

1.0 Overview

This Bloodborne Pathogens Exposure Control Plan (ECP) has been developed as part of the Weill Cornell Medicine (WCM) Environmental Health and Safety (EHS) Program Manuals.

The Occupational Safety and Health Administration (OSHA) implemented the regulation, "Occupational Exposure to Bloodborne Pathogens," contained in rule 29 Part 1910.1030 of the Code of Federal Regulations (CFR); to help protect workers from the health hazards associated with occupational exposure to pathogenic organisms present in blood and other body fluids. This regulation aims to minimize or prevent the transmission of bloodborne diseases including, but not limited to, Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV).

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Environmental Health and Safety

TEL 646-962-7233WEB weill.cornell.edu/ehsEMAIL ehs@med.cornell.eduWeill Cornell Medicine402 East 67th Street, Room LA-0020New York, NY 10065



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3.0 Objective

This Exposure Control Plan (ECP) has been developed to minimize or eliminate employee occupational exposure. Occupational exposure is any "reasonably anticipated skin, eye, mucous membrane or parenteral contact with blood or other potentially infectious materials that may result from the performance of any employee's duties" without regard to the use of personal protective equipment. Sources of potentially infected material for the purposes of this ECP include humans and closely related primates.

4.0 Applicability

This Bloodborne Pathogens Exposure Control Plan applies to all WCM faculty, staff, and students whose work may involve the possible exposure to human blood or other potentially infectious material(s), as well as other unfixed tissue specimens. Activities by WCM faculty, staff, and students involving patient contact may additionally be governed by the NewYork-Presbyterian Hospital's Exposure Control Plan.

This ECP applies to the Hepatitis B Virus (HBV), a causative agent of infectious hepatitis, Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV), the causative agent of Acquired Immune Deficiency Syndrome (AIDS), and other Bloodborne diseases.

5.0 Responsibilities

5.1 ENVIRONMENTAL HEALTH AND SAFETY (EHS)

- Writes, updates, and enforces the rules and regulations contained in this ECP.
- Distributes this ECP to all WCM departments and administrative units.
- Provides appropriate Bloodborne Pathogens Exposure Control Training to all WCM faculty, staff, and students who may be occupationally exposed.

5.2 INSTITUTIONAL BIOSAFETY OFFICER

- Provides technical guidance and assists in the implementation of the ECP.
- Conducts inspections to ensure that all WCM areas are following appropriate exposure prevention procedures.

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5.3 DEPARTMENTS / ADMINISTRATIVE UNITS

- Implement all rules and regulations discussed in this manual.
- Develop site-specific policies and procedures to supplement this general ECP as needed.

Ensure that all staff receives the appropriate Bloodborne Pathogens Exposure Control training.

5.4 FACULTY, STAFF, & STUDENTS

- Attend Bloodborne Pathogens Exposure Control training upon beginning employment at WCM, and annual refresher courses thereafter.
- Follow all rules and regulations as outlined in this ECP.

6.0 Bloodborne Pathogen Exposure Control Plan Procedures

6.1 OCCUPATIONAL EXPOSURE DETERMINATION

The potential for occupational exposure to bloodborne pathogens has been assessed for all WCM employees and was made without regard to the use of personal protective equipment, as required by the regulations. While some employees routinely face occupational exposure, others may have the risk of possible exposure periodically or rarely. Each Department has the duty to identify specific positions that fall within these categories. A list of general job duties that may lead to occupational exposure is described in Section 6.4.

6.2 ROUTINE OCCUPATIONAL EXPOSURE

All employees in the job classifications listed below are considered to have routine occupational exposure:

- Pathologists
- Pathology Assistants
- Dieners
- Phlebotomists

6.3 POSSIBLE OCCUPATIONAL EXPOSURE

Some employees in the job classifications listed below are considered to be at reasonable risk of contact with blood and other potentially infectious materials (OPIM):

- Faculty
- Physicians
- Physician Assistants/Surgical Assistants
- Nurses (except for administrative nurses)
- Research Fellows
- Research Associates
- Research Specialists
- Senior Research Technicians
- Research Technicians
- Laboratory Aides
- Maintenance Workers
- Building Service Workers
- Housekeepers
- Students with patient care responsibilities

6.4 RARE OCCUPATIONAL EXPOSURE

Some employees in the job classifications listed below have rare occupational exposure.

- Social Workers/Case Managers/Counselors
- Patient Representatives

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- Telecommunications
- Facilities Supervisors
- Human Resources
- Medical Records Staff
- Pharmacy Staff
- Housing Director and Staff

6.5 TASKS AND PROCEDURES

The following functions and procedures cause an Occupation Exposure to the personnel conducting them when employing human blood or other potentially infectious material.

- Tissue culture procedures
- Histological/cytological procedures (unfixed tissues)
- Collection of blood and other body fluids (specimens) and tissues
- Transportation of specimens to laboratory areas
- Preparation of blood and other body fluids and tissue specimens for assay or storage
- Phlebotomy
- Patient Care Activities:
 - Direct patient care contact, including emergency first aid
 - Suturing
 - Accessing IVs
 - Administration of medicine, vaccine, anesthetic using needles
 - Assisting or performing diagnostic or therapeutic patient care procedures
 - Assisting in surgical procedures
 - Assisting in routine personal care activities
- Handling of Human Blood, Body Fluids or Tissue:
 - Collecting body fluid or tissue specimens
 - Transporting body fluid or tissue specimens
 - Operating laboratory equipment used in blood, blood derivative or other body fluid testing
 - Performing qualitative and quantitative tests and examinations of body fluid or tissue specimens
 - Disposal or storage of body fluid or tissue specimens

Cleaning of Patient Care Areas or Laboratory Areas and Equipment:

- Washing/cleaning laboratory glassware, apparatus, floors, workbenches, or counters
- Cleaning and sterilizing equipment and instruments
- Collecting soiled linen
- Cleaning patient care areas
- Handling infectious, or potentially infectious agents, animals, or research material
- Handling blood or other tissues from primates
- Handling potentially infectious medical wastes (PIMW), including sharps
- Laboratory bench work:
 - Centrifuging specimens
 - Vortexing specimens
 - Dispensing/pipetting samples
 - Separation procedures
 - Isolation procedures
 - Concentration procedures
 - Assay procedures

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7.0 Universal Precautions

Universal Precautions is an approach to infection control that assumes that all human blood and other bodily fluids and tissues are potentially infectious materials (see definition of Other Potentially Infectious Materials). It is the policy of WCM that Universal Precautions should be applied when handling these materials; even when it is believed that the specimens are not contaminated with any infectious agents. Therefore, contact with blood or other potentially infectious materials must be prevented.

At WCM, Engineering Controls, and Standard Work Practice Controls are utilized to eliminate or minimize employee exposures. If there is still a potential for exposure after Engineering Controls and Work Practices Controls have been implemented, employees must wear Personal Protective Equipment (PPE).

8.0 Engineering Controls

Engineering Controls are controls used to isolate or remove bloodborne pathogen hazards from the worker. Examples include:

- Puncture-resistant sharps containers
- Splash guards
- Biological safety cabinets
- Mechanical pipetting devices
- Centrifuge safety cups
- Sealed centrifuge rotors
- Containment caging for animals
- Needleless IV systems
- Self-sheathing syringes

The Biosafety Officer will examine and evaluate all engineering controls for appropriateness and performance as specified in 29 CFR 1910.1030 and other accepted consensus standards recognized by OSHA; and will report all Engineering Controls that are found to be non-compliant or defective to the appropriate WCM department for remediation or replacement. Departments will use engineering controls like sharps containers, biological safety cabinets, and mechanical pipetting devices as the primary means to protect employees.

Each department will develop written procedures to ensure that engineering controls are examined and maintained or replaced on a regular schedule to ensure they function effectively. Where applicable, this will be done in accordance with the Manufacturer's guidelines. Records of inspection and maintenance will be kept within the department.

Each department will evaluate the effectiveness of existing controls and review the feasibility of instituting more advanced engineering controls, replacing conventional needles with safer needle devices (e.g., re-sheathing needles, blunt-tipped needles, retractable needles).

8.1 SHARPS CONTAINER ENGINEERING CONTROLS

Sharps containers must be:

- Easily accessible to personnel.
- Located close to the immediate area where sharps are used.
- Placed in areas where it can be reasonably anticipated that sharps may be found.

8.2 BIOLOGICAL SAFETY CABINET ENGINEERING CONTROLS

All biological safety cabinets will be certified:

- When installed.
- Whenever they are moved.
- Annually.

9.0 Standard Work Practices

The following standard work practices apply to all work areas and other areas where potentially infectious materials may be stored.

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9.1 HAND WASHING

- Hand washing facilities will be available in work areas in which activities covered by this plan are performed. Employees are
 required to wash their hands immediately (or as soon as feasible) following removal of gloves or other personal protective
 equipment. The use of gloves does not preclude the necessity for hand washing.
- All personnel must wash their hands with soap and water following completion of laboratory activities before leaving the laboratory.
- Employees must wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or soon
 as feasible following contact with blood or other potentially infectious materials.
- Where a provision of handwashing facilities is not feasible, WCM will provide either an appropriate antiseptic hand cleanser in conjunction with clean paper towels. When antiseptic hand cleansers are used, hands will be washed with soap and running water as soon as feasible.
- When an employee is removing gloves and has had contact with blood or blood or other potentially infectious materials (OPIM), hands must be washed with an appropriate soap and running water. If a sink is not readily accessible (e.g., in the field) for instances where there has been occupational contact; hands may be decontaminated with a hand cleanser or towelette, but must be washed with soap and running water as soon as feasible. If there has been no contact with blood or OPIM, antiseptic hand cleansers may be used as an appropriate "handwashing" practice.

9.2 NEEDLES & SHARPS

- Preventing exposures requires a comprehensive program, including the use of engineering controls (e.g., needless devices, shielded needle devices, and plastic capillary tubes) and proper work practices (e.g., no-hands procedures in handling contaminated sharps, eliminating hand-to-hand instrument passing in the operating room).
- Needles and other sharps will only be used in situations where there are no other alternatives.
- Needles or other sharps must be disposed of without recapping, bending, or shearing in the rigid puncture-proof containers that are delivered to each laboratory, as described in the WCM Research Biosafety Manual, available at the EHS website.
- If used needles must be recapped as required by a specific medical procedure and there is no feasible alternative, a singlehanded method must be used, such as a re-sheathing device or the "scoop" technique (see definition of "scoop" technique in Section 20.0). The need to use this method must be clearly documented.
- Reusable sharps must be stored in a puncture-resistant, leak-proof, 'BIOHAZARD' labeled container (see Section 17.0). Never reach by hand into this container; always use appropriate forceps or another mechanical gripping device. Such reusable sharps must be sterilized by autoclaving before reuse.

9.3 EATING AND DRINKING

Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are strictly prohibited in the work area. Eating and drinking are permissible in spaces outside of the work area that are specially designated for this purpose, such as the seating areas in elevator lobbies of the LC building. If there is no such designated space, lab personnel can contact EHS.

9.4 FOOD STORAGE

Food or drink will not be kept in refrigerators, freezers, shelves, cabinets, or other places in the work area.

9.5 PIPETTING

Mechanical pipetting devices must be used for the manipulation of all liquids in the laboratory. Mouth Pipetting is prohibited.

9.6 SPLASH / SPRAY PREVENTION

Human blood and other potentially infectious materials must always be handled to minimize splashing, or the formation of aerosols.

9.7 SPECIMEN HANDLING

Specimens of human blood, lab cultures, or other potentially infectious materials shall be kept in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping. The container for storage or transport shall be labeled or color-coded according to Section 17.0 of this document and closed prior to being stored or transported.

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When using 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, as described in Section 17.0 is required when such specimens/containers leave the facility.

Shipping of Biohazardous specimens must be in accordance with the <u>Biological Material and Dry Ice Shipments Manual</u>, which is available on the EHS website.

If outside contamination of the primary container occurs, the primary container shall be placed within a secondary container that prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of Section 17.0 of this document.

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

Transporting of materials (specimens) between floors and buildings require secondary containment such as tubs, buckets, or trays if they are contained in a material that is subject to breakage or spillage (i.e., caps on plastic Eppendorf tubes can open up upon hitting the ground). Stairways should not be used to transport lab materials. The preferred method of transport is to use the designated elevator and a cart for the specimens. For small amounts of material that can be hand carried, a closed container should be used.

9.8 SERVICING / SHIPPING EQUIPMENT

Equipment that may be contaminated (mechanical pipettors, incubators, centrifuges, biosafety cabinets) will be examined and decontaminated prior to servicing or shipping off-site, unless decontamination is not feasible.

When decontamination is not feasible, a readily observable label (see Section 17.0) will be attached to the equipment. The label will indicate which portions of the equipment are contaminated. EHS must be contacted for appropriate procedures and labeling, including transmission of necessary information to persons having any contact with this equipment.

10.0 Personal Protective Equipment

Personal Protective Equipment (PPE) is specialized clothing or equipment worn by an employee for protection from direct exposure to blood or other potentially infectious materials. PPE includes items such as gloves, masks, eye protection, chin-length face shields, and protective clothing. PPE will be used as outlined in 29 CFR 1910.1030 Section (d) (3). The Biosafety Officer must be consulted regarding selection, maintenance, and training needed for proper PPE use.

10.1 PROVISION, USE, & ACCESSIBILITY

The employer will provide appropriate PPE at no cost to the employee. The equipment will be selected to ensure that it does not permit blood or other potentially infectious materials to pass through to 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 PPE will be used.

Employees will use PPE whenever working with human blood or other potentially infectious materials. PPE in appropriate sizes will be readily accessible at the worksite or issued to the employees. Alternative gloves or glove liners will be provided for employees who are allergic to the gloves usually provided.

10.2 GLOVES

Gloves will be worn whenever contact with blood, body fluids, secretions, excretions, mucous membranes, and non-intact skin is expected. Said expected contact includes touching contaminated environmental surfaces and items soiled with blood, body fluids, or moist body substances; during invasive procedures, for drawing blood and performing finger or heel sticks, and/or if an employee has cuts, abraded skin, chapped hands, or dermatitis. Gloves must be removed immediately upon leaving the work area.

- Disposable (single-use) gloves, such as surgical or examination gloves, will be replaced between patient contacts, when contaminated, or when torn or punctured. Disposable gloves may not be washed or decontaminated for reuse.
- Utility gloves, such as rubber gloves, may be decontaminated for reuse if the integrity of the glove is not compromised. They will
 be discarded if they are cracked, peeling, torn, or punctured, exhibit other signs of deterioration, or when their ability to function as
 a barrier is not intact.

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10.3 MASKS, EYE PROTECTION, & FACE SHIELDS

Masks in combination with eye protection devices, such as safety goggles or glasses with solid side shields or chin-length face shields, will be worn if eye, nose, or mouth contamination can be reasonably anticipated due to the generation of splashes, spray, spatter, droplets of blood, or other potentially infectious materials. EHS may be consulted for proper selection and instruction in the use of such PPE.

10.4 PROTECTIVE CLOTHING

Appropriate protective clothing, such as lab coats, gowns, or uniforms, must be worn while working with any potentially infectious material. These garments must not be worn outside the laboratory work area and must be changed at a minimum of once per week and promptly after overt contamination. Garments that are overtly contaminated must be decontaminated by autoclaving prior to disposal or laundering. Surgical caps or hoods and/or shoe covers or boots will be worn in instances when gross contamination can be reasonably anticipated.

10.5 CLEANING, LAUNDERING, & DISPOSAL

WCM will provide for the cleaning or laundering of reusable protective clothing, such as uniforms and lab coats. Home laundering of contaminated protective clothing is not permitted, since it could lead to the migration of contaminants to the home. Most disposable PPE can be discarded as regular (non-infectious) trash. Disposable gloves that are soaked, caked, or dripping with blood or other potentially infectious materials must be discarded as red bag waste according to Section 7.0 of the <u>WCM Waste Disposal Procedures</u> <u>Manual</u> on the EHS website.

10.6 REMOVAL / REPAIR / REPLACEMENT

Before leaving the work area, all PPE will be removed carefully so as not to contaminate surfaces or hands. The clothing/equipment will be placed in designated areas or containers for storage, washing, decontamination, or disposal. PPE will not be worn in public corridors, elevators, cafeterias, conference rooms, or other public access areas. WCM will repair or replace all PPE as needed to maintain its effectiveness.

11.0 Decontamination

All equipment and environmental and working surfaces must be cleaned and decontaminated after contact with blood or other potentially infectious materials. All objects to be disinfected or sterilized should first be thoroughly cleaned to remove all organic matter (blood and tissue) and residue.

Laboratory work surfaces must be decontaminated with an appropriate germicide solution (e.g., modified Dakin Solution: 1:10 dilution of 5.25 % sodium hypochlorite, household bleach) at the completion of daily work activities, as well as following any spill of potentially infectious materials. Procedures to be followed in the event of a spill are described in the <u>WCM Research Biosafety Manual</u>. In the event of a spill, contact EHS immediately.

11.1 DECONTAMINATION PROCEDURES

- Protective coverings such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper may be used to cover equipment and environmental surfaces. These coverings will be removed and replaced as soon as feasible when they become overtly contaminated, or at the end of each work shift if they may have become contaminated during the shift.
- All garbage cans and similar receptacles that may become contaminated will be inspected and decontaminated on a regularlyscheduled basis. These containers will also be cleaned and decontaminated immediately or as soon as feasible upon visible contamination.
- All protective coverings and equipment that have had contact with blood and other potentially infectious materials will be discarded as red bag waste as given in Section 7.0 of the <u>WCM Waste Disposal Procedures Manual</u>.
- Broken glassware that may be contaminated will not be picked up directly with the hands. It will be cleaned up using mechanical means, such as a brush and dustpan, tongs, or forceps.
- As necessary, engineering and work practice controls must be used when handwashing of instruments that should be pre-cleaned before being disinfected or sterilized in order to reduce employee exposure either by removing, eliminating, or isolating the hazard. This would include the use of existing, feasible, commercially available engineering controls, such as the use of ultrasonic cleaners. In circumstances where ultrasonic cleaners or other engineering control measures are deemed infeasible, the implementation of work practices, such as the use of long-handled brushes for physically removing organic material on reusable sharps, is expected in order to reduce the potential for employee exposure to blood or OPIM on contaminated sharp instruments.

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12.0 Waste Disposal

WCM waste disposal procedures are detailed in the Waste Disposal Procedures Manual, available on the EHS Website.

12.1 CONTAMINATED WASTE REMOVAL/DISPOSAL

To minimize harm to people and the environment resulting from the disposal of infectious and potentially infectious materials, the Regulated Medical Waste section of the <u>Waste Disposal Procedures Manual</u> specifies how waste is to be collected, segregated, and stored. Disposal is done as established by the New York State Department of Health (NYSDOH) regulations, New York City Department of Health and Mental Hygiene (NYCDOHMH) regulations, and OSHA requirements.

12.2 BIOLOGICALLY CONTAMINATED WASTE

All biologically contaminated waste will be discarded as described in Section 7.0 of the Waste Disposal Procedures Manual.

12.3 SHARPS DISPOSAL

Used and unused sharp items (needles, scalpel blades, serological pipettes, pipette tips, and other sharp instruments) will be considered as potentially infectious and handled with extraordinary care to prevent accidental injuries. Disposable syringes and needles, scalpel blades, glass pipettes, and other sharp items will be placed in puncture-resistant Sharps containers explicitly designated for this purpose. Sharps containers will be disposed as required by Section 7.0 of the WCM Waste Disposal Procedures Manual.

13.0 HIV, HBV, & HCV Research Laboratory Work Practices

In addition to the critical elements of the Bloodborne Pathogens Exposure Control Plan, research laboratories and animal facilities working with the culture, production, experimentation, and manipulation of HIV, HBV, or HCV must implement additional features.

- Every HIV, HBV, or HCV research laboratory will prepare specific Standard Operating Procedures (SOPs) for the laboratory. The SOPs will be reviewed and updated at least annually. Personnel who work in HIV, HBV, or HCV research labs will be advised of potential hazards and required to read and follow instructions on practices and procedures.
- Each HIV, HBV, or HCV research laboratory will have a facility for hand washing and an emergency eyewash readily available within the work area.
- Only authorized personnel can access HIV, HBV, or HCV research laboratories. The Principal Investigator (PI) is responsible for establishing written policies and procedures whereby only persons who have been advised of the potential biohazard, meet any specific entry requirements, and comply with all entry and exit procedures are allowed to enter the work areas and animal rooms.
- The PI will determine the sufficiency of training and experience for all technical staff working in HIV, HBV, or HCV laboratories. No faculty, staff, or students may begin to work with HIV, HBV, or HCV-containing materials before they demonstrate proficiency in standard microbiological techniques, and in the specific operations to be performed involving these infectious agents. Employees lacking adequate prior training or experience will receive appropriate instruction and experience under the guidance of the faculty member in charge of the laboratory. Initial work activities and training experience will not include the handling of infectious agents. A progression of work activities will be assigned as techniques are learned, and proficiency is developed.
- Warning signs will be posted on all access doors to work areas or containment modules when activities involving biological materials derived from human blood, tissues, OPIM, or infected animals are present. EHS provides signs as needed.
- All doors to these laboratories will be closed when work with HIV, HBV, or HCV is in progress.
- Dedicated laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing will be used in the work areas and animal rooms. These garments will not be worn outside the work area. Protective clothing which is overtly contaminated will be decontaminated by autoclaving, prior to disposal or laundering. When working with concentrated viral preparations, disposable garments will be used and will be appropriately disposed of immediately at the termination of a work session.
- Special care will be taken to avoid skin contact with potentially infectious materials. Gloves will be worn when handling infected animals, and when making hand contact with OPIM is unavoidable. Gloves will be removed immediately upon leaving the work area.
- All manipulations of potentially infectious materials will be performed carefully to minimize the creation of aerosols. Face shields
 and masks will be used for procedures where a "splash" hazard exists. Head and foot coverings and fluid-resistant aprons will be
 used for such tasks.
- Hypodermic needles and syringes will be used for injection and aspiration of fluids from laboratory animals and diaphragm bottles.
 Only needle-locking syringes or disposable syringe-needle units (that is, the needle is integral to the syringe) will be used for the

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injection or aspiration of OPIM. Extreme caution will be used when handling needles and syringes. Needles will not be bent, sheared, replaced, or removed from the syringe following use. The needle and syringe will be discarded in accordance with Section 7.0 of the <u>WCM Waste Disposal Procedures Manual</u>.

- Certified Class II biological safety cabinets and other primary containment devices (e.g., centrifuge safety cups) will be used for handling all biological materials derived from persons or animals known or suspected to be infected with HIV, HBV, or HCV. Work involving OPIM will not be conducted on an open bench.
- Laboratory work surfaces will be decontaminated with an appropriate EPA-approved disinfectant (e.g., modified Dakin Solution: 1:10 dilution of 5.25 % sodium hypochlorite, or household bleach) at the completion of daily work activities, as well as following any spill of potentially infectious materials. Procedures to be followed in the event of a spill are described in the WCM Research Biosafety Manual. EHS must be notified promptly in the event of a spill.
- Vacuum lines will be protected with liquid disinfectant traps and High-Efficiency Particulate Air (HEPA) filters or filters of equivalent or superior efficiency. This equipment will be checked routinely and maintained or replaced as necessary.
- Each HIV, HBV or HCV lab will have access to an autoclave for the decontamination of waste.
- Prior to disposal, all contaminated waste from work areas and animal rooms will be decontaminated by a method known to destroy bloodborne pathogens effectively. Autoclaving is the preferred method of decontamination (Section 7.0 of the WCM manual Waste Disposal Procedures).
- Experimental animals inoculated with potentially infectious materials must be maintained in approved animal facilities. The staff of the Research Animal Resource Center must be informed in advance of initiation of any studies with HIV, HBV, HCV or with biological samples from subjects known or suspected to be infected with HIV, HBV, or HCV that involve the use of experimental animals.
- The WCM Biosafety Officer will inspect all HIV, HBV, HCV research areas for compliance with the provisions of this plan. The inspections will be performed on a random basis. Deficiencies will be recorded and their subsequent correction documented.
- Each department is responsible for developing any additional protocols needed to protect workers from occupational exposure. The protocols should be submitted to EHS for review.

14.0 Other Bloodborne Pathogens in Research Laboratories

All research with bloodborne pathogens other than HIV, HBV or HCV must employ the precautions outlined in the WCM Research Biosafety manual and the CDC-NIH publication *Biosafety in Microbiological and Biomedical Laboratories*. For agents listed in the WCM Research Biosafety Manual as Risk Group 3 or higher, specific written Standard Operating Procedures must be developed, approved by EHS prior to initiating work, and kept in the SOP Booklet in the laboratory.

15.0 Hepatitis B Vaccination

All WCM students, faculty, and staff who have reasonably anticipated skin, eye, mucous membrane, or parenteral contact with human blood, other human body fluids or other potentially infectious materials will be offered Hepatitis B vaccination free of charge.

Hepatitis B vaccinations are offered at the NewYork-Presbyterian Hospital Workforce Health and Safety (NYP WHS), Monday through Friday 8:00 a.m. - 4:00 p.m. Vaccinations will be performed under the supervision of a licensed physician or other licensed health care professional, according to the current recommendations of the U.S. Public Health Service.

Employees at occupational risk for HBV will be offered vaccination at the time of initial pre-placement evaluation after appropriate education and counseling, and within 10 working days of initial assignment, unless medically contraindicated or antibody testing has revealed that the employee is immune.

The HBV vaccination will be offered to all employees following a potential exposure to blood or OPIM, unless medically contraindicated or antibody testing has revealed that the employee is immune. Post-exposure vaccination will be made available in WHS during business hours and in the Emergency Department after business hours and on weekends and holidays.

Employees at occupational risk for acquiring HBV must sign a mandatory Declination Statement if they choose not to accept the vaccine. If an employee initially declines the HBV vaccine and then decides to accept the vaccine at a later date, it will be provided at no cost.

Booster dose(s) shall be made available to the employee as medically indicated. HBV antibody titers may be performed at the appropriate interval post-vaccination at no cost.

Workforce Health and Safety (WHS) shall have a policy that shall include whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.

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Vaccine-induced Hepatitis B surface antibody (anti-HBs) levels may decline over time; however, immune memory (anamnestic anti-HBs response) remains intact indefinitely following immunization. Persons with declining antibody levels are still protected against clinical illness and chronic disease. For those with normal immune status who have demonstrated an anti-HBs response following vaccination, booster doses of the vaccine are not recommended, nor is periodic anti-HBs testing.

If the U.S. Public Health Service, at some future date, recommends routine booster dose(s) of the Hepatitis B Vaccine, then such booster dose(s) will be made available to occupationally exposed workers.

16.0 Accidental Exposures

In the event of exposure to bodily fluids, such as a splash or spray to the eyes, nose, mouth, broken skin, or a skin puncture, the employee should follow the procedure listed below for management of accidental exposures to potentially infectious substances.

16.1 MANAGEMENT OF NEEDLESTICK & BODILY FLUID EXPOSURE

WCM has developed procedures to provide immediate care for employees exposed to needle sticks and bodily fluids. Enforcement of these processes permits documentation of exposures and initiation of preventative measures. Exposure is defined as a contact by:

Needlestick or sharp puncture wound;

- Open cut, burn, or abrasion contaminated by bodily fluids such as blood, pus, visibly bloody saliva, urine, or stool
- Splash to mucous membranes (e.g., eyes, nose, or mouth) with such materials.

16.1.1 Immediate Instructions to Healthcare Worker at Time & Site of Injury

Wound care should be done immediately at the site of an accident when possible:

- 1. Clean wound with soap and water.
- 2. Flush mucous membranes with water/saline.
- 3. Give other wound care as dictated by injury or accident. Report incident to a supervisor.
- 4. Obtain source patient's identification (including name, location, and medical record number) to facilitate testing.
- 5. Report to Workforce Health and Safety (WHS) for evaluation and treatment (Monday Friday, 8:00 a.m. 4:00 p.m.) or Emergency Department at all other times.*

*For detailed information on applicable locations, please see the **Medical Assistance Map (For Weill Cornell Medicine Students, Faculty, and Staff).** It is available on the EHS website and posted in key locations in laboratory and clinical workspaces.

All puncture wounds and other exposures to blood and body fluids should be reported immediately to WHS to ensure the incident can be documented and appropriate preventive measures initiated.

Each case will be assessed, and counseling will be given concerning the epidemiology of Hepatitis B, C, and HIV and will include, if appropriate, indications for prophylactic treatment and/or immunization.

Since maximum benefit from therapy is most effective when begun within two hours post-exposure, the following policy should be followed:

- For exposures Monday through Friday, 8 a.m. to 4 p.m., the employee will report to WHS.
- During nights, weekends, or holidays, the employee will report to the NYP Emergency Department for immediate and, if appropriate, early treatment.
- All exposures reported to the Emergency Department will be followed by WH&S on the next business day.
- Initial treatment of Hepatitis exposure will depend on the employee's antibody status and the source of the patient's antigen status.
- Follow-up HIV serologic testing is encouraged. If the employee consents to HIV testing, a baseline HIV antibody will be obtained and repeated at six weeks, three months, six months, and 12 months post-exposure.
- WHS will provide follow-up treatment for all exposures.

16.1.2 Immediate Instructions to All Other WMC Employees

For facilities not serviced by WCM/NYP WHS (e.g., Burke Research Institute) or Student Health Services, management of needle sticks, and bodily fluid exposures will be handled according to specific procedures for those facilities.

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- WCM students should report blood and body fluid exposures to Student Health Services. *
- During nights, weekends and holidays, WCM employees and students must report to NewYork-Presbyterian Hospital Emergency Department 68th Street entrance, between York Avenue and the East River.*
- WCM students can get more information from the <u>Student Health Services</u> website.

* For detailed information on applicable locations, please see the **Medical Assistance Map (For Weill Cornell Medicine Students, Faculty, and Staff)**. It is available on the EHS website and posted in key locations in laboratory and clinical workspaces.

16.2 POST-EXPOSURE EVALUATION & FOLLOW-UP

NYP WHS and Student Health Services maintain a copy of the OSHA Standard 29 CFR 1910.1030 and will be provided with:

- A description of the individual's duties as related to exposure incident.
- A description of the route of exposure; nature of the material to which the individual was exposed, and circumstances under which the exposure occurred.

The post-exposure evaluation provided by WHS or Student Health Services will include:

- A risk assessment of the incident to determine the severity of the exposure and the need for treatment. It will include information concerning the circumstances of the exposure, the health status of the person whose blood or tissue was implicated, the risk of contracting infection, and the immunization status as well as health status of the staff member.
- The risk assessment and treatment plan will follow the guidelines set out by the CDC, and WHS staff will consult with the Hospital's medical staff specializing in the treatment of HIV and others as the need arises, on treatment plans for individual cases. Prophylactic therapy is available for HIV and Hepatitis B. There is no prophylaxis against Hepatitis C; however, there is an effective treatment for most strains of Hepatitis C, particularly if treatment is initiated early in the course of infection.
- The primary healthcare staff taking care of the source patient will arrange to have the source patient tested for Hepatitis B and Hepatitis C and to get source patient consent for HIV testing, so that the laboratory results are available for the management of the exposure. If the source patient cannot consent to HIV testing due to incapacitation, the patient's surrogate may consent.
- In cases of occupational exposures that create a significant risk of contracting or transmitting HIV infection, an anonymous test may be ordered without the consent of the source patient if all of the following conditions are met:
 - The source person is deceased, comatose, or is determined by his or her attending professional to lack mental capacity to consent.
 - The source person is not expected to recover in time for the exposed person to receive appropriate medical treatment.
 - There is no person available or reasonably likely to become available who has the legal authority to consent in time for the
 exposed person to receive appropriate medical treatment.
 - The exposed person will benefit medically by knowing the source person's HIV test results.
- If the status of the source is unknown, WHS will request HIV counseling and testing by source patient's physician as soon as feasible.
- The exposed staff member will be placed on a follow-up schedule based on risk assessment. WHS will follow all exposures in WCM healthcare personnel. Staff may consult with their private physicians in addition to, but not instead of WH&S.
- The exposed employee will be given appropriate post-exposure prophylaxis as recommended by the U.S. Public Health Service guidelines and will receive appropriate counseling, medical advice, and evaluation of any reported illnesses.

A copy of the healthcare professional's written opinion will be made available to the employee within 15 days of completion of the evaluation. The written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for the employee and if the employee has received it. The written opinion for post-exposure evaluation and follow-up should be restricted to stating that the employee has been informed of the results of the evaluation, as well as any medical condition resulting from the exposure which requires further evaluation or treatment. All other findings or diagnoses shall remain confidential and not be included in the written report.

EHS will review all accidents involving exposures involving the scenarios described below and provide follow-up to reduce the risk of exposure to bloodborne pathogens in the workplace:

- Human blood, body fluids, or other tissues
- Culture fluids or other laboratory materials known to contain HIV, HBV, HCV, or other bloodborne pathogens
- Needle-stick/puncture wounds (sharps)

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17.0 Hazard Communication

17.1 LABELS & SIGNS

Biohazard labels will be affixed to refrigerators, freezers, incubators, and other containers used to store, transport, or ship blood or other potentially infectious materials. Biohazard labels are available from EHS. Labels will have a fluorescent orange or orange-red background, with the word "BIOHAZARD" and the universal biohazard symbol in black, as shown in Figure 1.

17.2 RED BAGS

Pre-printed red bags with the Biohazard symbol and WCM address *must* be utilized for disposal of biological waste as instructed in the <u>WCM Waste Disposal Procedures Manual</u>.

17.3 EXEMPTIONS

The following receptacles are exempted from the labeling requirements detailed above:

- Containers of blood, blood components, or blood products that are labeled to indicate their contents and have been released for transfusion or other clinical use.
- Individual containers of blood or other potentially infectious materials placed in a labeled container during storage, transport, shipment, or disposal.

18.0 Training

OSHA Bloodborne Pathogens (BBP) training is provided to all WCM employees and students whose work involves potential exposure to HIV, HBV, HCV, and other bloodborne pathogens. EHS provides BBP as part of the Laboratory Safety and Annual Hospital Training sessions. All occupationally exposed faculty, staff, and students are required to attend either Laboratory Safety (if they work in a lab) or Annual Hospital Training (if they work in a clinical area or are otherwise exposed) before assignment to work involving bloodborne pathogens and annually thereafter. For training availability, please visit the EHS website.

During the initial instructor-led training, trainees have the opportunity to participate and ask questions or make comments to their trainer. The subject matter includes information and discussion on the:

- OSHA Bloodborne Pathogens Standard.
- Epidemiology and symptoms of HIV, HBV, HCV, and other bloodborne pathogens.
- Modes of transmission of HIV, HBV, HCV, and other bloodborne pathogens.
- WCM Bloodborne Pathogens Exposure Control Program.
- Appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials.
- Safer medical devices:
 - Needleless systems
 - Sharps with engineered sharps injury protection (e.g., retractable needles, self-sheathing needles on syringes)
- Use and limitations of Standard Precautions, engineering controls, work practices, and PPE.
- Types, proper use, location, removal, handling, decontamination and/or disposal of PPE.
- PPE Selection.
- Hepatitis B Vaccine, including its efficacy, safety, method of administration, and the benefits of being vaccinated.
- Appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials.
- 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.
- Post-exposure evaluation and follow-up.
- Color-coding, signs, and labeling that are used to identify biohazardous materials.
- WCM Biological Waste Disposal Procedures.

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Figure 1- EHS Biohazard Label.



19.0 Record Retention, Availability, & Revisions

19.1 MEDICAL RECORDS

NYP WHS will maintain medical records for WCM faculty and staff, and WCM Student Health Services will maintain medical records for WCM students. The records will document all Hepatitis B vaccinations and results of medical examinations and tests performed in compliance with 29 CFR 1910.1030. Copies of healthcare professionals' written opinions regarding exposure incidents will be kept in the medical record, as will copies of information provided to health care professionals as discussed above. Medical records will remain confidential and disclosed only with the employee's written permission, except as required by 29 CFR 1910.1030 or by law. Medical records shall be maintained for at least the duration of employment, plus 30 years.

19.2 ACCIDENT / INCIDENT INVESTIGATION RECORDS

Records of accident investigations related to issues covered by 29 CFR 1910.1030 will be maintained by NYP WHS for at least 7 years after the accident. Records of these investigations will include all information gathered relating to the nature of the exposure, route of the exposure and circumstances under which the exposure occurred. If the exposure involved a needle-stick/puncture wound, the type and brand of device involved, if applicable, will also be recorded as part of the accident investigation. A log of sharps injuries shall be maintained by the WCM Human Resources Department in addition to the normal OSHA injury log.

19.3 TRAINING RECORDS

EHS will maintain all training records for at least 3 years after the date of training completion. The training records shall include the dates of the training sessions, a summary of the material covered in the training sessions, names and qualifications of the session instructor(s), and names and job titles of the attendees.

19.4 ANNUAL & PERIODIC REVIEW

This Exposure Control Plan shall be reviewed and updated by EHS at least annually and whenever necessary to:

- Reflect new or modified tasks and procedures that affect occupational exposure.
- Reflect new or revised faculty, staff, or student positions with occupational exposure.
- Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens.
- Document annual consideration and implementation of appropriate, commercially available, and effective safer medical devices designed to eliminate or minimize occupational exposure.

20.0 Definitions

Antiseptic: A chemical germicide formulated to be used on skin or tissue.

Blood: Human blood and its components, as well as products derived from human blood.

Bloodborne Pathogens: Pathogenic microorganisms including, but not limited to, Hepatitis B and C Viruses, and Human Immunodeficiency Virus, that are present in human blood and that can cause disease in humans.

Clinical Laboratory: Workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

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

Contaminated Laundry: Laundry soiled with blood, or other potentially infectious materials, or may contain sharps.

Contaminated Protective Clothing: Protective clothing such as lab coats, gowns, or uniforms that have been soiled with blood, or other potentially infectious materials.

Contaminated Sharps: 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: 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.

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Disinfection: A procedure that kills pathogenic microorganisms, but not necessarily their spores. Chemical germicides, which are formulated as disinfectants, are used on inanimate surfaces (medical devices, etc.) and should not be used on skin or tissues.

Engineering Controls: Items that isolate or remove the bloodborne pathogens hazard from the workplace, such as sharps disposal containers or self-sheathing needles.

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

Hand hygiene: A general term that applies to either handwashing, antiseptic handwash, antiseptic hand rub, or surgical hand antisepsis.

Hand Sanitizing Facilities: Alcohol-based hand rubs or similar facilities as determined by Infection Prevention and Control (IPC).

Hand Washing Facility: A facility that provides an adequate supply of running potable water, soap, and single-use towels or hot airdrying machines.

HBV: Hepatitis B virus.

HIV: Human Immunodeficiency Virus.

Occupational Exposure: Described as reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials (body fluids, unfixed tissues, and organs, cell lines, etc.) that results from the performance of an employee's duties.

Other Potentially Infectious Materials (OPIM):

- 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 bodily fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids.
- Any unfixed tissue or organ (other than intact skin) from a human (living or dead).
- HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions.
- Blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Parenteral: Piercing mucous membranes or another skin barrier through such events as needle sticks, human bites, cuts, and abrasions.

Personal Protective Equipment (PPE): 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 to be considered to be personal protective equipment.

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 are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

Research Laboratory: 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.

Scoop Technique: A single-handed technique for recapping a needle. With one hand, hold the syringe with the attached needle and scoop or lift up the cap, which is lying on a flat surface, onto the needle's sharp end. Once the point of the needle is covered, push together the cap and the needle against a hard surface or object to ensure a tight fit. The entire procedure should involve the use of only one hand, as shown in Figure 2.



Figure 2- Scoop Technique.

Sharps: Any glass, metal, or plastic instrument or item that can cut or has the potential to cut, puncture, scratch, or abrade skin, whether it is contaminated or not. This includes but is not limited to hypodermic

needles, syringes (with or without the attached needle), Pasteur pipettes, serological pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of the presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and coverslips.

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Source Individual: Any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee.

Sterilize: The use of physical or chemical procedures to destroy all microbial life, including highly resistant bacterial endospores.

Universal Precautions: An approach to infection control. According to the concept of Universal Precautions, all human blood and other potentially infectious materials (see definition of Other Potentially Infectious Materials) are treated as if known to be infectious for HIV, HBV, or other bloodborne pathogens. Universal Precautions do not apply to feces, nasal secretions, sweat, tears, urine, and vomitus unless they contain visible blood. Universal Precautions do not apply to saliva except when visibly contaminated with blood or in the dental setting where blood contamination of saliva is predictable.

Work Area: Any research laboratory, clinical laboratory, patient care area, or service area where potentially infectious materials may be stored.

Work Practice Controls: 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).

21.0 References

- 29 CFR 1910.1030, Bloodborne Pathogens.
- CDC/NIH manual on Biosafety in Microbiological and Biomedical Laboratories, 6th edition, June, 2020.
- CDC, Public Health Service Guidelines for the Management of Healthcare Workers Exposed to HIV and Recommendations for Post-Exposure Prophylaxis; MMWR 2005; 54 (RR09): 1-17.
- CDC, Updated U.S. Public Health Service guidelines for the management of occupational exposures to HBV, HCV, and HIV and recommendations for post-exposure prophylaxis. MMWR 2001; 50 (No. RR-11):1--52.
- NewYork-Presbyterian Hospital Bloodborne Pathogen Exposure Control Plan (EOC.33, B105).
- NYSDOH: Part 63 HIV/AIDS Testing, Reporting and Confidentiality of HIV-Related Information.
- EHS Safety Manual, Section 5.2 Waste Disposal Procedures
- EHS Safety Manual, Section 6.2 Biological Materials and Dry Ice Shipments

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Appendix A ·

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APPENDIX B TO \$1910.1029—INDUSTRIAL HY-GIENE AND MEDICAL SURVEILLANCE GUIDE-LINES

I. INDUSTRIAL HYGIENE GUIDELINES

A. *Sampling* (Benzene-Soluble Fraction Total Particulate Matter).

Samples collected should be full shift (at least 7-hour) samples. Sampling should be done using a personal sampling pump with pulsation damper at a flow rate of 2 liters per minute. Samples should be collected on 0.8 micrometer pore size silver membrane filters (37 mm diameter) preceded by Gelman glass fiber type A-E filters encased in threepiece plastic (polystyrene) field monitor cassettes. The cassette face cap should be on and the plug removed. The rotameter should be checked every hour to ensure that proper flow rates are maintained.

A minimum of three full-shift samples should be collected for each job classification on each battery, at least one from each shift. If disparate results are obtained for particular job classification, sampling should be repeated. It is advisable to sample each shift on more than one day to account for environmental variables (wind, precipitation, etc.) which may affect sampling. Differences in exposures among different work shifts may indicate a need to improve work practices on a particular shift. Sampling results from different shifts for each job classification should not be averaged. Multiple samples from same shift on each battery may be used to calculate an average exposure for a particular job classification.

B. Analysis.

1. All extraction glassware is cleaned with dichromic acid cleaning solution, rinsed with tap water, then dionized water, acetone, and allowed to dry completely. The glassware is rinsed with nanograde benzene before use. The Teflon cups are cleaned with benzene then with acetone.

2. Pre-weigh the 2 ml Teflon cups to one hundredth of a milligram (0.01 mg) on an autobalance AD 2 Tare weight of the cups is about 50 mg.

3. Place the silver membrane filter and glass fiber filter into a 15 ml test tube.

4. Extract with 5 ml of benzene for five minutes in an ultrasonic cleaner.

5. Filter the extract in 15 ml medium glass fritted funnels.

 $6.\ Rinse test tube and filters with two <math display="inline">1.5\ ml$ aliquots of benzene and filter through the fritted glass funnel.

7. Collect the extract and two rinses in a 10 ml Kontes graduated evaporative concentrator.

 $\boldsymbol{8}.$ Evaporate down to 1 ml while rinsing the sides with benzene.

9. Pipet 0.5 ml into the Teflon cup and evaporate to dryness in a vacuum oven at 40 $^{\circ}\mathrm{C}$ for 3 hours.

10. Weigh the Teflon cup and the weight gain is due to the benzene soluble residue in half the Sample.

II. MEDICAL SURVEILLANCE GUIDELINES

A. General. The minimum requirements for the medical examination for coke oven workers are given in paragraph (j) of the standard. The initial examination is to be provided to all coke oven workers who work at least 30 days in the regulated area. The examination includes a 14" × 17" posterior-anterior chest x-ray reading, pulmonary func-tion tests (FVC and FEV 1.0), weight, urinalysis, skin examination, and a urinary cytologic examination. These tests are needed to serve as the baseline for comparing the employee's future test results. Periodic exams include all the elements of the initial exam, except that the urine cytologic test is to be performed only on those employees who are 45 years or older or who have worked for 5 or more years in the regulated area; periodic exams, with the exception of x-rays, are to be performed semiannually for this group instead of annually; for this group, xrays will continue to be given at least annually. The examination contents are minimum requirements; additional tests such as lateral and oblique x-rays or additional pulmonary function tests may be performed if deemed necessary.

B. Pulmonary function tests.

Pulmonary function tests should be performed in a manner which minimizes subject and operator bias. There has been shown to be learning effects with regard to the results obtained from certain tests, such as FEV 1.0. Best results can be obtained by multiple trials for each subject. The best of three trials or the average of the last three of five trials may be used in obtaining reliable results. The type of equipment used (manufacturer, model, etc.) should be recorded with the results as reliability and accuracy varies and such information may be important in the evaluation of test results. Care should be exercised to obtain the best possible testing equipment.

[39 FR 23502, June 27, 1974, 41 FR 46784, Oct. 22, 1976, as amended at 42 FR 3304, Jan. 18, 1977; 45 FR 35283, May 23, 1980; 50 FR 37353, 37354, Sept. 13, 1985; 54 FR 24334, June 7, 1989; 61 FR 5508, Feb. 13, 1996; 63 FR 1290, Jan. 8, 1998; 63 FR 33468, June 18, 1998; 70 FR 1142, Jan. 5, 2005; 71 FR 16672, 16673, Apr. 3, 2006; 71 FR 50189, Aug. 24, 2006]

§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.

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(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.

29 CFR Ch. XVII (7-1-07 Edition)

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

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

HBV means hepatitis B virus.

HIV means human immunodeficiency virus.

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

 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

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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

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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.

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(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 occurences in the future.

(iii) *Accessibility.* The employer shall ensure that appropriate personal protective equipment in the appropriate

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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;

(*if*) 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 chinlength 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.

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(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:

(1) Closable:

(*ii*) Puncture resistant;

(*iff*) 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);

(*it*) 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;

(*if*) 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:

(1) Closable;

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

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(*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 soakthrough 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 colorcoded 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.

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(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 highefficiency 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 punctureresistant 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

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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).

graph (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)(I) and within 10 working days of initial assignment to all employees who have occupational exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.

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(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.

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(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 record keeping. 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:



BIOHAZARD

(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.

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

(ii) Training shall be provided as follows:

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

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(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

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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 and social security number 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

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

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

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

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

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

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

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

(C) An explanation of how the incident occurred.

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

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

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.

[56 FR 64175, Dec. 6, 1991, as amended at 57 FR 12717, Apr. 13, 1992; 57 FR 29206, July 1, 1992; 61 FR 5508, Feb. 13, 1996; 66 FR 5325, Jan. 18, 2001; 71 FR 16672, 16673, Apr. 3, 2006]

§1910.1043 Cotton dust.

(a) *Scope and application.* (1) This section, in its entirety, applies to the control of employee exposure to cotton dust in all workplaces where employees engage in yarn manufacturing, engage in slashing and weaving operations, or work in waste houses for textile operations.

(2) This section does not apply to the handling or processing of woven or knitted materials; to maritime operations covered by 29 CFR Parts 1915 and 1918; to harvesting or ginning of cotton; or to the construction industry.

(3) Only paragraphs (h) Medical surveillance, (k)(2) through (4) Recordkeeping—Medical Records, and Appendices B, C and D of this section apply in all work places where employees exposed to cotton dust engage in cottonseed processing or waste processing operations.

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