathogens trainers must ensure that training performed by the covered department conforms to the requirements of the Standard and Section 8.3. Departments must provide all covered employees with training 1) at the time of assignment to the task where occupational exposure may occur and 2) annually thereafter. Departments may utilize the training seminars presented by EHS to fulfill this requirement.
- Immediate supervisors and/or Principal Investigators must acquire the knowledge and information needed to recognize and control bloodborne pathogen hazards.
- Immediate supervisors and/or Principal Investigators must select and employ laboratory practices and engineering controls that reduce the potential for exposure to bloodborne pathogens. They must also ensure that employees follow the control strategies outlined in Sections 5 and 6 of this policy.
- Immediate supervisors and/or Principal Investigators must supervise the performance of his/her staff to ensure the required work practices are followed and ensure appropriate controls (engineering and personal protective equipment) are used and in good working order.
- Immediate supervisors and/or Principal Investigators must ensure that when a new position description is prepared, it is reviewed and classified with respect to bloodborne pathogens exposure prior to approval. See Appendix 6 for Principal Investigators’ and Immediate supervisors’ responsibilities checklist.
Immediate supervisors must ensure that all who are exposed or injured immediately wash the affected area for 15 minutes in an eyewash for facial mucous membrane exposures or wash skin and wounds with soap and water for 15 minutes.

After immediate washing, staff must also seek medical assistance by first calling the appropriate location to speak with a nurse and make arrangements for evaluation and treatment. This change is due to the COVID-19 pandemic. Please check with EHS or Employee Health for updates to this procedure. Refer to Section 7.2.

Following the report of an exposure incident, the immediate supervisor will file a claim online for the exposure or injury:

For Employees: Search "Yale First Report of Injury" to access the form.

For Non-Employees (students, visitors): Search "Yale Reporting Accidents and Insurance Claims". Please work with your Department’s Lead Administrator to complete this form if help is needed.

Immediate supervisors must ensure that exposed or injured staff contact Yale Employee Health for follow-up after an injury or exposure. Call 203-432-7978 to reach Yale Employee Health to schedule a follow-up appointment within 48 hours after immediate medical assistance has been provided.

3.5 Employees Covered by the Standard

After appropriate training, employees are expected:

- to complete a Hepatitis B vaccination notification form and contact Yale Employee Health to schedule an appointment to receive the vaccination (if desired).
- to know what tasks they perform that have the potential for occupational exposure to bloodborne pathogens.
- to attend annually, as assigned, bloodborne pathogens training sessions.
- to consistently use all the engineering controls, work practices and appropriate personal protective equipment as set forth in this plan (Sections 5 and 6).
- to plan and conduct all operations in accordance with this plan.
- to immediately report to their supervisor all unsafe conditions and all bloodborne pathogens exposure incidents or near miss situations.

3.6 Custodial Services

Custodial Services is responsible for determining and implementing appropriate written schedules and methods for cleaning areas of the facility where there is the potential for exposure to bloodborne pathogens or other potentially infectious materials.

Section 4 Exposure Determination

OSHA requires employers to determine which employees may incur an occupational exposure to blood or other potentially infectious materials using the definition listed in Section 2. The exposure determination will be made without regard to the use of personal protective clothing.
Exposure determinations will be made by EHS personnel in conjunction with departmental business managers, area administrators and Principal Investigators using the criteria established by the Yale Biological Safety Committee. Exposure determinations of personnel working in non-laboratory areas will be reviewed by EHS personnel and area administrators prior to conducting annual retraining in the area.

Jobs are categorized as follows:

- **Category I** - Job classifications in which required tasks routinely involve a potential for mucous membrane or skin contact with potentially infectious materials. Use of appropriate control measures is required for every employee falling under this category.

- **Category IIA** - Job classifications in which required tasks normally do not involve Category I exposure potential, but may require performing some Category I tasks. In these job classifications, the work routine normally does not involve exposure to potentially infectious materials. However, exposure or potential exposure may be required as a condition of employment.

- **Category IIB** - Job classifications whose description does not meet category I or IIA criteria and are, therefore, not covered by the Standard.

Employees are required to perform their exposure determination by completing the Training Requirement Assessment through the Training Management System (TMS) [http://ehs.yale.edu/training](http://ehs.yale.edu/training). The Training Requirement Assessment must be completed at time of hire by new employees and annually thereafter. Jobs that are assigned to category I or IIA are listed in Appendix 3. The tasks performed by category I or IIA personnel that could lead to exposure are also listed in Appendix 2.

**Section 5  Methods of Compliance**

This section describes exposure control methods required by the Standard.

### 5.1  Universal Precautions

All activities involving contact with human blood or other potentially infectious materials (including the handling of contaminated or potentially contaminated equipment) must be conducted as if the materials are known to be infectious. In circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids must be considered to be potentially infectious materials. When performing activities involving potential contact the following standard practices shall be followed:

- Gloves must be worn when contact is anticipated with human blood or other potentially infectious materials.

- Hands are washed following removal of personal protective equipment, after glove contamination, prior to leaving the laboratory and after using the restroom.

- An impervious gown, apron or lab coat must be worn if contamination of clothing by splash or splatter of blood or other potentially infectious materials is possible.

- Full face protection is worn any time liquids or tissues are handled. Full face protection may be achieved with a full-face shield or safety glasses/goggles and a surgical mask.
• Employees with breaks in the skin should not handle blood or other potentially infectious materials. Employees should consult with immediate supervisors and Yale Employee Health for an evaluation of breaks in the skin to determine if waterproof bandages and double gloving can serve as a barrier to exposure.

• Sharps must be handled carefully (See section 5.3.3).

• Mouthpieces, resuscitation bags and other resuscitation devices must be made available to staff for use in areas where the need for resuscitation is likely. This includes emergency response personnel.

5.2 Engineering Controls

"Engineering Controls" are controls (e.g., biological safety cabinets, sharps disposal containers or self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate the bloodborne pathogen hazard by placing a barrier between staff and the contaminated material. Engineering controls should be utilized first when attempting to control exposures to blood and other potentially infectious materials. The engineering controls listed below should be provided and must be examined, maintained or replaced periodically to ensure their effectiveness.

5.2.1 Safe Sharps

Sharps injuries can occur in any situation where sharps are utilized. Safe sharps devices and safe work practices, when used together, can reduce the chance of an exposure. Safe sharps are not a substitute for proper disposal in needle boxes.

“Sharps with Engineered Sharps Injury Protections” include non-needle sharps or needle devices containing built-in safety features that are used for collecting fluids or administering medications or other fluids or other procedures involving the risk of sharps injury. This description covers a broad array of devices, including:

• syringes with a sliding sheath that shields the attached needle after use
• needles that retract into a syringe after use
• shielded or retracting catheters
• intravenous (IV) medication delivery systems that use a catheter port with a needle housed in a protective covering

“Needleless Systems” are devices that provide an alternative to needles for various procedures to reduce the risk of injury from contaminated sharps. Examples include IV medication systems which administer medication or fluids through a catheter port using non-needle connections and jet injection systems that deliver liquid medication beneath the skin or through a muscle.

Safe sharps devices, such as needleless systems and needles that include safety features, must be evaluated by the employer to prevent or minimize exposure. The employer must solicit input from non-managerial staff in the evaluation and selection of effective engineering controls. The employer must also evaluate whether these devices could prevent future incidents as part of its responsibility under the law in evaluating exposures that occur in the workplace. The employer must document each evaluation
and continue to pursue engineering controls that are designed to prevent occupational exposure. Finally, where a new engineering control is issued, suitable training on its use must be provided to the employees and documented.

Whenever an injury involves a sharp and human material (body fluid, tissue, cell line, etc.) EHS must perform an investigation to determine if a safe sharps device is available to prevent future occurrences of the injury. If safe sharps devices are available, they must be evaluated by EHS in conjunction with the Group or Department. The incident must also be recorded on the University’s Sharps Injury Log, maintained by the Worker’s Compensation Office. The confidential log will include: the type and brand of device involved in the incident; the Department or work area where the exposure incident occurred; and an explanation of how the incident occurred.

Where engineering controls will reduce employee exposure either by directly removing, eliminating or isolating the hazard, they must be used. Sample evaluation forms for safety devices can be found in Appendix 4. Examples of safe sharps devices currently used at Yale are: Vanish-Point Syringes, Point-Lok Sharps Safety Device, Needle-Pro Needle Protection Devices, Safety Glide Shielding Hypodermic Needle, Safety Glide Syringe Safety-Lok Syringe, Eclipse Needle, Vacutainer Safety-Lok Blood Collection set and Personna Safety Scalpel.

5.2.2 Sharps Containers
Where sharps are stored, handled or reasonably anticipated to be encountered, sharps containers must be installed. These containers must meet the following criteria: 1) closable; 2) puncture resistant; 3) leakproof on sides and bottom and 4) properly marked.

5.2.3 Mechanical hand-pipetting devices.
Mouth pipetting is prohibited at Yale University. Mechanical pipetting devices must be utilized.

5.2.4 Biosafety Cabinets
Biosafety Cabinets must be provided as required in Section 6.

5.3 Work Practice Controls
Work Practice Controls reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting the recapping of needles).

5.3.1 Good General Work Practices
The following good work practices must be followed:

- Eating, drinking, smoking, applying cosmetics or lip balm and handling contact lenses are prohibited in work areas (e.g., laboratories). Please note: Non-petroleum based hand creams are not considered "cosmetics".

- Food and drink must not be kept in refrigerators, freezers, shelves, cabinets or on countertops or bench-tops in the laboratory or where blood or other potentially infectious materials are stored.

- Employees must change any contaminated clothing and wash before entering lunch or break rooms or public areas. Protective clothing worn in the laboratory or patient care areas is not to be worn outside the laboratory or patient care area.
• All procedures involving blood or other potentially infectious materials must be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.

• Mouth pipetting is prohibited at Yale University.

5.3.2 Hand Washing

Employees must wash their hands and any other body part potentially contaminated with blood or other potentially infectious materials with soap and water immediately. Employees must also wash their hands immediately after removing gloves. Each department must provide all covered employees with readily accessible hand washing facilities. If this is not possible due to the nature and location of the activity being conducted, antiseptic towelettes/cleansers must be provided. When antiseptic hand cleansers or towelettes are used, hands must be washed with soap and running water as soon as feasible.

5.3.3 Handling Sharps

The following work practices should be followed when handling and disposing of sharps:

• Minimize the handling of all sharps. Use plastic alternatives whenever possible.

• Dispose of the needle and syringe as an intact unit immediately after use. Do not remove needles from syringes.

• Never recap needles.

• Do not pick up broken glass by hand; use mechanical means (brush and dustpan, tongs, or forceps). Dispose of sharps properly (in a sharps container), making sure the container is properly labeled or colored.

• When reusable sharps (surgical needles, scalpels) that are contaminated with potentially infectious materials are either stored or processed, they must be placed in appropriate containers as soon as possible after use. They must not be handled in a manner that requires employees to reach by hand into the containers in which these sharps have been placed.

• No container will be opened, emptied or cleaned manually, or in any other manner, which would expose employee to the risk of percutaneous injury.

• Sharp containers must be kept in the immediate vicinity of use.

• Replace sharps containers when they are 3/4 full to prevent overfilling. The container must be closed prior to removal from the area to prevent spillage or protrusion of contents. Appropriate secondary containment must be used if leakage is possible.

• Sharps must be disposed or transferred only in the appropriate, labeled sharps containers provided by EHS (Environmental Affairs Section). The containers must remain upright and not be overfilled. Needle sharps boxes are no longer delivered to the laboratory, but are available for free through the Medical School, KBT and West Campus stockrooms. Contact the Environmental Affairs Section at 432-6545 for more information.
5.3.4 Specimen Handling and Processing

Specimens of blood or other potentially infectious materials must be placed in a leak-proof container during collection, handling, processing and storage. When transporting specimens between labs or buildings, two leak-proof containers must be used. The requirements for transport are:

- A sealed primary container
- A sealed secondary container
- Absorbent, such as paper towels, between the primary and secondary containers suitable for the volume transported
- A biohazard sticker on the outside of the secondary container with the agent name listed
- Lab address and phone number on the outside of the secondary container

Utilize plastic containers whenever feasible; avoid glass. Sealed plastic (not glass) primary vials can be transported within sealed, labeled plastic bags. If glass primary containers must be used, place containers within a sealed rigid plastic container with absorbent and padding to cushion vials during transport.

Decontaminate the outside of the primary container before placing into the secondary container.

Decontaminate the secondary container before leaving the laboratory.

5.3.5 Equipment Decontamination

Equipment which may have become contaminated with blood or other potentially infectious materials must be examined prior to shipping or discard and must be decontaminated as necessary, unless the area supervisor or principal investigator can demonstrate that decontamination of such equipment or portions of such equipment is not feasible. If complete decontamination is not possible a readily observable biohazard label must be attached to the equipment stating which portions remain contaminated. The area supervisor or Principal Investigator must ensure 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.

5.4 Personal Protective Equipment

Personal protective equipment (PPE) must not be used as a substitute for proper engineering and work practice controls. Departments or Principal Investigators must provide, at no cost to the employee, personal protective equipment to Category I, and when appropriate to Category IIA employees. This equipment must be readily accessible to users, impermeable to blood and other potentially infectious materials, and of appropriate size for the user. Personal protective equipment should cover all body surfaces that may come in contact with blood or other potentially infectious material. Personal protective equipment will include, but not be limited to, the following:

- Gloves - 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; and when handling or touching contaminated items or surfaces. If employees are allergic to the gloves normally provided, alternatives must be provided.
- Non-disposable utility gloves - worn when appropriate (these may be decontaminated and reused provided their ability to function as a barrier is not compromised).
- Protective clothing (gowns, laboratory coats, aprons, etc.) - worn when appropriate for the task being performed and the degree of exposure anticipated. In situations when gross contamination can reasonably be anticipated, surgical caps and shoe covers must be provided and used.

- Face protection sufficient to shield the eye, nose and mouth from splashes, sprays, splatter or droplets of potentially infectious materials - worn when contamination can be reasonably anticipated.

- Ventilation devices (pocket masks, resuscitation bags, mouthpieces, etc.)

Personal protective equipment must be repaired or replaced regularly to maintain effectiveness.

5.4.1 Changing, Cleaning, Laundering, and Disposal of Personal Protective Equipment

Personal protective equipment required by the Exposure Control Plan must be cleaned, laundered, and disposed of at no cost to the employee whenever necessary to maintain effectiveness. Contaminated personal protective equipment (such as lab coats) must be decontaminated (autoclaving preferred) prior to laundering.

A garment must be removed immediately, or as soon as feasible, if it is penetrated by blood or other potentially infectious materials and prior to leaving the work area. Personal protective equipment must be placed in an appropriately designated area or container for storage, washing, decontamination or disposal following removal.

Disposable (single-use) gloves, such as surgical or examination gloves, must not be washed or decontaminated for re-use. They must 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.

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.

5.5 Housekeeping

All areas of the facility where there is the potential for bloodborne pathogens or other potentially infectious material exposure will be cleaned in accordance with the schedules and methods developed by Custodial Services. Principal Investigators and area supervisors will determine and implement appropriate written schedules for cleaning and method of decontamination when technical or professional staff also perform housekeeping activities. These schedules will be based upon the location within the university, type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area.

Principal Investigators or area supervisors must ensure that all equipment and work surfaces are cleaned and decontaminated after contact with blood or other potentially infectious materials as follows:

- Contaminated work surfaces must be decontaminated with an appropriate disinfectant (e.g. 1 – 10% bleach or an effective EPA-registered tuberculocidal disinfectant): 1) after completion of procedures; 2) when surfaces are overtly contaminated (such as after a spill of blood or other
potentially infectious materials and 3) at the end of the work shift if the surface may have become contaminated since the last cleaning.

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

- 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 must be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination.

Do not use hands to pick up broken glassware. Use mechanical means such as a brush and dust pan, tongs or forceps. Vacuum cleaners are not appropriate for the cleanup of broken glass.

5.6 Regulated Waste

Principal Investigators and immediate supervisors must ensure that all regulated waste (defined in Section 2) is disposed of through the EHS Environmental Affairs Section in compliance with the procedures outlined in Yale's "Biomedical Waste Management Guide". Only containers approved by Environmental Health and Safety will be used. All sharps must be handled and disposed of as outlined in section 5.3.3.

5.7 Laundry

Contaminated laundry (bedding, etc.) must be handled as little as possible with a minimum of agitation. Contaminated laundry must be bagged or containerized at the location where it was used and must not be sorted or rinsed in the location of use. Contaminated laundry must be placed and transported in bags or containers that are labeled with the biohazard symbol or are red in color. Whenever contaminated laundry is wet and presents a reasonable likelihood of leakage from the bag or container, the laundry must be placed and transported in secondary containers to prevent leakage. Immediate supervisors must ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment.

Yale employees will not send contaminated laundry off site to a second facility that has not been approved by the Purchasing Department and Environmental Health and Safety.

Section 6 Research with Human Immunodeficiency Virus and Hepatitis B virus

In addition to all other requirements listed in this policy, all departments engaged in the culture, production, concentration, experimentation and manipulation of HIV or HBV, including laboratory and animal facilities, must comply with Section 6 requirements. Clinical or diagnostic laboratories engaged solely in analysis of blood, tissues or organs are exempt from this Section. The Principal Investigator or laboratory supervisor of HIV and HBV research laboratories must ensure the following criteria are met.

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

- A sign containing the international biohazard symbol in fluorescent orange or orange red with lettering or symbols in a contrasting color must be posted at all entrances to work areas covered under this Section. The sign must read "BIOHAZARD" and include: 1) name of infectious agent, 2) special requirements for entering the area and 3) name and telephone number of the laboratory director or another responsible person(s).

- All activities involving potentially infectious materials must be conducted in biosafety cabinets and not on open counters or benches. The biosafety cabinet must have a current (annual) inspection certificate. Biosafety cabinets must be certified when originally installed, following repairs or when moved. Consult Yale's "Clean Air Device Program Guide" for additional information on this topic.

- 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, will be used for all activities with "other potentially infectious materials" that pose a threat of exposure to droplets, splashes, spills or aerosols.

- Supervisory personnel must strictly enforce the use of personal protective equipment, including but not limited to protective clothing, by all persons in the work area. Laboratory coats, gowns, smocks, uniforms or other appropriate protective clothing must be worn. Special care must be taken to avoid skin contact with potentially infectious materials. Gloves must be worn when handling infected animals and when making hand contact with potentially infectious materials is unavoidable. Under no circumstances will personnel be allowed to leave the work area prior to removal or decontamination of protective clothing.

- All spills must be immediately or as soon as feasible cleaned up by laboratory staff properly trained and equipped to work with concentrated infectious materials. A spill or accident that results in an "exposure incident" must be immediately reported to the laboratory supervisor and the employee's immediate supervisor.

- Where vacuum lines are used, they must be equipped with liquid disinfectant traps and high efficiency particulate air (HEPA) filters. These should be checked and maintained routinely.

- Hypodermic needles and syringes must 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) will be used for the injection or aspiration of "other potentially infectious materials". Extreme caution must be used when handling needles and syringes. A needle must not be re-capped, bent, sheared, replaced in the sheath or guard or removed from the syringe following use. The needle and the syringe must be promptly placed in a puncture-resistant sharps container and autoclaved or decontaminated before disposal.

- Handwashing and eyewash facilities must be installed in each laboratory, within the work area, so these are readily available to the occupants.
• Autoclave facilities must be available for decontamination of regulated waste. Before disposal, all waste from work areas and from animal rooms must be decontaminated by a method (such as autoclaving) known to effectively destroy bloodborne pathogens. Contaminated materials that are to be decontaminated at a site away from the work area must be placed in a durable, leakproof, labeled or color-coded container that is closed before being removed from the work area.

• Within each laboratory there must be accessible and readily available copies of the following documents: 1) this Exposure Control Plan and the OSHA Bloodborne Pathogen Standard; 2) the current edition of the CDC/NIH publication "Biosafety in Microbiological and Biomedical Laboratories" and 3) Yale's Biomedical Waste Management Guide. In addition, a laboratory-specific biosafety manual must be prepared, periodically reviewed and updated at least annually. This manual will contain any additional procedures that are necessary to protect employees in situations unique to a HIV or HBV research facility. Personnel must be advised of potential hazards, must be required to read instructions on practices and procedures, and must be required to follow them.

• Each Principal Investigator or immediate supervisor will ensure that research employees: 1) 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 and 2) have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.

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

• Production of HIV or HBV is specifically prohibited under this Policy. A waiver may be granted after review by the Yale Biological Safety Committee, upon demonstrable evidence of strict compliance and adherence with the Section of the Standard governing HIV and HBV production facilities.

Section 7 Medical Surveillance

All Hepatitis B vaccination medical evaluations and procedures and post-exposure follow-up will be made available at no cost to covered employees as well as employees experiencing an exposure incident. Yale Health will provide these evaluations and procedures. The evaluations and procedures will be performed under the supervision of a licensed healthcare professional and per the current recommendations of the U.S. Public Health Service. Any laboratory tests will be conducted by an accredited laboratory at no cost to the employee.

7.1 Hepatitis B Vaccination

Yale Health will make available to all covered employees, at no cost to the employee and during normal business hours, the HBV vaccination series and antibody testing which shows the employee has sufficient immunity to hepatitis B virus. This will also include any routine booster dose(s) that may be recommended by the U.S. Public Health Service at a future date. All HBV vaccinations will be performed under the direction of the Employee Health Physician.
The vaccine will be made available after initial training and within 10 working days of the category I or IIA employee’s initial assignment to tasks involving the potential for occupational exposure to blood or other potentially infectious materials. The term "made available" includes the healthcare professional's evaluation and arranging for the administration of the first dose of the hepatitis B vaccination series to begin within 10 days. The vaccine will be administered only after the employee has received information on the vaccine, its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge. EHS will make a diligent effort to identify all covered employees. However, it is the responsibility of the immediate supervisor to ensure that covered employees working for them are aware of the vaccination series and have the opportunity to receive vaccinations.

Covered employees who initially decline the vaccine but who later wish to have it may still have the vaccine provided at no cost. Covered employees who decline the hepatitis B vaccine must sign a waiver form, which uses the wording found in the OSHA Standard. Yale has incorporated the waiver statement into a document entitled "Hepatitis B Vaccination Notification Form". A copy of the notification form is presented in Appendix 5 of this document. EHS is responsible for maintaining signed or electronic copies of the "Hepatitis B Vaccination Notification Form".

The vaccine need not be administered if the employee has previously had the vaccine or antibody testing shows that the employee has sufficient immunity to hepatitis B virus. The vaccine need not be administered if medically contraindicated and this must be documented in the employee’s medical record. Employee Health will not make participation in a prescreening program a prerequisite for receiving hepatitis B vaccination. However, pre-vaccination screening can be offered by Employee Health if it is made available at no cost to the employee.

7.2 Post-exposure Evaluation and Follow-up

Immediate supervisors must ensure that all who are exposed or injured immediately wash the affected area for 15 minutes in an eyewash for facial mucous membrane exposures or wash skin and wounds with soap and water for 15 minutes. After immediate washing, staff must also seek medical assistance by first calling the appropriate location to speak with a nurse and make arrangements for evaluation and treatment. This change is due to the COVID-19 pandemic. Please check with EHS or Employee Health for updates to this procedure.

All Campus Areas:
Yale Health Center
55 Lock Street
Employee Health, 2nd Floor 203-432-7978
Mon.—Fri. / 8:30am—5:00pm
Acute Care. 1st Floor, 24hrs./7 days a week 203-432-0123

In Medical Area ONLY may select:
Y-NHH Occupational Health Services
East Pavilion 1—Room 40 (behind cafeteria)
Mon.—Fri. excluding holidays
Following the report of an exposure incident, the immediate supervisor will file a claim online for the exposure or injury:

For Employees: Search "Yale First Report of Injury" to access the form.

For Non-Employees (students, visitors): Search "Yale Reporting Accidents and Insurance Claims".

Immediate supervisors must ensure that exposed or injured staff contact Yale Employee Health for follow-up after an injury or exposure. Call 203-432-7978 to reach Yale Employee Health to schedule a follow-up appointment within 48 hours after immediate medical assistance has been provided.

Section 8 Communication of Hazards to Employees

Employees must be advised of the presence of blood or other potentially infectious materials via appropriate labeling and signage. Training sessions for covered employees must further define and communicate the hazards associated with bloodborne pathogens.

8.1 Warning labels

Warning labels must be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious materials and other containers used to store, transport or ship blood or other potentially infectious materials. Exceptions to this requirement are: 1) red containers, 2) containers of blood, blood components or blood products that are labeled as to other contents and have been released for transfusion or other clinical use and 3) individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal.

- Labels required under this Section must consist of the international biohazard symbol in fluorescent orange or orange red with lettering or symbols in contrasting color.
- Labels must be affixed as close as feasible to the container by string, wire, adhesive or other methods that prevent their loss or unintentional removal.
- Labels required for contaminated equipment will be in accordance with this Section and must also indicate which portions of the equipment are contaminated (see Section 5.3.5).

8.2 Door Signs

As indicated in Section 6.0, a sign containing the international biohazard symbol in fluorescent orange or orange red with lettering or symbols in a contrasting color must be posted at all entrances to work areas covered under Section 6.0. The sign will read "BIOHAZARD" and must include: 1) name of infectious agent, 2) special requirements for entering the area and 3) name and telephone number of the laboratory director or another responsible person(s).
8.3 Information and Training

All training must incorporate the required elements listed in the Standard. Training will be provided to all covered employees: 1) at the time of assignment to the task where occupational exposure may occur and 2) annually thereafter. Departments may train their employees or have them attend training sessions presented by personnel from EHS. If departments perform their own training, they must submit a copy of their training curriculum and trainer's qualifications to EHS for approval prior to providing training to covered employees. Training records must be submitted to EHS and will include 1) the date of training, 2) the name of the trainer and 3) the name and job titles of the attendees. The person conducting the training session must be knowledgeable in the subject matter contained in the training program as it relates to the workplace that the training will address.

Immediate supervisors must 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.

The material presented must be appropriate in content and vocabulary to educational level, literacy and language of employees.

Section 9 Recordkeeping

Required documentation and records retention compliance will be as follows:

9.1 Medical Records

The Department of Employee Health within Yale Health will establish and maintain an accurate medical record for each employee with occupational exposure at the point s/he receives the initial HBV vaccination. The record will meet all requirements of the OSHA "Access to employee exposure and medical records" Standard (29 CFR 1910.1020) and this Standard. Yale Health will ensure that required employee medical records are kept confidential. Medical records are available only to healthcare professionals providing care to the employee/patient or the employee. Yale Health will not disclose or report the required employee medical records without the employee's express written consent to any other person within or outside the workplace except as required by this section or as may be required by law. Yale Health will maintain the required medical records for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020.

9.2 Training Records

EHS will maintain all training records. The records will contain the following information: 1) the dates of the training sessions; 2) the contents or a summary of the training sessions; 3) the names and qualifications of persons conducting the training and 4) the names and job titles of all persons attending the training sessions. EHS will ensure all required training records are maintained for 3 years from the date on which the training occurred. Departments performing their own training are responsible for forwarding training records to EHS.

9.3 Availability of Training and Medical Records

EHS will ensure all required training records are made available upon request for examination and copying to employees, to employee representatives, to the Assistant Secretary of Labor for Occupational
Safety and Health (or designated representative) and the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services (or designated representative) in accordance with 29 CFR 1910.1020.

Yale Health will ensure that required medical records are provided upon request for examination and copying to the subject employee, anyone having written consent of the subject employee, the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services (or designated representative) and the Assistant Secretary of Labor for Occupational Safety and Health (or designated representative) in accordance with 29 CFR 1910.1020.

9.4 Transfer of Records

Yale University will comply with all records transfer requirements outlined in 29 CFR 1910.1020(h).

9.5 Sharps Injury Log

Yale University has established and maintains a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The sharps injury log contains: the type and brand of device involved in the incident, the department or work area where the exposure incident occurred and an explanation of how the incident occurred. The sharps injury log will be maintained as outlined in 29 CFR 1904.8

Section 10 Implementation Schedule

Pursuant to the OSHA Bloodborne Pathogens Standard, Yale University must set forth the schedule for implementation of the various requirements of the Standard. Historically, the University has been proactive in protecting its employees against exposure to biological hazards. Training in operational procedures and use of personal protective equipment to protect employees in microbiological laboratories has been provided for many years and use of biosafety cabinets began during the 1970's. Universal precautions have been observed for over a decade. Hepatitis B vaccination has been offered to occupationally exposed employees since 1989. Medical counseling and evaluation following exposure incidents is also offered.

As offered in accordance with the standard, the dates set forth by OSHA for implementation of the components of the OSHA regulation on Occupational Exposure to Bloodborne Pathogens were as follows:

- May 5, 1992 Exposure Control Plan
- June 4, 1992 Training and Recordkeeping
- April 18, 2001 Sharps with Engineered Sharps Injury Protections
Needleless Systems

The Needlestick Safety and Prevention Act, which was signed into law on November 6, 2000, directed OSHA to revise its Bloodborne Pathogens Standard. That revision took effect on April 18, 2001. The revision set forth in greater detail and made more specific OSHA’s requirement for employers to identify, evaluate, and implement safer medical devices.
Appendix 1: OSHA Bloodborne Pathogens Standard

e-CFR data is current as of June 4, 2020

Title 29 → Subtitle B → Chapter XVII → Part 1910 → Subpart Z → §1910.1030

§1910.1030 Bloodborne pathogens.

(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 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—(1) Exposure Control Plan. (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.

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

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

(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) The procedure for the evaluation of circumstances surrounding exposure incidents as required by paragraph (f)(3)(i) of this standard.
(iii) Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.20(e).

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

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

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

(v) An employer, who is required to establish an Exposure Control Plan shall solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan.

(vi) The Exposure Control Plan shall be made available to the Assistant Secretary and the Director upon request for examination and copying.

(2) Exposure determination. (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:

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

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

(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.

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

(d) Methods of compliance—(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.

(2) Engineering and work practice controls. (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.

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

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

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

(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.

(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.

(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.

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

(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:

(A) Puncture resistant;

(B) Labeled or color-coded in accordance with this standard;

(C) Leakproof on the sides and bottom; and

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

(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.

(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.

(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.

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

(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.

(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.

(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.

(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.

(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.

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

(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.

(3) Personal protective equipment—(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.

(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.

(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.

(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.
(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.

(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.

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

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

(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.

(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.

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

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

(1) Periodically reevaluate this policy;

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

(3) Not discourage the use of gloves for phlebotomy; and

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

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

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

(iii) When the employee is receiving training in phlebotomy.

(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.

(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.

(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).

(4) **Housekeeping**—(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.

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

(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.

(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.

(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) 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.

(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.

(iii) **Regulated Waste**—(A) **Contaminated Sharps Discarding and Containment.** (1) Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:

(i) Closable;

(ii) Puncture resistant;

(iii) Leakproof on sides and bottom; and

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

(2) During use, containers for contaminated sharps shall be:

(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);
(ii) Maintained upright throughout use; and

(iii) Replaced routinely and not be allowed to overfill.

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

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

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

(A) Closable;

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

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

(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.

(B) Other Regulated Waste Containment—(1) Regulated waste shall be placed in containers which are:

(i) Closable;

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

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

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

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

(i) Closable;

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

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

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

(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.

(iv) Laundry. (A) Contaminated laundry shall be handled as little as possible with a minimum of agitation. 

(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.
(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.

(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.

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

(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. (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.

(2) Research laboratories and production facilities shall meet the following criteria:

(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.

(ii) Special practices. (A) Laboratory doors shall be kept closed when work involving HIV or HBV is in progress.

(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.

(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.

(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) 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.
(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.

(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.

(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.

(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.

(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.

(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.

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

(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.

(iii) Containment equipment. (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.

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

(3) HIV and HBV research laboratories shall meet the following criteria:

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

(ii) An autoclave for decontamination of regulated waste shall be available.

(4) HIV and HBV production facilities shall meet the following criteria:
(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.

(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.

(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.

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

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

(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).

(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—(1) General. (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.

(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:

(A) Made available at no cost to the employee;

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

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

(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).

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

(2) Hepatitis B Vaccination. (i) Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii)(l) 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.

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

(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.

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

(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).

(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:

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

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

(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.

(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.

(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.

(iii) Collection and testing of blood for HBV and HIV serological status;

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

(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.

(iv) Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;
(v) Counseling; and

(vi) Evaluation of reported illnesses.

(4) Information Provided to the Healthcare Professional. (i) The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

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

(A) A copy of this regulation;

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

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

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

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

(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.

(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.

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

(A) That the employee has been informed of the results of the evaluation; and

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

(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—(1) Labels and signs—(i) Labels. (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).

(B) Labels required by this section shall include the following legend:
(C) These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color.

(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.

(E) Red bags or red containers may be substituted for labels.

(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) 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.

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

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

(ii) Signs. (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.

(B) These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color.
(2) **Information and Training.** (i) The employer shall train each employee with occupational exposure in accordance with the requirements of this section. Such training must be provided at no cost to the employee and during working hours. The employer shall institute a training program and ensure employee participation in the program.

(ii) Training shall be provided as follows:

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

(B) At least annually thereafter.

(iii) [Reserved]

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

(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.

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

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

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

(B) A general explanation of the epidemiology and symptoms of bloodborne diseases;

(C) An explanation of the modes of transmission of bloodborne pathogens;

(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;

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

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

(H) An explanation of the basis for selection of personal protective equipment;

(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;

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

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

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

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

(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.

(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.

(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.

(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.

(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—(1) Medical Records. (i) The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020.

(ii) This record shall include:

(A) The name of the employee;

(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);

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

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

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

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

(A) Kept confidential; and
(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.

(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.

(2) **Training Records.** (i) Training records shall include the following information:

(A) The dates of the training sessions;

(B) The contents or a summary of the training sessions;

(C) The names and qualifications of persons conducting the training; and

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

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

(3) **Availability.** (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.

(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.

(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.

(4) **Transfer of Records.** The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(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 part 1904.

(iii) The sharps injury log shall be maintained for the period required by 29 CFR 1904.33.

(i) **Dates**—(1) **Effective Date.** The standard shall become effective on March 6, 1992.

(2) The Exposure Control Plan required by paragraph (c) of this section shall be completed on or before May 5, 1992.
(3) Paragraphs (g)(2) Information and Training and (h) Recordkeeping of this section shall take effect on or before June 4, 1992.


Appendix A to Section 1910.1030—Hepatitis B Vaccine Declination (Mandatory)

I understand that due to my occupational exposure to blood or other potentially infectious materials 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 myself. However, I decline hepatitis B vaccination 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 blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.

Appendix 2: Tasks and procedures for Category IIA Job Classifications

Laboratory and Clinical Task and Procedures:

1. Processing, handling or removing waste contaminated with human blood or other potentially infectious materials
2. Performing vascular access procedures
3. Processing or handling human blood (including human blood products), or other potentially infectious materials (including unfixed human tissues or organs) for research or clinical use
4. Working with human cell lines (primary human cell lines or continuous human cell lines that have not been shown to be free of bloodborne pathogens)
5. Working with animals infected with HIV, HBV, or other bloodborne pathogens (including field work with exposure to ticks or other vectors)
6. Working with animal or human cells, tissues or organs infected with HIV, HBV or other bloodborne pathogens
7. Working with non-human primates or unfixed material from non-human primates
8. Transporting human blood or other potentially infectious materials
9. Manipulating blood or other potentially infectious materials from patients
10. Working with non-human materials, but use the same lab equipment other employees use with human blood or other potentially infectious material
11. First Aid responder

Custodial Tasks and Procedures:

1. Clean-up human blood or body fluid spills in common areas

Physical Plant Tasks and Procedures:

1. Respond to waste-line repairs and clean-up of waste water
2. Repair/service drains used for the disposal of human blood or body fluids

Police Tasks and Procedures:

1. Arrest injured suspects
2. Emergency first-aid responder
3. Collect sharps evidence

Other Areas (not listed above) Tasks and Procedures:

1. First Aid responder
2. Clean up human blood or body fluid spills
Appendix 3: Category IIA Job Classifications Where Some Employees are "Occupationally Exposed"

**Job Title**

<table>
<thead>
<tr>
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<td>Clin Receptionist II</td>
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<td>Clin Res Nurse I</td>
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<td>Equipment Mechanic</td>
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Furniture Mover
Gardener IX
Gardener VIII
Genetic Counselor I
Genetic Counselor II
Genetic Counselor III
Graduate Student Fellowship Hold
Groundskeeper IV
Groundskpr III
Groundskpr VI
Hd Athletic Trnr II
Health Educator
Health/Safety Technician 3
Hd Athletic Trnr II
Health Educator
Health/Safety Technician 3
Hospital Resident
HVAC Mechanic
HVAC Mechanic
HVAC Mechanic
Instructor
Intern-NE
IVF Laboratory Manager
Lab Assistant I
Lab Assistant II
Lab Assistant III
Laboratory Associate
Lecturer
Licensed Practical Nurse (E)
Light Custodian
Locksmith
Manager I
Manager II
Manager III
Manager IV
Manager V
Manager VI
Managerial Upper
Managing Editor, Journal
Master Gardener
Master Grounds Maintenance Mechanic
Materials Assistant I
Media Technician II
Medical Assistant
Medical Assistant II
Museum Educator
New Recruit
Nurse Manager
Nurse Mid-Wife
Nurse Practitioner
Office Assistant III
Optometrist
Paid New Recruit
Pathology Assistant
Pharmacist
Pharmacy Technician
Physician
Physician's Assistant
Plumber
Police Lieutenant
Police Officer
Police Sergeant
Postdoctoral Associate
Postdoctoral Fellow
Postgraduate Associate
Postgraduate Fellow
Professor Adjunct
Professor Adjunct of Research
Professor, Clinician-Educator
Professor, Clinician-Scholar
Professor, Investigator
Professor, Phased Retirement
Professor, Tenure
Program Coordinator 2, Expert Resou
Psychiatric Assistant
Radiologist Assistant
Registered Nurse I
Registered Nurse II
Rehabilitation Counselor
Research & Development Tech 4
Research & Development Tech II
Research & Development Tech III
Research Aide
Research Assistant 3 HSS
Research Assistant 3 MS
Research Assistant I
Research Assistant I-HSS
Research Assistant II
Research Assistant II-HSS
Research Associate I, HSS
Research Associate I, HSS
Research Associate I, MS
Research Associate II, HSS
Research Associate II, MS
Research Associate III, HSS
Research Associate III, MS
Research Associate IV, MS
Research Scientist
Research Scientist/Scholar
Research Support Specialist III
Retired Faculty
Sanitation Truck Driver
Sanitation Worker
Senior Administrative Assistant
Senior Administrative Assistant 2
Senior Research Scientist/Scholar
Service Assistant I
Shift Coordinator
Social Worker I
Social Worker II
Special Education Teacher
Sr Custodian
Sr. Supervisor, Facilities Function
Staff Affiliate
Staff Psychologist
Student Aide 5
Student Aide I
Student Aide II
Student Aide III
Student Aide IV
Student Services Officer IV
Substance Abuse Counselor
Supervisor I
Supervisor II
Supervisor II
Supervisor III
Supervisor IV
Supervisor, OTE
Teaching Assistant
Teaching Fellow I
Temporary CT
Temporary MP
Temporary Student
Visiting Assistant Professor
Visiting Associate Professor
Visiting Professor
Visiting Research Scientist/Scholar
Visiting Student in Research
Woodbridge Fellow
Appendix 4: Safety Device Evaluation Form

Sharps Safety Device Evaluation Record

**Evaluation performed due to:**
- Follow-up to an injury/exposure involving a contaminated sharp
- Proactive review of sharps use with human material, other potentially infectious materials (e.g. human or animal pathogens)

<table>
<thead>
<tr>
<th>Evaluation Date:</th>
<th>Principal Investigator:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Department:</th>
<th>Building/Room#:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Contact Employee:</th>
<th>Phone:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Fax:</th>
<th>Email:</th>
</tr>
</thead>
<tbody>
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<td></td>
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</tbody>
</table>

Procedure involving a contaminated sharp:

Type/Brand of sharp currently in use:

**Recommendation:**
- Elimination of sharp from procedure
- Substitution with a safe sharps device
- Use of engineering controls
- Implementation of safe work practices
- Personal Protective Equipment
- No recommendation needed at this time, effective safety device(s) currently in use.

Device(s) in use:

**Results of training and evaluation of new device:**
- Type/Brand of sharp(s) evaluated:
- List employees involved in formal evaluation of safe sharps device(s): ____________________________
- Training date for work with new safe sharps device(s): ____________________________
- Device(s) formally in use following evaluation (selection/use date): ____________________________

Complete and return all forms to: Environmental Health & Safety
135 College St., Suite 100
Fax: 203-785-7588
SAFETY DEVICE FEATURE EVALUATION FORM (continued)

Device: 

Number of times used: 

Product Name/Supplier: 

Applications: 

Reviewer: Department: Date: 

Circle the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

### SAFETY SYRINGES

#### During Use:

1. The safety feature can be activated using a one-handed technique
   
<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

2. The safety feature does not obstruct vision of the tip of the sharp
   
<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>N/A</th>
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</thead>
<tbody>
<tr>
<td></td>
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</tr>
</tbody>
</table>

3. Use of this product requires you to use the safety feature
   
<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

4. This product does not require more time to use than a non-safety device
   
<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</tbody>
</table>

5. The safety feature works well with a wide variety of hand sizes
   
<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

6. The device is easy to handle while wearing gloves
   
<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

7. This device does not interfere with uses that do not require a needle
   
<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

8. This device offers a good view of any aspirated fluid
   
<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>N/A</th>
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</tbody>
</table>

9. This device will work with all required syringe and needle sizes
   
<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>N/A</th>
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</tbody>
</table>

10. This device provides a better alternative to traditional recapping
    
    | 1 | 2 | 3 | 4 | 5 | N/A |
    |---|---|---|---|---|-----|
    |   |   |   |   |   |     |

#### After Use:

11. There is a clear and unmistakable change (audible or visible) that occurs when the safety feature is activated
    
    | 1 | 2 | 3 | 4 | 5 | N/A |
    |---|---|---|---|---|-----|
    |   |   |   |   |   |     |

12. The safety feature operates reliably
    
    | 1 | 2 | 3 | 4 | 5 | N/A |
    |---|---|---|---|---|-----|
    |   |   |   |   |   |     |

13. The exposed sharp is permanently blunted or covered after use and prior to disposal
    
    | 1 | 2 | 3 | 4 | 5 | N/A |
    |---|---|---|---|---|-----|
    |   |   |   |   |   |     |

14. This device is no more difficult to process after use than non-safety devices
    
    | 1 | 2 | 3 | 4 | 5 | N/A |
    |---|---|---|---|---|-----|
    |   |   |   |   |   |     |

#### Training:

15. The user does not need extensive training for correct operation
    
    | 1 | 2 | 3 | 4 | 5 | N/A |
    |---|---|---|---|---|-----|
    |   |   |   |   |   |     |

16. The design of the device suggests proper use
    
    | 1 | 2 | 3 | 4 | 5 | N/A |
    |---|---|---|---|---|-----|
    |   |   |   |   |   |     |

17. It is not easy to skip a crucial step in proper use of the device
    
    | 1 | 2 | 3 | 4 | 5 | N/A |
    |---|---|---|---|---|-----|
    |   |   |   |   |   |     |

### I.V. ACCESS DEVICES

1. The safety feature can be activated using a one-handed technique
   
<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>N/A</th>
</tr>
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<tr>
<td></td>
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</tbody>
</table>

2. The safety feature does not interfere with normal use of this product
   
<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>N/A</th>
</tr>
</thead>
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<tr>
<td></td>
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</tr>
</tbody>
</table>

3. Use of this product requires you to use the safety feature
   
<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
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<th>5</th>
<th>N/A</th>
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<tr>
<td></td>
<td></td>
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</tbody>
</table>

4. This product does not require more time to use than a non-safety device
   
<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
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<tr>
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</table>

5. The safety feature works well with a wide variety of hand sizes
   
<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
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</table>

6. The device allows for rapid visualization of flashback in the catheter or chamber
   
<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
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</tbody>
</table>

7. Use of this product does not increase the number of sticks to the patient
   
<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

8. The product stops the flow of blood after the needle is removed from the catheter (or after the butterfly is inserted) and just prior to line connections or hep-lock capping
   
<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9. A clear and unmistakable change (either audible or visible) occurs when the safety feature is activated
   
<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>N/A</th>
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</thead>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

10. The safety feature operates reliably
    
    | 1 | 2 | 3 | 4 | 5 | N/A |
    |---|---|---|---|---|-----|
    |   |   |   |   |   |     |

11. The exposed sharp is blunted or covered after use and prior to disposal
    
    | 1 | 2 | 3 | 4 | 5 | N/A |
    |---|---|---|---|---|-----|
    |   |   |   |   |   |     |

12. The product does not need extensive training to be operated correctly
    
    | 1 | 2 | 3 | 4 | 5 | N/A |
    |---|---|---|---|---|-----|
    |   |   |   |   |   |     |
SAFETY DEVICE FEATURE EVALUATION FORM (continued)

I.V. CONNECTORS

<p>| | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Use of this connector eliminates the need for exposed needles in connections</td>
<td>agree……disagree</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>The safety feature <strong>does not</strong> interfere with normal use of this product</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Use of this product requires you to use the safety feature</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>This product <strong>does not</strong> require more time to use than a non-safety device</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>The safety feature works well with a wide variety of hand sizes</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>The safety feature allows you to collect blood directly into a vacuum tube, eliminating the need for needles</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>The connector can be secured (locked) to Y-sites, hep-locks, and central lines</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>A clear and unmistakable change (either audible or visible) occurs when the safety feature is activated</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>The safety feature operates reliably</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>The exposed sharp is blunted or covered after use and prior to disposal</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td>The product does not need extensive training to be operated correctly</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
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</tr>
</tbody>
</table>

VACUUM TUBE BLOOD COLLECTION SYSTEMS

<p>| | | | | | |</p>
<table>
<thead>
<tr>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>The safety feature can be activated using a one-handed technique</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>The safety feature does not interfere with normal use of this product</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Use of this product requires you to use the safety feature</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>This product does not require more time to use than a non-safety device</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>The safety feature works well with a wide variety of hand sizes</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>The safety feature works with a butterfly</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>A clear and unmistakable change (either audible or visible) occurs when the safety feature is activated</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td>The safety feature operates reliably</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td>The exposed sharp is blunted or covered after use and prior to disposal</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td>The inner vacuum tube needle (rubber sleeved needle) does not present a danger of exposure</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11.</td>
<td>The product does not need extensive training to be operated correctly</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

PATIENT SAFETY AND COMFORT

<p>| | | | | | |</p>
<table>
<thead>
<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>Does the device minimize the risk of infection to the patient (e.g., through cross-contamination)?</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Can the device be used without causing more patient discomfort than a conventional device?</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>For IV devices: Does the device attach comfortably (i.e., without causing patient discomfort at the catheter … port or IV tubing)</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are there other questions that you feel should be asked regarding the safety/utility of this product?</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Would you recommend using this device? | Yes | No |

**Comments** (e.g., describe problems, list incompatibilities)
Sharps Safety Device Evaluation Form

Device: ___________________________ Number of times used: ___________________________

Product Name/Supplier: ___________________________

Applications: ___________________________

Reviewer: ___________________________ Department: ___________________________ Date: _______

**Circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

<table>
<thead>
<tr>
<th>HEALTHCARE WORKER SAFETY:</th>
<th>agree</th>
<th>disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The device prevents needlesticks during use (i.e., before disposal)</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
</tr>
<tr>
<td>2. After use, the safety mechanism remains activated through disposal of the device</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
</tr>
<tr>
<td>3. The device provides protection in one of the following ways: Either intrinsically or automatically (N/A&quot; if a specific action by the user is required to activate the safety mechanism.)</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
</tr>
<tr>
<td>4. If “N/A,” the mechanism is activated in one of the following ways: either by one-handed technique or by a two-handed technique accomplished as part of the usual procedure</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
</tr>
<tr>
<td>5. During the use of device, the user’s hands remain behind the needle until activation of the safety mechanism is complete</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
</tr>
<tr>
<td>6. The safety mechanism is reliable when activated properly</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
</tr>
<tr>
<td>7. The device minimizes the risk of user exposure to the patient’s blood</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PATIENT SAFETY AND COMFORT:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The device minimizes the risk of infection to the patient (e.g., through cross-contamination)</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
</tr>
<tr>
<td>2. The device can be used without causing more patient discomfort than a conventional device</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
</tr>
<tr>
<td>3. For IV devices: the device is attached comfortably (i.e., without causing patient discomfort at the catheter port or IV tubing)</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EASE OF USE AND TRAINING:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The device operation is obvious. The device be used properly without extensive training.</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
</tr>
<tr>
<td>2. The device can be used by a left-handed person as easily as by a right-handed person.</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
</tr>
<tr>
<td>3. The technique required for using the device is the same as for using a conventional device.</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
</tr>
<tr>
<td>4. It is easy to identify the type and size of the product from the packaging.</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
</tr>
<tr>
<td>5. For intravenous (IV) catheters and blood collection needle sets: The device can provide a visible blood flashback during initial insertion</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
</tr>
<tr>
<td>6. Ease of using device</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>COMPATIBILITY:</th>
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<tbody>
<tr>
<td>1. The device is compatible with devices (e.g.,blood collection tubes) from a variety of suppliers.</td>
<td>1 2 3 4 5 N/A</td>
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<tr>
<td>2. The device is easy to dispose of in sharps containers of all sizes (if required)</td>
<td>1 2 3 4 5 N/A</td>
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<td>3. For IV devices:</td>
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<tr>
<td>A. The device is compatible with intralipid solutions.</td>
<td>1 2 3 4 5 N/A</td>
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<tr>
<td>B. The device is attached securely at the catheter port.</td>
<td>1 2 3 4 5 N/A</td>
<td></td>
</tr>
<tr>
<td>C. The device is attached securely or locks at a Y-site (e.g. for piggybacking).</td>
<td>1 2 3 4 5 N/A</td>
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</table>

Would you recommend using this device? Yes No

COMMENTS (e.g., describe problems, list incompatibilities)
HEPATITIS B VACCINE ACKNOWLEDGEMENT/WAIVER

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring Hepatitis B Virus (HBV) infection.

I understand that I may be vaccinated, free of charge, with hepatitis B vaccine at the Department of Employee Health (Employee Health). To schedule an appointment, or to confirm that a nurse is available to give the vaccination, please call (203) 432-7978.

The selection below indicates how I wish to proceed:

❑ I want to be vaccinated against hepatitis B if recommended by the Department of Employee Health and understand that I may go to Employee Health (55 Lock Street) after scheduling an appointment or calling ahead to confirm nurse availability at 203-432-7978. [TMS Code HPYES]

❑ I decline the hepatitis B vaccine at this time. I understand that due to my occupational exposure to blood or other potentially infectious materials 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 myself. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me. [TMS Code HPNO]

❑ I have already received the hepatitis B vaccine. (Please send this information to the Employee Health Office. You can drop off your record, or mail, or fax this information to: Employee Health, 55 Lock Street, P.O. Box 208237, New Haven, CT 06520-8237, Fax: 203-432-7828) [TMS Code HPHAD]

______________________________________________________________________________
Name                                                 Signature
______________________________________________________________________________
Department                                           NETID#
______________________________________________________________________________
Telephone (8:30 a.m. - 5:00 p.m.)                    Date
______________________________________________________________________________
Please return completed copy to: Environmental Health & Safety Bloodborne Pathogen Program 135 College Street, Suite 100 New Haven, CT 06511-2411 Email: safetytraining@yale.edu
Appendix 6: Principal Investigators/Lab Supervisor Responsibilities Checklist

A. Responsibilities with new occupationally exposed employees

Principal Investigators/Area Supervisors must ensure:

- an exposure determination has been completed for each new employee with occupational exposure to human blood or other potentially infectious materials (OPIM*);
- new occupationally exposed employees receive training prior to initiation of work with human blood or OPIM;
- new occupationally exposed employees have been offered the Hepatitis B vaccine within 10 working days of assignment.

New Employees with Occupational Exposure to Bloodborne Pathogens
(include name and relevant dates)

<table>
<thead>
<tr>
<th>Name</th>
<th>Date of Assignment</th>
<th>Exposure Determination Completed</th>
<th>Initial Bloodborne Pathogen Training</th>
<th>HBV Vaccine Offered</th>
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*OPIM: Other potentially infectious materials include semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, any body fluid that is visibly contaminated with blood, any unfixed human tissue or organ, HIV and HBV containing cell culture solutions, and blood, unfixed organs or tissues from experimental animals infected with HIV or HBV, and sharp items contaminated with any of the materials listed above.
B. Use of Personal Protective Equipment

Identify tasks and procedures that may result in skin, eye, mucous membrane or parenteral contact with blood or OPIM, and list the personal protective equipment that will be utilized to minimize the exposure potential.

List Procedure and Check Required Protective Clothing

<table>
<thead>
<tr>
<th>Task or Procedure with Blood/OPIM Exposure</th>
<th>Lab Coat</th>
<th>Surgical Gloves</th>
<th>Face Shield</th>
<th>Eye Wear &amp; Surgical mask</th>
<th>Other: Solid Front Gown, Tyvek Jump Suit, Sleeve Covers, Booties, Head Cover, Respiratory Protection, etc.</th>
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</table>

Identify the location where supplies of personal protective equipment are kept: ________________

____________________________________________________________________________________

Identify the person responsible for maintaining the supply of personal protective equipment:

____________________________________________________________________________________

List the location where employees store personal protective equipment before leaving the work area (personal protective equipment must be removed before leaving the laboratory):

____________________________________________________________________________________

____________________________________________________________________________________

____________________________________________________________________________________
C. Engineering Controls

List the engineering controls that will be utilized to eliminate or minimize occupational exposure, and identify personnel responsible for maintaining or replacing on a regular schedule to ensure their effectiveness.

<table>
<thead>
<tr>
<th>Engineering Control</th>
<th>Personnel Responsible</th>
<th>Maintenance Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sharps Container</td>
<td>All lab members</td>
<td>Replace when 2/3 - 3/4 full</td>
</tr>
<tr>
<td>Plexiglass bench shield</td>
<td>All users</td>
<td>Decontaminate after use</td>
</tr>
<tr>
<td>Biowaste bags</td>
<td>All lab members</td>
<td>Replace when 2/3 - 3/4 full</td>
</tr>
<tr>
<td>Biosafety Cabinet</td>
<td>All users</td>
<td>Decontaminate before and after use, and immediately following a spill of blood or OPIM</td>
</tr>
<tr>
<td>Vacuum filters</td>
<td>All users</td>
<td>Replace when contaminated, wet or damaged</td>
</tr>
<tr>
<td>Plastic transport bins</td>
<td>All users</td>
<td>Decontaminate after use</td>
</tr>
<tr>
<td>Forceps and other mechanical means of sharps collection</td>
<td>All personnel</td>
<td>Decontaminate after use</td>
</tr>
</tbody>
</table>

D. Disinfection and Decontamination

The Principal Investigator/Lab Supervisor is responsible for ensuring that laboratory is kept neat and clean. Work surfaces and lab equipment must be decontaminated with a suitable disinfectant (such as 1-10% household bleach or an EPA registered tuberculocidal disinfectant) after use, or immediately after a spill of human blood or OPIM.

Provide a schedule for general disinfection in the lab:

Provide an outline of the decontamination and spill response procedure:
List disinfectants that will be used for these purposes: ________________________________

________________________________________________________

Identify responsible personnel: ________________________________

________________________________________________________

E. Additional Responsibilities of the Principal Investigator/Lab Supervisor (Check the following has been completed)

• Antiseptic towellettes have been provided for pre-handwashing in areas without hand washing stations. Researchers have been instructed to wash hands as soon as feasible after the pre-wash.

• Equipment scheduled for moving, repair, or disposal has been appropriately decontaminated and labeled with a Biological Safety Notice. All components that could not be decontaminated have been labeled with the biohazard symbol.

• Contaminated laundry is placed in a biohazard bag and sent to a service that practices Universal Precautions.

• Personnel understand the appropriate post-exposure response and follow-up procedures.