

EAST CAROLINA UNIVERSITY

EXPOSURE CONTROL PLAN

Bloodborne Pathogen Exposure Control Plan

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SCOPE AND APPLICATION:

East Carolina University (ECU) is committed to providing a safe and healthy work environment for faculty, staff and students. This Exposure Control Plan is used as a means to eliminate or minimize occupational exposure to human blood and other potentially infectious materials (OPIM) or fluids. It is designed to comply with the OSHA Standard 29 CFR 1910. 1030, “Occupational Exposure to Bloodborne Pathogens”. (Appendix A)

A copy of this plan will be accessible to each department through the Infection Control Manual and through the Prospective Health / Infection Control Web site. Definitions used in this plan are enclosed as Appendix B.

This plan will be reviewed and updated annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposures by the Office of Prospective Health (744-2070). The plan will also:

- Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens
- Document consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure, in conjunction with the ECU Product Standardization Committee.

RESPONSIBILITIES:

Each clinical and research area shall evaluate its routine and reasonably anticipated tasks and procedures to determine where there is actual or potential exposure to blood or OPIM. The employees who perform these tasks or procedures will receive the training and immunizations described below. Employees involved in clinical/research areas will be monitored by their immediate supervisors, Infection Control and Biosafety to ensure that each employee is abiding by the recommendations and guidelines provided in this document.

It is our goal to reduce and minimize potential exposures with safer sharp devices. By comparing numbers of exposures year to year, we can determine if we are meeting our goals and also determine any developing trends.

I. EXPOSURE CONTROL PLAN: BLOODBORNE PATHOGENS (BBP)

A. Each clinical and research area manager must ensure that:

- This plan is accessible to all affected employees.

- Education is provided within 10 work days for new employees and annually thereafter; sooner should guidelines/recommendations change.
- Staff compliance is monitored by clinical and research supervisors as well as Infection Control and Biosafety.
- Personal protective equipment (PPE) is available and maintained.
- Equipment and environmental surfaces are cleaned and decontaminated.

B. ECU's compliance program for the OSHA Bloodborne Pathogen Standard is administered by Infection Control for clinical employees and Biological Safety for research employees.

The Chairman of each department, lead nurse of each clinic, Principal Investigator of each lab, or other responsible administrators, managers, or supervisors will be responsible for implementing this plan by ensuring that healthcare workers/students in their department, lab or facility are educated, adhere to this policy and procedures to minimize or eliminate bloodborne pathogen exposures. (While the OSHA standard does not legally apply to students, students with curricular exposures will be educated to follow protective practices comparable to those employees, with the support and oversight of their school or department.)

Departmental supervisors/managers/Principal Investigators will notify Infection Control or Biological Safety when changes occur in personnel assignments, equipment, or responsibilities that increase employees' exposure to bloodborne pathogens.

C. Exposed Occupation

1. A list of job classifications in which the employees are more susceptible to have occupational exposures.

Registered Nurses	Security Guard
Licensed Practical Nurses	Police Officer I-III
Nursing Assistants	Police Chief
Medical Office Assistant	Radiation Safety Officer
Radiation Safety Supervisor	Radiation Safety Specialist
Physician Extender I-III	Radiation Survey Technician
Pathologist Assistant	Physicians
Laboratory Supervisor	Therapeutic Recreation Specialist
Medical Laboratory Technician	Biohazardous Waste Collection
Medical Laboratory Assistant	Technician
Perfusionist	Laboratory Animal Technician I-III
Dentist	Biomedical Photographer
Dental Assistant	Medical Illustrator
Dental Hygienist	Medical Technologist
Physical Therapist	Clinical Instructor (clinical Pathology)
Physical Therapist Assistant	Ultrasound Technician

2. A list of job classifications in which some* employees may have occupational exposure:

Secretary I-IV	Electrical Supervisor I
Receptionist	Plant Engineer
Clerk Receptionist I-III	HVAC Technician
Clinical Dietitian I-III	Pharmacist
Social Worker	Research Technician I-IV
Plumber I-III	Research Associate
Carpenter Supervisor I	Graduate Assistant
Carpenter I-II	Lecturer
Painter	Instructor
Grounds Supervisor I	Associate Professor
Grounds Worker	Assistant Professor
Steam Plant Supervisor I	Professor
Boiler Operator I-III	Housekeeping Supervisor I-III
Housekeeper	Housekeeping Team Leader
	Student Worker

NOTE:

Due to the nonspecific nature of job categories at ECU, not all individuals with a given job title are exposed to the same hazards. The individual's need for coverage for BBP purposes is determined using the Initial Health History based on the actual risk in the individual's particular assignment, not on the job class per se.

*= visible blood spills should be cleaned up before calling in Facilities personnel for repair or maintenance activities.

D. Definitions of blood, body fluid or other potentially infectious materials (see (Appendix B for additional definitions)

1. Human blood
2. Human serum
3. Fluids-amniotic, pericardial, plural, peritoneal, synovial, cerebrospinal, seminal, vaginal (human)
4. Unfixed tissue (human)
5. HIV cultures
6. Human cell cultures

E. Non-infectious materials for bloodborne pathogens +

1. Feces
2. Nasal secretions
3. Sputum
4. Tears
5. Urine
6. Sweat
7. Vomitus
8. Saliva

+ Unless visibly blood tinged. However, may contain infectious agents which are not bloodborne pathogens.

II. Methods of Compliance

A. Standard (Universal) Precautions:

Since medical history and examination cannot reliably identify all patients infected with HIV or other bloodborne pathogens, STANDARD PRECAUTIONS should be consistently used for work with human blood and OPIM.

Standard/Universal Precautions shall be observed by faculty, staff, students and other healthcare workers to prevent contact with blood or OPIM. All blood/body fluids should be considered potentially infectious materials. Standard/Universal Precautions include the routine use of appropriate barrier precautions to prevent skin and mucous membrane exposure with the blood or OPIM of all patients or specimens.

B. **HAND WASHING:** Strict HAND WASHING technique is to be used in all instances of contact with any patient's blood or OPIM.

HAND WASHING facilities must be readily accessible to employees.

Whenever HAND WASHING facilities are not feasible, approved waterless hand sanitizing agents, or antiseptic towelettes shall be used. When waterless hand sanitizers or towelettes are used, hands shall be washed with soap and running water as soon as possible after use of the waterless agent.

Hands must be washed immediately after contact with blood or body fluid AND as soon as feasible after removal of gloves or other PPE.

Following unprotected contact of any body areas with blood or other potentially infectious material, employees must wash hands (or other affected skin) with soap and water, or flush mucous membranes with water as soon as possible after contact. (See Appendix B for definition of “exposure” and Section IIC Page 19 regarding what to do if exposed.)

- C. **PERSONAL PROTECTIVE EQUIPMENT (PPE):** PPE is provided to employees at no cost and is located in each clinical and research area. Training is provided by the department manager in the use of the appropriate PPE for the tasks or procedures employees will perform. Each department manager is responsible for ensuring that appropriate PPE is available to all their employees and that it is used when needed.

Appropriate protective barriers will be available and used to prevent exposure to blood and OPIM. The protective work clothing and equipment such as gloves, gowns, laboratory coats, face shields or masks and eye protection, mouthpieces, resuscitation bags, pocket masks, and other related devices are kept available in a variety of sizes, and easily accessible to the employee.

PPE will be considered appropriate if it does not permit blood or OPIM to penetrate 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 during which used. Reusable PPE must be repaired or replaced as needed to maintain effectiveness, and be cleaned, laundered or disposed of at no cost to the employee.

1. Gloves are worn when the worker has a potential for direct skin contact with blood, OPIM, mucous membranes or non-intact skin of patients, or when handling items or surfaces contaminated with blood or OPIM, and when performing vascular access procedures. Sterile gloves should be used for procedures involving contact with sterile areas of the body. Nonsterile examination gloves may be used for procedures involving contact with mucous membranes, and for other patient care or diagnostic procedures.

Single use surgical or examination gloves are not to be reused. They should be replaced when visibly soiled, torn, punctured, or when their ability to function as a barrier is compromised. They should NOT be worn to handle items in the environment when the procedure has been completed. Dispose single use gloves immediately after a procedure is completed.

Utility gloves (e.g. rubber or vinyl household gloves) for housekeeping chores involving potential blood contact or for instrument cleaning and

decontamination procedures may be reused. Utility gloves may be decontaminated and reused, but should be discarded if they are peeling, cracked, discolored, or have a puncture, tear, or other evidence of deterioration. Any of the above would make their ability to function as a barrier compromised.

Latex-free or hypoallergenic gloves, glove liners, powder less gloves, or other similar alternatives, shall be readily accessible for those employees who are allergic to the gloves normally provided. Use of non-latex gloves for cleaning or other tasks not requiring tactile sensitivity is strongly encouraged. Vinyl gloves and nitrile gloves are available in the ECU Medical Store Room. .

Consideration will be given to double gloving in situations where it is feasible.

2. Mask and eye protection, or chin-length face shields are worn when the employee has the potential for splashes, spray, spatters, droplets or aerosols of blood or other fluid to the eye or mouth. Masks must cover the nose and mouth and fit securely. Health care workers must not share goggles or wear masks dangling from neck. Eye glasses without a side shield do not protect eyes from splashes.
3. Appropriate protective clothing shall be worn when the worker has potential for exposure to blood and OPIM on their clothes or body. The clothing selected shall form an effective barrier and not permit potentially infectious materials to pass through or reach the employee's work clothes, street clothes, undergarments, and skin. Gowns, lab coats, aprons, similar clothing shall be worn if there is potential for soiling of clothes with blood or OPIM. Fluid resistant clothing shall be worn if there is potential for splashing or spraying of blood or OPIM. Surgical caps or hoods shall be worn if there is potential for splash on to the head. Fluid proof shoe covers shall be worn if there is potential for shoes to become contaminated or splashed. If any garment is penetrated by potentially infectious material, the garment shall be removed immediately or as soon as feasible. All PPE shall be removed prior to leaving the work area and placed in the appropriately designated area or container for disposal or washing and decontamination.
4. Refer to each Departmental Infection Control policy for a detailed list of Procedures performed and Protective Equipment needed. Compliance with Standard (Universal) Precautions and Work Practice Controls will be monitored by each departmental manager or clinical instructor, or supervisor.

D. ENGINEERING CONTROLS:

Engineering controls will be used to eliminate or minimize worker exposure. Revisions in Engineering controls or work practices will be made by each

department through review of exposure reports, inspections, employee input, committee activities, etc.

1. Shields/Guards:

Stationary shields or guards may be installed to eliminate the necessity for other facial barriers to keep splashes from contacting the face. For example, a transparent plastic shield can be used as a barrier between the worker and a vial of blood being uncapped.
2. Sealed Units:

When splashes or aerosols are anticipated, containment devices can be employed as a method to eliminate the necessity for facial protection. For example, sealed centrifuge cups can be employed to contain aerosols formed during centrifugation.
3. Biological Safety Cabinets:

Enclosed cabinets with exhausted air may be employed when splashes or aerosols are anticipated as a method to eliminate the necessity for facial protection by providing a barrier between the worker and a specimen handled in a way which may create an aerosol.
4. Washing facilities are located in areas that are readily accessible
 - a. Handwashing sinks – in clinical & research areas
 - b. Eyewash stations – in laboratories
 - c. Use of waterless hand cleaners – where sinks are not available
5. Needles/Sharps:

All workers should take precautions to prevent injuries caused by needles, scalpels, and other sharp instruments or devices and when handling used sharp instruments after procedures.

 - a. Contaminated needles and other contaminated sharps shall not be bent, recapped, removed, or otherwise manipulated by hand except when there is no feasible alternative or that such action is required by a specific medical procedure. If recapping or removing of contaminated needles or sharps must be done, it is only done by use of a mechanical device or a one-handed technique.
 - b. After use, contaminated sharps should be placed in an appropriate container for sharps. Reusable sharps are placed into appropriate containers.
 - c. Containers for sharps are puncture resistant, labeled or colorcoded, leak-proof on the sides and bottom and are not stored or processed in a manner that requires employees to reach by hand into the containers.
 - d. Containers for disposable sharps are located in each exam room, treatment rooms, clinical and research labs and any other area where sharps are used. These containers will be checked routinely by staff and when 3/4 full, they are to be sealed for pick up by the Biohazardous Waste Collection Technician for incineration.

Safety needle and other devices are evaluated by the ECU Standardization Committee, Safety Devices Subcommittee, chaired by the Infection Control Nurse. Safer medical devices for vascular access, devices for intramuscular access, devices for intramuscular, subcutaneous injections and other safety devices for specialty clinic situations are evaluated by the subcommittee and recommended for purchase through the Product Standardization Committee. Representatives from clinical sites, research, dental, School of Medicine and Pathology review the devices. Samples are taken to the work sites and evaluated over a period of time when front line workers can handle and use them during work situations. When all samples have been used, they are evaluated and rated. It is determined at that time which new products should be purchased for use on the Health Science Campus if any. It is our goal to reduce and minimize potential exposures with safer needle devices. By comparing numbers of exposures year to year, we can determine if we are meeting our goals and also determine any developing trends.

E. WORK PRACTICES:

1. Personal Hygiene

Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in laboratories and other work areas where blood or OPIM are likely to be present.

Food and drink are not stored in refrigerators, freezers, or cabinets where blood or OPIM are present or other areas of possible contamination such as clinic or laboratory counter tops.

Healthcare workers who have exudative lesions, weeping open wounds or sores on the hands which preclude effective hand washing may require removal from work in patient contact. Other lesions or skin breaks may be covered with a protective dressing if they do not preclude adequate hand washing. (Refer to the [Work Restrictions for Personnel policy](#).)

2. Work Practices

All procedures involving blood or OPIM are performed in such a manner as to minimize splashing, spraying or aerosolization of the substances. Examples may include covers on centrifuges, dental dams and surgical barriers.

- a. Mouth pipetting/suctioning of blood or any materials is prohibited.
- b. Use of glass hematocrit tubes is prohibited.
- c. Vacutainer holders are disposed of after a single use, without removing the needle.

d. Broken glassware will be cleaned up using mechanical means, such as a brush and dust pan, tongs or forceps.

3. Labels and Warnings

Warning labels are affixed to containers of infectious waste, refrigerators and freezers containing blood or OPIM or other containers used to store or transport blood or OPIM. The labels are fluorescent orange or orange-red, using the universal biohazard label and affixed in a highly visible location. Red bags or red containers may be substituted for labels on containers of infectious waste.

4. Waste

Non-contaminated waste is placed in clear or brown plastic bags for pickup by Housekeeping. Contaminated waste is placed into covered receptacles lined with red or orange bags with biohazard label for pick up by Prospective Health. Some satellite clinics' staff may remove the red bags to a central pick-up site. If outside contamination of the primary container occurs, the primary container shall be placed into a secondary container which prevents leakage during handling, processing, storage, transport, or shipping, and is labeled or color-coded appropriately. Waste materials known to be infectious are collected by Prospective Health and then removed from the institution by an outside contractor for incineration.

5. Specimens

If the specimen could puncture the primary container, the primary container will be placed within a puncture-resistant container.

Specimens of blood or OPIM shall be placed in a sealable, leak-proof container and labeled or color-coded prior to being stored or transported. If outside contamination of the primary container is likely, then a second leak-proof container that is labeled or color coded shall be placed over the outside of the first one and closed to prevent leakage during handling, storage, or transport. If a puncture in the container is likely, it shall be placed in a leak-proof, puncture resistant secondary container.

All laboratory specimens will be placed in a plastic bag marked with the biohazard label. All specimens transported from the patient clinical areas to the laboratory, or from one laboratory to another laboratory, through public access hallways will be placed in a secondary container marked with the biohazard label. These containers will be located in each patient clinical area, clinical lab area or research area for use.

6. Equipment

Equipment which may be contaminated with blood or OPIM shall be cleaned and decontaminated as necessary prior to servicing, transporting, shipping or being moved, stored or sent to surplus. If decontamination of such equipment or portions of such equipment is not feasible, a biohazard label shall be attached to the equipment stating which portions remain contaminated. This information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so the appropriate precautions will be taken. Examples may include centrifuges, chemistry/hematology equipment, refrigerators, laser machinery, etc.

All equipment used to puncture skin, mucous membranes or other tissues in medical, dental, or other settings must be disposed of after use or sterilized prior to reuse. Instruments and devices that enter sterile tissue or the vascular system of any patient or through which blood flows must be sterilized before reuse.

Devices or items that have contact with mucous membranes should be sterilized or receive high level disinfection. Medical and dental instruments that require sterilization or disinfection should be thoroughly cleaned before being exposed to the germicide. The manufacturer's instructions for concentration, temperature and contact time will be followed. Cleaning products approved for use at East Carolina University are stocked in the BSOM Medical Storeroom. The individual clinic or lab may designate the appropriate process and products to be used for their workplace.

F. Housekeeping

All equipment, environment, and working surfaces shall be properly cleaned and disinfected after contact with blood or OPIM. The work site will be maintained in a clean and sanitary condition. A written schedule for cleaning and method of decontamination is developed based upon the location within the facility, the type of surface to be cleaned, type of soil present, and the tasks and procedures being performed. (Refer to [the Equipment Disinfection and Cleaning Inventory and the Housekeeping Practices policies](#)). The written schedule for cleaning and disinfection procedures may be included in the departmental Infection Control plan or Biological Safety Plan.

G. Cleaning and Disinfection

1. Chemical germicides that are approved by Infection Control are available in the Medical Storeroom. (See Equipment Disinfection and Cleaning Inventory policy). These disinfectants are tuberculocidal when used at recommended dilutions and can be used to decontaminate surfaces exposed to blood or OPIM. Visible materials

should first be removed by cleaning; then the area is decontaminated with disinfectant. Gloves are worn during cleaning and decontaminating procedures; gowns and face shields may be worn if needed.

2. Work surfaces exposed to blood and OPIM should be cleaned and disinfected immediately or as soon as feasible after completion of a procedure. Cleaning should be done when surfaces are contaminated or after any spill of blood or OPIM and at the end of the work shift. Protective covering such as plastic wrap, aluminum foil, or imperiouslybacked absorbent paper may be used to cover equipment and environmental surfaces. These coverings shall be removed and replaced when they become overtly contaminated or at the end of the work shift.

If a large spill of blood or OPIM occurs, a spill kit with adsorbent is available in clinical areas. Housekeeping may be called to respond to the immediate situation if mops/buckets are needed for clean up of disinfectant or if the spill cannot be contained by the spill kit. The Brody Housekeeping Supervisor will replace materials used in the spill kit as needed, upon request.

3. Cleaning Spills of Blood and OPIM

Use (PPE), gown, mask, and protective eyewear) appropriate for the task.

a. To clean a small spill (<20ml)

- 1) Don gloves
- 2) Carefully remove visible blood or OPIM with paper towels or some other absorbent paper and dispose in biohazard waste container.
- 3) Mechanical means such as forceps should be used to pick up any contaminated sharps or broken glass and place in biohazard sharps containers.
- 4) Swab the area with a cloth or paper towel moderately wetted with a disinfectant (an EPA-registered sodium hypochlorite product such as Dispatch). Allow disinfectant to sit for 10 minutes.
- 5) Wipe with a clean paper towel or air dry.
- 6) Dispose of PPE and all contaminated items into a biohazard waste container.
- 7) Wash hands using soap and water.

b. To clean large amounts of blood (>100ml) or more than can be absorbed by paper towels:

- 1) Secure the area to prevent employees or visitors from exposure.
- 2) Report spill to supervisor. Utilize biohazard spill kit. Contact housekeeping if assistance is needed.

- 3) Don PPE (gloves, gown, mask and eye protection).
 - 4) Mechanical means such as forceps should be used to pick up any contaminated sharps or broken glass and place in biohazard sharps containers.
 - 5) Remove visible blood or other organic material. A fluid control solidifier may be sprinkled on the spill.
 - 6) Discard all cleaning materials into a biohazard waste container.
 - 7) Apply disinfectant (an EPA-registered sodium hypochlorite product such as Dispatch) to the spill area, keeping the area wet for 10 minutes.
 - 8) Wipe clean or air dry.
 - 9) Remove PPE and place in the biohazard waste container. 10) Wash hands using soap and water.
- c. As a general guideline, spills larger than 100cc probably would be considered large. Those less than 10 to 20cc would be considered small. For others, the pattern of the spill would determine the approach to clean up.
 - d. For advice or assistance with blood spills which cannot be contained by using the Biohazard Spill Kit or which exceeds the cleaning capability of Housekeeping, contact Infection Control (744-2070) or Biological Safety (744-3437) for guidance; an outsider contractor may be required for extensive clean-up, e.g., exceeding 4x4 ft in area, e.g.; trauma site or crime scene

4. All bins, pails, cans, and similar receptacles intended for reuse which may become contaminated with blood or OPIM shall be inspected, cleaned and decontaminated immediately or as soon as feasible after visible contamination occurs.

H. Contaminated Sharps and Other Regulated Waste

Regulated waste is any waste grossly soiled with human blood or OPIM.

Infectious waste is a broader term and includes regulated waste as well as other infectious materials, such as culture plates and stocks that may contain pathogenic organisms.

1. Sanitary sewers may be used to dispose of limited liquid (trace amounts) waste capable of being flushed into the sewer, such as residual blood or excretions. Infectious biomedical waste at ECU will be incinerated. All infectious waste for disposal shall be placed in a closable, leak-proof red biohazard bag. It will be closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping. If outside contamination of a container or bag occurs or is likely to occur, then a second leak-proof container or bag which is closable and labeled or color coded shall be placed over the outside of the first and closed to prevent spillage or protrusion of contents during handling, storage,

shipping or transport. Waste receptacles with red bags with biohazard labels for contaminated waste are located in the patient exam areas, clinical laboratory areas, and clinical research/teaching areas for discarding materials grossly contaminated with blood or other potentially infectious body fluids. Red bags are picked up by trained staff from Prospective Health. They are stored in a secure area for pick up by a contract service.

2. Immediately after use, sharps shall be disposed of in a closable, leak-proof, puncture resistant, disposable container that is labeled or color coded. These containers shall be maintained upright during use, easily accessible to personnel and located as close as feasible to the immediate area of use. They shall be replaced routinely and not be allowed to overfill. Containers which are 3/4 full shall be closed and removed from the clinic and replaced with an empty container. The closed container will be stored safely until collected. Sharps containers are located in the patient clinic areas, clinical laboratory areas, and clinical research/teaching areas. Containers will be collected by trained Prospective Healthcare workers on waste collection rounds, placed into leak-proof, covered waste disposal carts and transported for incineration.
3. Contaminated reusable sharps shall be stored or processed so healthcare workers do not reach by hand into a container used to transport, store or clean them. (For example, employees should not reach blindly into a basin filled with water and sharp instruments to clean them). When moving containers of contaminated sharps from the area of use, the containers will be closed immediately prior to removal to prevent spillage or protrusion of contents during handling, storage, transport or shipping. If leakage is possible, the container will be placed in a secondary container, which is closable, contains all contents, is leak-proof, labeled or color-coded. Sharps or their containers shall not be handled opened, emptied or cleaned in any manner which would expose healthcare workers to the risk of percutaneous injury.

I. Laundry Procedures

Laundry contaminated with blood or OPIM will be handled as little as possible. Such laundry will be placed in appropriately marked leak-proof bags at the location where it was used. It will not be sorted or rinsed in the area of use.

All employees who handle contaminated laundry will utilize PPE to prevent contact with blood or other potentially infectious materials. Contaminated laundry and lab coats used as PPE at ECU will be sent out to be cleaned by a contract linen service approved to perform this function.

J. Hazard Communications/Training

1. Labels and signs

Warning labels shall be affixed to containers of infectious waste, refrigerators and freezers containing blood or OPIM; and other containers used to store, transport or ship blood or OPIM. The accepted biohazard

label shall be a fluorescent red-orange background with lettering and symbols in contrasting colors. The label shall be an integral part of the container and affixed as closely as possible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal. Bio-hazard labeled red bags or boxes will be used for infectious waste. Regulated waste that has been decontaminated need not be labeled or color-coded.

2. Information and Training

- a. All employees covered by this document shall participate in a training program at the time of their initial employment. This is held during the BSOM New Employee Orientation and is open to all ECU Employees, both EPA and SPA, and paid student workers. Training is updated annually and is provided at no cost and during working hours. Material appropriate in content and vocabulary to the educational level, literacy, and language background of the employees shall be used.
- b. The training program shall contain the following:
 - An accessible copy of the OSHA Standard on Occupational Exposure to Bloodborne Pathogens (29CR part 1910.1030) and general explanation of its contents. (Appendix G)
 - A general explanation of the epidemiology and symptoms of bloodborne diseases.
 - The modes of transmission of blood-borne pathogens.
 - The exposure control plan and means by which the employee can obtain the written plan.
 - The appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials.
 - The use and limitations of practices that will prevent and reduce exposure including appropriate engineering controls, work practices, and PPE.
 - Information on the types, proper use, location, removal, handling, and decontamination or disposal of PPE.
 - The basis for selection of PPE.
 - Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administrations and the benefits of being vaccinated.
 - Information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM.
 - 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.
 - An explanation of the signs, labels, and color-coding.
 - An opportunity for interactive questions and answers.

- c. Training is provided to the employees by the Office of Prospective Health.
 - 1) Initial or New Employee Training is held twice a month and is open to all ECU staff, faculty and student workers exposed to human blood, body fluid or OPIM. The calendar for New Employee orientation is available on-line at <http://www.ecu.edu/cs-dhs/staffdev/neo-schedule.cfm>
 - 2) Annual training is available online at <http://www.ecu.edu/prospectivehealth/traininged.htm>
Face-to-face training is provided upon request to employee

groups.

K. RECORD KEEPING

1. Medical Records

An accurate employee health record for each employee subject to medical surveillance under this document will be maintained and include:

- a. The name and banner access number of the employee.
 - 1) His/her hepatitis B status, including the dates of all hepatitis B vaccinations and/or hep B surface antibody titer or signed declination form and any medical records relative to the employee's ability to receive vaccination.
 - 2) All results of examinations, medical testing, follow-up, and written opinions as they relate to the employee's ability to wear protective clothing and equipment or receive vaccination or to post-exposure evaluation following an occupational exposure incident are completed within 15 days.
 - 3) A copy of the information provided to the provider and provider's written opinions. (Appendix C)
 - 4) Employee Medical Records are retained for duration of employment plus 30 years.

2. Employee Training Records

Training records shall include the following information:

- a. The dates of the training sessions.
- b. The contents or title of the training sessions.
- c. The name and qualifications of persons conducting the training
- d. The name and job titles of all persons attending the training sessions.

The training records shall be maintained for 3 years by ECU Infection Control at the Office of Prospective Health. Training records are also maintained on the ECU One Stop database for employees who register by that route.

3. Availability

All required records shall be made available upon request to anyone as required or permitted by law. The employee medical records will be kept confidential and will not be disclosed or reported without the employees' expressed written consent to any person within or outside the workplace except as required by law. These records will also be provided upon request for examination and copying to the employee or to anyone having written consent of the employee.

4. Transfer of Records

Records will be transferred as required by federal law (29 CR 1910.20). Any other state or federal laws governing transfer of these records will be followed in accordance with those directives.

II. Medical Services/Surveillance

A. Hepatitis B Vaccination

Employees in positions having occupational contact with blood or OPIM will be offered the vaccine within ten (10) working days of initial assignment. If an employee for whom Hepatitis B vaccine is indicated declines the HBV vaccine, a declination form will be signed and retained in the Employee Health chart (see appendix). If the employee has previously been vaccinated, the employee must provide documentation of three (3) vaccines or a positive surface antibody. If employee does not have any of the above, employee will be offered three vaccines with post vaccination titer to document immunity or the need for a booster vaccination.

B. Bloodborne Pathogens Exposure

Any employee or student covered by this policy who has a *puncture*, cut, or scratch with a contaminated object or a *splash* into the eye or mucus membrane with blood or OPIM or who has cutaneous exposure with such material on broken skin (chapped, abraded, or dermatitic) is considered to have a bloodborne pathogens exposure incident. The employee/student will have a confidential medical evaluation and follow-up provided by a licensed medical practitioner, following the guidelines of Appendix D. This evaluation will occur at Prospective Health for employees. For students, the evaluation will occur at Student Health Service (or Prospective Health for Brody School of Medicine students). As a part of a confidential medical evaluation, the circumstances of the exposure, other relevant information will be recorded on an exposure evaluation form (Appendix E)

- Route(s) of exposure
- The activity in which the work was engaged at the time of the exposure. The extent to which appropriate work practices and protective equipment were used

- Identification and documentation of the source individual, unless identification is unfeasible
- The specific medical device involved (needle, scalpel, lancet) and brand, if any.

Reporting under federal and state laws will be performed as required.

C. When an employee or student is involved in an exposure incident:

Immediately perform decontamination

1. Wash the skin or wound with soap and water
2. Flush mucous membranes with water
3. Remove contaminated clothing

Abbreviations used in this section:

Vidant OH—Vidant Occupational Health

BSOM--Brody School of Medicine

ECU SHS -- East Carolina University Student Health Service

ED--Emergency Department

PEP--Post Exposure Prophylaxis

D. Recording the Incident

Whenever an employee/student is involved in an exposure incident, the following forms must be completed:

1. ECU Non-Patient Incident Report Form – for all incidents. (Appendix E)
2. Facility Incident Report: if incident occurs at a non- ECU facility (such as Vidant) the local Facility Incident Report is completed. This remains with the facility which investigates the source patient.
3. If an ECU patient or visitor is exposed to the blood of an ECU employee, an ECU Non-Patient Incident Report is completed. In addition, the Incident Report is also forwarded to BSOM Risk Management if the patient or visitor exposure occurs at a BSOM clinic (Appendix E)
4. If a non-BSOM student is exposed, the SHS will follow the guidelines of Appendix F.

III. Content of Evaluation and Surveillance Program

A. Source patient evaluation

1. All source patients are considered “at risk” according to universal precautions.
2. Laboratory studies
 - a. Done at no cost to the source patient
 - b. No need to repeat tests done within past 3 months unless continued risk behavior/events
 - c. Test the mother if source is an infant under age 15-18 months with no personal risk factors
 - d. Tests
 - i. HIV antibody
 - ii. Hepatitis B surface antigen, surface antibody and core antibody.

iii. Hepatitis C antibody

e. If source patient blood is drawn by unit:

i. Draw a red top tube ii. Label tubes

with the following information:

Patient's code (contact Prospective Health for confidential identifier)

Patient's date of birth

Initials of person drawing blood,

The date the blood was drawn, and the time drawn

iii. Send the blood to the lab with the code HEPBP2 written on the lab order form.

4. If source patient refuses to submit to testing, the county health director may be contacted to order testing per NC Administrative Code (15A NCAC 19A.0203). Testing can be ordered by director, particularly if risk factors are present.

B. Exposed patient evaluation

1. History of exposure, event, and device used
2. Personal medical history of prior infections or immune suppression
3. Protective equipment used
4. Medical devices used during incident-specify models/brands
5. Baseline laboratory studies

a. Hep B surface antibody (unless previously documented as positive/ immune)

b. HIV antibody

c. Hepatitis C antibody

d. If exposed person refuses baseline HIV testing, blood may be obtained and frozen for 90 days should the person change his/her mind and agree to HIV testing during that 90-day period. At the end of 90 days, the blood will be disposed of.

C. Treatment

1. Treat any injuries based upon the nature of the injury: laceration, bite, etc.
2. Provide post exposure prophylaxis if exposed to known or suspected HIV positive source
3. Treatment of other specific infections based upon source patient history/labs

D. Follow-up

1. Duration and content of follow-up laboratory surveillance is based upon the actual exposure risk
2. Exposure to an unknown source will result in surveillance for all BBP
3. Employees exposed to an HIV negative source may elect to have serologic surveillance for HIV for up to 6 months.

- E. Confidentiality
1. Confidentiality will be maintained throughout the entire testing, counseling, evaluation, and treatment process. All records regarding blood and OPIM exposures investigated by Prospective Health will be kept in the Employee (or BSOM student) Health record in locked files. Any reporting required by law will be performed in such a way as to protect confidentiality. The employee's physician may be contacted if needed with the employee's permission.

The ECU employee/ BSOM student may obtain a copy of his/her exposure evaluation laboratory results by signing a medical release form.

IV. Preventive/treatment measures for documented exposure to:

- A. Hepatitis B: If source patient is hepatitis B surface antigen positive and employee/student is:
1. Unvaccinated
 - a. Administer a single dose of hepatitis B immune globulin, (HBIG) within 7 days
 - b. Begin hepatitis B vaccine series
 - c. Test for hepatitis B antigen in 3 months
 - d. If hepatitis B vaccine is contraindicated, a second dose of HBIG will be administered
 2. Previously demonstrated to be immune – no further treatment or followup is indicated
 3. Previously vaccinated with no documentation of immunity
 - a. Check titer
 - b. Administer a single dose of hepatitis B vaccine, if titer is not immune, with follow-up titer (6 weeks later).
- B. Hepatitis C
1. No prophylaxis is available
 2. Follow-up with Hepatitis C RNA at 2-6 weeks if source patient is positive for Hep C.; add ALT at 3 months, Hep C antibody at 3 and 6 months.
 3. Refer for early treatment if sero-conversion occurs
- C. HIV
1. **Time Frame**
 - a. Preventive treatment with antiretroviral drugs can prevent infection when provided as soon as possible after exposure.
 - b. Treatment within the first several hours post exposure is optimal e.g. within the first 2 – 3 hours; however, treatment may still be effective within the first 24-48 hours.
 - c. In very high-risk cases, PEP may be considered two weeks after exposure. There is no contraindication to “late prophylactic treatment”

2. **Exclusion criteria: Health care workers (HCW) will be ineligible if any of the following criteria are present:**
 - a. HIV infection diagnosed at baseline (or within 2 weeks of exposure)
 - b. Failure to give written informed consent
 - c. Men and women are counseled to avoid pregnancy during treatment (see 3 below).
 - d. Active substance abuse
 - e. Active malignancy, hepatic, pancreatic, or renal disease, or other illness contraindicating treatment.
 - f. If questions arise as to contraindications to PEP, ECU Infectious Disease will be consulted for guidance.⁰⁹
3. **Relative Contraindication: Pregnancy**
Pregnancy is not an absolute contraindication but the decision to initiate medication should involve the woman and her personal health care provider if she is pregnant or breast feeding.
4. Antiretroviral agents are individualized when initiating treatment in employees who have used myelosuppressive, hepatotoxic, or nephrotoxic agents within the past four weeks.
5. If the exposure meets the criteria in Appendix I, CDC Guidelines Step 1 and the patient meets the criteria on Steps 2 and 3, PEP will be offered as soon as possible. Exposures reported after 72 hours post-exposure may be considered for prophylaxis based upon risk assessment and reason for delay for up to 2 weeks.
6. Any exposure to concentrated HIV (e.g. in a research laboratory) will be treated as a highest risk exposure.
7. Exposure to an unknown source patient will be evaluated by Prospective Health on a case-by-case basis.
8. Exposure to an unknown source will be considered for PEP in specific extenuating circumstances. Examples may include:
 - a. An exposure that occurs in a geographic area where injecting drug use is prevalent.
 - b. An AIDS unit in a health care facility.
 - c. Known increased prevalence of HIV in the population served.
9. **Treatment with PEP**
Post-exposure prophylaxis may consist of two or 3
 - a. antiretroviral drugs taken for 4 weeks. Infectious Disease physician is consulted for current drug recommendations.
 - b. Baseline metabolic screen for renal or liver disease and CBC and differential will be obtained prior to initiation of PEP. Pregnancy test will be obtained as needed.
 - c. All employees placed on a four-week PEP program will be scheduled for follow-up with ECU Prospective Health at 2 weeks to monitor for drug side effects. Repeat CBC and CMP.

10. The bloodborne pathogen follow-up for HIV and other infections will continue for at least six (6) months per Employee Health protocol.
11. Follow-up for HIV will be extended to 9 months if Hepatitis C is present in source patient or exposed person.

E. Bite Wounds

1. If a bite wound occurs, the mouth of the source is examined for presence of bleeding gums, mouth ulcers, or other sources of blood/serum into the mouth.
2. Saliva alone is a poor source of transmission of bloodborne pathogens. Hepatitis B would be the greatest risk, but is rare, unless blood is present.
3. If the bitten person bleeds there is the potential for employee to source exposure especially if mouth wounds are present.

F. When a previously unsuspected infection is discovered in an ECU source patient:

1. It is the responsibility of the facility conducting the exposure evaluation to inform the source about these results and to provide appropriate counseling or referral. The facility whose patient, client or research subject is the source is responsible for ensuring that this counseling occurs.
2. When the source patient is seen at BSOM clinics:
 - a. PH will contact the attending physician with positive results and ask physician to provide such counseling/treatment/referral
 - b. PH will provide written documentation of the abnormal laboratory studies for patient's medical record.
3. If the source patient exposure occurs in a non-clinical setting, ECU will:
 - a. Ensure that the source receives appropriate counseling by a physician or licensed healthcare professional.
 - b. Ensure that the source's physician is notified and receives copies of the abnormal lab reports.

G. Counseling

1. Source Patient: Prospective Health representative, the attending physician or designee will speak with the source patient (or parent/guardian in the case of the minor or incompetent patient) about the following:
 - a. That an employee/student exposure occurred without identifying the person by name.
 - b. Explain that the exposure was accidental.
 - c. The ECU policy regarding requests for source patient testing (rapid HIV antibody, hepatitis B panel, hepatitis C antibody.)
 - d. That the tests will be ordered anonymously and will be no cost to them.

- e. Documentation will indicate that the reason for testing is “followup for exposure” versus “diagnostic”. If test results are negative, a notice will be sent to the attending physician, documenting that an exposure incident occurred. If any laboratory result is positive for infection, the actual result will be sent to their physician with notification that follow-up is needed. These will be filed in the medical record.

2. **Exposed Employee/ Student Counseling**

Prospective Health will provide and document the following counseling as part of the response to a blood or other potentially infectious materials exposure:

- a. What constitutes an exposure.
- b. Evaluating the risk from the exposure through source patient chart review, interview or testing.
- c. Protocol for follow-up of exposure to HIV, hepatitis B, or hepatitis C. The ECU protocol for post exposure prophylaxis after known/suspected HIV exposure.
- d. Counsel the exposed healthcare worker/student to:
 - i. Report and seek medical evaluation for any acute febrile illness that occurs during twelve (12) weeks after the exposure.
 - ii. Refrain from blood donation during follow-up. iii. Delay pregnancy.
 - iv. Use appropriate precautions (i.e., condoms) during sexual intercourse.
 - v. Continue universal precautions vi. Any PEP treatment needed

V. **Procedure for Initiating Exposure Investigation and Follow-up ECU Employee Procedure**

A. When an employee is involved in an exposure at ECU, contact the Office of Prospective Health at 744-2070, Monday – Friday, 7:45 am-4:45 pm. PH will

- 1. Obtain a history of the event
- 2. Investigate the source of the exposure by history and laboratory studies (HIV, Hepatitis B surface antigen, surface antibody and core antibody, Hepatitis C antibody. See Appendix G.
- 3. Obtain baseline labs on the employee
- 4. Administer any treatment required
- 5. Enroll the employee in surveillance for potential resultant infection as needed
- 6. Complete the ECU Non-Patient Incident Report.

B. Exposure of ECU employee on Vidant property

1. Employee reports the incident to Vidant Occupational Health (847-4386)
 - a. Complete the Vidant Facility Incident Report
 - b. Vidant Occupational Health will investigate the source patient and the exposure.
 - c. If the source patient is HIV+
 - i. Vidant Occupational Health will do a Pregnancy Test (if indicated) on the exposed worker.
 - ii. Occupational Health will consult Infectious Disease via phone for evaluation of post exposure prophylaxis. iii. If indicated, prescriptions will be written and the employee will be referred to ECU Pharmacy to have them filled.
 - iv. The employee will report to ECU Prospective Health ASAP to initiate PEP.
 - d. Vidant will notify PH of the source patient results
 - e. Prospective Health will perform subsequent surveillance for seroconversion post-exposure.
 2. If the source patient is HIV-, report the incident to ECU Office of Prospective Health ASAP
 - a. PH will do baseline and interval blood tests on employee
 - b. PH will receive information on source patient results from Vidant
 - c. PH will institute any needed treatment or preventive therapies for the employee.
- C. For a blood exposure at ECU Clinic during evening or weekend hours
1. Contact the nursing supervisor or attending physician and consult the ECU Infection Control policy regarding indications for HIV post exposure prophylaxis. (See PH SOP for guidance on whom to call)
 - a. Obtain blood for labs on source patient as listed per **Section III A. 3.** on page (red top tube), after counseling and obtaining consent for HIV testing. Requires a rapid HIV test for source patient; write "HEPBP2" on lab request form.
 - b. If SP is HIV + by history or lab test, refer employee to Vidant Emergency Department to receive Post Exposure Prophylaxis with HIV antiviral medications ASAP.
 - c. Employee should follow-up with Prospective Health on next regular work day to initiate long-term surveillance.
- D. For a blood exposure at ECU in a nonclinical setting during evening or weekend hours:
1. Blood exposures without a known source are typically not prophylaxed for HIV unless there are factors which increase the risk for infection. This is determined on a case by case basis, as HIV does not survive for more than a few hours in the environment.

2. ECU Police may contact ECU Biological Safety/Infection Control for advice in such situations using the emergency call list via ECU police.
- E. For a blood exposure at Vidant during evening or weekend hours
1. Call blood exposure hotline 847-4386. If the main line, listen for instructions.
 2. Contact the patient care to:
 - a. Assess source patient risk for HIV infection
 - b. Facilitate testing of source
 - c. Complete referral form
 - d. Send employee to ED with referral to obtain HIV prophylaxis
(PEP) IF SOURCE IS HIV POSITIVE OR HIGH RISK
 3. If source tests negative for HIV, emergency PEP is not indicated. Report to Prospective Health during regular work hours for surveillance on nonemergence basis (Student Health Services will follow-up non-BSOM students).
- F. ECU employee at another site or facility
1. Report the incident to supervisor or facility employee health representative
 2. Facility performs source patient workup per facility policy
 3. Contact Prospective Health to report the incident to ECU and coordinate the employee's baseline evaluation and long-term follow-up activities with the facility in most practical manner.
 4. If source is HIV+, either the offsite facility initiates PEP or contacts PH or SHS to initiate it ASAP. Source may go to Vidant or local ED if after work hours.
- G. If an employee sero-converts as a result of a bloodborne exposure
1. The infection will be reported to the county health department of residence as required for Infectious Disease surveillance by 10A NCAC 41A. 0100.
 2. The employee may be required to report this to the NC Health Director per NC AC GS130A-144, 130A-145 if:
 - a. They become infected with HIV or develop chronic Hepatitis B
(greater than 6 months) **AND**
 - b. They perform surgical, dental or obstetrical procedures or assist with them
 - c. **THEN**, Job duty or work practice modifications may result from review by the State Health Director or ECU Expert Review panel
- H. Reporting
- Prospective Health will make an anonymous (de-identified) report for the ECU OSHA log when an employee experiences:
1. Any exposure due to a sharp's stick or puncture
 2. Any wound requiring treatment beyond first aid
- Prospective Health will also:
1. Retain documentation of the specific type of medical device or

- sharps involved in the incident (Sharps Injury Log)
2. Report the devices involved in exposure incidents to the Safe Medical Devices subcommittee of the BSOM Product Standardization Committee on an annual basis

VI. If a Vidant Employee or Other Non-ECU Employee is Exposed at ECU Clinical Facility.

- A. Contact Prospective Health
- B. Source patient will be tested for bloodborne pathogens
- C. Non-employee will be referred to home institution for surveillance
- D. Prospective Health will inform home institution of exposure risk

VII. East Carolina University Students Procedure

- A. Student exposure at ECU Physicians
 1. Report incident to faculty/supervisor
 2. Complete Non-Patient Incident Report
 3. Report exposure to Prospective Health
 - a. Prospective Health will investigate source patient
 - b. Student evaluation, treatment, follow-ups
 - i. Done by Prospective Health for BSOM medical or graduate student
 - ii. Done by Student Health Service for all other ECU students
(See Appendix H)
If exposure after hours, see Section D. on page 29 or Algorithm in Appendix F.
- B. Student exposure at other ECU Health Science Center facility
 1. Report incident to faculty supervisor
 2. Faculty supervisor will contact Prospective Health for assistance in completing source patient evaluation
 3. Faculty supervisor will refer the student to SHS for evaluation, follow-up and/or treatment
 4. If exposure occurs after hours see Section D. on page 29 or Algorithm in Appendix F.
- C. Student exposure at other ECU facility
 1. Student will report exposure to ECU faculty/supervisor
 2. Faculty supervisor will perform the source patient evaluation and may contact PH for advice
 3. Faculty supervisor will refer the student to SHS for evaluation, follow-up and/or treatment.
 4. If source is HIV+, arrangements are made by SHS to begin PEP ASAP
- D. ECU Student exposure at Vidant
 1. Student will report exposure to faculty supervisor

2. Student or faculty supervisor will report exposure to Vidant Occupational Health (OH), 847-4386
3. Vidant Occupational Health will investigate source patient and report results to:
 - a. Student Health Services provider or
 - b. Prospective Health for BSOM student
4. If SP is HIV +, Vidant OH will contact Infectious Disease Physician to initiate PEP.
5. After PEP is started or if source is HIV -, student will present ASAP for follow-up or treatment.
 - a. At Prospective Health if medical student
 - b. At Student Health Services for all other students.

E. ECU Student exposed at other facility

1. Report exposure to faculty supervisor on site AND at ECU
2. Complete facility incident
3. Facility will evaluate source patient
4. Faculty supervisor will refer student for evaluation:
 - a. At Student Health Services or Prospective Health if student returns to Greenville daily
 - b. At facility if return to ECU is not possible
5. Student surveillance will resume at SHS/PH upon return to campus if initiated at facility.
6. Costs of student surveillance (or PEP if indicated) to facility to be handled per ECU agreement with facility.

F. Other student issues

1. If the exposure adversely affects the academic or curricular performance of the student, the Dean of the school or director of the curriculum may be notified by the physician caring for the student (with the student's consent) or by the faculty supervisor. If the student develops HIV or chronic Hepatitis B, or Hep C until cured, modification of the curriculum may be required to limit performance of high-risk procedures in the spirit of NCAC (10A NCAC 41A. 0207).

Appendix A

Thursday, January 18,
2001

Part IX

Department of Labor

Occupational Safety and Health

Blood Borne Pathogen Exposure Plan Control Plan-19

Administration

29 CFR Part 1910

Occupational Exposure to

Bloodborne

Pathogens; Needlesticks and Other

Sharps

Injuries; Final Rule

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Thursday, January 18, 2001 / Rules and Regulations

DEPARTMENT OF LABOR

Occupational Safety and Health

Administration

29 CFR Part 1910

[Docket No. H370A]

RIN 1218-AB85

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

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

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

SUMMARY: The Occupational Safety and Health Administration is revising the Bloodborne Pathogens standard in conformance with the requirements of the Needlestick Safety and Prevention Act. This Act directs OSHA to revise the Bloodborne Pathogens standard to include new examples in the definition of engineering controls along with two new definitions; to require that Exposure Control Plans reflect how employers implement new developments in control technology; to require employers to solicit input from employees responsible for direct patient care in the identification, evaluation, and selection of engineering and work practice controls; and to require certain employers to establish and maintain a log of percutaneous injuries from contaminated sharps. **DATES:** Effective Date: The effective date is April 18, 2001. Written comments: Written comments on the Information Collection Requirements must be submitted on or before March 19, 2001. **ADDRESSES:** Copies of materials in the docket may be obtained from the OSHA Docket Office, Room N-2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, Telephone (202) 693-2350. Referenced documents are included in Docket H370A and are identified by the exhibit number indicated. Submit written comments on the Information Collection Requirements to the Docket Office, Docket No. ICR-0180 (2001), OSHA, U.S. Department of Labor, Room N-2625, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693-2350. Commenters may transmit written comments of 10 pages or less in length by facsimile to (202) 693-1648. In compliance with 28 U.S.C. 2112(a), the Agency designates the Associate Solicitor for Occupational Safety and Health, Office of the Solicitor, Room S-4004, U.S. Department of Labor, 200

Constitution Avenue, NW., Washington, DC 20210, as the recipient of petitions for review of the standard.

FOR FURTHER INFORMATION

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

SUPPLEMENTARY INFORMATION:

I. Events Leading to the Amended Final Rule

Blood and other potentially infectious materials have long been recognized as a potential threat to the health of employees who are exposed to these materials by percutaneous contact (penetration of the skin). Injuries from contaminated needles and other sharps have been associated with an increased risk of disease from more than 20 infectious agents (Exs. 3-172GG, 3-274C). The primary agents of concern in current occupational settings are the human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV). To reduce the health risk to workers whose duties involve exposure to blood or other potentially infectious materials, OSHA promulgated the Bloodborne Pathogens (BBP) standard (29 CFR 1910.1030) on December 6, 1991 (56 FR 64004). The provisions of the standard were based on the Agency's determination that a combination of engineering and work practice controls, personal protective equipment, training, medical surveillance, hepatitis B vaccination, signs and labels, and other requirements would minimize the risk of disease transmission. Needlesticks and other percutaneous injuries resulting in exposure to blood or other potentially infectious materials continue to be of concern due to the high

frequency of their occurrence and the severity of the health effects associated with exposure. The Centers for Disease Control and Prevention has estimated that healthcare workers in hospital settings sustain 384,325 percutaneous injuries involving contaminated sharps annually (Ex. 5-4). When non-hospital healthcare workers are included, the best estimate of the number of percutaneous injuries involving contaminated sharps is 590,164 per year (Ex. 3-172V). When these injuries involve exposure to infectious agents, the affected workers are at risk of contracting disease. Workers may also suffer from adverse side effects of drugs used for post-exposure prophylaxis and from psychological stress due to the threat of infection following an exposure incident. Since publication of the BBP standard, a wide variety of medical devices have been developed to reduce the risk of needlesticks and other sharps injuries. These "safer medical devices" replace sharps with non-needle devices or incorporate safety features designed to reduce the likelihood of injury. In a September 9, 1998, Request for Information (RFI), OSHA solicited information on occupational exposure to bloodborne pathogens due to percutaneous injury (63 FR 48250). Based in part on the responses to the RFI, the Agency has pursued an approach to minimize the risk of occupational exposure to bloodborne pathogens that involves three components. First, the Agency proposed that the revised Recordkeeping standard (29 CFR 1904) include a requirement that all percutaneous injuries from contaminated needles and other sharps be recorded on OSHA logs (61 FR 4030). Second, OSHA issued a revised compliance directive for the BBP standard on November 5, 1999, to reflect advances made in medical technology and treatment. The directive guides OSHA's compliance officers in enforcing the standard and ensures that consistent inspection procedures are followed. Third, the Agency placed amendment of the bloodborne pathogens standard on its regulatory agenda to more effectively address sharps injuries.

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

II. Statutory Authority

On November 6, 2000, President Clinton signed the Needlestick Safety and Prevention Act, Pub. L. 106-430. The Act requires OSHA to revise the

BBP standard within six months of the Act's enactment. To facilitate expeditious completion of this directive, Congress explicitly exempted OSHA from procedural requirements generally attending rulemaking under OSH Act 6(b) and from the procedural requirements of the Administrative Procedure Act (5 U.S.C. 500 et seq.).

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Thursday, January 18, 2001 / Rules and Regulations

III. Summary and Explanation

The revisions to OSHA's BBP standard required under the Needlestick Safety and Prevention Act can be broadly categorized into four areas: modification of definitions relating to engineering controls; revision and updating of the Exposure Control Plan; solicitation of employee input; and recordkeeping. The revised standard adds two additional terms to the definition section found in paragraph (b) and alters the definition of one other term. It adds "Sharps with Engineered Sharps Injury Protections" and defines this term as "a nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident." This term encompasses a broad array of devices that make injury involving a contaminated sharp less likely, and includes, but is not limited to, syringes with a sliding sheath that shields the attached needle after use; needles that retract into a syringe after use; shielded or retracting catheters used to access the bloodstream for intravenous administration of medication or fluids; and

intravenous medication delivery systems that administer medication or fluids through a catheter port or connector site using a needle that is housed in a protective covering. The revised standard also adds the term "Needleless Systems," which is defined as "a device that does not use needles for: (A) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (B) the administration of medication or fluids; or (C) any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps." "Needleless Systems" provide an alternative to needles for the specified procedures, thereby reducing the risk of percutaneous injury involving contaminated sharps. Examples of needleless systems include, but are not limited to, intravenous medication delivery systems that administer medication or fluids through a catheter port or connector site using a blunt cannula or other non-needle connection, and jet injection systems that deliver subcutaneous or intramuscular injections of liquid medication through the skin without use of a needle. The definition of "Engineering Controls" has been modified to include as examples "safer medical devices, such as sharps with engineered sharps injury protections and needleless systems." This change clarifies that safer medical devices are considered to be engineering controls under the standard. The term "Engineering Controls" includes all control measures that isolate or remove a hazard from the workplace, encompassing not only sharps with engineered sharps injury protections and needleless systems but also other medical devices designed to reduce the risk of percutaneous exposure to bloodborne pathogens. Examples include blunt suture needles and plastic or mylar-wrapped glass capillary tubes, as well as controls that are not medical devices, such as sharps disposal containers and biosafety cabinets. The expanded definitions reflect the intent of Congress to have OSHA amend the BBP standard to clarify

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

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

Paragraph (c)(1)(iv) of the standard is revised to add new requirements to the annual review and

update of the Exposure Control Plan. The review and update of the plan is now required to "(A) reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and (B) document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure." Thus, the additional provisions require that employers, in their written Exposure Control Plans, account for innovations in procedure and technological developments that reduce the risk of exposure incidents. This would include, but would not be limited to, newly available medical devices designed to reduce the risk of percutaneous exposure to bloodborne pathogens. Consideration and implementation of safer medical devices could be documented in the Exposure Control Plan by describing the safer devices identified as candidates for adoption; the method or methods used to evaluate devices and the results of evaluations; and justification for selection decisions. This information must be updated at least annually. The revised Exposure Control Plan requirements make clear that employers must implement the safer medical devices that are appropriate, commercially available, and effective. No one medical device is appropriate in all circumstances of use. For purposes of this standard, an "appropriate" safer medical device includes only devices whose use, based on reasonable judgment in individual cases, will not jeopardize patient or employee safety or be medically contraindicated. Although new devices are being continually introduced, OSHA recognizes that a safer device may not be available for every situation. If a safer device is not available in the marketplace, the employer is not required to develop

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

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18JAR6. **5320 Federal Register** / Vol. 66, No. 12 / Thursday, January 18, 2001 / Rules and Regulations involvement in informal problem-solving groups; participation in safety audits, worksite inspections, or exposure incident investigations; participation in analysis of exposure incident data or in job or process hazard analysis; participation in the evaluation of devices through pilot testing; and involvement in a safety and health committee properly constituted and operated in conformance with the National Labor Relations Act. Employee input can serve to assist the employer in overcoming obstacles to the successful implementation of control measures. A number of respondents to the RFI indicated that they encountered some resistance when new devices required staff members to adopt new techniques, or when staff members perceived that use of the device might have an adverse effect on the patient (e.g., Exs. 3-50, 3-79, 3-99, 3-133). As a way of addressing this resistance, staff involvement in the selection process can play an important role in the acceptance and proper use of safer medical devices (e.g., Exs. 3-18, 3-42, 3-56, 3-88, 3-324, 3-355). According to their experience, the participation of frontline workers can

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

The Community Health Network (CHN) of San Francisco provides an example of a safety and health committee with responsibility for sharps injury prevention (Ex. 5-5). Representatives of both labor and management serve on the committee, and are provided with access to non-confidential information regarding bloodborne pathogen exposure incidents at CHN facilities. The committee is responsible for establishing criteria for safer devices; overseeing device evaluation by representative groups of device users; and selecting preferred devices for purchase. The committee is also responsible for developing safer alternatives to work practices that are associated with exposure incidents. The concept of involving a team in sharps injury prevention programs is supported by the American Hospital Association (AHA) in guidelines to assist hospitals and health systems in developing such programs (Ex. 5-1). According to AHA, a successful program revolves around communication, education, training, and collaboration. Among the specific steps recommended are assembling a multidisciplinary team that includes representation of frontline workers and departments using devices; selecting targeted devices for evaluation; pilot-testing of devices; and collecting data after a device is adopted to evaluate its impact. The standard requires that employers seek input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps. Employees involved in

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

The revised standard requires that solicitation of input from employees be documented in the Exposure Control Plan. Employers can meet this obligation by identifying the employees who were involved and describing the process by which input was requested. Employers should also describe the input obtained with regard to identification, evaluation, and selection of controls. Evidence that employee input has been sought can include, for example, meeting minutes, copies of documents used to request employee participation, or records of responses received from employees such as reports evaluating the effectiveness of a safer medical device in trial applications. The requirement for solicitation of input from employees has been designated as paragraph (c)(1)(v) in the revised standard. The requirement that the Exposure Control Plan be made available to the Assistant Secretary of Labor for Occupational Safety and Health and the Director of the National Institute for Occupational Safety and Health upon request, previously designated as paragraph (c)(1)(v), has been moved and is now paragraph (c)(1)(vi) in the revised standard. The recordkeeping requirements of the standard at paragraph (h) have been amended by adding paragraph (h)(5) to require that employers maintain a sharps injury log to serve as a tool for identifying high risk areas and evaluating devices. Paragraph (h)(5)(i) now states, "The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from

contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum: (A) The type and brand of device involved in the incident, (B) the department or work area where the exposure incident occurred, and (C) an explanation of how the incident occurred." The sharps injury log must be maintained for the period required by 29 CFR 1904. The requirement to establish and maintain the log only applies to employers who are otherwise required to maintain a log of occupational injuries and illnesses under 29 CFR 1904 (OSHA's Recordkeeping rule). The sharps injury log must include the specified minimum information regarding the device involved (if known), the location of the incident, and the description of the events that resulted in the injury. The level of detail presented should be sufficient to allow ready identification of the device, location, and circumstances surrounding an exposure incident (e.g.,
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Rules and Regulations the
procedure being performed, the
body part affected, objects or
substances involved and how they
were involved) so that the intended
evaluation of risk and device
effectiveness can be accomplished.
Information in the sharps injury
log must be recorded and
maintained in a manner that
protects the privacy of the
injured employee. If data from
the log are made available to
other parties, any information
that directly identifies an
employee (e.g., name, address,
social security number, payroll
number) or information that

could reasonably be used to identify indirectly a specific employee (e.g., exact age, date of initial employment) must be withheld.

The format of the sharps injury log is not specified. The employer is permitted to determine the format in which the log is maintained (e.g., paper or electronic), and may include information in addition to that required by the standard, so long as the privacy of injured workers is protected. The Agency recognizes that many employers already compile reports of percutaneous exposure incidents in a variety of ways. Existing mechanisms for collecting these reports will be considered sufficient to meet the requirements of the standard for maintaining a sharps injury log, provided that the information gathered meets the minimum requirements specified in the standard, and the confidentiality of the injured employee is protected. Under newly published revisions to OSHA's Recordkeeping rule (29 CFR 1904), employers are required to record sharps injuries involving contaminated objects on the OSHA 300 Log of Work-Related Injuries and Illnesses and the OSHA 301 Injury and Illness Incident Report (the new forms replace the current 200 and 101 forms). When the revisions become effective, employers may elect to use the OSHA 300 and 301 forms to meet the sharps injury log requirements, provided two conditions are met. First, the employer must enter the type and brand of the device on either the 300 or 301 form. Second, the employer must maintain the records in a way that segregates sharps injuries from other types of work-related injuries and illnesses, or allows sharps injuries to be easily separated. For example, if OSHA 300 and 301 records are maintained on a computer, the employer must ensure that the computer is able to produce a record of sharps injuries that does not include other types of work-related injuries and illnesses (i.e., through using a program that allows for sorting of entries by injury type). If records are kept on paper forms, the employer would need to use a separate page of the 300 Log for sharps injuries.

The revisions to the Recordkeeping rule will not become effective until January 1, 2002, at the earliest, and until then many sharps injuries involving contaminated objects will not be recordable on the OSHA log. Therefore, employers must keep a separate sharps log from the effective date of this rule until the revised Recordkeeping rule becomes effective. These revisions to the BBP standard become effective April 18, 2001. Exposure Control Plans that are reviewed and updated on or after this effective date must reflect the requirements of the revised standard. Percutaneous exposure incidents that occur on or after this effective date must be recorded on the

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

IV. Economic Analysis

Incremental Costs of the Mandated

Revisions to the Standard OSHA has determined that the total cost of this action is \$33,814,991 per year, and thus, that it is not an economically significant regulatory action within the meaning of Executive Order 12866. However, the rule is defined as a significant rule under the Executive Order, and has been reviewed by the Office of Management and Budget. This amendment to the final standard does not involve any new engineering requirements to protect workers from sharps injuries, but it does include two new recordkeeping requirements: First, the amended standard requires employers to "establish and maintain a sharps injury log for the recording of percutaneous injuries * * *" However, for recordable needlestick incidents, OSHA already requires employers to collect much of the information needed for developing such a log under other rules, the Recording and Reporting Occupational Injuries and Illnesses regulation (29 CFR 1904) in particular. Moreover, OSHA has recently published revisions to 29 CFR 1904 that would cover the remaining, previously nonrecordable needlestick injuries. Second, the current action requires any employer "who is required to establish an Exposure Control Plan" to "solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan." The methodology OSHA has used for computing costs for each requirement of the amended standard is presented in the next two sections. Cost of Establishing and Maintaining a Sharps Injury Log The rule requires employers to maintain a log for all needlestick and sharps injuries. At a minimum, the sharps injury log must contain: "(A) The type and brand of device involved in the incident, (B) the department or work area where the exposure incident occurred, and (C) an explanation of how the incident occurred." The costs attributable to the log correspond directly to the number of needlestick and

sharps injuries. The International Health Care Worker Safety Center (IHCWSC) provides the best available estimate of the number of needlestick injuries (Ex. 3-172V). IHCWSC has computed that 590,164 needlestick and sharps injuries occur annually. Needlestick and sharps injury cases will require an effort pertaining to collection of data on the type and brand of device, the department or work area where the incident occurred, and an explanation of how the incident occurred. Because the amount of information required to be collected is limited, OSHA estimates that it will require an average of five minutes per case (0.08 hours) to collect the data and enter it onto the separate log. Assuming that the task of collecting information related to the incident and entry onto the log will be conducted by an individual with the skill level of a Personnel Training and Labor Relations Specialist, an hourly wage of \$26.32 is used to compute cost. (The hourly wage for Personnel Training and Labor Relations Specialist as reported in the Bureau of Labor Statistics Occupational Employment Statistics Survey is \$19.03; benefits are computed at 38.3 percent of the hourly wage.) Thus, the incremental annual cost of the separate sharps injury log is:

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

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In summary, OSHA estimates that the total annual cost of maintaining a sharps injury log will be \$1,294,352. This estimate is likely to overstate true costs for at least three reasons. First, for already recordable incidents, the data needed to maintain a separate sharps injury log are already collected and entered into a log format for other purposes, namely for the requirements set forth by 29 CFR Part 1904. It is unlikely that the data will need to be "re-entered." Instead, businesses are likely to develop procedures for automating the process or for organizing log information, thereby significantly reducing the incremental costs associated with this incremental action. For nonrecordable cases, the data collection required by the Needlestick Safety and Prevention Act and this revision to the BBP standard will be required under 29 CFR Part 1904 (once revisions to Part 1904 become effective), so that the incremental costs associated with the separate sharps injury log are short-term in nature. Finally, and perhaps most importantly, the above cost estimate significantly overstates costs because it includes costs for all establishments in SIC 80. Under revisions to 29 CFR Part 1904, SICs 801, 802, 803, 804, 807, and 809 are exempted from recordkeeping requirements under Part 1904 and will thus not be required by this amendment to the BBP standard to keep a needlestick and

sharps injury log. This is potentially significant because SICs 801, 802, 803, 804, 807, and 809 constitute 31 percent of employment for SIC 80, though not necessarily 31 percent of sharps injuries. Cost of Solicitation of Employee Input
The cost associated with solicitation of employee input is comprised of three components: (1) The initial solicitation, conducted by a manager; (2) the employee response; and (3) documentation of the solicitation in the Exposure Control Plan. The cost of the initial solicitation is likely to vary with establishment size, number of incidents, and employee interest. The establishments that will be affected are those that are: (1) Required to develop an Exposure Control Plan, and (2) have employees who are involved in direct patient care and who are potentially exposed to needlestick injuries. The overwhelming majority of such establishments are in SIC 80, Health Services. County Business Patterns reports that in 1997 (1997 data are used as the most recent year for which data are available using the SIC reporting system), there were 502,724 establishments in SIC 80. OSHA estimates that the initial solicitation or call for employee input will require an average of 15 minutes (0.25 hours) of managerial time. The wage rate of a Medicine and Health Care Manager is \$33.22 per hour, including fringe benefits. (The hourly wage for a Medicine and Health Care Manager reported in the Bureau of Labor Statistics Occupational Employment Statistics Survey is \$24.02; benefits are computed at 38.3 percent of the hourly wage.) The estimated cost of the initial solicitation is:
(502,724 establishments) \times (0.25 hours/establishment) \times (\$33.22/hour) = \$4,175,080. The cost associated with the employee response varies with the

number of employees and the response rate to the initial solicitation. According to County Business Patterns, there were 11,348,141 individuals employed in SIC 80 in 1997. OSHA estimates that it will require 15 minutes (0.25 hours) of employee time to respond to the solicitation and that approximately 33 percent of employees will respond. Using a wage rate of \$25.90 (which is the total hourly compensation in 1998 for professional specialty and technical employees in Health Services reported in the Bureau of Labor Statistics publication Employer Costs for Employee Compensation, 1986–1988), the estimated costs associated with employee response are:

(11,348,141 employees) \square (33% response rate) \square (0.25 hours/employee) \square (\$25.90/hour) = \$24,248,140. Note that it is implicitly assumed that input is solicited from all employees. This assumption will result in an overstatement of costs because the standard requires that input be solicited only from the fraction of employees who are involved in direct patient care and who are potentially exposed to needlestick injuries. Finally, the revised standard requires that the employer document the solicitation in the Exposure Control Plan. Because the affected employers are already required to establish a Plan, the incremental effort associated with this documentation will be small. OSHA estimates that it will require only 15 minutes (0.25 hours) of managerial time. Thus, the total annual cost of documenting the solicitation in the Exposure Control Plan is estimated to be:

(502,724 establishments) \square (0.25 hours/establishment) \square (\$33.22/hour) = \$4,175,080. In summary, OSHA has estimated the total cost of the solicitation to be \$32,598,300 (\$4,175,080 + \$24,248,140 + \$4,175,080). This estimate is likely to overstate the cost because employers have several avenues for achieving this requirement of the standard, many of which will reduce costs. For example, employers are not required to solicit input from all employees and could meet the requirement by, for example, consulting a properly constituted safety committee consisting of a subset of employees. In fact, recent state legislation has mandated sharps safety committees in a number of states. In these situations, the only incremental cost associated with the solicitation mandated by this amendment to the BBP standard will be documentation of the solicitation in the Exposure Control Plan.

Total Cost and Cost Per Establishment According to the above analysis, the maximum total annual cost of this action is \$33,892,653, consisting of \$1,294,352 associated with maintaining a sharps injury log and \$32,598,300 associated with soliciting and documenting employee input into the Exposure Control Plan. This amounts to \$67 per establishment, per year, which will not cause significant economic impact on either large or small affected establishments.

V. Unfunded Mandates

OSHA has determined that, for the purposes of section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C.

1532), this rule does not include any

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Thursday, January 18, 2001 / Rules and Regulations federal mandate that may result in increased expenditures by state, local, or tribal governments in the aggregate of more than \$100 million, or increased expenditures by the private sector of more than \$100 million. Moreover, the Agency has determined that for purposes of section 203 of the Act, this rule does not significantly or uniquely affect these entities.

Background

The Unfunded Mandates Reform Act was enacted in 1995. While much of the Act is designed to assist the Congress in determining whether its actions will impose costly new mandates on state, local, and tribal governments, the Act also includes requirements to assist federal agencies to make this same determination with respect to regulatory actions. Analysis As discussed in Section IV, Economic Analysis, this rule will have incremental costs of \$34 million per year, all of which are associated with maintaining the sharps injury log and soliciting and documenting employee information. These total costs represent an average cost of \$67 per year per affected establishment. OSHA does not anticipate any disproportionate budgetary effects upon any particular region of the nation, or particular state, local or tribal governments, or urban or rural communities. **VI.**

Environmental Impacts

The National Environmental Policy Act requires that “major Federal actions significantly affecting the quality of the

human environment” be accompanied by a statement addressing the environmental impact of the proposed action. (42 U.S.C. 4332(C)) Department of Labor regulations establish a criteria for determining when an environmental impact statement is required in a rulemaking proceeding:

Preparation of an environmental impact statement will always be required for proposals for promulgation, modification or revocation of health standards which will significantly affect air, water or soil quality, plant or animal life, the use of land or other aspects of the human environment. 29 CFR 11.10 (a)(3) OSHA has concluded that no significant environmental impacts would result from this rulemaking. This final standard expands the universe of engineering controls permissible for reducing occupational exposure to bloodborne pathogens. It also widens the scope of Exposure Control Plan review, requires maintenance of a sharps injury log, and mandates the solicitation of input from employees on the identification, evaluation, and selection of effective engineering and work practice controls. The Agency has not identified any impacts of these requirements on the environment. **VII. Federalism** This standard has been reviewed in accordance with the Executive Order on Federalism (Executive Order 13132, 64 FR 43255, Aug. 10, 1999). The order requires that agencies, to the extent possible, refrain from limiting state policy options; consult with states prior to taking actions that would restrict state policy options; and take such action only when there is clear constitutional authority and the presence of a problem of national scope. Executive Order 13132 also provides that agencies shall not promulgate regulations that have significant Federalism implications and impose substantial direct compliance costs on state or local governments, unless the agency consults with state and local officials early in the process of developing the proposed regulation and provides a summary Federalism impact statement in the preamble of the final rule.

Finally, the Order provides for preemption of state law only if there is a clear Congressional intent for the agency to do so, and provides that any such preemption is to be limited to the extent possible. Under Section 6(b) of the Executive Order, an agency is exempt from state consultation requirements if it is promulgating a regulation that is required by statute. The amendments to OSHA’s BBP standard codified in this rule were explicitly written by Congress and enacted as Public Law 106–430. Moreover, Congress clearly intended the revised BBP standard to have the same legal effect as other standards issued under 6(b) of the Occupational Safety and Health Act of 1970. Nonetheless, OSHA has consulted extensively with those 25 States and territories that operate OSHA-approved State plans with regard to OSHA policy on safe needle devices and the requirements of the subject legislation. Section 18 of the

OSH Act expresses Congress’ intent to preempt state laws relating to issues on which Federal OSHA has promulgated occupational safety and health standards. Under the OSH Act, a state can avoid preemption only if it submits, and receives Federal approval for, a State plan for the development and enforcement of standards. OSHA-approved State plans operate under authority of State law and must adopt occupational safety and health standards which, among other things, must be at least as effective in providing safe and healthful employment and places of employment as Federal standards. In *Gade v. National Solid Wastes*

Management Assoc., the U.S. Supreme Court reaffirmed the view that Section 18 of the OSH Act effectively preempts states without approved plans from adopting or enforcing any laws that directly, substantially, and specifically regulate occupational safety and health. 505 U.S. 88, 107 (1992). However, needlestick laws in states without an OSHA-approved State plan would not be affected to the extent to which they regulate the occupational safety and health conditions of state or local government employees (see Section 3(5) of the OSH Act). **VIII. State Plan States** The 23 states and 2 territories that operate their own federally approved occupational safety and health plans must adopt a comparable amended standard within six months of the publication date of a final Federal OSHA standard. The States and territories with this obligation include: Alaska, Arizona, California, Connecticut (for State and local government employees only), Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York (for State and local government employees only), North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virginia, Virgin Islands, Washington, and Wyoming. Until such time as state and territorial standards are amended, Federal OSHA will provide interim enforcement assistance, as appropriate. **IX. Paperwork Reduction Act** This final rule contains new collection of information (paperwork) requirements in revisions to the Bloodborne Pathogen Standard (1910.1030 and 1915.1030) made as a result of the Needlestick Safety and

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

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Regulations paperwork and respondent burden.

The information helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. The Needlestick Safety and Prevention Act requires employers, who have exposure control plans in accordance with § 1910.1030 (c)(1)(iv), "to review and update such plans to reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens." The exposure control plan must also "document consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure." Employers required to have exposure control plans must also "solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan."

The Needlestick Safety and Prevention Act also requires employers, who currently maintain a log of occupational injuries and illnesses under 29 CFR 1904, to "establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps." The information in the sharps injury log must be recorded and maintained so that the confidentiality of the injured worker is protected. The log must contain at least the following information: "(A) the type and brand of device involved in the incident; (B) the department or work area where the exposure incident occurred; and (C) an explanation of how the incident occurred." Respondents are not required to comply with collection of information (paperwork) requirements unless a currently valid OMB control number is displayed (§ 1320.5 (b)(2)(i)). OSHA will publish the OMB control number as soon as it receives approval on its ICR for the revised collections. A copy of the Agency's revised ICR for the BBP standard is available for inspection and copying as part of Docket ICR1218- 0180(2000) in the OSHA Docket Office,

U.S. Department of Labor, Room N- 2625, 200 Constitution Avenue, NW., Washington, DC 20210, or you may request a mailed copy by telephoning Todd Owen at (202) 693-2444. Comments on the ICR should be submitted to the Docket Office, Docket Number ICR-0180 (2001), OSHA, U.S.

Department of Labor, Room N-2625, 200 Constitution Avenue, NW., Washington, DC 20210, telephone: (202) 693-2350. Commenters may transmit written comments of 10 pages or less in length by facsimile to (202) 693-1648. The Department and OMB are particularly interested in comments that Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

Evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; Enhance the quality, utility, and clarity of the information to be collected; and Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses. Title: Bloodborne Pathogens standard (29 CFR 1910.1030).

OMB Number: 1218-0180

(Revision). Frequency:

Employers must: annually review their exposure control plans; initially establish and maintain a sharps injury log; as necessary, make injury recordings in the log; and solicit input from non-managerial employees. Affected Public: The respondents are those employers that must maintain an exposure control plan, and employers who are required to maintain a log of occupational injuries and illnesses under 29 CFR part 1904. Total Respondents: 502,724

establishments. Average time per response: Three to five minutes for employers to record needlestick incidents; fifteen minutes for employers to solicit non-managerial employees on effective engineering and work practice controls; fifteen minutes for employers to modify their existing exposure control plans. Estimated Burden Hours: 49,180 hours for employers to log needlestick incidents; 125,681 hours for employers to solicit non-managerial employees; and 125,681 hours for employers to update existing exposure control plans. Estimated Cost (Operation and Maintenance): 0.

X. Authority and Signature

This document was prepared under the direction of Charles N. Jeffress, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. Accordingly, pursuant to sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657) and the Needlestick Safety and Prevention Act (Pub. L. 106-430, 114 Stat. 1901, November 6, 2000); and Secretary of Labor's Order No. 3-2000 (65 FR 50017), 29 CFR part 1910 is amended as set forth below. **List of Subjects in 29 CFR Part 1910**

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

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

Charles N. Jeffress,

Assistant Secretary of Labor for Occupational Safety and Health.

XI. Amended Final Rule and Appendix

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

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

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

Authority: Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12-71 (36 FR 8754), 8-76 (41 FR 25059), 9-83 (48 FR 35736), 1-90 (55 FR 9033), 6-96 (62 FR 111), or 3-2000 (65 FR 50017), as applicable; and 29 CFR part 1911. All of subpart Z issued under Sec. 6(b) of the Occupational Safety and Health Act, except those substances that have exposure limits listed in Tables Z-1, Z-2, and Z-3 of 29 CFR 1910.1000. The latter were issued under Sec. 6(a) (29 U.S.C. 655(a)). Section 1910.1000, Tables Z-1, Z-2 and Z-

3 also issued under 5 U.S.C. 553, Section 1910.1000 Tables Z-1, Z-2, and Z-3 not issued under 29 CFR part 1911 except for the arsenic (organic compounds), benzene, and cotton dust listings. Section 1910.1001 also issued under section 107 of the Contract Work Hours and Safety Standards Act (40 U.S.C. 333) and 5 U.S.C. 553.

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

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

653.

VerDate 11<MAY>2000 22:27 Jan 17, 2001 Jkt 194001 PO 00000 Frm 00008 Fmt 4701 Sfmt 4700 E:\FR\FM\18JAR6.SGM pfrm01 PsN:

18JAR6. 5325 Federal Register / Vol. 66, No. 12 / Thursday, January 18, 2001 / Rules and Regulations

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

2. Section 1910.1030 is amended as follows:

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

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

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

D. A new paragraph (h)(5) is added to read as set forth below: **§ 1910.1030 Bloodborne pathogens.**

(b) ***

Engineering controls means controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace.

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

- (1) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established;
- (2) The administration of medication or fluids; or
- (3) Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

Sharps with engineered sharps injury protections means a nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism employee positions with occupational exposure. The review and update of such plans shall also: (A) Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and (B) Document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure. (v) An employer, who is required to establish an Exposure Control Plan shall solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan.

(h) ***

(5) Sharps injury log. (i) The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum: (A) The type and brand of device involved in the incident, (B) The department or work area where the exposure incident occurred, and (C) An explanation of how the incident occurred. (ii) The requirement to establish and maintain a sharps injury log shall apply to any employer who is required to maintain a log of occupational injuries and illnesses

that effectively reduces the risk of an exposure incident.

(c) ***

(1) ***

(iv) The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised

under 29 CFR 1904. (iii) The sharps injury log shall be maintained for the period required by 29 CFR 1904.6.

* * * * *

[FR Doc. 01-1207 Filed 1-17-01; 8:45 am]
BILLING CODE 4510-26-P

Appendix B

Definitions used in the ECU Bloodborne Pathogen Exposure Control Plan

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

Bloodborne Pathogens—refers to pathogenic microorganisms that are present in human blood or other potentially infectious materials (OPIM). These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

Pathogenic micro organisms can also cause diseases such as hepatitis C, malaria, syphilis, babesiosis, brucellosis, leptospirosis, arboviral infections, relapsing fever, CreutzfeldtJakob disease, adult T-cell leukemia/Lymphoma (caused by HTLV-I), HTLV-I associated myelopathy, diseases associated with HTLV-II, and viral hemorrhagic fever.

Clinical Laboratory--a 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 which has been soiled with blood or other potentially infectious materials or may contain sharps. (At ECU, all laundry is handled as though contaminated and is placed in leak proof clear bags.)

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.

Engineering Controls--controls which isolate or remove the bloodborne pathogens hazards from the workplace. (e.g. controls relating to sharps disposal containers and safer medical devices, such as sharps with engineered sharps injury protection and needless systems.) **Exposure Incident**--a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

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

HBV--hepatitis B virus

HIV--human immunodeficiency virus

Needless System—a device that does not use needles for the 1) 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—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 (OPIM)

- The following human fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures.
- Any body fluids 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); and
- 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--piercing mucous membranes or the skin barrier through such events as needlesticks, 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, scrubs, pants, shirt, or blouses) are not intended to function as protection against a hazard and are not considered 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 during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other infectious materials.

Standardization Committee—an ECU committee in which products used at ECU are evaluated. A subgroup of this committee (Needle Safety Subcommittee) will solicit input from non-managerial employees in direct patient care (who are potentially exposed to injuries from contaminated sharps) to identify, evaluate, and select effective safety devices and will document the results. Members of the Nursing Leadership will appoint one or more staff-level representatives from each division and to evaluate devices.

Sharps with engineered sharps injury protection— a non-needle “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 feature or mechanism that effectively reduces the risk of an exposure incident by shielding or retracting sharp after use.

Source Individual--any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but not limited to, hospital and clinic patients, clients in institutions for the developmentally disabled; 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.

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

Standard (Universal) Precautions—is an approach to infection control. All blood and all fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens. Wherein it involves the use of personal protective equipment to prevent any contact with human blood and other potential infectious materials.

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)

Appendix C

HEPATITIS B IMMUNIZATION CONSENT FORM

Employee's Full Name
Department/Campus

Print Only

CONSENT

I have read the information about the Hepatitis B vaccine on the reverse side of this form. I have had the opportunity to ask questions, which were answered to my satisfaction. I request that the Hepatitis B vaccine series be given to me. I understand that there is a 510% possibility that no immunity from Hepatitis B will result subsequent to the vaccine. I further acknowledge that I do not have any of the listed conditions which would preclude me from being vaccinated.

Date

Employee's Signature

Witness

DECLINE TO ACCEPT

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) infections. 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 the 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. I can receive the vaccination series at no charge to me.

Date

Employee's Signature

Witness



DECLINE TO ACCEPT

_____ **Have previously received Hepatitis B series** _____
(Year)

_____ Date

Employee's Signature _____

Witness

Appendix C
ECU OFFICE OF PROSPECTIVE HEALTH
HEPATITIS B IMMUNIZATION CONSENT FORM

Hepatitis B virus is a virus that causes systemic infection with a major pathology in the liver. It can have serious complication such as a massive hepatic necrosis, cirrhosis of the liver, chronic active hepatitis, and hepatocellular carcinoma. It is most commonly spread by infected blood; the incubation period is six weeks to six months.

Benefits of Receiving Vaccine

The Hepatitis B vaccine has been shown in clinical studies to be over 90% effective in preventing Hepatitis B. It provides protection against Hepatitis B but against no other type of hepatitis or virus that affects the liver. Available data shows that immunity from vaccination will last about fifteen years or longer in patients who receive all (3) three doses of the vaccine. (No blood products are used in the manufacture of this vaccine).

Side Effects of the Vaccine

No serious side effects have been reported in clinical trails. However, as with any expanded commercial use of vaccine, it is possible that rare adverse reactions may be observed and revealed. Reactions that may occur are:

- Soreness at the injection site
- Redness at the injection site
- Swelling at the injection site
- Warmth at the injection site
- Low-Grade Fever (less than 101)

These effects are usually mild and subside within two days of vaccination. Systemic effects including malaise, fatigue, headache, nausea, dizziness, myalgia, and arthralgia are rare and have been limited to the first few days following vaccination. Rash has been reported rarely.

Do Not Take This Vaccine If

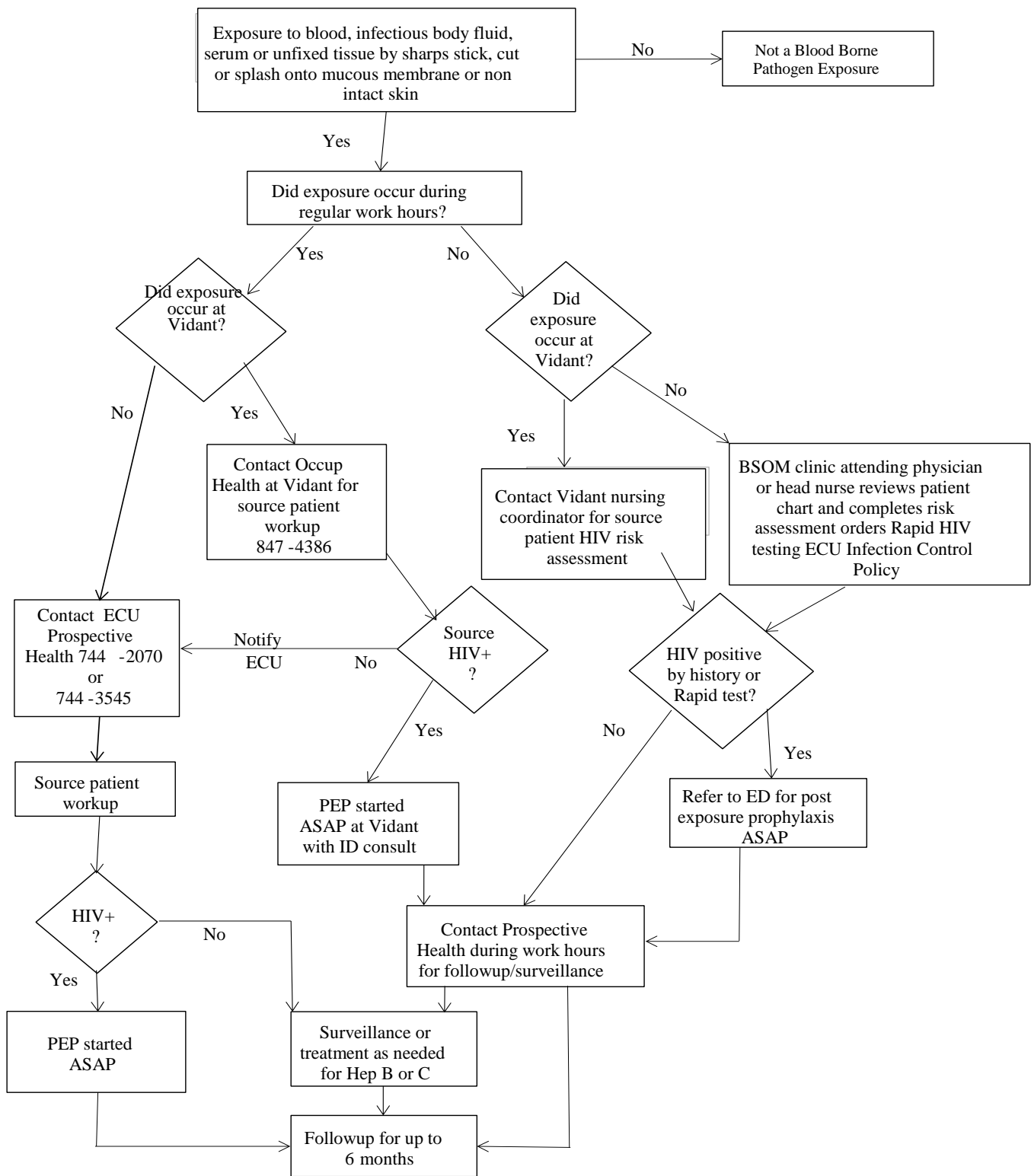
- You are ill with a serious active infection
- You are pregnant
- You have severe, multiple allergies
- Hypersensitivity to yeast

You have experienced hypersensitivity to a similar injection

If you are immunodeficient or are receiving immunosuppressive therapy, you must provide a note from your physician before receiving the vaccine.

Appendix D

ECU Employees/Medical Students/Dental Students



Appendix E: EXPOSURE EVALUATION

ECU: PROSPECTIVE HEALTH SERVICE

NON-PATIENT INCIDENT REPORT

NAME _____ SS# _____
 HOME ADDRESS _____ HOME PHONE _____
 DEPT/WK.STATION _____ WORK PHONE _____
 JOB TITLE _____ SUPERVISOR = S NAME _____
 DATE OF INCIDENT _____ TIME OF INCIDENT _____
 LOCATION OF INCIDENT _____

NATURE OF INCIDENT

<u>Blood or Body Fluid Exposure</u>	<u>Infectious Respiratory Exposure</u>	<u>Body Accident</u>
stick	inhalation sprain	sprain
splash	other	strain
spray	<u>Radiation Exposure</u>	hit
cut internal struck bite external puncture		
scratch	<u>Chemical Exposure</u>	fall
scrape/abrasion	inhalation	other _____
other _____	skin absorption	<u>Electrical Injury</u>
Source pt. _____		other _____
MR# _____		

BRIEF NARRATIVE OF INCIDENT _____

Was protective equipment used? yes ___ no ___ Were appropriate work practices followed? yes ___ no ___

Employee Signature _____ Title _____ Date _____
 Supervisor Signature _____ Date _____

Seen By: _____ Employee Health Nurse _____ Physician _____ Physician Extender _____

Nature of Injury

_____ laceration	_____ abrasion
_____ chemical burn	_____ thermal burn
_____ dermatitis	_____ fracture
_____ contusion	_____ strain/sprain
_____ puncture/needlestick	_____ blood/body fluid exposure
_____ other	

Medical Evaluation _____

RESULTS

_____ first aid Hepatitis B vaccine _____ indicated _____ given _____
 _____ blood/body fluid exposure protocol
 -----return to work _____ work restriction _____
 _____ follow up _____ no _____ yes 6 wk _____ 6 mo _____ other _____ 3 mo _____ 12 mo _____ other _____
 Provider _____ Date _____

_____ The results of this evaluation have been discussed with the employee. The employee has been informed regarding medical conditions which may result from exposure to blood or other potentially infectious materials, educated regarding risk reduction practices and had the surveillance program explained in detail.

Appendix F



East Carolina University Student Health Service

Policy No. CM69
Effective Date 05/03/2000
Revised Date 04/18/2017
Page 1 of 4
Approved by _____

BLOODBORNE PATHOGEN EXPOSURE POLICY FOR STUDENTS WITH CLINICAL EXPOSURES

Policy:

Student Health Services (SHS) will adapt and modify the policies and procedures of ECU Prospective Health to evaluate students with clinical exposures to blood and other potentially infectious materials. (i.e. Nursing, P.A., Allied Health, Sports Medicine, Recreation Services, Human Performance Lab, etc.)

BSOM medical students should contact Occupational Health Services (OHS) at Vidant Medical Center (or the Patient Care Services Coordinator if OHS is closed) and post-exposure follow up will be conducted by Prospective Health.

Purpose:

To insure complete and effective management and care to the students receiving exposures. For a full copy of ECU Prospective Health's Bloodborne Pathogen Exposure Control policy, or for listed Appendix documents, visit <http://www.ecu.edu/cs-dhs/prospectivehealth/infection.cfm> and click on the "Bloodborne Pathogen Exposure Control Plan".

Procedure:

I. Responsibility of Academic Departments

- Review policy with all students before clinical rotation annually
- Ensure proper vaccination of students
- Be aware of specific contact persons and policy for each clinical site including after hours policy

II. When an exposure occurs:

- The student should immediately notify the supervisor or preceptor and complete appropriate paperwork.
- The facility policy for counseling and screening the source patient should be instituted immediately (see Algorithm, Appendix D, or at end of this policy). Exposures that occur at Vidant Medical Center are first directed to contact Occupational Health Service (or the Patient Care Services Coordinator if OHS is closed), who will ascertain risk of blood borne pathogen transfer, source patient labs and make arrangements for PEP if the source patient is HIV positive. Students at other facilities should check with their preceptor or clinical coordinator regarding facility policy.

- The results of source patient testing should be forwarded to SHS as soon as possible, by either the source facility or by the patient hand carrying results to SHS, as SHS will handle all post exposure follow up (with the exception of BSOM students who will follow up at Prospective Health.)



III. Student with low risk exposure should:

-Have the following initial screening (either at clinical site or at SHS):

- HIV antibody
- Hepatitis B titer (surface antigen & antibody)
- Hepatitis C antibody
- Syphilis

-Bring the complete name and demographic information (to include DOB) on the source patient if the lab reports are not immediately available so that SHS may obtain lab reports from involved facility. Lab reports should include:

- HIV Antibody
- Hepatitis B Surface Antigen, Hepatitis B surface antibody, Hepatitis B core antibody
- Hepatitis C Antibody
- Syphilis

-Receive counseling including:

- ✓ What constitutes exposure, protocol for determining risk
- ✓ Responsibilities of SHS and student
- ✓ HIV counseling protocols
- ✓ Implications of positive and negative results
- ✓ Reporting symptoms of febrile illness
- ✓ Refraining from blood donation
- ✓ Avoiding pregnancy
- ✓ Using condoms

-Have follow-up screening.

- 6 wks. – HIV
- 3 mos. – HIV, Syphilis
- 6 mos. – HIV, Hepatitis C (if source patient positive)

-Be treated for any positive tests per protocol

-Be offered PEP as soon as possible after exposure if benefit outweighs risk

IV. Student with known HIV exposure or high risk exposure should:

-Follow clinical site policy initially; at Vidant Medical Center, Occupational Health will ascertain risk and arrange for PEP if necessary. Other facilities may have specific policies as well.

-Report to SHS as soon as possible. In high risk, (PEP) may be considered up to two weeks after exposure. After hours exposure can be handled through the ED per facility policy and report to SHS the next day.

-Bring the complete name and demographic information (to include DOB) on the source patient, so that SHS may obtain lab reports from involved facility as soon as available. Lab reports should include:

- HIV antibody
- Most recent CD4 count
- Viral load



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- Current and previous antiviral treatment
 - Be evaluated by the SHS provider to see if the exposure meets the criteria (Appendix G) and if the source patient meets risk criteria (Appendix C). If so, PEP may be offered after consultation with ECU Infectious Disease.
 - Receive counseling by SHS provider concerning:
 - ✓ risks of developing communicable disease
 - ✓ student's relevant history
 - ✓ side effects of medications
 - Have the following labs drawn:
 - HIV Antibody
 - Hepatitis B titer (surface antigen and antibody)
 - Hepatitis C antibody
 - Syphilis
 - Serum HCG
 - Executive I
 - Be scheduled by SHS for follow-up appointment with Infectious Disease.
 - Receive counseling including:
 - ✓ What constitutes exposure, protocol for determining risk
 - ✓ Responsibilities of SHS and student
 - ✓ HIV counseling protocols
 - ✓ Implications of positive and negative results
 - ✓ Reporting symptoms of febrile illness
 - ✓ Refraining from donating blood
 - ✓ Avoiding pregnancy, using condoms
 - Have follow-up screening including:
 - 6 wks. – HIV
 - 3 mos. – HIV, Syphilis
 - 6 mos. – HIV, Hepatitis C (if source patient positive for Hepatitis C)
 - Other follow up labs may be indicated per Infectious Disease to monitor for side effects of PEP
 - Be treated for any positive tests per protocol
- V. Billing charges may be handled through interdepartmental transferred funds where a departmental fund exists. In incidences where no departmental policy or procedure exists, the student is evaluated at SHS following the above protocols at the student's expense.
- VI. Only source patients who are ECU students may be screened and counseled at SHS. Otherwise, the involved facility/department will be responsible for approaching the source and obtaining blood specimens after consent. Options for screening would include referring the source to his family physician or the Pitt County Public Health Center (will screen for HIV and syphilis only).
- VII. Lab reports for the source patient will be kept in a locked cabinet in the Tracking nurse's office. Blood exposure hotline at Vidant Medical Center for additional assistance: 847-8500.



East Carolina University Student Health Service

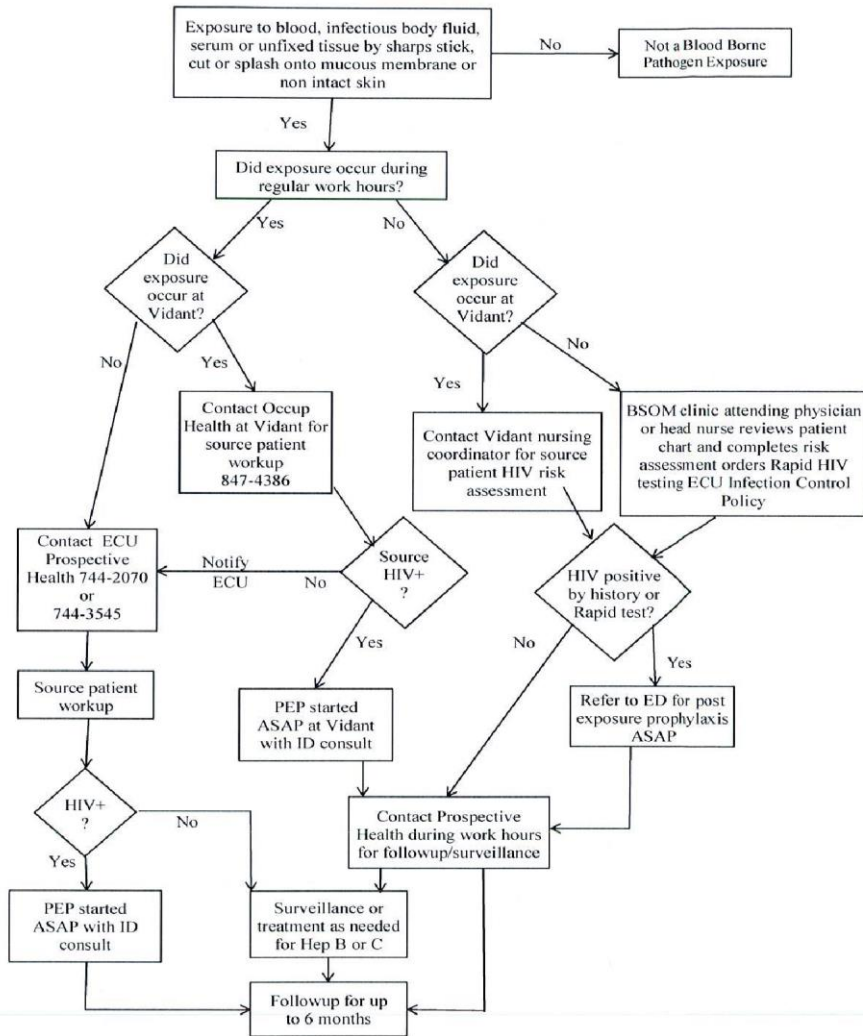
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Approved by _____



Appendix G
ECU: Post Exposure Risk Assessment for HIV/AIDS
 (TO BE COMPLETED BY ECU HEAD NURSE OR ECU ATTENDING PHYSICIAN)

_____ Employee: _____ Department: _____

Date/time of exposure: _____

Source patient: _____

		YES	NO
1			
A.	Is the source patient known to have AIDS/HIV? _____ CD4 count _____ Symptomatic/Asymptomatic	↑	↑
B.	Is the source patient suspected to have AIDS/HIV due to known risk behavior, such as IV drug use, prostitution, sexual contact of AIDS patient, multiple transfusion before 1985 or hemophilia, opportunistic infection or other signs or symptoms <u>OR</u> has the attending physician begun workup for AIDS/HIV independent of this incident? In other words, is there strong clinical suspicion of AIDS as part of differential diagnosis?	↑	↑
C.	See questions on back for additional screen of source for high risk.	↑	↑

If “yes” go to 2. If “no” to A or B, instruct employee to followup with Employee Health in person for blood and body fluid exposure followup as soon as the Services re-opens.

		YES	NO
2			
A.	i. Was the source fluid blood? ↑ ii. Was the sharp visibly bloody? iii. Was the sharp a hollow needle extracted from a vascular site-carrying a volume of patient blood? Was the exposure a mucous membrane splash of fluid into the eye, nose or mouth?	↑	↑
B.	Was the exposure a splash on to broken or non-intact skin?	↑	↑
C.			↑

If “yes” to A, B, or C go to #3.

If all “no” no PEP indicated instruct employee to followup with Employee Health in person for blood and body fluid exposure followup as soon as the service re-opens.

3	
----------	--

	YES	NO
A. Was the source fluid blood?	↑	↑
Was the source fluid semen, vaginal, cerebrospinal, synovial, pleural, pericardial, amniotic fluid or peritoneal fluid?	↑	
C. Was the source unfixed tissue?	↑	↑
D. Was the source fluid other than above, but obviously blood-tinged?	↑	↑

If “no” to A, B, C, and D, no PEP indicated. Instruct employee to followup with Employee Health in person for blood and body fluid exposure followup as soon as the service re-opens.

If “yes” to A, B, C, or D refer to the Emergency Department for further evaluation. Provide a copy of this form to employee to take to ED.

 Attending Physician or designee

Date/Time