

EAST CAROLINA UNIVERSITY

INFECTION CONTROL POLICY

Bloodborne Pathogen Exposure Control Plan

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SCOPE AND APPLICATION:

ECU is committed to providing a safe and healthful 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 or fluids. It is designed to comply with the OSHA Standard 29 CFR 1910. 1030, "Occupational Exposure to Bloodborne Pathogens". (Appendix G)

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.

This plan will be reviewed and updated annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposures, and to reflect new or revised employee positions with occupational exposure. 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 other potentially infectious materials. The employees who perform these tasks or procedures will receive the training and immunizations described below.

I. EXPOSURE CONTROL PLAN: BLOODBORNE PATHOGENS

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.
- Staff compliance is monitored.
- Personal protective equipment is available and maintained.
- Equipment and environmental surface are cleaned and decontaminated.

B. East Carolina University'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 and are protected from bloodborne pathogen exposure. (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.

1. A list of all job classifications in which all employees have occupational exposure:

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

2. A list of all 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

*Those who are assigned to work in an ECU health care facility, clinical or research and teaching areas and who have possible occupational exposure in the course of their work.

3. A list of all tasks and procedures or groups of closely related tasks and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in which **some** employees have occupational exposure:

Secretary I-IV-- work in the clinical areas interviewing patients where spills of blood and other potentially infectious materials may occur. Receptionist-- work in the clinical areas interviewing patients where spills of blood and other potentially infectious materials may occur.

Clerk-Receptionist I-III-- work in the clinical areas interviewing patients where spills of blood and other potentially infectious materials may occur.

Clinical Dietitian I-II--work in the clinical areas evaluating patients where spills of blood and other potentially infectious materials may occur.

Social Worker--work in the clinical areas interviewing patients where spills of blood and other potentially infectious materials may occur.

Pharmacist--work in the clinical areas where blood and other potentially infectious materials may be present

Administrative Secretary--work in clinical or research areas which handle or transport specimens of blood and other potentially infectious materials.

Plant Engineer--maintenance and repair work in the clinics, clinical and research labs where spills of blood and other potentially infectious materials may be present.

Electrical Supervisor I--maintenance and repair work in the clinics, clinical and research labs where spills of blood and other potentially infectious materials may be present.

Electrician II--maintenance and repair work in the clinics, clinical and research labs where spills of blood and other potentially infectious materials may be present.

Laborer--maintenance and repair work in the clinics, clinical and research labs where spills of blood and other potentially infectious materials may be present.

HVAC Supervisor--maintenance and repair work in the clinics, clinical and research labs where spills of blood and other potentially infectious materials may be present.

HVAC Technician---maintenance and repair work in the clinics, clinical and research labs where spills of blood and other potentially infectious materials may be present.

HVAC Mechanic--maintenance and repair work in the clinics, clinical and research labs where spills of blood and other potentially infectious materials may be present.

Maintenance Mechanic I-IV---maintenance and repair work in the clinics, clinical and research labs where spills of blood and other potentially infectious materials may be present.

Plumber I-III--maintenance and repair work in the drains and sinks in clinics, clinical and research labs where spills of blood and other potentially infectious materials may be present. (Follow Facilities Services protocols for decontamination of pipes in clinics or labs prior to disassembling).

Carpenter Supervisor I--maintenance and repair work in the clinics, clinical and research labs where spills of blood and other potentially infectious materials may be present.

Carpenter I-III--maintenance and repair work in the clinics, clinical and research labs where spills of blood and other potentially infectious materials may be present.

Painter--maintenance and repair work in the clinics, clinical and research labs where spills of blood and other potentially infectious materials may be present.

Steam Plant Supervisor I--maintenance and repair work in the drains and pipes in clinics, clinical and research labs where spills of blood and other potentially infectious materials may be present.

Boiler Operator I-III--maintenance and repair work in the clinics, clinical and research labs where spills of blood and other potentially infectious materials may be present.

Grounds Supervisor/worker--grounds work in an area in which needles and other potentially contaminated materials may be found.

Housekeeper--housekeeping tasks in the clinical labs and patient-care areas where blood and other potentially infectious materials may be present.

Housekeeping Team Leader-- housekeeping tasks in the clinical labs patient-care areas where blood and other potentially infectious materials may be present.

Housekeeping Supervisor I-III-- housekeeping tasks in the clinical labs patient-care areas where blood and other potentially infectious materials may be present.

Professor--work in the research and teaching labs or in a clinical setting, handling patients or specimens of blood and other potentially infectious materials.

Assistant Professor--same as professor

Associate Professor--same as professor.

Research Instructor-- work in the research and teaching labs with blood other potentially infectious materials.

Lecturer--work in the research or teaching labs or clinical area with patients or obtaining, handling, and transporting specimens of blood and other potentially infectious materials.

Graduate Assistant--work in the research and teaching labs in obtaining, handling, and transporting specimens of blood and other potentially infectious materials.

Research Associate---work in the research and teaching labs in obtaining, handling, and transporting specimens of blood and other potentially infectious materials.

Research Technician I-IV--work in the research and teaching labs in obtaining, handling, and transporting specimens of blood and other potentially infectious materials.

Electronics Technician--work in the research and teaching labs or clinical area where handling, and transporting specimens of blood and other potentially infectious materials.

Student Worker – Students employed by ECU working in clinical or research labs where spills of blood and other potentially infectious materials may occur.

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.

- C. Definitions of blood, body fluid or other potentially infectious materials (see Appendix A 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
 - D. 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. May contain infectious agents which are not bloodborne pathogens, however.

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 other potentially

infectious materials. Standard/Universal Precautions shall be observed by faculty, staff, students and other healthcare workers to prevent contact with blood or other potentially infectious materials. 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 other potentially infectious materials of any patient or specimen.

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

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 personal protective equipment.

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 A for definition of "exposure" and Section IIC Page 22 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 other potential infectious materials. 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 appropriate sizes, and easily accessible to the employee.

Personal protective equipment will be considered appropriate if it does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth or other mucous membranes under normal conditions of use and for the duration of

time during which used. Reusable personal protective equipment 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, other potentially infectious materials, mucous membranes or non-intact skin of patients, or when handling items or surfaces contaminated with blood or other potentially infectious materials, and when performing vascular access procedures. . Sterile gloves should be used for procedures involving contact with normally sterile areas of the body. Non-sterile examination gloves may be used for procedures involving contact with mucous membrane, and for other patient care or diagnostic procedures.

Single use surgical or examination gloves (single use) are not to be washed or disinfected for reuse. They should not be used 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.

Utility gloves (e.g. rubber or vinyl household gloves) for housekeeping chores involving potential blood contact or for instrument cleaning and decontamination procedures can be reused. Utility gloves may be decontaminated and reused, but should be discarded if they are peeling, cracked, or discolored, or if they have puncture, tears, or other evidence of deterioration or other ability to function as a barrier is 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. Latex gloves, vinyl gloves, and nitrile gloves are available in the ECU Medical Store Room.

2. Mask and eye protection, or chin-length face shields are worn when the healthcare worker 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.
3. Appropriate protective clothing shall be worn when the worker has potential for exposure to blood and other potentially infectious materials 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 other potential infectious material. Fluid resistant clothing shall be worn if there is potential for splashing or spraying of blood or other potentially infectious material. Surgical caps or hood 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 personal protective equipment shall be removed prior to leaving the work area and placed in appropriately designated area or container for disposal or washing and decontamination.

4. Resuscitator Devices are provided and readily available to employees who can be reasonably expected to perform resuscitation procedures. Each clinical manager is responsible for ensuring that these devices are available and that staff are adequately trained. Documentation of training in their use can be found in the CPR certification records.

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. Need for changes in Engineering controls or work practices will be made by each department through review of exposure reports, inspections, employee input, committee activities, etc.

1. Shield/Guards:
Stationary shields or guards may be installed to alleviate the necessity for other facial barriers to keep splashes from contacting the face. As an 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. As an example, biological safety cabinets provide 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 alternative feasible 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, immediately or as soon as possible, contaminated, disposable syringes and needles, scalpel blades, and other sharp items should be placed in appropriate disposal containers as close as practical to the use area. Reusable sharps are placed into appropriate containers.
 - c. Containers for sharps are puncture resistant, labeled or color-coded, 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 patient clinic room, treatment rooms, clinical and research lab and any other area where sharps are used. These containers will be checked routinely by staff and when 2/3 to 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 intra muscular 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.

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 other potentially infectious materials are likely to be present.

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

Healthcare workers who have exudative lesions or 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 other potentially infectious materials 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 which may be contaminated will not be picked up directly by the hands. It shall be cleaned up using mechanical means, such as a brush and a dust pan, tongs, or forceps.

3. Labels and Warnings

Warning labels are affixed to containers of infectious waste, refrigerators and freezers containing blood or other potentially infectious material or other containers used to store or transport blood or other potentially infectious materials. The labels are fluorescent orange or orange-red, using the accepted biohazard label and affixed as closely as safely possible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal. Red bags or red containers may be substituted for labels on containers of infectious waste.

4. Waste

Non-contaminated trash is placed in clear or brown plastic bags for pick-up by Housekeeping. Contaminated trash 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 second container which prevents leakage during handling, processing, storage, transport, or shipping, and is labeled or color-coded appropriately. Waste materials known to be infectious should be rendered non-infectious by processes such as autoclaving or immersion in liquid disinfectant.

5. Specimens

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

Specimens of blood or other potentially infectious materials shall be placed in a close able 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 first 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 become contaminated with blood or other potentially infectious materials shall be cleaned and decontaminated as necessary prior to servicing, shipping or being moved, stored or sent to surplus. If decontamination of such equipment or portions of such equipment is not feasible, a readily observable 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 machinery, 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 devices or 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 other potentially infectious materials.

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 spills of blood or other potentially infectious materials. 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 other potentially infectious materials should be cleaned and disinfected after completion of a procedure; immediately or as soon as feasible. Cleaning should be done when surfaces are overtly contaminated or after any spill of blood or potentially infectious material; and at the end of the work shift. Protective covering such as plastic wrap, aluminum foil, or imperiously-backed 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 other potential infectious material 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 Other Potentially Infectious Material

Use protective gloves and other personal protective equipment (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 other potentially infectious material 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 gloves and all contaminated items in 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 in 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 personal protective equipment 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 about 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); 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 other infectious materials shall be inspected and cleaned and decontaminated on a regular basis by the users, or 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 other potentially infectious materials. Infectious waste is a broader term and includes regulated waste as well as other infectious materials, such as culture plates and stocks, which contain (organisms which are not bloodborne but which can be pathogens).

1. Sanitary sewers may be used to dispose of limited liquid 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 closeable 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 clinic 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 loaded into leak-proof, covered waste disposal carts for transport to the incinerator by trained utility workers.
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 2/3 to 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 utility 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 other potentially infectious materials 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. Such laundry will not be sorted or rinsed in the area of use.

All employees who handle contaminated laundry will utilize personal protective equipment to prevent contact with blood or other potentially infectious materials. Contaminated Laundry and lab coats used as PPE at this facility will be sent out to be cleaned by contract linen services.

J. Hazard Communications

1. Labels and signs

Warning labels shall be affixed to containers of infectious waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials. 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 or 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 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 personal protective equipment.
 - Information on the types, proper use, location, removal, handling, and decontamination or disposal of personal protective equipment.
 - The basis for selection of personal protective equipment.
 - Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administrations, the benefits of being vaccinated.
 - Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials.
 - 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 currently is held twice a month and is open to all ECU staff, faculty and student workers exposed to human blood, body fluid or other potentially infectious material. The calendar for New Employee orientation is available on-line at the ECU One Stop Web site under "Faculty/Staff Development/Training."
 - (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.
- b. His/her hepatitis B status including the dates of all hepatitis B vaccinations and any medical records relative to the employees ability to receive vaccination.
- c. All results of examinations, medical testing, follow-up, and written opinions as they relate to the employees 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.
- d. A copy of the information provided to the provider and provider's written opinions. (Appendix C)
- e. 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 also will be provided upon request for examination and copying to the subject employee or to anyone having written consent of the subject 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/Medical Surveillance

A. Hepatitis B Vaccination

1. Employees in positions having occupational contact with blood or other potentially infectious materials will be offered the vaccine within ten (10) working days of initial assignment. If the employee is immune on antibody testing due to a previous HBV vaccination, or past infection or the vaccine is contraindicated for other medical reasons, this will be ascertained from the medical history. If an employee for whom hepatitis B vaccine is indicated declines HBV vaccine, a declination form will be signed and retained in the Employee Health chart (*See appendix I*). An employee may subsequently request vaccination and it shall be provided at that time. Currently booster doses are not recommended. Should booster doses ever be recommended in the future, such booster doses shall also be provided. At present, (2010), routine booster doses are not recommended.
2. After receiving the 3 doses of hepatitis B vaccine, a post vaccination titer shall be drawn to document immunity or the need for a booster vaccinations.

B. Bloodborne Pathogens Exposure

Any employee or student covered by this policy who has a *stick*, cut, or scratch with a contaminated object or a *splash* into the eye or mucus membrane with blood or other potentially infectious material; or who has cutaneous exposure with such material onto 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. 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:

- 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 is involved in an exposure incident the following forms must be completed:

1. ECU Non-Patient Incident Report Form – for all incidents. The Non-Patient Incident Report is brought to Prospective Health by the employee on initial visit. (Appendix C)
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 a BSOM Incident Report is also filled out and forwarded to BSOM Risk Management if the patient or visitor exposure occurs at a BSOM clinic (Appendix K)

III. Content of Evaluation and Surveillance Program

A. Source patient evaluation

1. Medical history review
2. Risk factor history for blood pathogens (less reliance on these to define risk; replaced by rapid HIV testing)
 - a. Blood transfusion prior to 1990
 - b. Use of blood products, e.g. anti-hemophilia factor
 - c. IV drug use, current or past
 - d. Homosexual or bisexual behavioral
 - e. Known HIV, Hep B or Hep C
 - f. Sexual contact for money
 - g. Other high risk behavior, STD's, etc.
3. 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 – rapid
 - ii. Hepatitis B surface antigen, surface antibody and core antibody
 - iii. Hepatitis C antibody
 - iv. Serum RPR – not done routinely unless history indicates
 - e. If source patient blood is drawn by unit:
 - i. Draw a purple top tube and a red top tube

- ii. Label tubes with the following information:
 - Patient's name
 - 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 "Blood Exposure Panel" written on the lab slip
 - 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 person 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 (rapid)
 - c. Hepatitis C antibody
 - d. Serum RPR – if needed based on source history
 - e. If exposed person refuses baseline HIV testing, blood may be obtained and frozen for 90 days as an alternative means of assessing baseline status
- 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 (See PEP policy)
 - 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 other potentially infectious materials 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. Specific 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 globin within 7 days
 - b. Begin hepatitis B vaccine series
 - c. Test for hepatitis B antigen 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.
- 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.
 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 1-2 weeks.
 6. Any exposure to concentrated HIV (e.g. in a research laboratory) will be treated as a highest risk exposure.
 7. Exposure to the blood of a high risk individual, not already known to be HIV positive, will be considered on a case-by-case basis (Appendix D Risk Assessment). HIV testing is ordered stat; (PEP may be initiated pending results).
 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
 - a. Post-exposure prophylaxis may consist of two or three 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 4 week PEP program will be scheduled for follow-up with ECU Infectious Disease at 2 weeks to monitor for drug side effects.
 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.
- D. Syphilis (if indicated by source history) NOTE: No longer screening source routinely
1. If the source patient RPR $\geq 1:16$ and verified with specific treponemal test
 2. Prophylax the exposed person with appropriate dose of penicillin (e.g. Benzathine PCN 2.4 million units IM) or tetracycline po x 14 days

3. Serologic follow-up with RPR at 6-12 weeks
- 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 "follow-up 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, hepatitis C or syphilis. 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 drug 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 (rapid HIV, Hepatitis B surface antigen, surface antibody and core antibody, Hepatitis C antibody, and possibly Serum RPR if history indicates risk)
 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. Fill out 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 OH will do a Pregnancy Test (if indicated) on the exposed worker.

- ii. OH 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 Vidant pharmacy to have them filled.
 - iv. The employee will report to ECU Prospective Health ASAP after initiation of PEP
 - d. Vidant will notify PH of the 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 who to call)
 - a. Obtain blood work for labs on source patient as listed per **Section III A. 3.** on page 23 (red top and purple top tubes), after counseling and obtaining consent for HIV testing. Requires a rapid HIV test for source patient; write in “Blood Exposure Panel” on lab request form. (See Appendix D)
 - b. If SP is HIV + by history or rapid 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 (See IV-C.8. on page 26 above). 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 847-8500 for review of Vidant process if needed.
 - 2. Contact the Vidant nursing coordinator 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 initiation of long-term surveillance on non-emergence 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
- G. If an employee sero-converts as a result of a bloodborne exposure
1. A Workers Compensation Claim will be filed
 2. The infection will be reported to the county health department of residence as required for Infectious Disease surveillance by 10A NCAC 41A. 0100.
 3. 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 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 pathogen
- 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 BSOM
 - 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, followups
 - 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)
 - 3. 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, followup 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, treatment and/or follow-up.
 - 4. If source is HIV+, contacts are made 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 continue 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, 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

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, Creutzfeldt-Jakob 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

Needleless 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

- 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--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.

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 B: 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

Blood or Body Fluid Exposure

stick _____
 splash _____
 spray _____
 cut _____
 bite _____
 scratch _____
 scrape/abrasion _____
 other _____
 Source pt. _____
 MR# _____

Infectious Respiratory Exposure

inhalation sprain _____
 other _____
Radiation Exposure
 internal _____
 external _____
Chemical Exposure
 inhalation _____
 skin absorption _____

Body Accident

sprain _____
 strain _____
 hit _____
 struck _____
 puncture _____
 fall _____
 other _____
Electrical Injury
 other _____

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 C
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: _____

1		YES	NO
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.

2		YES	NO
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?	↑	↑
B.	Was the exposure a mucous membrane splash of fluid into the eye, nose or mouth?	↑	↑
C.	Was the exposure a splash on to broken or non-intact skin?	↑	↑

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?	↑	↑
B.	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?	↑	↑

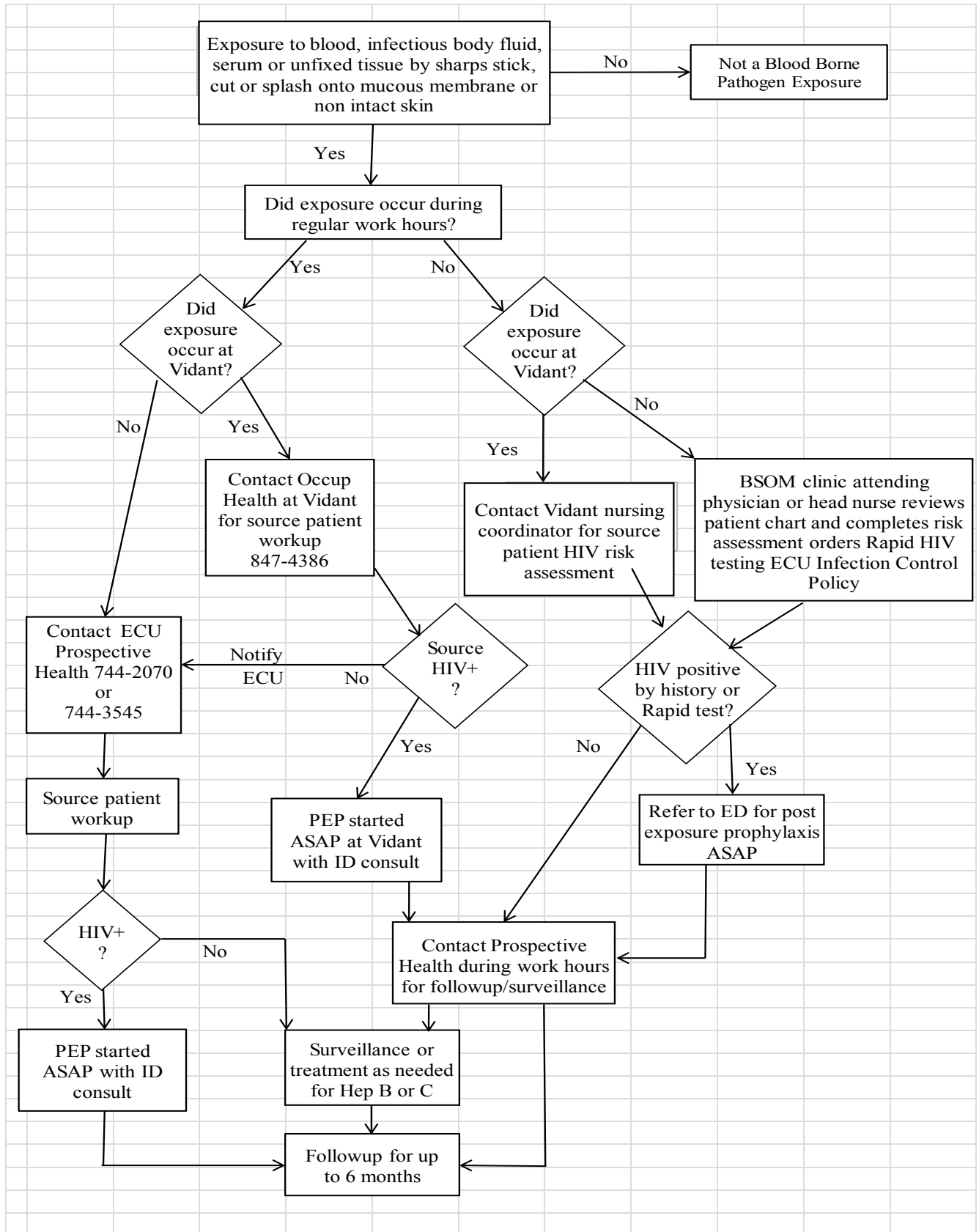
If “no” to A, B, C, and D, no PEP indicated. Instruct employee to followup with Employee Health in person for blood and body fluid exposure followup as soon as the service re-opens.

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

APPENDIX D



Appendix E

Thursday,
January 18, 2001
Part IX

Department of Labor

Occupational Safety and Health
Administration

29 CFR Part 1910

Occupational Exposure to Bloodborne
Pathogens; Needlesticks and Other
Sharps

Injuries; Final Rule

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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 needles 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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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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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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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:

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

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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:

$(502,724 \text{ establishments}) \cdot (0.25 \text{ hours/establishment}) \cdot (\$33.22/\text{hour}) = \$4,175,080.$

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

$(11,348,141 \text{ employees}) \cdot (33\% \text{ response rate}) \cdot (0.25 \text{ hours/employee}) \cdot (\$25.90/\text{hour}) = \$24,248,140.$

Note that it is implicitly assumed that input is solicited from all employees. This assumption will result in an overstatement of costs because the standard requires that input be solicited only from the fraction of employees who are involved in direct patient care and who are potentially exposed to needlestick injuries.

Finally, the revised standard requires that the employer document the solicitation in the Exposure Control Plan. Because the affected employers are already required to establish a Plan, the incremental effort associated with this documentation will be small. OSHA estimates that it will require only 15 minutes (0.25 hours) of managerial time. Thus, the total annual cost of documenting the solicitation in the Exposure Control Plan is estimated to be:

$(502,724 \text{ establishments}) \cdot (0.25 \text{ hours/establishment}) \cdot (\$33.22/\text{hour}) = \$4,175,080.$

In summary, OSHA has estimated the total cost of the solicitation to be \$32,598,300 (\$4,175,080 + \$24,248,140 + \$4,175,080). This estimate is likely to overstate the cost because employers have several avenues for achieving this requirement of the standard, many of

which will reduce costs. For example, employers are not required to solicit input from all employees and could meet the requirement by, for example, consulting a properly constituted safety committee consisting of a subset of employees. In fact, recent state legislation has mandated sharps safety committees in a number of states. In these situations, the only incremental cost associated with the solicitation mandated by this amendment to the BBP standard will be documentation of the solicitation in the Exposure Control Plan.

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

V. Unfunded Mandates

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

1532), this rule does not include any
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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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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.

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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 that effectively reduces the risk of an exposure incident.

(c) ***

(1) ***

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

- (A) Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and
- (B) Document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.

(v) An employer, who is required to establish an Exposure Control Plan shall solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to

injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan.

(h) ***

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

- (A) The type and brand of device involved in the incident,
- (B) The department or work area where the exposure incident occurred, and
- (C) An explanation of how the incident occurred.

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

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

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



East Carolina University Student Health Service

Policy No. **ECC02**

Page # ____50____ of ____4____

Effective Date ____5/3/00____

Revised Date ____4/28/03____

Approved by _____

Blood and other Potentially infectious Material Exposure Policy for Students, with Clinical Exposures

Blood and other Potentially Infectious Material Exposure Policy for Students, with Clinical Exposures

Policy:

The 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.)

Purpose:

To insure complete and effective management and care to the students receiving exposures.

Procedure (checklist):

- I. Responsibility of Departments:
 - Review policy with all students before clinical rotation annually
 - Ensure Hepatitis B vaccination of students
 - Be aware of specific contact persons and policy for each clinical site including after hours policy
 - Supply list of contact persons to SHS and update annually
 - Provide a copy of departmental policy to Student Health
- 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 (may use Risk Assessment of Source Patient, Appendix D, page 2)
 - The results of source patient testing should be forwarded to SHS as soon as possible
- III. Student with low risk exposure should:
Blood Borne Pathogen Exposure Plan Control Plan-11

- Report to SHS as soon as possible
- Have the following initial screening:
 - HIV antibody
 - Hepatitis B titer (surface antigen & antibody)
 - Hepatitis C antibody
 - STS
- 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 may be reported from the facility representative by calling SHS Urgent Care at 328-6841. Lab reports should include:
 - HIV Antibody
 - Hepatitis B Surface Antigen, Hepatitis B surface antibody, Hepatitis B core antibody
 - Hepatitis C Antibody
 - STS
- Receive counseling including:
 - What constitutes exposure, protocol for determining risk (page 1, Blood and OPIM Exposure Policy and Appendix D)
 - 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 including:
 - 6 wks. – HIV
 - 3 mos. – HIV, STS
 - 6 mos. – HIV, Hepatitis C (if source patient positive)
- Be treated for any positive tests per protocol

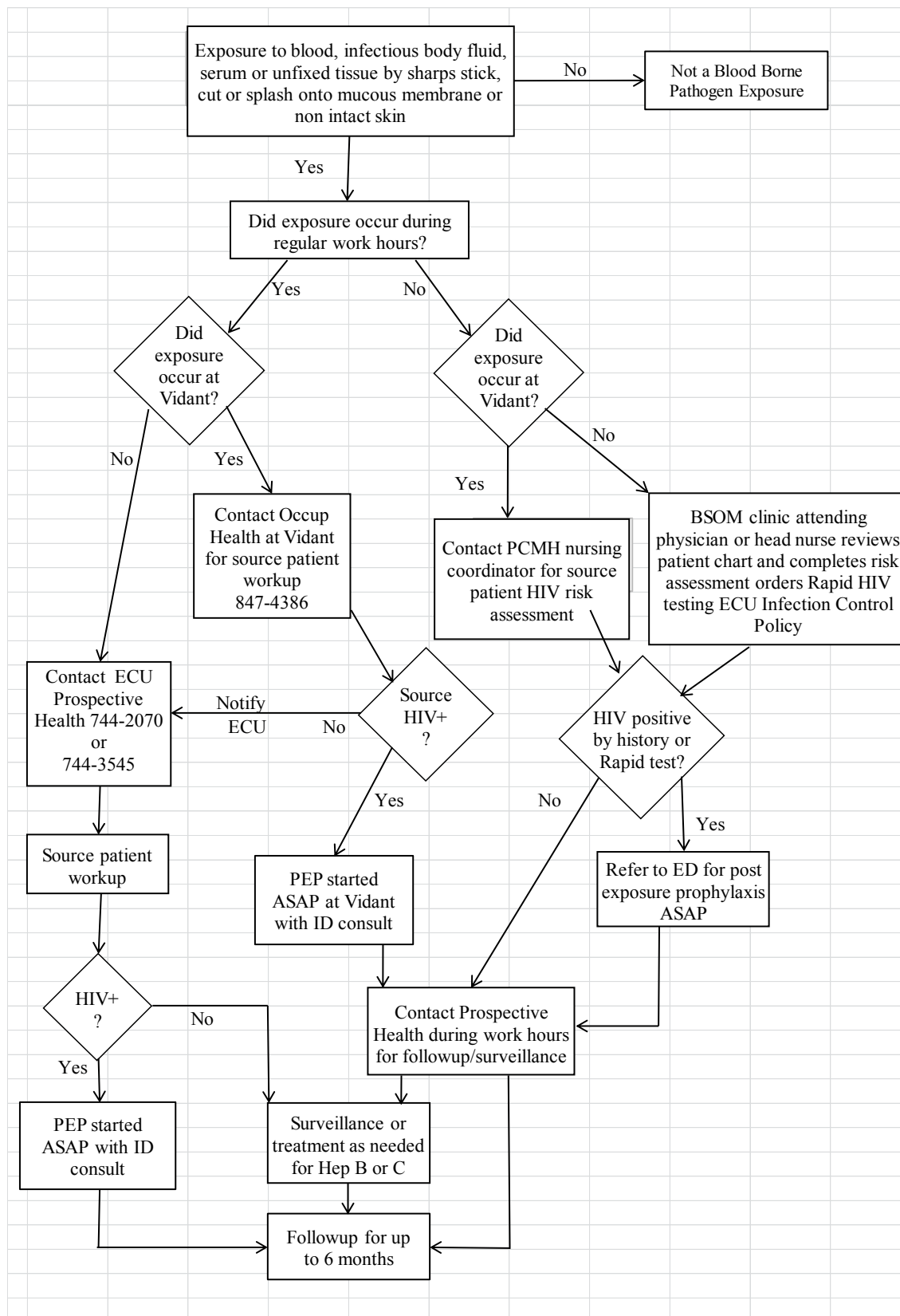
IV. Student with known HIV exposure or high risk exposure should:

- Report to SHS within the first 2 – 3 hours post-exposure. (In high risk, Post Exposure Prophylaxis (PEP) may be considered up to two weeks after exposure. After hours exposure should 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 may be reported from the facility representative by calling SHS Urgent Care at 328-6841. Lab reports should include:
 - HIV antibody
 - Most recent CD4 count
 - list out count & viral load
 - current antiviral treatment
 - Be evaluated by the SHS provider to see if the exposure meets the criteria in Step 1
- (Appendix E) and if the source patient meets the criteria (Appendix F). If so, PEP may be offered (Appendix G) after consultation with ECU Infectious Disease.
- Receive counseling by SHS provider concerning:
 - risks of developing communicable disease

- student's relevant history (Management of HIV Post Exposure Policy page 2)
- side effects of medications
- Receive general instructions (Appendix B)
- Have signed consent form before receiving prescription (Appendix A).
- Have the following labs drawn:
 - HIV Antibody
 - Hepatitis B titer (surface antigen and antibody)
 - Hepatitis C antibody
 - STS
 - 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 (page 1, Blood and OPIM Exposure Policy and Appendix D)
 - 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, STS
 - 6 mos. – HIV, Hepatitis C (if source patient positive)
- Be treated for any positive tests per protocol

* SHS provider should follow Blood and OPIM Exposure protocol.

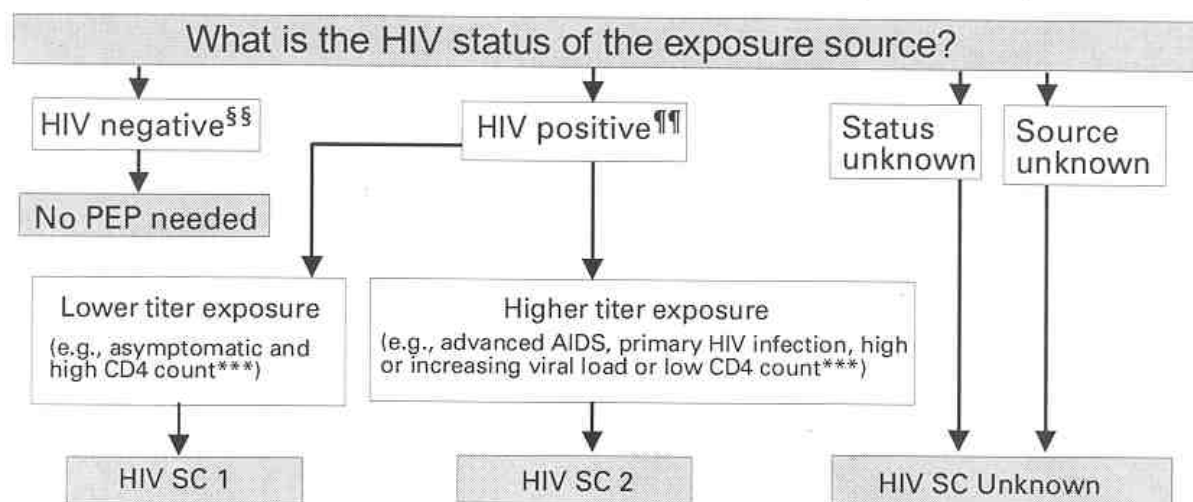
- V. Billing charges may be handled through interdepartmental transferred funds where a departmental fund exists. In incidences where no departmental policy or procedure exists, the student may be evaluated at SHS following the above protocols at the student's expense.
- VI. Only source patients who are ECU students may be screened and counseled at SHS. The SHS is responsible for advising the student/department of the need to screen the source. The 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 Health Department (will screen for HIV and syphilis only).



Appendix G

FIGURE 1. Determining the need for HIV postexposure prophylaxis (PEP) after an occupational exposure* — Continued

STEP 2: Determine the HIV Status Code (HIV SC)




^{§§} A source is considered negative for HIV infection if there is laboratory documentation of a negative HIV antibody, HIV polymerase chain reaction (PCR), or HIV p24 antigen test result from a specimen collected at or near the time of exposure and there is no clinical evidence of recent retroviral-like illness.

^{¶¶} A source is considered infected with HIV (HIV positive) if there has been a positive laboratory result for HIV antibody, HIV PCR, or HIV p24 antigen or physician-diagnosed AIDS.

^{***} Examples are used as surrogates to estimate the HIV titer in an exposure source for purposes of considering PEP regimens and do not reflect all clinical situations that may be observed. Although a high HIV titer (HIV SC 2) in an exposure source has been associated with an increased risk for transmission, the possibility of transmission from a source with a low HIV titer also must be considered.

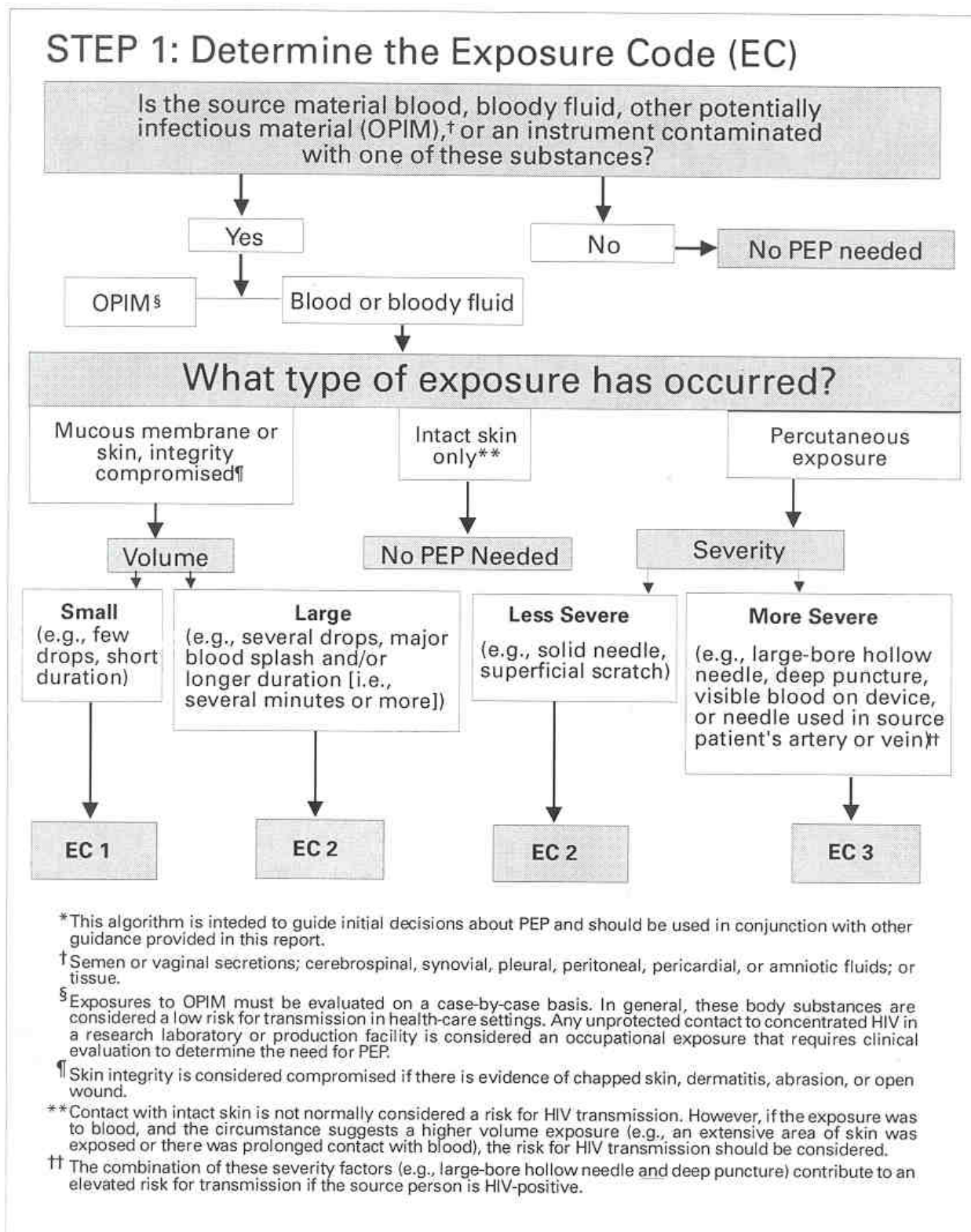
STEP 3: Determine the PEP Recommendation

EC	HIV SC	PEP recommendation
1	1	PEP may not be warranted. Exposure type does not pose a known risk for HIV transmission. Whether the risk for drug toxicity outweighs the benefit of PEP should be decided by the exposed HCW and treating clinician.
1	2	Consider basic regimen.^{†††} Exposure type poses a negligible risk for HIV transmission. A high HIV titer in the source may justify consideration of PEP. Whether the risk for drug toxicity outweighs the benefit of PEP should be decided by the exposed HCW and treating clinician.
2	1	Recommend basic regimen. Most HIV exposures are in this category; no increased risk for HIV transmission has been observed but use of PEP is appropriate.
2	2	Recommend expanded regimen.^{§§§} Exposure type represents an increased HIV transmission risk.
3	1 or 2	Recommend expanded regimen. Exposure type represents an increased HIV transmission risk.
Unknown		If the source or, in the case of an unknown source, the setting where the exposure occurred suggests a possible risk for HIV exposure and the EC is 2 or 3, consider PEP basic regimen. 

^{†††} Basic regimen is four weeks of zidovudine, 600 mg per day in two or three divided doses, and lamivudine, 150 mg twice daily.

^{§§§} Expanded regimen is the basic regimen plus either indinavir, 800 mg every 8 hours, or nelfinavir, 750 mg three times a day.

FIGURE 1. Determining the need for HIV postexposure prophylaxis (PEP) after an occupational exposure*



Appendix H

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 5-10% 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

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 trials. 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.