Bloodborne Pathogen Standard
OSHA’s Final Rule

William A. Rutala, PhD, MPH
Director, Hospital Epidemiology, Occupational Health and Safety; Research Professor of Medicine and Director, Statewide Program for Infection Control and Epidemiology
University of North Carolina at Chapel Hill, USA
OSHA’s Mandate

- OSHA’s mission is to protect the healthcare worker
- OSHA Rule is required compliance under Federal Law
OSHA INSTRUCTION

U.S. DEPARTMENT OF LABOR
Occupational Safety and Health Administration

DIRECTIVES NUMBER: CPL 2-2.69  |  EFFECTIVE DATE: November 27, 2001
SUBJECT: Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens

ABSTRACT

Purpose: This instruction establishes policies and provides clarification to ensure uniform inspection procedures are followed when conducting inspections to enforce the Occupational Exposure to Bloodborne Pathogens Standard.

Scope: This instruction applies OSHA-wide.

References: 29 CFR 1910.1030, Occupational Exposure to Bloodborne Pathogens
OSHA Instruction CPL 2.103, Field Inspection Reference Manual

Cancellations: This instruction cancels CPL 2-2.44D
BBP Standard Scope and Application

- Applies to all employees with occupational exposure to blood or other potentially infectious materials (OPIM) and includes:
  - All private sector employees
  - All public sector employees
  - Students receiving compensation (teaching/graduate assistants, internships)

- Does not include:
  - Self-employed persons
    - Includes sole practitioners and partners
  - Students not receiving compensation
  - Other employees covered by other federal statutes
Employees Potentially At Risk

- Physicians and surgeons
- Nurses
- Phlebotomists
- Medical examiners
- Dentists and dental workers
- Clinical/diagnostic laboratory workers
- Medical technologists
- Nursing home personnel
- Dialysis personnel
- Laundry and housekeeping employees
Types of Occupational Exposures to Bloodborne Pathogens

- Percutaneous injury (PI)
- Mucous membrane
- Non-intact skin
Infection Control Program Components

Develop written institutional Exposure Control Plan

- Exposure Determination
- Control Methods
  - Universal (Standard) Precautions
  - Engineering Controls
  - Work Practice Controls
  - Personal Protective Equipment
Infection Control Program Components (cont)

- HBV Vaccination
- Post-Exposure Evaluation and Follow-up
- Regulated Waste Disposal
- Tags, Labels, and Bags
- Housekeeping Practices
- Laundry Practices
- Training and Education of Employees
- Record Keeping
Exposure Determination

Considerations

- Employer shall identify all employees who are directly exposed or whose jobs have the likelihood of exposures to blood or other potentially infectious materials (OPIM).
- Employer shall make an exposure determination without regard to use of personal protective equipment (PPE).
Fluids Recognized by CDC as Directly Linked to Transmission of HBV and/or HIV

- blood
- bloody body fluids
- semen
- vaginal secretions
- amniotic fluid
- saliva in dental settings
- cerebrospinal fluid
- synovial fluid
- pleural fluid
- peritoneal fluid
- pericardial fluid
Bloodborne Pathogens

- Pathogenic organisms that are present in human blood, and
  - Can cause disease in humans
- Includes but not limited to:
  - Hepatitis B virus (HBV)
  - Hepatitis C virus (HCV)
  - Human immunodeficiency virus (HIV)
Other Bloodborne Pathogens

- Malaria
- Syphilis
- Babesiosis
- Brucellosis
- Leptospirosis
- Staphylococcus aureus
- Arboviral infections
- Relapsing fever
- Human T-Lymphotrophic Virus Type 1 and 2
- Viral hemorrhagic fevers
Shared responsibility between the contract provider and the host employer to ensure compliance with OSHA standards.

Contract provider is responsible for providing:
- General bloodborne pathogen training
- Appropriate vaccinations
- Follow-up evaluations to exposure incidents

Host employer is responsible for providing:
- Site-specific training
- Personal protective equipment (PPE)
- Control of potential hazards and exposure conditions
OSHA Enforcement Revision – Exposure Control Plan

- Reviewed and updated annually* (new or modified tasks, procedures, equipment)
- Procedure to evaluate circumstances surrounding exposure incidents
- Use of Body Substance Isolation or Standard Precautions is acceptable as long as all provisions of standard are adhered to.

* Annual = 365 days from last review
“Universal (standard) precautions” refers to a method of infection control in which all human blood and OPIM are treated as if known to be infectious with HIV and HBV. Universal (standard) precautions does not apply to feces, nasal secretions, sputum, sweat, tears, urine or vomitus unless they contain visible blood.
Control Measures

Engineering Controls

Use of available technology and devices to isolate or remove hazards from the worker

Considerations: Engineering Controls

- should be used in preference to other control methods
- must be examined and maintained or replaced on a regular scheduled basis to ensure their effectiveness
Examples of Engineering Controls

- Needleless IV systems
- Lasers (in place of scalpels), staples (not sutures)
- One way cardiopulmonary resuscitation (CPR) airway-mask
- Handwashing facilities placement
- Sharps containers
- Self-sheathing needles
- Blunted sutures/sutureless
- Safety scalpel
OSHA Enforcement Revision – Evaluation of Devices

- The employer must:
  - Review and evaluate available and new engineering control devices on an annual basis
  - Train employees on safe use and disposal
  - Implement use of appropriate engineering controls and devices
  - Document evaluation and implementation in the exposure control plan (ECP)
Needlestick Safety and Prevention Act
November 2002

- Directs OSHA to revise BBP standard to clarify requirement for employers to evaluate safer needles and involve employees in identifying and choosing devices

- Requires documentation of frontline provider participation in the evaluation of safety devices and decision making in product purchasing.
Collect data on device-related injuries including how exposure occurred . . .

- type and brand of device
- circumstances of injury
- job category

Use information on injuries to guide the selection and implementation of safety devices
Control Measures

Work Practice Controls

Alterations in the manner in which a task is performed to reduce likelihood of exposure

Considerations: Work Practice

- Handwashing ASAP after glove removal or contact with body fluids
- All PPE removed ASAP after leaving work area and placed in designated container for storage, decontamination, or disposal
- Used needles and sharps shall not be sheared, bent, broken, recapped or resheathed by hand.
NEVER:
- Recapped By Hand
- Removed From Disposable Syringes
- Bent, Cut Or Broken By Hand
Control Measures

Work Practice Controls

Considerations: Work Practice (cont)

- All procedures performed to minimize splashing and spraying
- Prohibit eating, drinking, smoking, applying cosmetics or lip balm in work areas where reasonable chance of exposure
- Prohibit storage of food and drink in refrigerators or freezers, shelves, cabinets or countertops or benchtops where blood or OPIM are present
Personal Protective Equipment (PPE)

- Gloves, masks, protective eyewear
Personal Protective Equipment

Specialized clothing or equipment used by workers to protect themselves from direct exposure to blood or OPIM

Considerations: PPE

- Employer shall provide and assure employee use of appropriate PPE such as gloves, gowns, laboratory coats, fluid resistant aprons, face shields, or masks, eye protection and mouthpieces, resuscitation bags, pocket masks or other ventilation devices

- Change if visibly soiled
Personal Protective Equipment (cont)

- Equipment shall be available in a variety of sizes and readily accessible
- Employer provides for the cleaning, laundering or disposal of all PPE
- Disposable gloves replaced when visibly soiled, torn, or punctured, and shall not be washed or disinfected for reuse.
- Utility gloves may be cleaned and disinfected for reuse if they show no signs of deterioration
Recommendations for Gloving

Remove gloves that are torn, cut or punctured

Do not wash, disinfect or sterilize gloves for reuse
Protective Face Masks, Surgical Masks, and Eye Guards

- Required when contamination of mucous membranes with body fluids may occur through splashes or aerosolization of these fluids.
- Prescription glasses may be used as protective eyewear as long as they are equipped with solid side shields.
- If protective eyewear is chosen over the use of a face shield, the eyewear must be worn in combination with a mask to protect the nose and mouth.
HBV Vaccination

- HBV vaccination shall be offered, at no cost, after training and within 10 days of initial job assignment, to all employees whose jobs include risk of directly contacting blood or OPIM.
- Vaccinations shall be given according to recommendations for standard medical practice.
- A declination form must be signed by employee who refuses the HBV vaccination (including those who do not complete the 3 shot series).
Post-Exposure Management Program

- Clear policies and procedures
- Education of healthcare workers
- Rapid access to
  - Clinical care
  - Post-exposure prophylaxis (PEP)
  - Testing of source patients/HCP
Post-Exposure Evaluation and Follow-up

- Within 15 days following report of an exposure incident, the employer shall make available to employee a confidential medical evaluation and follow-up.

- Employer shall document the route of exposure, HBV and HIV status of the source patient, if known, and the circumstances under which the exposure occurred.

- Employer shall notify the source patient of the incident, obtain consent if necessary and test the source for HIV or HBV unless known positive.
Employer shall offer to collect a blood sample from the exposed worker ASAP to test for HIV and or HBV status (if requested, must hold for 90 days)

Employer shall offer HIV testing of baseline, 6 weeks, and 6 months after exposure

Follow-up shall include counseling, medical evaluation of any febrile illness that occurs within 12 weeks

Post-exposure prophylaxis when indicated, as recommended by US Public Health Service
OSHA’s Definition of Medical Waste

OSHA states “regulated waste” is (1) liquid or semi-liquid blood or other potentially infectious material; (2) contaminated items that would release blood or OPIM in a liquid or semi-liquid state if compressed; (3) items that are caked with dried blood or OPIM and are capable of releasing these materials during handling; (4) contaminated sharps; and (5) pathological and microbiological wastes containing blood or OPIM
Infectious Regulated Medical Waste (RMW) Disposal

- Disposal of RMW shall be in accordance with all applicable federal, state, and local regulations.
- All RMW shall be placed in closable, leakproof containers, or bags that are color-coded, labeled or tagged.
- Disposable syringes, needles, scalpel blades and other sharp items shall be placed in puncture-resistant containers for disposal.
Infectious Regulated Medical Waste Disposal (cont)

- Puncture-resistant sharps containers shall be easily accessible to workers and located in areas where they are commonly used
- Double-bagging prior to handling, storing, and/or transporting is necessary if the outside of the bag is contaminated
- Lab specimens of body fluids shall be transported in a container that will prevent leaking and disposed of in accordance with institutional policies and regulatory requirements
Tags, Labels, and Bags

- Tags that are orange-red in color with a contrasting background are acceptable
- Tags shall contain the word “BIOHAZARD” or the biological hazard symbol and
- State the specific hazardous condition or the instructions to be communicated
- Word and message must be understandable to all
Tags, Labels, and Bags (cont)

- Label tags may be part of container or affixed as closely as possible by wire or adhesive to prevent their loss.
- Red bags or red containers may be substituted for labels on containers of Regulated Medical Waste.
- All employees must be informed of meaning of labels/tags.
Handling Specimens

- Employers may avoid labeling only if all employees who have contact with specimen containers can recognize them as requiring Universal Precautions and the employees have been trained to follow Universal Precautions.

- Employers must label or color-code specimen containers whenever they leave the facility.
Housekeeping Practices

- Employer shall assure that the worksite is maintained in a clean and sanitary condition.
- Employer shall determine and implement an appropriate cleaning schedule for rooms where BBP are depending on the site, type of surface, and amount of soil present.
- Employer shall ensure that housekeepers wear appropriate PPE including general purpose utility gloves during all cleaning of BBP and decontamination procedures.
Housekeeping Practices (cont)

- Initial clean-up of blood or OPIM shall be followed with the use of an EPA-approved hospital disinfectant chemical germicide that has either a tuberculocidal or HIV/HBV label claim or a solution of 5.25% sodium hypochlorite (household bleach) diluted between 1:10 and 1:100 with water.

- Equipment contaminated with blood or OPIM shall be decontaminated if possible prior to servicing or shipping.
Laundry Practices

- The employer shall ensure that laundry workers wear protective gloves and other appropriate PPE during handling and sorting of linen.
- Contaminated laundry shall be bagged at the location of use and not sorted or rinsed in patient areas.
- Contaminated laundry shall be placed and transported in bags that are labeled or color-coded that prevent leakage.
- When a facility uses UP in the handling of all soiled laundry, alternative labeling is acceptable if recognizable by all workers.
Provider Education and Training

- Strategies to prevent occupational exposure to blood
- Importance of reporting exposure incidents
- New employee orientation
- Annual inservices
- New procedure or equipment
Training

- Employers must train at-risk employee at no cost and on paid time
- Must train at time of initial assignment and at least annually thereafter, or if new occupational exposure
Training (cont)

- Training program must include
  - accessible copy of regulatory text of standard and explanation
  - general epidemiology and symptoms of BBP
  - explanation of modes of transmission
  - explanation of employer’s exposure control plan and how to get a copy
Training (cont)

- Training program must include
  - explanation of appropriate methods for recognizing tasks that may involve exposure
  - explanation of the use and limitations of methods to prevent exposures
  - info on types, use, locations, removal, handling of PPE
  - explanation of basis for selection of PPE
Training (cont)

- Training program must include
  - info on actions and persons to contact for exposure to BBP
  - method for reporting on exposure incidents
  - info on post-exposure evaluation and follow-up
  - explanation of signs and labels
  - opportunity to question trainer about standard; therefore training cannot be totally by videotape
Recordkeeping

• The employer must keep training records with the following information:
  ■ The dates of the training session
  ■ The contents or a summary of the training session
  ■ The names and qualifications of the persons conducting the training
  ■ The names and job titles of all persons attending the training sessions

• Employers must keep these records for 3 years from the date of the training session
Federal Legislation on Needle Safety

- Bloodborne Pathogens Standard amended with Needlestick Law requirements (Federal Register January 18, 2001)
  - Defining “engineering controls”
  - Exposure control plan requirements
  - Soliciting employee input
  - Recordkeeping
Exposure Control Plan Requirements

- In annual review of ECP employers must consider innovations in procedure or technological developments that reduce the risk of sharps exposure.
- Must state methods used to evaluate and justification for decisions of safety devices.
**Impact of Safety-Engineered Devices on the Incidence of BBP Exposures at UNC Hospitals**

Kanamori et al. ICHE. Feb 2016

Overall BBPE and incidence of percutaneous injuries reduced

---

**Figure 1.** Incidences of blood and body fluid exposures (BBFE) by nature of injury among healthcare personnel, University of North Carolina Hospitals, 2000–2014. Arrow shows the year 2001 of the Needlestick Safety and Prevention Act. FTE, full-time equivalents.
Incidence rate associated with percutaneous devices significantly reduced and percutaneous injuries associated with safety-engineered devices increased.

**Figure 2.** Incidences of percutaneous injuries associated with safety-engineered devices among healthcare personnel, University of North Carolina Hospitals, 2004–2014. FTE, full-time equivalents.
Impact of Safety-Engineered Devices on the Incidence of BBP Exposures at UNC Hospitals
Kanamori et al. ICHE. Feb 2016

The incidence rate for overall BBP was significantly reduced.
Employee Blood Exposures,
UNC Health Care System

Number of Exposures Per 1000 UNC HCS Employees

Years

Number of Exposures Per 1000 UNC HCS Employees

Blood Exposure Trends, 1999-2015

Number of Exposures

Years


Percutaneous/Lacerations
Mucous Membrane/Non-Intact Skin
Bite/Scratch
Blood Exposures by Occupation, 2015

Number of Exposures

- CRNA: 2
- Environmental Services: 2
- Lab: 6
- LPN: 2
- MD: 136
- N/A: 9
- Other: 45
- RN: 151
- Surgical Tech: 18
Devices Associated with Percutaneous Blood Exposures, 2015

Number of Exposures

1cc disposable syringe
1cc or greater safety
Blood Gas
Bone Chip
Drill Bit/Bur
Heparin Needles
Insulin Safety Syringe
Insulin disposable syringe
Introducer, Arterial
Introducer, Central Line
Lancet, Autolo
Lancet, Retractable
Nonvascular (e.g. biopsy)
Other
Pin
Prefilled Cartridge
Safe Needle
Specimen Test Tube
Sideral Sutures
Suture (Non-Blunt)
Suture, Blunt
Towel Clip
Vacuum
Wire

Exposures
Soliciting Employee Input

- Employers must invite participation of non-managerial employees who are potentially exposed to sharps injuries to participate in identification, evaluation and selection of engineering and work practice controls.

- Explain in exposure control plan how employer solicited employee participation.
The American Dental Association v. Martin decision upheld the bloodborne pathogen standard but restricted its application in home health services provided in private homes.

...feasibility of off-site control not appropriate

...OSHA may not cite employers when hazard is site-specific (housekeeping requirements such as clean and sanitary worksite, handling and disposal of regulated waste, ensuring use of PPE, engineering controls and handwashing)
The employer will be held responsible for all non-site specific requirements of the exposure control plan:

- hepatitis B vaccination
- post-exposure evaluation and follow-up
- recordkeeping
- generic training requirements
- appropriate supply of PPE
OSHA’s Mandate

• OSHA’s mission is to protect the healthcare worker

• OSHA Rule is required compliance under Federal Law