USACHPPM TG 190

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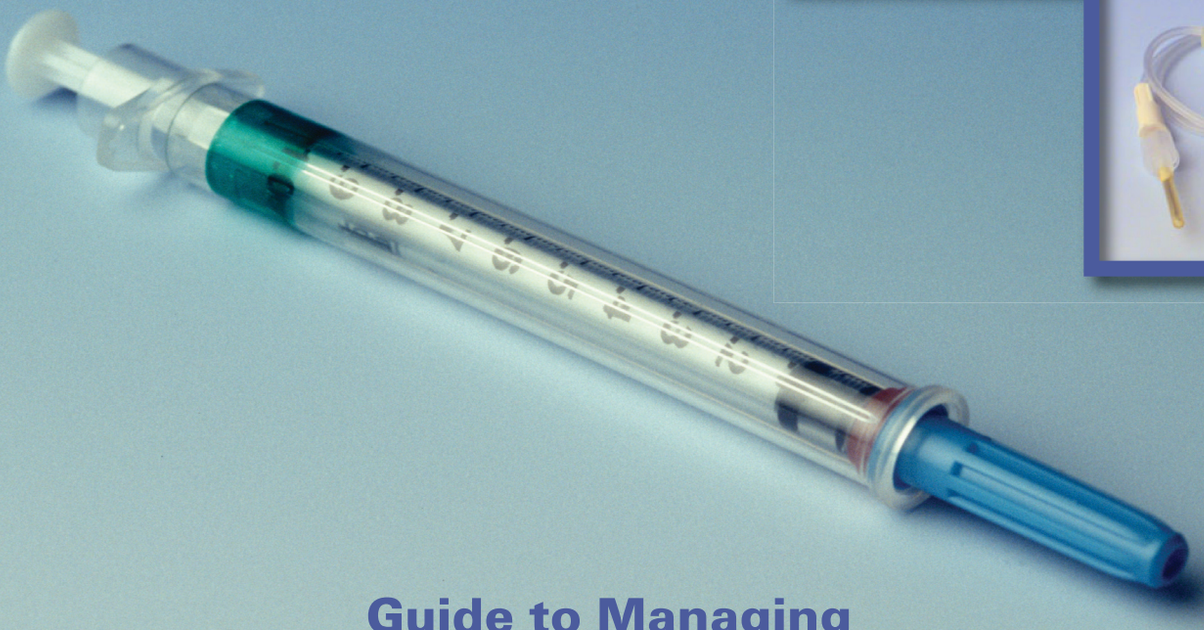

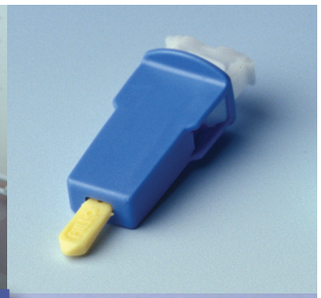

Guide to Managing Occupational Exposure to...

BLOODBORNE PATHOGENS

USACHPPM
Readiness thru Health

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INTRODUCTION

HISTORY

This is the second printing of *USACHPPM Technical Guide (TG) 190*, *Guide to Managing Occupational Exposure to Bloodborne Pathogens (BBPs)*. This update includes new provisions required by the Needlestick Safety and Prevention Act (Public Law 106-430) and the Occupational Safety and Health Administration's (OSHA's) new recordkeeping standard (29 CFR 1910.1904.8).

President Clinton signed the Needlestick Safety and Prevention Act into law on 6 November 2000 and it became effective on 18 April 2001. The Act directed the OSHA to revise 29 Code of Federal Regulations (CFR) 1910.1030, Bloodborne Pathogens and include —

- New examples in the definition of engineering controls and two new terms: needleless systems and sharps with engineered sharps injury protection (SESIP)
- A requirement to document in the Exposure Control Plan (ECP) modifications intended to eliminate or reduce worker exposure to BBPs; consideration and implementation of appropriate, commercially available, and effective safer medical devices; and worker involvement in the identification, evaluation, and selection of effective engineering and work practice controls
- A requirement to establish and maintain a sharps injury log

PURPOSE

TG 190 is designed to assist Infection Control, Safety, Environmental Science Officers, and Occupational Health and Industrial Hygiene personnel in developing and implementing their local ECPs. *TG 190* describes strategies for protecting workers against occupational exposures to BBPs and other potentially infectious materials (OPIM). It also contains information to enhance regulatory compliance with the BBP standard.

SCOPE AND APPLICATION - 29 CFR 1910.1030 (a) *Scope and Application*

Because there is no population that is free of risk from infection from BBPs, all workers having reasonably anticipated occupational exposure to blood or OPIM are included within the scope of the standard.

Bloodborne Pathogens

BBPs are infectious agents present in human blood and can cause disease in humans. BBPs include, but are not limited to –

- Human immunodeficiency virus (HIV)
- Hepatitis B virus (HBV)
- Hepatitis C virus (HCV)
- Hepatitis D virus (HDV)

Occupational Exposure to Blood and OPIM

Occupational exposure to blood and OPIM include –

- Contaminated needle-stick injuries
- Blood or body fluid contamination of eye, mouth or other mucous membranes
- Contact to non-intact skin, such as cuts, scrapes, burns, and dermatitis

Table 1, Bloodborne Diseases, describes the epidemiology, symptoms, and modes of transmission for these bloodborne diseases.

Table 1. Bloodborne Diseases

HIV Infection, Acquired Immunodeficiency Syndrome (AIDS) Human immunodeficiency virus (HIV) **HIV damages the body's immune system. Without the immune system's protection, the body is defenseless against serious and potentially life-threatening diseases, which can lead to the development of AIDS, the later stage of HIV infection.**	
Symptoms	• Fever • Weight loss • Swollen lymph glands in the neck, under arms or groin • White patches in the mouth (thrush) • Certain cancers (Kaposi's sarcoma, certain lymphomas, certain invasive cervical cancers) • Certain infections (Pneumocystis pneumonia, certain types of meningitis, toxoplasmosis) • Certain blood infections • Tuberculosis
Disease Spread	Through contact with infected blood, through sex with an infected person, and from mother to child during childbirth or by breast-feeding.
People at Risk	People who share needles, men who have sex with other men, babies born to mothers who have HIV infection, people who received blood transfusions or blood products before 1985, anyone who has sex with anyone who has or is at risk for AIDS or HIV infection.
Prevention	Abstaining from sex, monogamy, and use of barrier protection (condoms), following safe work practices (universal precautions), and avoiding behaviors like sharing drug needles.
Treatment	Many drugs are available to treat the infections and cancers associated with AIDS. There are also drugs available for people with HIV infection that can help prevent them from getting sicker.

***Viral Hepatitis* is inflammation of the liver. Hepatitis A, B. C, D, and E viruses cause acute, or short-term viral hepatitis. The Hepatitis B, C, and D viruses are considered bloodborne diseases, that can also cause chronic hepatitis, in which infection is prolonged, and sometimes lifelong.**	
Symptoms	• Jaundice (yellowing of the skin and eyes) • Fatigue • Abdominal pain • Loss of appetite • Nausea • Diarrhea • Vomiting Some people do not have symptoms until the disease is advanced.
Hepatitis B	**Disease Spread** Through contact with infected blood, through sex with an infected person, and from mother to child during childbirth.
	People at Risk Injection drug users, people who have sex with an infected person, men who have sex with men, children of immigrants from disease-endemic areas, people who live with an infected person, infants born to infected mothers, health care workers, and hemodialysis patients.
	Prevention Hepatitis B vaccine.
	Treatment Drug treatment with alpha interferon or lamivudine.
Hepatitis C	**Disease Spread** Primarily through contact with infected blood; less commonly, through sexual contact and childbirth.
	People at Risk Infectious drug users, hemodialysis patients, health care workers, people who have sex with an infected person, people who have multiple sex partners, infants born to infected women, and people who received a transfusion of blood or blood products before July 1992 or clotting factors made before 1987.
	Prevention There is no vaccine for Hepatitis C. The only way to prevent the disease is to reduce the risk of exposure to the virus. This means following safe work practices and avoiding behaviors like sharing drug needles or sharing personal items like toothbrushes, razors, and nail clippers with an infected person.
	Treatment Drug treatment with alpha interferon or combination treatment with interferon and the drug ribavirin.

Hepatitis D	**Disease Spread** Through contact with infected blood. This disease occurs only in people who are already infected with Hepatitis B.
	People at Risk Anyone infected with Hepatitis B. Injection drug users who have Hepatitis B have the highest risk. People who have Hepatitis B are also at risk if they have sex with a person infected with Hepatitis D or if they live with an infected person.
	Prevention Immunization against Hepatitis B for those not already infected; also following safe work practices and avoiding behaviors like sharing drug needles or sharing personal items like toothbrushes, razors, and nail clippers with an infected person.
	Treatment Drug treatment with alpha interferon.

Exposure to infectious materials affects workers in many types of employment and is not restricted to the health care industry. At the same time, all health care workers (HCWs) are not automatically covered by the standard unless they have potential or actual occupational exposure. The following job classifications may have tasks with occupational exposure to blood and OPIM –

- Physicians, physician's assistants, nurses, nurse practitioners, and other HCWs in clinics, physicians' offices, and hospitals
- Workers in clinical and diagnostic laboratories
- Housekeepers in health care facilities
- Personnel in hospital or commercial laundries that service health care or public safety institutions
- Tissue bank personnel
- Workers in blood banks and plasma centers who collect, transport, and test blood
- Freestanding clinic workers (e.g., hemodialysis clinics, urgent care clinics, health maintenance organization (HMO) clinics, and family planning clinics
- Workers in clinics in industrial, educational, and correctional facilities (e.g., those who collect blood and clean and dress wounds)
- Dentists, dental hygienists, dental assistants, and dental laboratory technicians
- Staff of institutions for the developmentally disabled
- Hospice workers
- Home HCWs

- Staff of nursing homes and long-term care facilities
- Workers in funeral homes and mortuaries
- HIV and HBV research laboratory and production facility workers
- Workers handling regulated medical waste (RMW)
- Medical equipment service and repair personnel
- Emergency medical technicians, Paramedics, and other emergency medical service providers
- Firefighters, law enforcement personnel, and correctional officers
- Lifeguards
- Part-time, temporary, and HCWs known as "per diem" employees
- Workers trained in first aid and designated by the employer as responsible for rendering medical assistance as part of their job duties
- Workers in the maritime industry who have occupational exposure to blood or OPIM

Good Samaritan Acts

Good Samaritan acts are not covered by the BBP standard. These acts involve a worker coming to the aid of a fellow worker that results in an exposure to blood or OPIM.

ADDITIONAL ASSISTANCE

Questions on any of the information in this TG may be directed to the Industrial Hygiene Medical Safety Management Program at DSN 584-2439 or commercial (410) 436-2439.

EXPOSURE CONTROL - 29 CFR 1910.1030 (c)

The ECP is a written document that sets forth policies and procedures to protect workers from occupational exposure to blood and OPIM.

EXPOSURE CONTROL PLAN

The ECP is a key provision of the standard because it requires the employer to identify the –

- Tasks and procedures with occupational exposure
- Job classifications that include tasks and procedures identified as having occupational exposure
- Workers who must receive training, personal protective equipment (PPE), vaccination, and other protections of the standard

Employers may develop a cohesive written plan or develop a guiding document that states the organization's overall policy goals and references the elements of existing separate policies, such as the Infection Control Manual, that contain the plan. Incorporation of the ECP into a larger document, such as an Infection Control Manual, will –

- Prevent policy/procedure duplication
- Allow for easy cross-referencing of the ECP sub-elements to specific infection control policies (for example, standard precautions (SP)) or specific safety policies (for example, RMW)
- Confirm the consistency between related infection control and safety policies and procedures

One disadvantage of incorporating the ECP into a larger document such as an Infection Control Manual is that the annual review may become a daunting process.

The ECP must include –

Exposure Determinations

Employers must conduct exposure determinations to identify and document–

- Job classifications in which all workers have occupational exposure (see Table 2)

- Job classifications with the tasks and procedures in which some workers have occupational exposure (see Table 3)

The specific tasks and procedures, or groups of closely related tasks and procedures that are associated with occupational exposure, must be defined when only some of the workers in a classification have occupational exposure. For example, all workers in a hospital laundry room have the same job title and classification, but only some of the workers are assigned the task of handling contaminated laundry. Also, the tasks and procedures that are grouped must be related (e.g., share a common activity such as performing vascular access procedures, handling of contaminated sharps, or handling of deceased persons).

Exposure determinations must be made without taking into consideration the use of PPE since use of PPE alone will not ensure protection from occupational exposure.

Table 2. Examples of Job Classifications in Which All Workers (Military or Civilian) Have Occupational Exposure to Blood or OPIM*

JOB CLASSIFICATIONS	
Assistant ***Autopsy*** ***Biological Services*** ***Field Medical*** ***Nursing*** ***Physician's***	**Pathologist**
Biochemist	**Patient Transporter**
Biologist/Histologist	**Phlebotomist**
Clinical Chemist	**Physician**
Dental ***Assistant*** ***Dentist*** ***Hygienist*** ***Laboratory Specialist*** ***X-Ray Technician***	**Radiologist**
Emergency Room Personnel	**Students ****
Enlisted Personnel (All 91 Series)	**Surgeon**
Medical Equipment Repairer	**Technician** ***Biological Laboratory*** ***Emergency Medical*** ***Medical*** ***Medical Instrument*** ***Medical/Surgical/Health*** ***Surgical*** ***X-Ray***
Medical Laboratory Specialist	**Technologist** ***Blood Bank*** ***Diagnostic Radiologic*** ***Medical***
Microbiologist	**Veterinary Microbiologist**
Midwife	**Veterinary Pathologist**
Mortician	**Volunteers ****
Nurse ***Practical*** ***Registered***	**Worker** ***Laboratory*** ***Laundry***
Oral Surgeon	

*This list of job classifications in which all workers have occupational exposure is not exhaustive.

**Employers are legally bound by OSHA to protect exposed employees. However, employers should consider the moral issues and protect all exposed individuals who perform some function (voluntary, educational, etc.) in their facilities. Additionally, the Staff Judge Advocate (SJA) has determined that, "exposing personnel, including students and volunteers, to hazardous materials without providing every reasonable protection may be considered employer negligence," since "... the Government is always subject to liability for personal injury caused by the wrongful acts or omissions of Federal employees acting within the scope of employment."

Table 3. Examples of Job Classifications in Which Some Workers (Military or Civilian) Have Occupational Exposure to Blood or OPIM*

JOB CLASSIFICATION	TASK
Child Care Givers	Administering first aid or cardiopulmonary resuscitation (CPR) to children
Clinic Receptionist	Receiving and transporting laboratory specimens
Central Material Services (CMS) Personnel	Handling contaminated instruments
Dental Receptionist	Filling in for dental assistant
Engineering Personnel	Installing, repairing, moving, and removing systems and equipment (medical/surgical vacuum, Biological Safety Cabinets (BSCs), High-Efficiency Particulate Air (HEPA) filters, ducting, etc.)
Firefighter/Rescue Worker	Making informed judgments at accident scenes, fires, or other unpredictable, dangerous, and life-threatening situations
Food Service Worker	Picking up trays after meals (improperly disposed needles are the primary means of exposure)
Housekeeper	Cleaning patient care areas and laboratories; collecting, transporting, storing, and disposing of regulated waste
Lab Medical Clerk	Receiving and transporting laboratory specimens
Lab Receptionist	Receiving and transporting laboratory specimens
Laundry Handler	Collecting, transporting, and processing soiled linen
Law Enforcer	Making an informed judgments at crime scenes and after fights and/or assaults to protect oneself since unusual circumstances or events arise
Optometrist	Examining ocular trauma patients
Recreation Sports Specialist	Administering first-aid to participants injured during sporting activities
Ward Clerk	Receiving and transporting laboratory specimens
Warehouse Worker	Handling packages containing unfixed tissue

* This list of job classifications in which *some* workers have occupational exposure is not exhaustive.

Schedule and Method of Implementation

The schedule and method of implementation for the following elements of the standard, appropriate to the circumstances of the particular workplace, must be addressed in the ECP –

- Methods of Compliance
- HIV and HBV Research Laboratories and Production Facilities
- Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-Up
- Communication of Hazards to Workers
- Recordkeeping

Small facilities may annotate a copy of the final standard, stating when and how the provisions of the standard were implemented. Larger facilities may develop a broad facility-wide program incorporating provisions from the standard that apply to their workplaces.

Exposure Incident Evaluation Procedures

The ECP must include the procedures for evaluating the circumstances surrounding exposure incidents, including:

- An evaluation of the policies and "failures of control" at the time of the exposure incident
- Engineering and work practice controls in place at the time of the incident
- PPE used at the time of the incident

ECP AVAILABILITY

The ECP must be available in a location accessible to all workers. The location of the plan may be adapted to the circumstances of a particular workplace provided workers can access a copy at the workplace during the work shift. If the plan is maintained solely on computer, workers must be trained to operate the computer and the computer must be accessible by workers during the work shift. If the plan is comprised of several policy documents, copies of all of the documents must be available.

A hard copy of the plan must be made available to workers within 15 working days of their requests. Also, the ECP must be made available to OSHA's Assistant Secretary of Labor and the Director of National Institute for Occupational Safety and Health (NIOSH), or their designated representatives.

ECP ANNUAL REVIEW

The ECP **must** be reviewed and updated at least annually and as often as necessary to ensure the ECP remains current. The annual review should reflect –

- New or modified tasks and procedures that affect occupational exposure
- New and revised job classifications that include identified tasks and procedures with occupational exposure
- Changes in technology that eliminate or reduce exposure to BBPs
- Consideration and implementation of appropriate commercially available and effective engineering controls designed to eliminate or minimize exposure
- Input from non-managerial workers who are at risk of sharps related injuries, regarding the identification, evaluation, and selection of SESIP

METHODS OF COMPLIANCE - 29 CFR 1910.1030 (d)

The OSHA requires employers to implement measures that will protect workers' health by preventing occupational exposures to BBPs. This section of the standard addresses four fundamental principles for preventing or reducing occupational exposure to BBPs —

- Universal precautions (UP) or acceptable alternatives
- Engineering and work practice controls
- Personal protective equipment (PPE)
- Proper housekeeping

UNIVERSAL PRECAUTIONS

UP are —

- A set of safety measures designed to prevent transmission of HIV, HBV, and other BBPs when providing first aid or health care. Under UP, all human blood and OPIM are treated as if they are infectious with HIV, HBV, or other BBPs regardless of the perceived "low risk" of a patient or patient population
- OSHA's accepted method of control to protect workers from exposure to all human blood and OPIM

UP require —

- Routine use of appropriate PPE (gloves, masks, protective eyewear, gowns, etc.) to prevent skin and mucous membrane contact with blood and OPIM
- Immediate washing of hands and other skin surfaces with soap and water after any contact with blood, OPIM, or contaminated items or surfaces even if gloves were worn and after removing gloves
- Safe handling and disposal of needles, scalpels, and other sharp instruments
- Availability and use of mouthpieces, resuscitation bags, or other breathing devices for mouth-to-mouth resuscitation

UP apply to —

- Blood and OPIM listed in Table 4
- All body fluids in situations where it is difficult or impossible to differentiate between body fluid types
- Any unfixed tissue or organ other than intact skin from a human (living or dead)
- HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing cultures or other solutions, as well as blood, organs, or other tissues-from experimental animals infected with HIV or HBV
- Immune globulins, albumin, and other products derived from human blood

Table 4. Application of UP to Blood and Body Fluids

Body Fluids to which UP Apply	Body Fluids to which UP Do Not Apply*	Precautions for Other Body Fluids in Special Settings
Blood	**Nasal secretions**	**Human breast milk in settings where exposure is frequent, such as breast milk banks**
Body fluids containing visible blood	**Sputum**	
Saliva in dental settings	**Sweat**	
Semen	**Tears**	
Vaginal secretions	**Urine**	
Tissues	**Vomitus**	
Cerebrospinal fluid	**Feces**	
Synovial fluid		
Pleural fluid		
Peritoneal fluid		
Pericardial fluid		
Amniotic fluid		

* Unless these body fluids contain visible blood and/or are encountered in situations where it is difficult or impossible to differentiate between body fluids.

UP Alternatives

Acceptable alternatives to UP are **body substance isolation (BSI)** and **standard precautions (SP)**, provided the employer adheres to all other provisions of the BBP standard. These alternatives are normally used by the health care industry.

Body Substance Isolation (BSI)

BSI incorporates the fluids and materials covered by the BBP standard, and expands coverage to include all moist and potentially infectious body substances from all patients.

BSI require —

- Wearing of gloves where contact with moist body substances are likely
- Hand washing after glove removal if hands are visibly soiled

BSI apply to —

- Blood
- Feces
- Urine
- Sputum
- Saliva
- Wound drainage
- Other body fluids

Standard Precautions (SP)

SP combine the major features of UP and BSI, and apply them to all patients receiving care in hospitals, regardless of their diagnosis or presumed infection status. Because SP were developed to reduce risk of transmission of microorganisms from recognized and unrecognized sources of infection in hospitals, they may not be appropriate for other settings where UP are used, such as schools and child care settings.

SP require –

- Immediate washing of hands with soap and water after contact with blood, body fluids, secretions, excretions, and contaminated items even if gloves were worn; after removing gloves; between patient

contacts; and between tasks and procedures on the same patient to prevent cross-contamination of different parts of the body
- Use of anti-microbial soap or waterless antiseptics as specified in the organization's Infection Control Program
- Wearing of gloves where contact with blood, body fluids, secretions, excretions, non-intact skin, mucous membranes, and contaminated items are likely
- Wearing of PPE (gloves, masks, protective eye wear, gowns, etc.) during activities that are likely to produce splashes or sprays of blood or other body fluids
- Prompt removal of soiled PPE, cleaning and disinfecting reusable PPE, and proper disposal of single-use items
- Proper handling and processing of soiled linen; cleaning and disinfecting or sterilizing of reusable patient-care equipment, and routine cleaning and disinfecting of environmental surfaces
- Safe handling and disposal of needles, scalpels, and other sharp instruments
- Availability and use of mouthpieces, resuscitation bags, or other breathing devices for mouth-to-mouth resuscitation
- Placing a patient whose blood or body fluids are likely to contaminate surfaces or other patients, in an isolation room or area

SP apply to —

- Blood and body fluids, secretions, and excretions (except sweat) whether or not they contain visible blood
- Non-intact skin
- Mucous membranes such as those in the eyes, nose, and mouth

ENGINEERING CONTROLS AND WORK PRACTICE CONTROLS

Engineering and work practice controls must be used to eliminate or minimize risk of occupational exposure to BBPs resulting from —

- Parenteral contact with blood or OPIM
- Contact between mucous membranes and blood and OPIM
- Ingestion, absorption, or inhalation of blood or OPIM

Workers must use PPE in combination with engineering and work practice controls when occupational exposure to BBPs remains after appropriate controls are instituted.

Engineering controls –

- Eliminate or reduce occupational exposures to BBPs by removing or isolating the hazard
- Must be used whenever there is evidence that they will eliminate or reduce worker exposure
- May require routine preventive maintenance or replacement to sustain operability
- Are most effective when used in combination with work practice controls

Examples of engineering controls include –

- Safer medical devices, such as sharps with engineered sharps injury protection (SESIP), needleless systems, blunted suture needles, and plastic capillary tubes
- Sharps disposal containers
- Biological safety cabinets (BSCs)
- Centrifuge safety equipment such as safety cups, rotors with covers, and O-rings
- Mechanical pipetting aids
- Splash shields
- Dental dams

Table 5 provides a listing of some commercially available engineering controls and their use in a variety of work settings.

Table 5. Engineering Controls for Certain Work Settings

Health care	Research and Production Laboratories	Emergency Response
-Puncture-resistant sharps disposal containers	-Puncture-resistant sharps disposal containers	-Pocket mouth-to-mouth resuscitation devices
-Sharps with engineered sharps injury protection	-Biological safety cabinets	-Disposable airway equipment
-Needleless systems	-Centrifuge safety equipment	-Resuscitation bags and mechanical respiratory assistance devices (for example, oxygen demand valve resuscitators)
-Puncture-resistant and leak proof specimen containers	-Puncture-resistant and leak proof specimen containers	
-Instrument retrieval mechanical devices	-Containment caging for animals	
-Dental high-speed evacuators	-Mechanical pipetting aids	
-Dental dams	-Splash guards	

Engineering Control Maintenance Program

Employers must examine and maintain or replace engineering controls on a regular schedule to ensure their proper function and effectiveness. Also, employers must determine the appropriate frequency for inspecting each control used. For example, employers should conduct routine inspections of the workplace to verify that —

- Protective shields have not been removed or broken
- Sharps disposal containers are being replaced at sufficiently frequent intervals to prevent overfilling
- Ventilation systems in HIV/HBV research laboratories are operational
- Other physical or mechanical controls are functioning as intended

Department of Defense Policy Letter on Needlestick Safety for Health care Workers Requires Services to —

- Comply with the newly revised OSHA 29 CFR Part 1910 and all applicable state regulations

- Coordinate all safety device decisions under the guidance of the Regional Tri-Service Product Standardization Boards
- Include workers representing the range of exposure situations encountered in the workplace in Clinical Product Teams for needlestick safety devices
- Submit the Quarterly Product Standardization Reports to the TRICARE Management Activity

A copy of the DOD policy letter is provided in Appendix C.

Sharps Injury Prevention Program

An organization-wide Sharps Injury Prevention Program is one approach employers can use to systematically consider and implement safer medical devices. Key elements of a Sharps Injury Prevention Program are —

- Obtaining leadership and support for the patient/worker safety program from senior management
- Designating a person in charge and a multi-disciplinary team responsible for program development and implementation (for example, representation from infection control, risk management, quality improvement, nursing, medical staff, laboratory, occupational health, safety, logistics, and end users, as appropriate)
- Establishing program goals and components necessary for reaching goals
- Collecting data and identifying devices, work areas, procedures, and job classifications with the greatest risk of exposure to BBPs
- Prioritizing devices targeted for replacement, pilot-testing, and implementing safer medical devices
- Educating and training workers on the use of safer medical devices
- Monitoring the program for opportunities for improvement and for effectiveness

The American Hospital Association's Sharps Injury Prevention Program explains each of these program elements in greater detail (see Pugliese, references pg H-2).

Safer medical devices

Employers must select and use safer medical devices to prevent sharps injuries based on reasonable judgment. The device must:

- Not jeopardize patient or worker safety
- Be appropriate for the medical procedure

- Reduce the likelihood of a sharps injury
- Be commercially available
- Comply with the FDA's recommended design features for safer medical devices

Design features of safer medical devices as recommended by the FDA are—

- The safety feature provides a barrier between the worker's hands and the needle after use
- The safety feature allows or requires the worker's hands to remain behind the needle at all times
- The safety feature is an integral part of the device and not an accessory
- The safety feature is in effect before disassembly and remains in effect after disposal to protect workers who may subsequently handle the device
- The device is simple and easy to use, requiring little or no training

Commercially available safer medical devices include —

- Injection equipment used for intramuscular and subcutaneous injections and includes disposable syringes (syringe and needle), needles with needle guards for attachment to syringes, and needleless jet injection systems
- Medication vial adaptors used to access ports of medication vials
- Intravenous (IV) medication delivery systems used to administer medication or fluids through an IV catheter port or IV connector site
- IV insertion equipment used to access the bloodstream for IV administration
- Blood collection equipment such as blood collection needles, reusable and disposable needle holders/housing, and vacuum blood collection tubes
- Lancets
- Laboratory devices such as hemoglobin readers, mylar-wrapped glass capillary tubes, plastic capillary tubes, plastic fingerstick sampling blood collection tubes, protected needles for blood culture vial access, slide preparation devices, and vacuum tube stoppers
- Blood bank and nuclear medicine devices

- Surgical devices such as quick-release scalpel blade handles, retracting scalpels, blunted suture needles, alternative skin closure devices, magnetic floor sweep, hands-free transfer disposable magnetic drapes, sharps counting and disposal systems, cut- or puncture-resistant barrier gloves and protective pads
- Hemodialysis devices
- Apheresis and fluid sampling devices
- Sharps disposal containers
- Bone marrow collection systems

Evaluation of safer medical devices
To help employers comply with the Needlestick Safety and Prevention Act, OSHA has included forms for evaluating safer medical devices in OSHA Directive CPL 2-2.69, Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens. This reference document is available online at
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=DIRECTIVES&p_id=2570#APPB

Resources for obtaining safer medical devices
Current vendors for obtaining safer medical devices are provided in Table 6. However, readers should periodically review electronic resources for new information on commercially available safer medical devices and the resources for obtaining them. Two recommended on-line resources are —

- University of Virginia's International Health care Worker Safety Center **http://www.healthsystem.virginia.edu/internet/epinet/**
- California Department of Health Services Sharps Program **http://www.dhs.cahwnet.gov/ohb/SHARPS/Default.htm**

Table 6. Vendor List for Obtaining Safer Medical Devices

COMPANY NAME		
Health care Corp. Route 120 and Wilson Rd. Round Lake, IL 60073 888/229-0001 847/546-6311 FAX 847/270-3391	Bayer Corp. Diagnostics Div. 511 Benedict Ave. Tarrytown, NY 10591 800/431-1970 x. 2973	B. Braun Medical Inc. 824 12th Ave. Bethlehem, PA 18018 800/523-9695 610/691-5400 FAX 610/691-6249
Becton Dickinson One Becton Dr. Franklin Lakes, NJ 07417 888/237-2762 201/847-4500 FAX 201/847-6475	Beech Medical Products 16 S. State St. Newtown, PA 18940 800/235-5833 215/579-1570 FAX 215/579-4585	Bemis Manufacturing Corp. 300 Mill St. Sheboygan Falls, WI 53085 800/558-7651 920/467-4621
BioAccess 4000 Hudson Street Baltimore, MD 21224 410/675-8586	Bioject, Inc. 7620 SW Bridgeport Rd. Portland, OR 97224 800/683-7221 503/639-7221 FAX 503/624-9002	Bio-Plexus, Inc. 129 Reservoir Rd. Vernon, CT 06066 800/223-0010 860/870-6112 FAX 860/870-6118
Care Medical Distributed by Empire Medical Products Albany, NY 800/836-8492	Cell Robotics International, Inc. 2715 Broadbent Parkway, NE Albuquerque, NM 87107 800/846-0590 x 100 FAX 505/344-8112	Chronimed Inc. 13911 Ridgedale Dr. Minnetonka, MN 55305 800/888-5957
DeRoyal 200 DeBusk Lane Powell, TN 37849 800/261-9864	Discount Medical Supply, Inc. 13212 Raymer St. North Hollywood, CA 91605 800/366/0546 FAX 818-982-8539	Drummond Scientific Co. 500 Parkway, Box 700 Broomail, PA 19008 800/523-7480
Edge Medical 1107 Fair Oaks Ave. Suite 106 Pasadena, CA 91030 310/275-7654	Ethicon, Inc. Div./Johnson & Johnson Medical, Inc. P.O. Box 151 Somerville, NJ 08876 800/438-4426	Ethicon Endo-Surgery Div./Johnson & Johnson Medical, Inc. 4545 Creed Road Cincinnati, OH 45242 800/USE-ENDO (800/873-3636)

Equidyne Systems **11770 Bernardo Plaza Court** **Suite 351** **San Diego, CA 92128** **877/474-6539** **FAX 858-451-7002**	**Futura Medical Corp.** **380 Stevens Ave, Suite 212** **Solana Beach, CA 92075** **800/631-0076** **505/342-9638** **FAX 505/342-9735**	**Gimbel Glove Company** **10640 N. 28th Drive A-200** **Phoenix, AZ 85029** **888/NO-STICK**
Greiner Meditech, Inc. **260 Gateway Dr., Suite 17A** **Bel Air, MD 21014** **888/286-3883** **Helena Laboratories** **P.O. Box 752** **Beaumont, TX 77704** **800/231-5663 x252**	**HemoCue, Inc.** **23263 Madero, Suite C** **Mission Viejo, CA 92691** **800/323-1674** **714/859-2630**	**Hemox, Inc.** **P.O. Box 362115** **Melbourne, FL 32936-2115** **800/323-4393** **407/777-4772**
ICU Medical **951 Calle Ananecer** **San Clemente, CA 92673** **800/824-7890** **714/366-2183**	**InjectiMed, Inc.** **Frontline Medical Products** **2737 Palma Dr.** **Ventura, CA 93003** **805/658-1601** **FAX 805/658-7625**	**Innovative Laboratory Acrylics, Inc.** **P.O. Box 956** **Brighton, MI 48116** **800/777-5511**
International Medication Systems (IMS) Ltd. **1886 Santa Anita Ave.** **South El Monte, CA 91733** **800/423-4136** **818/442-6757** **FAX 818/913-4728**	**International Technidyne Corp. (ITC)** **8 Olsen Ave.** **Edison, NJ 08820** **732/548-5700**	**Isolyser Health care** **650 Engineering Dr.** **Norcross, GA 30092** **770/582-6363**
JMS North America Corporation **22320 Foothill Blvd.** **Suite 350** **Hayward, CA 94521** **510/888-9090** **Fax 510/888-9099**	**Johnson & Johnson Medical, Inc.** **2500 Arbrook Blvd.** **Arlington, TX 76014** **800/433-5170** **817/465-3141**	**M.C. Johnson Co., Inc.** **2037 J&C Blvd.** **Naples, FL 34109-6213** **800/553-8438** **941/591-2600** **Fax 800/643-0343**

Kendall Health care Products Co. **15 Hampshire St.** **Mansfield, MA 02048** **800/325-7472**	**MPS Acacia** **499 Nibus Street** **Brea, CA 92821** **800/486-6677** **714/257-0470** **FAX 800/299-4849** **FAX 714/257-0513**	**Maxxim Medical** **1445 Flat Creek Road** **Athens, TX 75751** **800/456-7701**
McGaw, Inc. **2525 McGaw Ave.** **P.O. Box 19791** **Irvine, CA 92713** **800/345-7744** **714/660-2000**	**MedCare Medical Group, Inc.** **Safety Products Division** **234 Old Homestead Highway** **East Swanzey, NH 03446** **800/243-2442** **603/352-3230 in NH**	**Medical Safety Products, Inc.** **2771 West Oxford Ave., #1** **Englewood, CO 80110** **800/677-1115**
Medi-Hut Co., Inc. **1935 Swarthmore Avenue** **Lakewood, NJ 08701** **732/901-0606** **FAX 732/901-1177**	**Medisystems Corp.** **701 Pike Street, 16th Floor** **Seattle, WA 98101-3016** **800/369-6334** **303/646-5212** **FAX 303/646-5219**	**Miles, Inc./Diagnostic Div.** **P.O. Box 3100** **Elkhart, IN 46515** **800/248-2637**
New Medical Technology, Inc. **1500 W. Oak St., Suite 200** **P.O. Box 317** **Zionsville, IN 46077** **800/522-1512** **317/733-9560** **FAX 317/733-9563**	**NIC Americas, Inc.** **P.O. Box 1945** **Duluth, GA 30096** **770/814-2954**	**Norfolk Scientific Statspin Technology** **85 Morse St.** **Norwood, MA 02062** **800/782-8774**
North American Medical Products, Inc. (NAMP) **Draper Center** **901 Vischer Ave.** **Schenectady, NY 12306** **800/488-6267** **518/847-1646** **FAX 518/347-1648**	**On-Gard Systems, Inc.** **1800 15th St.** **Denver, CO 80202** **800/878-8111** **303/825-5210**	**Owen Mumford, Inc.** **849 Pickens Industrial Dr.** **Suite 14** **Marietta, GA 30062** **800/421-6936** **FAX 770/426-5365**

Personna Medical **Div./American Safety Razor Co.** **1 Razor Blade Lane** **P.O. Box 979** **Verona, VA 24482-0979** **800/457-2222**	**Post Medical** **P.O. Box 29863** **Atlanta, GA 30359** **800/876-8678** **404/475-0667**	**Premium Plastics Inc.** **465 W. Cermak Rd.** **Chicago, IL 60616-1992** **800/621-1550** **312/225-8700**
Pro-Western Plastics Inc. **Box 261** **30 Riol Dr.** **St. Albert, AB T8N 1N3** **CANADA** **403/459-4491**	**Qlicksmart Pty. Ltd.** **1/148 Boundary Street** **West End, Qld 4101** **Australia** **International:** **61/7/3844/1182** **U.S.: 800/714/1304** **FAX: 61/7/3844/1183**	**Retractable Technologies, Inc.** **622 South Mill St.** **Lewisville, TX 75057** **888/703-1010** **972/221-6644** **FAX 972/221-9786**
Roche Diagnostics Corporation **9115 Hague Road** **Indianapolis, IN 46250** **800-428-5074**	**Safe-Tec Clinical Products, Inc.** **142 Railroad Dr.** **Ivyland, PA 18974** **800/356-6033**	**Safetech Intl., Inc.** **Distributed by Medical Specialties Group, Inc.** **58 Norfolk Ave.** **South Easton, MA 02375** **800/967-6400**
Safety 1st Medical Inc. **30100 Town Center Dr.** **Laguna Niguel, CA 92677** **800/997-2331**	**Safety Medical Supply International** **729 Boylston St.** **Boston, MA 02116** **617/262-7373**	**SafetySyringes, Inc.™** **1925 Palomar Oaks Way, Suite 204** **Carlsbad, CA 92008** **877/477-0776** **760/918-9908** **FAX 760/918-0565**
Sage Products Inc. **815 Tek Dr.** **Crystal Lake, IL 60014** **800/323-2220** **815/455-4700**	**Sanofi Winthrop Hospital Products** **90 Park Ave.** **New York, NY 10016** **800/446-6267** **212/907-2000** **FAX 212/907-3626**	**Septodont, Inc.** **New Castle, DE 19720** **800/872-8305** **Sherwood Davis & Geck (see Kendall Health care Products Inc.)**

SIMS Portex, Inc. **10 Bowman Dr.** **P.O. Box 0724** **Keene, NH 03431** **800/258-5361** **603/352-3812** **FAX 603/352-3703**	**Specialized Health Products, Inc.** **655 E. Medical Dr.** **Bountiful, UT 84010** **800/306-3360**	**Sterimatic Ltd** **Abnash** **Chalford Hill** **Stroud, Glos. UK** **44(0)1453884944** **FAX44(0)1453886481**
Sterimatic Medical Corp. **22 Main St.** **Southboro, MA 01772** **800/554-4066** **508/485-7695** **FAX 508/485-7695**	**StickSafe, LLC** **465 Ware St.** **Mansfield, MA 02048** **888/914-9600**	**Syncor International Corporation** **6464 Canoga Avenue** **Woodland Hills, CA 91367-2407** **800/678-6779** **FAX 818/737-4676**
Terumo Medical Corp. **2101 Cottontail Lane** **Somerset, NJ 08873** **800/283-7866**	**Tri-State Hospital Supply Corp.** **301 Catrell Dr.** **Howell, MI 48843** **800/248-4058** **517/546-5400** **FAX 517/546-9388**	**Univec** **22 Dubon Court** **Farmingdale, NY 11735** **631/777-2000** **FAX 631/777-2786**
Vadus, Inc. **3150 N. Republic Blvd., Suite 8** **Toledo, OH 43615** **888/290-2284**	**Venetec International** **12555 High Bluff Dr., Suite 170** **San Diego, CA 92130** **800/833-3895** **619/350-4444**	**ViGARD Medical Products Division of Lovell-Schenck, Inc.** **1515 Mockingbird Lane, Suite 710** **Charlotte, NC 28209** **704/527-9093**
Whizard Protective Wear Bettcher Industries, Inc. **P.O. Box 336** **Vermilion, OH 44089** **216/965-4422**	**Wyeth-Ayerst Laboratories** **P.O. Box 8299** **Philadelphia, PA 19101** **610/688-4400** **FAX 610/995-4693**	**Zimmer Patient Care Division** **200 W. Ohio Ave.** **Dover, OH 44622** **800/348-2759**

This listing does not imply endorsement by the U.S. Army but is intended only to assist in identification of resources to obtain specific product information.

Work practice controls –

- Reduce, but do not eliminate the likelihood of worker exposure to BBPs, by altering the manner in which a task is performed
- Require the worker to take defensive action

Examples of work practice controls include–

- Hand hygiene
- Managing sharps
- Practicing good personal hygiene
- Eliminating or minimizing inadvertent contact with blood or OPIM

Hand Hygiene

Hand hygiene is —

- A fundamental infection control practice and the most effective means of preventing the spread of infection
- A process for removing soil and microorganisms from the hands
- Accomplished by vigorously rubbing together all surfaces of lathered hands for at least 10 seconds, followed by a thorough rinsing of hands under a stream of tepid water

Handwashing Facilities

Where occupational exposure to BBPs is anticipated, handwashing facilities should be located so that workers do not have to travel excessive distances from their normal work areas (for example, through several doorways, halls, and stairways) to wash their hands. Conveniently located handwashing facilities located in all areas where occupational exposure to BBPs is anticipated will —

- Increase the likelihood that workers will wash their hands as required
- Minimize the amount of contact time between blood or OPIM and workers' skin
- Prevent contaminant migration to areas outside the work area
- Encourage compliance with the infection control procedures and the BBP standard

In health care facilities, a sink should be located in or just outside every patient room and in rooms where diagnostic or invasive procedures that require handwashing are performed (for example, cardiac catheterization, bronchoscopy, sigmoidoscopy, etc.). Table 7 lists the American Institute of Architects (AIA) recommendations for locating handwashing stations in a variety of health care settings. Although, compliance with these guidelines is nonmandatory, convenient location of handwashing sinks should be a consideration for new construction and renovation projects.

Table 7. AIA Recommendations for Placement of Handwashing Stations in Health care Facilities

WORK AREA	HANDWASHING FACILITY PLACEMENT
Isolation rooms and protective environment rooms	Located directly outside or immediately inside the entry door to the room
Critical care units	Located near the entrance to the room or the patient cubicle (Note: One station shall be placed in each patient room or one station shall be provided for every three beds in open plan areas. Facilities should be equipped with hands-free controls.)
Dietary facilities	Conveniently located throughout the unit (Note: should be equipped with hands-free controls.)
Labor, delivery, and recovery rooms	Located within each room. (Note: Sinks with hands-free operation are acceptable for scrubbing.)
Laundry facilities	Located in each room where soiled or clean linen is processed and handled
Linen services	Located in each area where unbagged, soiled linen is handled
Magnetic resonance imaging (MRI) department	Conveniently located to the MRI room and within each procedure room, unless the procedure room is used for routine screening where the patient is not physically handled by staff
Mobile, transportable, and relocatable units	Located within each unit (Note: Mobile units providing noninvasive procedures that are not equipped with handwashing facilities, must provide handwashing facilities within a 25 foot proximity to the unit)
Newborn intensive care	Located within 20 feet of every bed in multiple-bed rooms, and within each individual infant-care room (Note: All sinks must have hands-free controls)
Nuclear medicine facilities	Located within each procedure room, clean linen storage, and soiled and contaminated material storage rooms
Nurse stations	Conveniently located to the nursing station, medication station, and nourishment center (Note: One handwashing station may serve several areas if it is located convenient to each)
Nursing units	Located in examination/treatment rooms, soiled utility rooms, and in clean utility rooms when the rooms are used for preparing patient care items
Occupational therapy facility	Located within the department

Outpatient Facilities	Located within each general-purpose examination room, special-purpose examination rooms, and in minor surgery and cast treatment rooms
Patient rooms	Located in each toilet room (Note: In new construction, a handwashing station, in addition to the one located in the toilet room, shall be installed in the room and located outside the cubicle curtain)
Pharmacy	Located in each room where open medication is handled
Physical Therapy	Located within each treatment area (Note: One handwashing facility may serve several treatment stations)
Post-anesthesia care units	Located within the department
Postpartum units	Located within each patient bedroom (Note: In multi-bedded rooms the handwashing station shall be located outside of the patients' cubicle curtains)
Renal dialysis unit	Conveniently located to the nurses station and patient treatment areas (Note: There should be one handwashing station for every four stations and they should be uniformly distributed throughout the area)

Handwashing sink design
Sinks equipped with faucets that can be turned off by means other than the hands (for example, foot pedals, automatic shut-off controls, etc.) and that minimize splashing can help workers avoid immediate recontamination of washed hands. In the absence of hands-free controls, workers should use a paper towel to shut off the faucet.

Handwashing products
Persons knowledgeable about the purpose of use, advantages, disadvantages, cost, and acceptance of the products by the workers, should choose the handwashing products to be used in the facility.

The Centers for Disease Control and Prevention (CDC) recommends use of either a non-antimicrobial soap or an antimicrobial soap for handwashing when hands are visibly soiled with blood or OPIM, before eating, and after using the restroom. If hands are not visibly soiled, an alcohol-based hand rub may be used for routine decontamination, unless the Local Infection Control Program specifies otherwise.

If bar soap is used, choose small bars that can be changed frequently and place soap on racks to allow water drainage between uses. (Note: the use of bar soap is not recommended in health care facilities.) If liquid soap is used, the dispenser should be replaced or cleaned and filled with fresh product when empty. Liquids should never be added to a partially full dispenser.

Hand drying products
Paper towels or warm-air dryers (if they do not interfere with ventilation) should be placed within easy reach of the sink, but in an area that will not become contaminated by splashing. Hanging or roll type cloth towels are not recommended for use in health care facilities.

Routine inspections of handwashing facilities
Housekeeping personnel should routinely inspect handwashing facilities and make sure that soap and towel dispensers function properly and are adequately supplied.

Alternative procedures when handwashing facilities are unavailable
If handwashing facilities are unavailable, as is often the case with police, ambulance-based paramedics, emergency medical technicians, firefighters, and mobile blood collection personnel, workers must use alternative handwashing methods as an interim measure until they can wash their hands with soap and water.

- Use of alcohol-based hand rubs (waterless-hand disinfection) if hands are not soiled with dirt or heavily contaminated with blood or OPIM
- Use of detergent-containing towelettes to remove dirt and gross contamination, followed by use of alcohol-based hand rubs if hands are soiled or heavily contaminated

Training in handwashing procedures
Employers are responsible for training workers in handwashing procedures and for making sure that they wash their hands as required. Continuing education and motivational programs should address —

- Hand washing rationale and techniques
- Patient care activities that can result in hand contamination
- Advantages and disadvantages of various handwashing or disinfecting methods

- Worker participation in the planning and implementation of strategies to improve compliance and feedback regarding their performance
- Educating patients and family members to remind workers to wash or decontaminate their hands

Sharps Management

Sharps include needles, lancets, scalpel blades, and anything that might produce a puncture wound that would expose workers to blood or OPIM such as the ends of contaminated orthodontia wires or broken glass.

Workers must immediately discard disposable sharps, **including blood tube holders with needles attached and SESIP**, into a readily accessible sharps container unless there is no feasible alternative or a specific medical procedure requires bending, recapping or removal of contaminated needles. In such cases, employers must include written justification in the ECP, demonstrating that there are no feasible alternatives, or a specific medical procedure requires such action. When bending, recapping, or removing contaminated needles is necessary, workers must use a mechanical device or a one-hand scoop method to accomplish the task safely. Shearing or breaking contaminated needles is completely prohibited.

Immediately or as soon as possible after use, workers must place contaminated reusable sharps (such as large bore needles, scalpels, saws, etc.) into appropriate containers until they are properly reprocessed. Containers must meet the same characteristics as disposable sharps containers except they do not have to be closeable. To facilitate cleaning, reusable containers with rounded corners and joints are recommended.

Employers must train workers on the safe work practices for reprocessing reusable sharps. Contaminated, reusable sharps must be stored or reprocessed in containers that do not require reaching into them by hand.

Hands-free, no pass, and no touch techniques

While not specifically mentioned in the BBP standard, use of hands-free, no pass, and no touch techniques will prevent sharps injuries in the operating room. The “neutral zone” involves a no touch passing of sharp instruments by placing contaminated instruments on a tray or specific area to avoid hand-to-hand transfer of sharp instruments. A verbal cue may be used to make sure that the scrub nurse is not retrieving a contaminated instrument at the same time as the surgeon is attempting to deposit an additional one. The

"no-touch" technique involves strategies to avoid self-inflicted injuries and injuries from coworkers by making sure that no one touches the same sharp instrument simultaneously during surgical procedures.

Personal hygiene

Workers may not consume food and beverages in work areas where actual or potential exposure to blood or OPIM exists. Hand cream is not considered a cosmetic and may be used provided workers thoroughly wash their hands immediately before application. However, some petroleum-based hand creams can adversely affect glove integrity, thus resulting in unsuspected contamination of the hands.

Food and beverages must be stored in a manner to prevent contamination of the containers and their contents resulting from leakage, spillage, splashes, sprays, and droplets of blood and OPIM and contact with contaminated items. Areas designated for consumption and storage of food and beverages must be separated from work areas having potential for exposure. For example, workers may be permitted to eat and drink in an ambulance cab only if they –

- Wash up and change contaminated clothing prior to entering the ambulance cab
- Avoid consuming, handling, storing, and transporting food and drink in the rear of the vehicle
- Keep patients and contaminated materials behind the separating partition
- Perform all procedures involving the handling of blood or OPIM in a manner that decreases the chances for direct exposure and potential for contamination of surfaces in the work area
- Wear eye protection and a mask or face shield to prevent contamination of the mucous membranes of the eyes, nose, and mouth if splashing, spattering, or generation of droplets is anticipated

Aerosolizing devices

Surgical power tools, lasers, and electrocautery devices may generate aerosols as well as be a source for splashing and spattering. Employers are responsible for complying with manufacturers' recommendations for local exhaust ventilation and the proper operation of these devices. While, there is some evidence of HIV viability in aerosols, both the CDC and NIOSH

have stated that there are no cases traceable to airborne transmission. Therefore, OSHA currently does not require workers to wear NIOSH-approved respirators when performing these procedures.

Pipetting
Pipetting or suctioning of blood or OPIM by mouth is prohibited.

Containment
Blood and OPIM must be contained and identified to prevent or minimize accidental worker contact with blood and OPIM. Employers must —

- Provide containers that will prevent leakage
- Warn workers when blood or OPIM are or may be present

Primary containers
Primary containers used for the collection, handling, processing, storage, transport, or shipping of blood or OPIM must—

- Be appropriate for the specimen housed in the container and the anticipated handling procedures
- Prevent leakage
- Be labeled or color-coded, unless workers are trained to handle all specimen containers with UP ***AND*** the specimen containers remain in the facility
- Be closed before being stored, transported, or shipped

Secondary containers
Secondary containers that prevent leakage must be used if the —

- Primary container could be punctured by its contents (for example, sharps, teeth, bone slivers, etc.); in these situations, the secondary container must be puncture resistant
- Exterior surface of the primary container is likely to be contaminated
- Primary container may not prevent leakage

Unique situations
Extracted teeth, that are being discarded or used as specimens, must be containerized and labeled according to the provisions of this paragraph.

However, dentists and doctors are not precluded from giving patients their extracted teeth, gallstones, and kidney stones. In instances such as these, teeth and stones are not subject to containerization and labeling requirements.

Transport of clinical specimens in pneumatic tube systems may result in leakage of the specimen into the carrier and potentially into the system tubing as well. To prevent leakage, workers must pay particular attention to proper packaging and selection of an appropriate primary container. Workers must wear gloves when opening a carrier since there is always a possibility that it may be contaminated due to leakage. Employers must train all workers who may potentially open a pneumatic tube carrier, in decontamination procedures for the carrier and if needed, the tube system as well.

Any potentially contaminated equipment used for diagnosis, treatment, research, and other applications where they may become contaminated with blood or OPIM must be examined and decontaminated before maintenance, repair, or shipment. If it is not possible to decontaminate the equipment or parts of the equipment due to equipment design, a biohazard label must be attached to the equipment. The label must identify the equipment parts that remain contaminated. Workers responsible for servicing or repairing equipment that has not been decontaminated must use UP until the equipment is disassembled and properly disinfected.

Personal Protective Equipment

Employers must —

- Select and provide workers with appropriate PPE when occupational exposure remains after engineering controls and work practices are implemented
- Select the types and characteristics of the PPE to be used based on the type of procedure performed, the type of exposure anticipated, and the quantity of blood or OPIM anticipated to be encountered
- Provide PPE at no cost to the worker
- Require all occupationally exposed workers to use and wear appropriate PPE

Examples of PPE used to prevent occupational exposure to blood and OPIM include —

- Gloves
- Gowns
- Laboratory coats
- Face shields
- Masks
- Eye protection
- Head and shoe covers
- Resuscitation devices (e.g., masks, mouthpieces, resuscitation bags, shields/overlay barriers)

PPE Program

When PPE is used to prevent occupational exposure to blood and OPIM, employers must develop and implement a PPE program that meets the requirements specified in 29 CFR 1910.132. This program must contain provisions for —

- Identifying and evaluating hazards in the workplace that call for the use of PPE
- Selecting and maintaining PPE
- Training workers in the use, wear, limitations, proper care, maintenance, and disposal of PPE

In addition to the training described in the previous paragraph, workers must also be trained in the proper methods for —

- Decontaminating reusable PPE
- Obtaining PPE (for example, know the locations where PPE is stored and the procedures for obtaining replacement PPE)
- Removing contaminated PPE in a manner to avoid contact with skin and outer surfaces
- Storing contaminated PPE until it can be laundered or disinfected

Table 8 provides assistance in selecting the appropriate PPE for workers. General information regarding the use and maintenance of PPE is provided in the following paragraphs.

Table 8. PPE for Specific Circumstances

TASK/PROCEDURE	GLOVES*	COVER	MASK	EYEWEAR
Injections				
Physical examinations (measuring blood pressure, etc.)				
Drawing blood (except for all phlebotomies in volunteer blood donation centers)	R			
Finger or heel sticks	R			
Examinations of mouth, rectum, genitalia	R			SP
During invasive procedures	R	SP	SP	SP
Handling and processing blood and body fluid specimens	R			SP
Examination of non-intact skin or patients with active bleeding	R			SP
Decontaminating procedures	R			SP
Handling and cleaning contaminated instruments and equipment	R (REUSABLE)			SP
Emptying wastebaskets, regulated waste containers, and any other waste handling activities	R			
Surface/equipment cleaning	R			
Resuscitation	R and plastic mouthpieces			
Dressing change, large amount of drainage	R	S (apron)		
Ostomy change, teaching, and irrigation	R	S (apron)		
Wound, irrigation	R	S (apron)	SP	SP

Emergency childbirth	R	G (gown)	SP	SP
Changing the bed of an incontinent patient	R	R (gown)		
Lifting or moving a patient with draining wounds	R	R (gown)		
Cleaning HIV and HBV research and production facilities	R	S (apron) R (shoe)	R	SP
Cleaning soiled beds	R	S (apron)		
Dental lab - incoming and outgoing case disinfection processing	R	R (lab coat)		
Dental lab - production area	R	R (lab coat)	R	R (safety glasses appropriate for the ballistic hazard associated with grinding)
Certain surgical and invasive procedures	R	R (gown)	R	R
Endotracheal suctioning	R	S (gown)	SP	SP
Surgical procedures	R	R (gown) R (shoe) R (head)	R	R
Dental procedures (including surgery)	R	R (gown)	R	R (face shield)
GI endoscopy	R	R (gown)	R	R

Key: R = Routinely; S = If soiling likely; SP = If spattering/splashing likely
*If a worker has an open cut or abrasion on their hands, gloves must be worn during all listed tasks/procedures.
This table provides the minimum requirements during controlled situations to protect the worker from potentially infectious agents. This list is not exhaustive; judgment is required on the part of the employee to assess the need for additional barrier protection in less controlled situations.

PPE Use
Limited exceptions for the use and wear of PPE are permitted in rare and unexpected circumstances where the life or safety of a patient, worker or co-worker is threatened. Examples of acceptable exceptions are —

- A sudden change in patient status occurs such as when an apparently stable patient unexpectedly begins to hemorrhage profusely, putting the patient's life in immediate jeopardy.
- A firefighter rescues an individual who is not breathing from a burning building and discovers that his resuscitation equipment is damaged or lost and he must administer CPR
- A police officer is attacked by a bleeding suspect or a suspect is wielding a knife

However, once the situation changes/improves workers must immediately, take steps (e.g., remove contaminated clothing, wash exposed skin, flush mucous membranes, use PPE, etc.) to prevent further occupational exposure.

After each incident, employers must investigate and document why PPE was not used, evaluate the circumstances surrounding the incident, and take actions necessary to reduce the likelihood of a future unprotected incident.

PPE Accessibility
All PPE that is expected to be needed must be —

- Readily accessible
- Appropriate to the specific task or procedure performed
- The correct size for the worker's proper use
- Durable under normal conditions of use

Employers must —

- Periodically inspect supply inventories at both fixed and in non-fixed worksites and restock supplies as needed to ensure PPE availability
- Provide alternatives such as hypoallergenic gloves, glove liners, powderless gloves, or similar alternatives that provide adequate protection if a worker is allergic to the gloves normally provided

PPE Cleaning, Laundering, and Disposal
Employers must clean, launder, and/or dispose of PPE at no cost to the worker. Home laundering of PPE is prohibited.

PPE Repair and Replacement
Employers must—

- Repair or replace PPE as needed to maintain its effectiveness
- Define work area boundaries and require workers to remove PPE before leaving the work area
- Provide designated areas or containers for the storage of contaminated PPE
- Permit only trained personnel to handle contaminated PPE

Workers must –

- Remove PPE and underlying clothing immediately or as soon as feasible when PPE is penetrated by blood or OPIM
- Remove all PPE before leaving their work areas
- Place contaminated PPE immediately after removal in an appropriately designated container for storage until it can be washed, decontaminated, or properly disposed
- Replace damaged or unserviceable PPE as soon as possible/feasible

Gloves
Gloves must be worn to provide a protective barrier and prevent gross contamination of the hands when touching blood, OPIM, mucous membranes, and non-intact skin. The wearing of gloves does not replace the need for handwashing because —

- Even new gloves may have small, undetectable defects
- Gloves may become torn during use
- Hands may become contaminated during glove removal

Workers must wear gloves when they —

- Anticipate contact with blood, OPIM, or mucous membranes
- Handle or touch contaminated items or surfaces
- Perform invasive procedures
- Examine abraded or non-intact skin

- Render emergency medical or non medical assistance to individuals sustaining traumatic injury
- Clean up blood spills by hand

Workers are not required to wear gloves when giving injections unless contact with blood or OPIM is reasonably anticipated.

Gloves may be disposable or reusable. Workers must replace disposable gloves as soon as practical when they become visibly contaminated and as soon as feasible when they are torn, punctured, or their ability to function as a barrier is compromised. Disposable (single use) gloves must be discarded after use. Workers must decontaminate reusable (utility) gloves after each use. At a minimum, gloves should be replaced based on a schedule as recommended by the glove manufacturer and whenever they are cracked, peeling, torn, punctured, or show any other signs of deterioration.

MEDCOM Regulation No. 40-44, Latex Allergy Prevention provides policy and guidance in the selection and use of powder-free and latex-free gloves to prevent latex sensitization. A copy of this regulation is provided in Appendix C.

Plastic film food handling gloves are not appropriate PPE to prevent exposure to blood and OPIM.

The exemption for not requiring routine gloving for all phlebotomies applies to volunteer donor blood collection centers and does not apply to phlebotomies conducted in other settings such as plasmapheresis centers or hospitals. To take advantage of this exemption, employers must provide workers with information to make well-informed decisions regarding the wearing of gloves.

Masks, Eye Protection, and Face Shields
Workers must wear eye and face protection during procedures or patient care activities that are likely to generate splashes, spray, spatter, or droplets of blood and OPIM and when eye, nose, or mouth exposure is anticipated. Eye and face protection includes wearing of chin-length face shields or splash resistant goggles or glasses with solid side shields in combination with surgical masks that cover both the nose and mouth.

Gowns, Aprons, and other Protective Body Clothing
Appropriate fluid-resistant protective clothing must be worn to prevent contamination of skin and clothing when contact with blood and OPIM is reasonably anticipated. To be considered appropriate, protective clothing must prevent blood or OPIM from penetrating and contaminating its inner surfaces and subsequently contaminating workers' street clothing and skin.

Surgical caps, hoods, shoe covers
Head and shoe covers must be worn to provide greater protection to the skin where large quantities of blood or OPIM are anticipated.

Housekeeping

Employers must maintain their worksites in clean and sanitary conditions to protect workers from unknowingly being exposed to blood and OPIM. A "worksite" refers to permanent fixed and temporary non-fixed workplaces. Examples of affected workplaces include —

- Hospitals, dental/medical offices, clinics, etc.
- Diagnostic and research laboratories
- Morgues and funeral homes
- Health care laundry services
- Ambulances
- Bloodmobiles and temporary blood collection centers
- Other non-fixed worksites that have a reasonable possibility of becoming contaminated with blood or OPIM

Employers must train workers in proper housekeeping and spill clean-up procedures. They must also develop and implement written schedules and methods for cleaning and decontaminating environmental surfaces, work surfaces, and equipment to meet the needs of the area. Considerations include —

- Type of facility (for example, hospital versus laundry)
- Location within the facility (for example, surgical operatory versus patient room versus biomedical maintenance equipment repair)
- Type of surface to be cleaned (for example, hard-surfaced flooring versus carpeting)
- Type of soil or spilled infectious material present (for example, gross contamination versus spattering, or blood versus urine)
- Tasks or procedures being performed in the area (for example, laboratory analyses versus normal patient care)

Cleaning and decontaminating schedules

Cleaning is the removal of all foreign material (for example, soil and organic material) from objects. Cleaning must precede disinfection and sterilization procedures. Decontamination is a process that renders a medical device, instrument, or environmental surface safe to handle by reducing the microbiological burden.

The OSHA BBP standard provides minimum requirements for cleaning and decontaminating equipment and working surfaces that are contaminated with blood and OPIM. Therefore, workers must also follow their local infection control procedures and written schedules for cleaning and disinfecting equipment and working surfaces.

At a minimum, all contaminated equipment and environmental work surfaces must be cleaned and decontaminated with an appropriate disinfectant —

- Upon completion of procedures or when a worker leaves the work area for a period of time
- Immediately after any contact with blood or OPIM
- At the end of the work shift if surfaces have become contaminated since the last cleaning

Table 9 provides a suggested routine cleaning schedule and Table 10 provides recommended methods for decontaminating equipment and surfaces.

Table 9. Routine Cleaning Schedule

LOCATION*	MINIMUM FREQUENCY
Patient Room	**Daily**
Patient Bathroom	**Daily**
Exam Room	**Daily**
Procedure Room	**Between Procedures**
Operating Room	**Between Cases**
Delivery Room	**Between Deliveries**
Dialysis	**Between Patients**
Laboratory	**When Overtly Contaminated or Daily, Whichever Occurs First**
Ambulance	**Between Calls**

*This list of locations is not exhaustive.

Table 10. Methods for Decontaminating Equipment and Surfaces

METHOD	EQUIPMENT/SURFACES
Sterilization	
Instruments or devices that penetrate skin or contact normally sterile areas of the body (for example, scalpels, needles, dental hand pieces and prophy angles, etc.).	Steam under pressure, gas, dry heat, or immersion in an EPA-registered chemical "sterilant" for prolonged period according to manufacturer's instructions. Note: Use liquid chemical "sterilants" only on those instruments that are impossible to sterilize or disinfect with heat. Contact the manufacturer if you are unsure.
High-Level Disinfection	
For reusable instruments or devices that come into contact with mucous membranes (for example, laryngoscope blades and endotracheal tubes).	Hot water pasteurization (80-100°C, 30 minutes) or exposure to an EPA-registered chemical as above, except for a short exposure time in accordance with manufacturer's instructions.
Intermediate-Level Disinfection	
For those surfaces that contact only intact skin (for example, blood pressure cuffs, stethoscopes, splints, etc.) and are visibly contaminated with blood or OPIM. Pre clean all surfaces of visible material before chemical application.	EPA-registered "hospital disinfectant" chemical with tuberculocidal efficacy claims are acceptable; commercially available hard surface germicides or solutions containing at least 500 ppm free available chlorine.
Low-Level Disinfection	
Use for routine housekeeping or removal of soil without visible blood contamination.	EPA-registered "hospital disinfectant" chemical without tuberculocidal efficacy claims.
Environmental Disinfection	
Surfaces including floors, walls, ambulance seats, countertops, etc.	Clean and disinfect soiled environmental surfaces using any cleaner or disinfectant agent intended for environmental use.

*All sterilants and disinfectants must be FDA- or EPA- labeled for their intended use and all labeling instructions must be completely followed.

Exceptions
Where procedures are performed on a continual basis throughout a shift or a day, workers may decontaminate the work surfaces after the procedures are completed. For example, a clinical laboratory technician performing blood analyses, may decontaminate work surfaces after completing a "set" of analyses.

In instances in which "immediate" decontamination of overt contamination and spills may not be practical (for example, an operating table during surgery), workers must clean and disinfect work surfaces as soon as feasible.

Disinfectants
Persons knowledgeable about the purpose of use, efficacy, acceptability of the product by the users, safety and cost should choose products for cleaning and disinfecting equipment and work surfaces. The particular disinfectant used, as well as the frequency with which it is used, will depend upon the circumstances in which the housekeeping task occurs. Appropriate disinfectants include —

- Diluted bleach solutions
- EPA-registered products such as tuberculocides, sterilants, or products registered against HIV/HBV
- FDA-cleared sterilants and high level disinfectants

Diluted bleach solutions
Use of diluted (1:10 to 1:100) household bleach (5.25% sodium hypochlorite solution) is appropriate for disinfection of environmental surfaces and for decontamination of sites contaminated with blood or OPIM spills (Note: bleach may damage some medical instruments). Workers must clean-up gross contamination with soap and water before applying the bleach solution. Contact time for bleach is generally considered the time it takes the product to air dry. Diluted bleach solutions should always be stored in a plastic container, similar to the container used by the manufacturer, and the container must be labeled according to the local Hazard Communication Program requirements.

EPA-registered products
The EPA has jurisdiction for all pesticide use of non-liquid chemical sterilants including ethylene oxide and for liquid chemical sterilants that bear claims for use on devices, surfaces, or objects other than critical or semi-critical devices, such as veterinary instruments, environmental surfaces, and in manufacturing and packaging processes. A listing of EPA-registered products may be found at http://www.epa.gov/oppad001/chemregindex.htm.

FDA-cleared sterilants and high-level disinfectants
The FDA has jurisdiction for pesticide liquid chemical sterilants cleared for use on critical or semi-critical devices. Critical devices are devices that are introduced directly into the human body, either in contact with the bloodstream or normally sterile areas of the body. Semi-critical devices are devices that contact intact mucous membranes but do not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. A listing of FDA-cleared sterilants and high level disinfectants may be found at http://www.fda.gov/cdrh/ode/germlab.html.

Sterilants/high-level disinfectants must be registered with the FDA or with the EPA. They cannot be registered with both agencies at the same time.

Workers must follow the manufacturer's instructions regarding the amount of disinfectant used and the time that it must remain wet on the surface. Also, before using a disinfectant, workers must check the manufacturer's expiration date on the label or expiration date of mixed solution to make sure that the disinfectant is still utilizable.

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

Carpets and fabric upholstery
OSHA's position is that there are no products currently available that can clean and fully disinfect carpets and fabric upholstery without causing

damage. Therefore, facilities should avoid installing carpeting in areas where spills are likely to occur (for example, laboratories, areas around sinks, janitor closets, and in areas where patients may be at greater risk of infection from airborne environmental pathogens). Facilities electing to install carpeting should choose carpet tiles since they are easier to remove, discard, and replace should they become contaminated with blood and OPIM. Selection of furniture made of fabrics or surfaces that can be easily wiped clean (e.g., woven crypton or vinyl) are more appropriate in areas where blood or OPIM may be frequently spilled or come in contact with furniture surfaces.

Receptacles
All bins, pails, cans, and receptacles intended for reuse that are likely to be contaminated with blood or OPIM (for example, trash cans and large plastic carts used to collect and transport regulated medical waste (RMW) and soiled linen) must be inspected and decontaminated on a regularly scheduled basis, and they must be cleaned and decontaminated with soap and water immediately or as soon as feasible upon visible contamination.

Broken glassware and contaminated sharps
Contaminated broken glass is capable of causing percutaneous injury and direct injection of blood and OPIM into the bloodstream. Workers must not pick up broken glassware and contaminated sharps directly with the hands. Vacuum cleaners are not appropriate for cleanup of broken glass either. Instead, glass and contaminated sharps must be cleaned up using mechanical means such as a brush and dustpan, tongs, or forceps. The tools that are used in cleanup must be properly decontaminated or discarded after use and the broken glass gently placed in a sharps container.

Contaminated reusable sharps must be stored or processed in containers such as strainer type baskets that do not require workers to reach into them by hand. Workers should use forceps to remove the items from the containers.

Regulated waste
The term "regulated waste" (also known as regulated medical waste (RMW), infectious waste, and infective waste) refers to the following categories of waste requiring specific handling —

- Liquid or semi-liquid blood or OPIM

- Items contaminated with blood or OPIM and which would release these substances in a liquid or semi-liquid state if compressed
- Items caked with dried blood or OPIM and are capable of releasing these materials during handling
- Contaminated sharps
- Pathological and microbiological wastes containing blood and OPIM

The MEDCOM has published extensive guidance on the management of RMW. A copy of MEDCOM Regulation 40-35, Management of Regulated Medical Waste, is provided in Appendix C.

Contaminated sharps
Contaminated sharps must be discarded immediately or as soon as feasible in containers that are —

- Closable
- Puncture resistant
- Leakproof on sides and bottom
- Properly labeled or color-coded

Sharps containers
Sharps containers may be constructed of a variety of materials (for example, cardboard and plastic). As long as containers meet the definition of a sharps container and there is no evidence that sharps have protruded through the container, they are acceptable regardless of their composition.

Sharps containers must be—

- Located as close as feasible to where sharps are used or can be reasonably anticipated to be found
- Secured or kept under direct observation to prevent unauthorized access
- Maintained upright throughout their use to prevent potential leakage and contaminant migration
- Replaced when they are ¾ full

When moving contaminated sharps containers from their area of use, the containers must be —

- Closed immediately, prior to removal or replacement
- Placed in a closable, leakproof, labeled or color-coded secondary container if leakage is possible

Duct tape may be used to a secure sharps container lid, but tape is not acceptable if it serves as the lid itself.

Reusable sharps containers must not be opened, emptied, or cleaned manually or in any way that would expose workers to injury. The only acceptable system is a fully automated container cleaning system and container emptying procedures or equipment that eliminates worker exposure to sharps.

USACHPPM Fact Sheet Number 59-002-1199 provides detailed guidance on the selection, placement and the safe use of sharps containers. A copy of the fact sheet follows.

USACHPPM
Readiness thru Health

59-002-1199

Just the Facts...

Selecting and Installing Sharps Disposal Containers

Contaminated needles and other sharp objects continue to top the list of serious occupational safety and health hazards in the health care industry. The National Institute for Occupational Safety and Health estimates that 800,000 needlestick injuries occur in U.S. hospitals annually, and records show that about one third of these injuries result from inadequate sharps disposal container design, inappropriate container placement, and unsafe work practices, such as overfilling containers[2].

Because health care facilities use many types of disposable needles and sharp objects, they require a variety of sharps disposal containers. Facilities should begin their selection process by determining each workstation's disposal needs. Factors, such as the size, type and volume of sharps generated; the environmental hazards (chemical, biological, radiological, and physical) present; security and portability requirements; and worker and procedure variability should be evaluated.[2] Once each workstation's disposal needs are known, facilities should choose well-designed sharps disposal containers that are compatible with those needs.

Only those sharps containers that meet the following basic design criteria and accessibility requirements should be considered for purchase. These criteria will guarantee that the sharps disposal containers remain operational from start to end of use in the safest possible manner.

- The container is leak-proof on the sides and bottom.
- The container is puncture resistant and constructed from durable materials of sufficient thickness.
- The container is stable when placed on horizontal surfaces or when placed in designated trays, holders, or enclosures.
- The container is closeable, and the disposal opening is identifiable, provides safe access (e.g., prevents needle-tip flip-back, catching, and snagging during insertion, and prevents spillage and removal of the container's contents).
- The closure mechanism minimizes exposure during engagement of the mechanism and prevents manual opening after engagement.
- If present, the handles are sturdy and positioned away from the disposal opening and above the full-fill level.
- If present, the unwinder mechanism must accomplish needle removal using a safe one-handed technique and must prevent movement of the needle during removal.
- If present, the brackets and locking mechanisms are durable, easily decontaminated, and designed specifically for the sharps container used at the workstation.
- If necessary, the container can be autoclaved.
- The container is earth friendly (e.g., composed of recycled materials and free of heavy metals)

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5158 Blackhawk Road, Aberdeen Proving Ground, MD 21010-5403
DSN 584-3040 or Commercial 410-436-3040

In addition, the following design features will promote safe and consistent sharps handling procedures.

- The container is simple to operate and allows one-handed disposal.
- The disposal opening is not blocked by special operational, safety, and security features such as mounting brackets or locking devices.
- The disposal opening's size and shape is appropriate for the size and type of sharps generated at the workstation.
- The disposal container's size and shape will accommodate the largest sharp used, the particular type(s) of sharps used, and the volume of sharps generated at the workstation.
- The full-fill level is marked on the container, and the container's fill status is easily seen.
- The container can be easily placed in and removed from mounting brackets and lockable fixtures.
- If required, the container is easy to assemble.

Facilities must ensure that sharps disposal containers are available in all areas where sharps are used and easily accessible to health care workers. The following installation guidelines will ensure that sharps disposal containers are readily visible and always within easy horizontal reach of the workstation.

- Only use containers that are red in color or labeled with a biohazard symbol.
- Place containers in lockable fixtures that are permanently installed within arms reach of the site of use.
- If portability is required, place containers in lockable fixtures that are permanently installed on carts, gurneys, or other wheeled equipment whenever possible.
- Position lockable fixtures and sharps disposal containers below eye level with a clear, unobstructed view of disposal opening (i.e., 52-56 inches above floor level for a standing workstation and 38-42 inches for a seated workstation).
- Remove all furniture and obstacles between the site of use and the container.
- Maintain a sufficient supply of replacement containers near workstations that generate sharps waste.

Facilities can significantly reduce needlestick injuries and improper sharps disposal simply by selecting appropriate sharps disposal containers and installing them at all work stations where sharps are used or likely to be found. Facilities can further reduce sharps hazards when they use these strategies in conjunction with other prevention techniques such as eliminating unnecessary sharps, using safer needle devices, enforcing safe device handling procedures, eliminating the need to recap needles, investigating all needlestick incidents and taking appropriate corrective action, and providing effective worker education and training.

References:

1. *United States Department of Labor. Title 29, Code of Federal Regulations (CFR), 1998 rev, Part 1910, Occupational Safety and Health Standards. Washington: GPO, 1998.*

2. *United States Department of Health and Human Services. DHHS (NIOSH) Publication No. 97-111, Selecting, Evaluating, and Using Sharps Disposal Containers. Atlanta: CDC, 1998.*

Sharps containing mixed waste (radioactive/chemical)
For handling and disposal guidance, contact the Radiation Protection Officer who supports the MTF. Guidance may include requirements for radiation decay times, locations to store the mixed waste while radiation decay occurs, and/or packaging requirements if the waste needs to be transported while still radioactive.

Autoclaved/decontaminated waste
RMW that has been decontaminated need not be labeled or color-coded. Records that reflect the treatment method and show the efficacy of treatment should be retained by the facility for sufficient time to answer questions or address crises should they occur.

Labeling
Even if the facility considers all of its waste to be RMW, the waste containers must still bear the required biohazard label or be color-coded red. This, requirement is in contrast to the labeling alternative allowed when laundries use UP for the handling of all soiled laundry.

Container Covers/Lids
The Association for Professionals in Infection Control and Epidemiology recommends that non-biohazardous waste containers with a capacity greater than 20 gallons be equipped with a noncombustible lid or a lid of other approved materials. In addition, RMW containers not in continuous use, such as those in soiled utility rooms or nurses' stations, should be kept covered.

If outside contamination of the regulated waste container occurs, it must be placed in a second container that also meets the above requirements. This provision does not require routine double-bagging but, requires double-bagging in circumstances such as —

- A waste container was splashed with blood during surgery or autopsy
- A container was handled by a worker with bloody gloves
- A waste bag leaked blood or OPIM onto an adjacent bag

State jurisdictions vary with regard to disposal requirements. Failure to comply with requirements pertaining to the facility may invite penalties (including fines) and adverse publicity.

Handling, Storage, Packaging, and Transport
Packaging, marking, and labeling requirements for RMW transportation by rail and highway are specified in 49 CFR 171 – 180. Transportation by air is governed by the International Air Transport Association (IATA) regulations. The requirements are specific, detailed, and enforceable. For assistance, seek advice from an individual who has successfully completed a course in transportation of Hazardous Materials from an approved DOD school. Most Clinical laboratories and many Logistics Departments in Army MTFs have individuals who have had the required training to provide the specific assistance that may be needed.

Laundry

Contaminated laundry is laundry that has been soiled with blood or OPIM or may contain sharps. Contaminated laundry in health care consists of —

- Bed sheets and blankets
- Towels
- Gowns
- Uniforms and scrub suits
- PPE such as laboratory coats
- Drapes for surgical procedures

To prevent contact exposure to blood or OPIM and the generation of potentially contaminated lint aerosols in patient care areas, workers must —

- Handle contaminated laundry as little as possible with a minimum of agitation
- Avoid sorting or rinsing contaminated laundry in the location where it was generated
- Bag or containerize contaminated laundry at the location where it was generated
- Place contaminated wet laundry in bags or containers that prevent soak-through or leakage of fluids to the exterior of the bags or containers
- Securely tie or close laundry bags to prevent leakage
- Place laundry in labeled or color-coded bags or containers

Bagged laundry may be transported by cart or by properly designed and maintained chutes.

Employers must ensure that workers who have contact with contaminated linen wear protective gloves and other appropriate PPE, including gowns, aprons, eye protection, disposable head covers, disposable shoe covers as deemed necessary to prevent exposure.

When workers use UP in the handling of all soiled laundry, alternative labels or color-codes may be used for the bags/containers. However, all workers must be trained to recognize them as containing soiled laundry which requires the use of UP.

When contaminated laundry is shipped off-site to a second facility that does not use UP in the handling of all soiled laundry, laundry bags/containers must be properly labeled with a biohazard symbol or color-coded red.

HIV AND HBV RESEARCH LABORATORIES AND PRODUCTION FACILITIES - 29 CFR 1910.1030 (e)

The OSHA has identified two types of laboratory work environments that require additional protective measures in addition to all of the other requirements of the BBP standard, to protect workers having a greater risk of acquiring an infectious bloodborne disease. These environments are research laboratories and production facilities.

Research Laboratories

The standard defines a "research laboratory," including an academic research laboratory, as a laboratory that —

- Cultures, produces, concentrates, experiments, and manipulates or uses research laboratory scale amounts of HIV or HBV
- Deals with solutions containing higher viral titers than those normally found in a patient's blood

Research laboratories not covered by paragraph (e) of the BBP standard —

- Conduct research unrelated to HIV or HBV on blood and other body fluids
- Use unconcentrated blood or blood components as the source of HIV or HBV

Research laboratories not covered by paragraph (e) must still comply with all of the other requirements of the BBP standard.

Production Facilities

The standard defines a "production facility" as a facility engaged in industrial scale, large volume, or high concentration production of HIV or HBV.

Biosafety Criteria

To prevent occupational exposure to BBPs, research laboratories and production facilities should adhere to both the OSHA's BBP standard and the Centers for Disease Control and Prevention's CDC-NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL). A copy of the BMBL is available at http://bmbl.od.nih.gov/.

The BMBL describes four levels of biosafety (BSL) criteria. These criteria consist of a combination of safe laboratory practices and techniques, containment equipment, and facility design and are defined as —

- BSL1 applies to undergraduate and secondary educational training and teaching laboratories as well as laboratories conducting work with microorganisms not known to consistently cause disease in healthy humans.
- BSL2 applies to clinical, diagnostic, teaching, and other laboratories in which laboratory workers risk infection resulting from accidental percutaneous or mucous membrane exposures, or ingestion of a broad spectrum of moderate-risk infectious microorganisms that are associated with human disease of varying severity.
- BSL3 applies to clinical, diagnostic, teaching, research, or production facilities in which additional safeguards are needed to protect laboratory workers, personnel in adjacent areas, and the environment from percutaneous and inhalation exposures, or ingestion of microorganisms that may cause serious and potentially lethal infection.
- BSL4 applies to laboratories carrying out work with dangerous and exotic microorganisms that pose a high risk of life threatening infections for which there is no available vaccine or therapy.

Recommended BSLs for Research Laboratories and Production Facilities
Activities, such as producing research laboratory-scale amounts of HIV, manipulating concentrated virus preparations, and conducting procedures that may produce aerosols or droplets should be performed in a facility that meets BSL2 design criteria and laboratory workers should follow BSL3 safe laboratory practices and use BSL3 containment equipment.

Activities involving industrial-scale, large-volume production or high concentration and manipulation of concentrated HIV should be conducted in a facility that meets BSL3 design criteria and laboratory workers should follow BLS3 safe laboratory practices and use BSL3 containment equipment.

This section of the standard does not apply to clinical and diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. However, the BSL2 criteria described in this chapter are relevant for these work environments.

Summaries of BSL 1, 2, and 3 are provided in Tables 11, 12, and 13 respectively.

Table 11. Summary of Safe Laboratory Practices

Safety Practices	BSL1	BSL2	BSL3
Biosafety procedures are incorporated into standard operating procedures or in a biosafety manual adopted specifically for the laboratory		R	R
The biosafety procedures are periodically reviewed and updated at least annually or as often as necessary		R*	R*
BSL3 operational procedures and facility design are documented and tested to verify that operational and design requirements are met; operational and design requirements are re-verified at least annually			R
Workers are advised of special hazards and are required to read and follow safety policies and instructions		R	R
Workers receive appropriate training on the potential hazards, necessary precautions to prevent exposure, and exposure evaluation procedures		R	R
Workers receive annual updates or additional training as necessary (for example, after procedural and policy changes)		R	R
Before working with agents at or above BSL3, workers demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory			R
Access to the laboratory is limited or restricted at the discretion of the laboratory director when work is in progress	R	R	R
Only persons who have been advised of the potential hazards and meet specific entry requirements (for example, immunization) may enter the laboratory		R	R
Persons who are at increased risk of infection (for example, immunocompromised or immunosuppressed persons) are prohibited from the laboratory or animal rooms		R	R
Minors are prohibited from the laboratory and animal rooms			S
Laboratory doors are kept closed when work is in progress		R*	R
Animals not involved in the work being performed, are not permitted in the laboratory		R	R

Plants not involved in the work being performed, are not permitted in the laboratory			R
A biohazard sign is posted at the laboratory entrance (name of the agent(s) in use and name and phone number of a responsible party)	R		
A biohazard sign is posted at the laboratory entrance (name of the agent(s) in use, BSL, required immunizations, name and phone number of a responsible party, required PPE and laboratory exit procedures)		R	R
Workers receive appropriate immunizations or tests for the microorganisms handled or potentially present (for example, Hepatitis B or TB skin testing)		R	R
When appropriate, considering the agents handled, baseline serum samples for workers and other at-risk personnel are collected and stored; additional samples are collected periodically, depending on the agents handled or the facility's function; the results are communicated to the workers		R	R
Spill procedures are developed and posted			R
Spills and accidents that result in overt exposures to infectious materials are immediately reported and medical evaluation, surveillance, and treatment are provided as appropriate and documentation is maintained		R	R
Appropriate professional staff or properly trained workers contain, clean-up, and decontaminate infectious material spills			R
Workers wash their hands after handling viable materials, after removing gloves, and before leaving the laboratory	R	R	R
Eating, drinking, smoking, handling contact lenses, applying cosmetics is prohibited in work areas	R	R	R
Food for human consumption is stored in designated cabinets or refrigerators outside the laboratory work areas	R	R	R
Persons who wear contact lenses in the laboratory also wear safety goggles or a face shield	R	R	R
An insect and rodent control plan is in effect	R	R	R

Key: R = CDC required; R* = more stringent OSHA requirement S = CDC suggested

Table 12. Summary of Containment Equipment

Containment Equipment	BSL1	BSL2	BSL3
Mechanical pipettes are used; mouth pipetting is prohibited	R	R	R
Policies for the safe handling of sharps are instituted	R	R	R
Needles, syringes and other sharp instruments are used only when there are no alternatives (e.g., parenteral injection, aspiration of fluids)		R*	R*
Re-sheathing, needleless systems, or other safety devices are used when appropriate		R	R
Only needle-locking syringes or disposable syringe-needle units are used for injection or aspiration of infectious materials		R	R
Used disposable needles and syringes are not bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal		R	R
Disposable sharps are immediately placed in a conveniently located puncture-resistant container		R	R
Non-disposable sharps are placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving		R	R
Plasticware is substituted for glassware whenever possible		S	S
Broken glassware is removed by mechanical means, such as a brush and dustpan, tongs, or forceps		R	R
Procedures are performed carefully to minimize splashing and aerosolization	R	R	R
All open manipulations involving infectious materials are conducted in BSCs or other physical containment devices		R*	R
Manipulation of BSL3 infectious materials, necropsy of infected animals, and harvesting of tissues or fluids from infected animals or embryonate eggs, etc. is conducted in a Class II or Class III BSC			R
Work surfaces within BSCs are protected with plastic-backed paper toweling			R

BSCs are tested and certified when installed, after each move, and at least annually		R*	R
Work surfaces are decontaminated at least once a day and after any spill of viable material with disinfectants that are effective against the agents handled or that are potentially present in the laboratory	R	R	R
Work surfaces and equipment are decontaminated after work with infectious materials is completed		S	S
All cultures, stocks, and other regulated wastes are decontaminated by an approved decontamination method before disposal	R	R	R
Materials to be decontaminated outside the immediate laboratory are placed in a durable, leakproof, labeled or color-coded container and closed before transport from the laboratory	R	R	R
Materials to be decontaminated outside of the immediate laboratory are packaged according to applicable local, state and Federal regulations before removal from the facility	R	R	R
Containers of contaminated disposable needles, sharps, and broken glass are decontaminated before disposal according to local, state, or federal regulations		R	R
RMW is not transported in public corridors			S
RMW is decontaminated before removal for off-site disposal			R
Contaminated equipment is decontaminated and packaged for transport according to local, state, or federal regulations before it is sent for repair, maintenance, or removed from the facility		R	R
Workers wear gloves if skin on hands is broken or if a rash is present	S		
Workers wear gloves when hands may contact potentially infectious materials, contaminated surfaces, or equipment		R	R
Workers remove and dispose of gloves when overtly contaminated, when work with infectious materials is completed, or when the integrity of the glove is compromised		R	R
Workers frequently change gloves			S
Disposable gloves are not washed, reused, or used for touching clean surfaces (e.g., keyboards, telephones, documents)		R	R

Alternatives to latex gloves are available	S	S	S
Workers wear protective eyewear when conducting procedures in which splashing of agents or other hazardous materials is anticipated	S		
When manipulations must be performed outside the BSC, workers wear appropriate PPE (for example, safety goggles, mask, respirator, face shield or other splatter guard) when there is potential for splashing or spraying to the face		R	R
Workers wear respiratory and face protection when in rooms containing infected animals			R
Workers wear laboratory coats, gowns, coveralls, or uniforms to prevent contamination or soiling of street clothes	S	R	R
Workers remove protective clothing and gloves before leaving for non-laboratory areas		R	R
Workers remove protective clothing when overtly contaminated			R
All protective clothing is either disposed of in the laboratory or laundered by the facility		R	R
Soiled reusable protective clothing is decontaminated (autoclaved) before laundering			R

Key: R = CDC required; R* = more stringent OSHA requirement S = CDC suggested

Table 13. Summary of Facility Design

Facility Design	BSL1	BSL2	BSL3
Laboratories are located away from public areas whenever possible		S	
Laboratories are separated from areas that are open to unrestricted traffic within the building			R
Laboratory entrances have doors to limit access	S	R	R
Lockable doors are provided for facilities that house restricted agents (42 CFR 72.6)		R	R
Access into the laboratory from the corridors is limited by means of two lockable, self-closing doors			R
Handwashing sinks are provided	R	R	R
Handwashing sinks are provided near work area exits and equipped with elbow, foot knee or automatic controls		R*	R
An emergency eyewash station is readily available		R	R
Surfaces can be easily cleaned (rugs and carpeting prohibited)	R	R	R
Chairs and other furniture are covered with a non-fabric material that can be easily decontaminated		S	S
Bench tops are impervious to liquids and resistant to moderate heat, organic solvents, acids, alkalis, and chemicals used to decontaminate work surfaces	R	R	R
Wall, floor, and ceiling surfaces are constructed for easy cleaning and decontamination: seams are sealed; penetrations in floors, walls, and ceiling surfaces are sealed; and openings around ducts and spaces between doors and frames are capable of being sealed to facilitate decontamination			R
Walls, ceilings, and floors are smooth, impermeable to liquids, and resistant to chemicals and disinfectants normally used in the laboratory; floors are monolithic and slip resistant; coved floor coverings are present			S
Furniture is capable of supporting anticipated loading	R	R	R

Spaces between benches, cabinets, and equipment are accessible for cleaning	R	R	R
Windows that open to the facility's exterior are equipped with fly screens	R	R	
All windows in the laboratory are closed and sealed			R
Illumination is adequate for all activities, avoiding glare that could impede vision		R	R
Properly maintained biological safety cabinets (BSCs) (preferably class II) are used whenever procedures with a potential for creating infectious aerosols or splashes are conducted and high concentrations or large volumes of infectious agents are used		R	R
BSCs are located away from doors, windows that can be opened, from heavily traveled areas, and from other potentially disruptive equipment (for example, supply louvers) to maintain the BSC's air flow parameters		R	R
When air is discharged to the outside through the building exhaust system, Class II BSCs are connected in such a manner to avoid interference with air balance of the BSCs and the building exhaust system			R
Class III BSCs are directly connected to the exhaust system			S
When Class III BSCs are directly connected to the supply system, it is done in such a manner that prevents positive pressurization of the cabinets			R
Continuous flow centrifuges or other equipment that may produce aerosols, are contained in devices that exhaust air through HEPA filters before discharge into the laboratory or such equipment is vented to the outside and dispersed away from occupied areas and air intakes (HEPA systems must be tested annually)			R
Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent; filters are checked routinely, maintained, and replaced as needed (an alternative is to use portable vacuum pumps that are also protected with traps and filters)		R*	R
New laboratory facilities have mechanical ventilation systems that provide an inward flow of air without recirculating to spaces outside of the laboratory		S	

A ducted exhaust air ventilation system is provided which creates directional air flow which draws air into the laboratory from clean areas and toward contaminated areas; exhaust air is not recirculated to any other area of the building; filtration and other treatments of exhaust air are not required, but should be considered based on specific agent manipulations and use conditions			R
A visual monitoring device is provided at the laboratory entrance to confirm directional inward airflow			S
Workers verify that laboratories are under negative pressure			R
An HVAC control system is installed to prevent sustained positive pressurization of the laboratory			S
Audible alarms are provided to notify workers of HVAC system failure			S
Outside exhaust is dispersed away from occupied areas and air intakes or HEPA-filtered			R
Additional environmental protection (personnel showers, HEPA filtration of exhaust air, containment of other piped services, and provisions for effluent decontamination) are installed			S
A method for decontaminating all laboratory waste (for example, autoclave, chemical disinfection, incineration) is available in the facility and used, preferably in the laboratory		R*	R

Key: R = CDC required; R* = more stringent OSHA requirement; S = CDC suggested

HEPATITIS B VACCINATION AND POST-EXPOSURE EVALUATION AND FOLLOW-UP - 29 CFR 1910.1030 **(f)**

The OSHA advocates the use of pre-exposure Hepatitis B vaccination combined with prompt, appropriate medical follow-up after an exposure to prevent or reduce the risk of HBV infection. Vaccination is the single most effective means of preventing HBV infection transmission.

Hepatitis B Vaccination

All workers, including part-time and temporary workers, who have occupational exposure to blood or OPIM, must be offered the Hepatitis B vaccine (also defined as the Hepatitis B vaccination series) regardless of how often the exposure may occur —

- Within 10 working days of initial assignment
- After specific training that includes efficacy, safety, administration methods of the vaccination, and benefits of the vaccination (workers who are thoroughly educated about the vaccine accept it more readily)

The CDC has published several fact sheets to inform workers on the health risks of hepatitis infection and the safety and efficacy of the Hepatitis B vaccine. These fact sheets are available on line at http://www.cdc.gov/ncidod/diseases/hepatitis/index.htm.

Employers are not required to make the vaccination available —

- To workers who have previously received the Hepatitis B vaccine series
- When a worker's immunity is confirmed through antibody testing
- When administration of the vaccine is contraindicated for other medical reasons

If the employer claims one of these exemptions, it must be documented in the worker's occupational health record.

Also, employers may not institute a program in which workers pay the original cost of the vaccine and are reimbursed by the employer if they remain employed for a specified period of time.

Department of Army Policy for Health care Workers

The Department of the Army (DA) has strict immunization policies for military personnel and DOD civilian health care workers who have occupational exposure to BBPs. Declination of the Hepatitis B vaccination is not an option for DOD military personnel serving in the medical or dental career fields. Also, civilian employees who were hired after 1 January 1997 and serve in the medical or dental career fields may not decline the Hepatitis B vaccination when immunization is specifically mandated in their work agreement or job description. Volunteers will be provided the Hepatitis B vaccination only if it is determined that they are at risk of contracting HBV as part of their services. The relevant guidance is provided in—

- *DOD Instruction 6205.2*, Immunization Requirements, addresses immunization policies for all military personnel and DOD civilian employees
- *DOD Memorandum Assistant Secretary of Defense (Health Affairs)* Subject: Hepatitis B Immunization Policy for Department of Defense Medical and Dental Personnel, 23 October 1996 and *DA Memorandum Office of the Assistant Secretary (Manpower and Reserve Affairs)* prescribes requirements for the Hepatitis B vaccination of all military personnel serving in the medical or dental career fields
- *HQDA Memorandum DASG-ZA (OASD/5 NOV 96)* Subject: Hepatitis B Immunization Policy for Department of Defense Medical and Dental Personnel, 26 March 1997 and *HQ U.S. Army Medical Command Memorandum MCHO-CL-W (OASD/5 Nov 96)* Subject: Hepatitis B Immunization Policy for Department of Defense Medical and Dental Personnel, 27 Mar 1997 prescribes requirements for the Hepatitis B vaccination of all DOD civilian employees, volunteers, students, and other temporary staff, with job duties involving direct patient contact and who were hired or began work after 1 January 1997

Appendix C contains copies of the DOD instruction and subsequent memorandums.

Non-Health care Workers

Non-health care workers, such as non-appropriated fund and contract workers, may decline the Hepatitis B vaccination unless it is included in their job description as a condition of employment. Non-health care workers declining the vaccination must sign a declination statement. The signed declination statement must be filed in the worker's occupational health record. The signing of the declination statement by the worker does not relieve the employer from the requirement to provide the vaccine at a later date if the worker so chooses. A sample declination statement is provided in Figure 1 below.

Contract Workers

Contracting Officer Representatives (CORs) must ensure that contractors are aware of the work-related risks associated with BBPs. The contract employer is responsible for developing and implementing a BBP Program.

HEPATITIS B VACCINATION
DECLINATION STATEMENT

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be a risk of acquiring Hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with Hepatitis B, at no charge to myself. However, I decline the Hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring Hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with Hepatitis B vaccine, I can receive the vaccination series at no charge to me.

_____ _____

Employee's Signature Date

_____

Employee's Job Classification

_____ _____

Witness Date

Figure 1.

Medical Evaluation

Employers must ensure that all medical evaluations and procedures, including prophylaxis, are made available —

- At no cost to the worker, including travel away from the work site
- At a time and place convenient to the worker, during normally scheduled work hours
- By or under the supervision of a licensed physician or another licensed health care professional (LHCP)
- In accordance with **current** United States Public Health Service (USPHS)/CDC guidelines.

Prevaccination Screening

Prevaccination screening for antibody status cannot be required of a worker, although employers can make prescreening available at no cost to workers. A worker may decline the prescreening, and the employer must still make the vaccination series available to the worker.

Vaccine Administration and Post Vaccination Testing

The current guidelines on immunization of adults at risk for Hepatitis B, including health care workers, from the CDC's Advisory Committee on Immunization Practices, is found at http://www.cdc.gov/nip/recs/adult-schedule.pdf. The current USPHS/CDC guidelines for Hepatitis B vaccination in the setting of an occupational exposure event, MMWR June 29, 2001: Updated US Public Health Services Guidelines for the Management of Occupational Exposures to HBV, HCV and HIV and Recommendations for Post-Exposure prophylaxis are available online at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5011a1.htm. The vaccine consists of 3 doses. If the series is interrupted after the first dose, the second dose should be administered as soon as possible. The second and third doses should be separated by an interval of at least 2 months. If the third dose is delayed, it should be administered when convenient.

Figures 2 and 3 describe processes for administering the hepatitis vaccination.

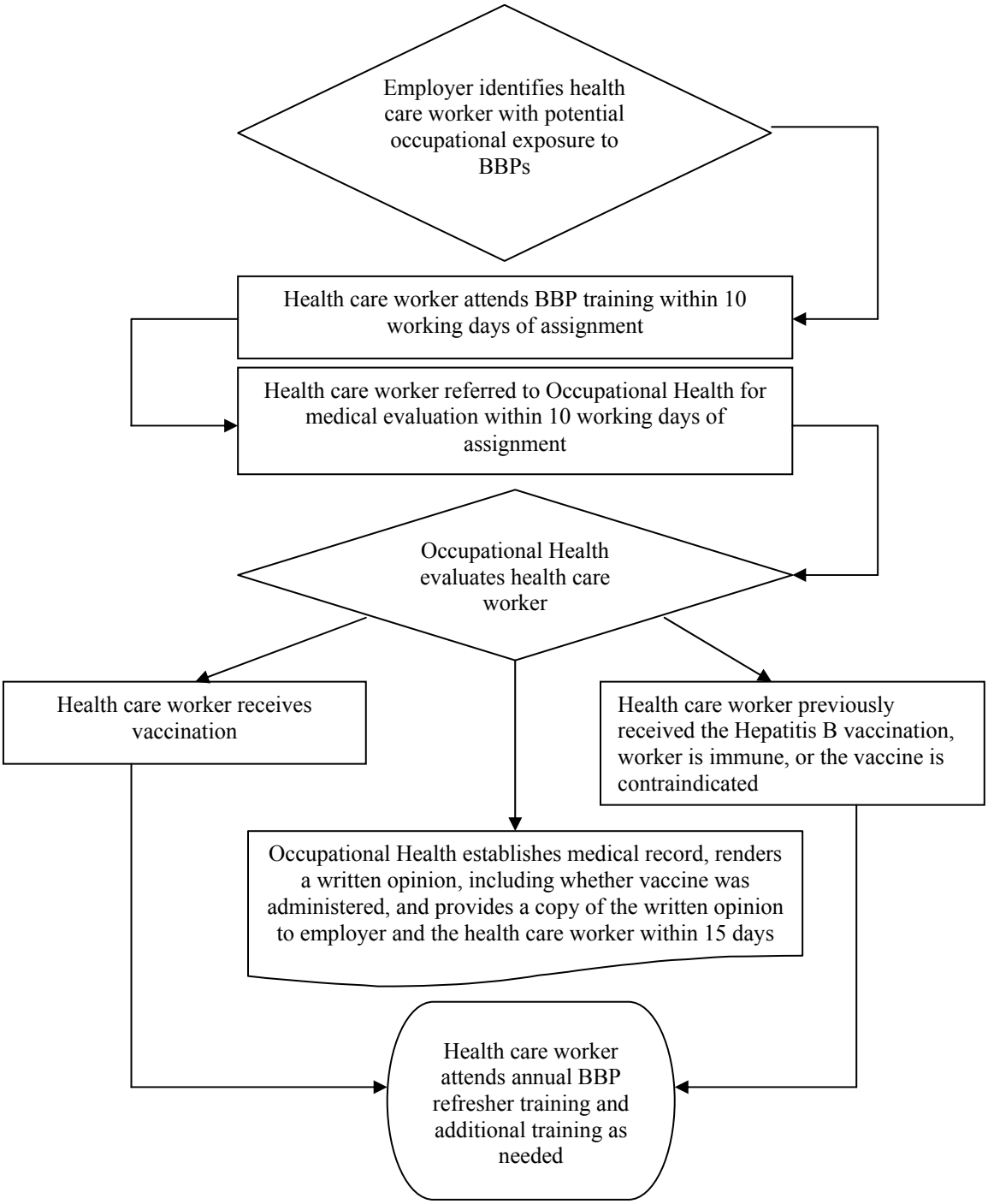

Figure 2. Hepatitis B Vaccination Process for Health Care Workers

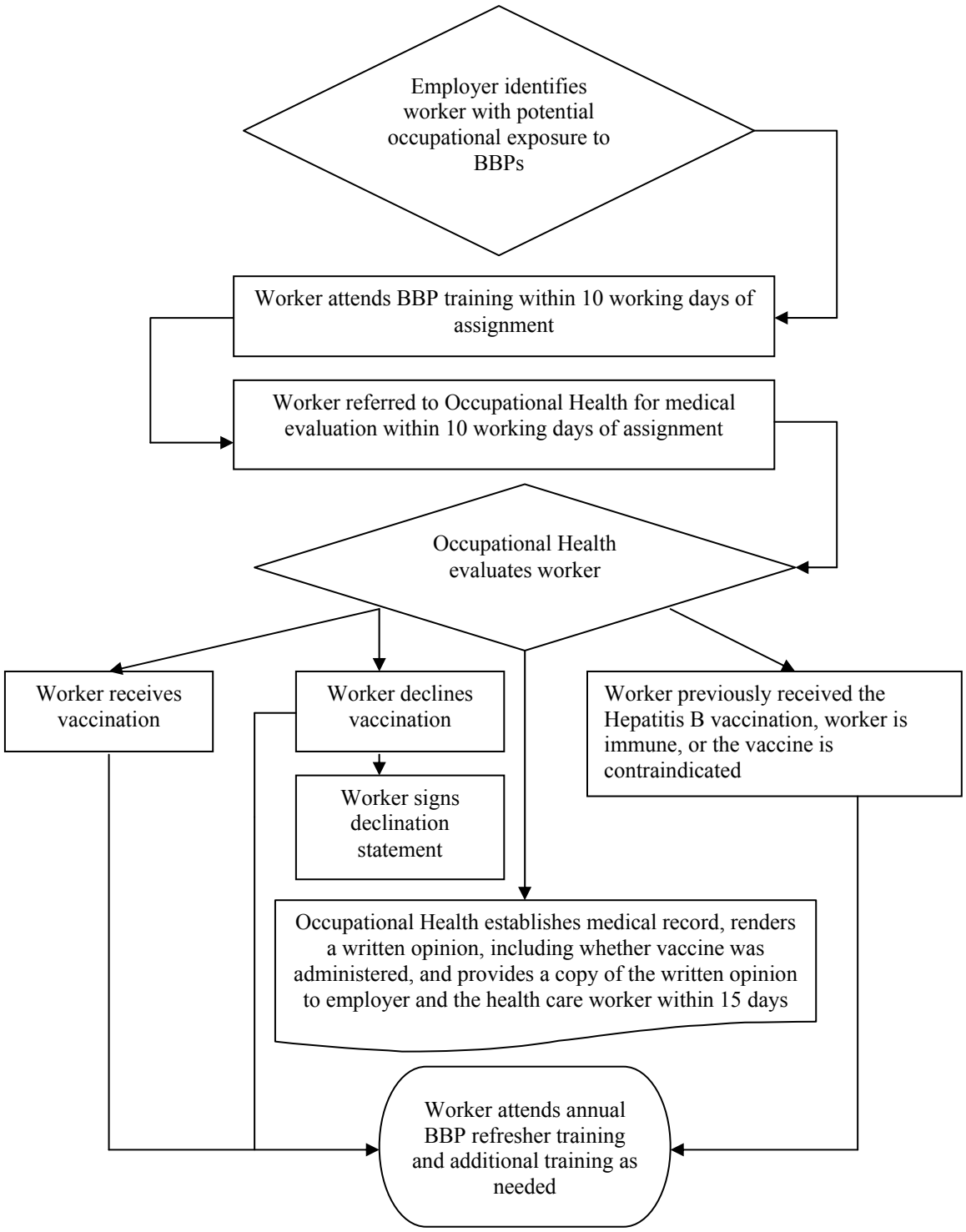

Figure 3. Hepatitis B Vaccination Process for Non Health Care Workers

Post Vaccination Testing

The USPHS recommends that workers be tested for immunity 1 to 2 months after completing the Hepatitis B series, and those workers whose anti-Hepatitis B Ag titer is less than 10 mIU/mL complete a second 3-dose vaccine series or be evaluated to determine if they are HBsAG-positive. Revaccinated workers should be tested for immunity 1 to 2 months after completing the second series. Workers who are HBsAG-positive should be counseled on preventing HBV transmission to others and regarding the need for medical evaluation.

Approximately 5 percent of workers given the vaccination series do not develop an antibody response to the vaccine and remain susceptible to HBV. A persistently negative response is an indication for using Hepatitis B Immune Globulin in the setting of either a suspected or confirmed Hepatitis B exposure.

Employers are not required to provide routine booster doses of the Hepatitis B vaccine to workers unless the USPHS recommends them at a future date.

Laboratory Accreditation

All laboratory tests must be conducted at a laboratory that is accredited by one of the following national accrediting bodies —

- American Association of Blood Labs
- College of American Pathologists
- Joint Commission on Accreditation of Health care Organizations
- An equivalent state agency that participates in a recognized quality assurance program

Exposure Management

Each facility with workers potentially exposed to blood through their work, must plan in advance and publicize access to emergency medical care procedures for BBP exposure management. Emergency medical care procedures must be consistent with current USPHS guidelines. Although these guidelines are written for health care and public-safety settings, they may be applied to other occupational settings with workers having potential for occupational exposure to BBPs. The guidelines also describe special circumstances (for example, delayed exposure report, unknown source person, pregnancy in the exposed person, resistance of the source virus to antiretroviral agents, or toxicity of the PEP regimen) when consultation with local experts and/or the National Clinicians' Post-Exposure Prophylaxis Hotline ((PEPline) 1-888-448-4911) is advised. (Note: this

number is only to be used by health care providers who are evaluating patients with a BBP exposure.)

Exposure Evaluation and Recommendations for Post-Exposure Prophylaxis (PEP)

Following an exposure incident, the exposed worker must be offered a **confidential** post exposure evaluation and follow-up. Types of exposure incidents requiring exposure management include –

- Percutaneous injury (for example, needlesticks and cuts with contaminated sharp objects)
- Mucous membrane or non intact skin (exposed skin that is chapped, abraded, or afflicted with dermatitis) contact with blood and OPIM
- Any direct contact with concentrated virus in a research laboratory or production facility setting
- A human bite where the person bitten or the person who inflicted the bite was exposed to blood or OPIM

Table 14 contains and overview of post-exposure evaluation and follow-up procedures in the event of an exposure incident.

Table 14. Post-Exposure Evaluation and Follow-Up Procedures

Exposure to Blood or OPIM		
Worker Responsibilities	**Supervisor/Employer Responsibilities**	**LHCP Responsibilities**
Wash with soap and water (flush if eye or mouth) Report incident to supervisor if available Go immediately to the emergency treatment area for evaluation	Direct worker to medical care Send to medical care provider: • BBP standard (if outside provider) • Worker's job description • Exposure incident investigation results • Source individual's HIV, Hepatitis B, Hepatitis C status (if known positive or currently negative) Document events on — • Exposure Incident Investigation Form • DA 285 (for military) and CA1 or CA16 (for civilians) • OSHA 300 log (or Safety and Occupational Health Program Injury/Illness Log) if first aid is rendered • BBP exposure log (maintained by Occupational Health) Give worker the written opinion of the LHCP when received (within 15 days of evaluation)	Evaluate exposure event Arrange for testing of worker and source patient at time of initial evaluation Notify worker of test results Provide counseling Provide medication if indicated Evaluate reported illnesses Document findings on Needlestick or Blood/Body Fluid Form and Blood and Body Fluid Exposure Form Send written opinion to employer on Physician's Written Opinion Form

First Aid

Immediately following an exposure incident, the exposed worker should receive immediate care —

- Flush wounds and skin with soap and water
- Flush mucous membranes with water
- Notify immediate supervisor, or if unavailable, immediately report to the health clinic during normal duty hours or to the emergency room after normal duty hours

Infection Risk

The employer must immediately identify and evaluate the exposure source, unless the employer can establish that identification is infeasible or prohibited by state or local law. The evaluation should include –

- An assessment of the risk of infection based on the type of fluid and the type of exposure
- An assessment of the exposed worker's immune status for HBV infection (for example, history of Hepatitis B vaccination and vaccine response)
- Immediate testing of known sources to determine HBV, HCV, and HIV infection status
- For unknown sources (or sources that cannot be tested), an assessment of the risk of exposure to HBV, HCV, or HIV infection (for example, for unknown sources consider prevalence of HBV, HCV, or HIV in the institution or the community served and for source individuals whose infection status remains unknown consider medical diagnoses, clinical symptoms, history of risk behaviors)

If the source individual is not infected with a BBP, baseline testing or further follow-up of the exposed worker is not necessary. Note that while old test results on the source individual may be helpful in guiding care if they indicate infection, old negative test results cannot be trusted to indicate the individual's **current** status, therefore re-testing of source individuals should be done even if there are records of past testing for HBV, HCV or HIV infection.

HBV, HCV, and HIV Infection Status

Testing discarded needles and syringes or other sharp instruments involved in an exposure incident, for virus infection is **not** recommended.

Immediately collect and test the exposed worker's blood. If the worker consents to baseline blood collection, but does not consent to HIV serologic testing, preserve the sample for at least 90 days in the event the worker elects to have testing.

Immediately inform the source individual of the incident, collect, and test the source individual's blood for HBV, HCV and HIV infection (if the source individual is already known to be infected with HBV, HCV or HIV, the relevant test does not need to be repeated). If law requires consent, it must be obtained prior to testing; if consent is not given, this must be documented in writing. When law does not require consent, available blood from the source individual must be tested and the results documented. The term available applies to blood samples that have already been drawn from the source individual. OSHA does not require drawing of blood specifically for HBV, HCV and HIV testing without consent of the source individual.

Confidentiality of the source individual must be maintained at all times. However, the exposed worker shall be informed of the source individual's test results and the worker shall be informed the laws and regulations concerning disclosure of the identity and infectious status of the source individual. Employers may not be informed of the results of source individual or exposed worker testing.

A Food and Drug Administration- (FDA-) approved rapid HIV-antibody test kit should be considered for expediting testing of source individuals, particularly if antibody testing by enzyme immunoassays (EIA) cannot be completed within 24-48 hours. Repeatedly reactive results by EIA or rapid HIV-antibody tests are considered to be highly suggestive of infection. Negative results are excellent indicators of the absence of HIV antibody. Confirmation of a reactive result by Western blot or immunoflourescent antibody is not necessary to make initial decisions about post exposure management, but should be done to complete the testing process and before informing the source individual of the test results. Repeatedly reactive results by EIA or anti-HCV should be confirmed by a supplemental test (for example, recombinant immunoblot assay or HCV polymerase chain reaction).

Post Exposure Prophylaxis

When medically indicated, initiate PEP as soon as possible, preferably within hours of the exposure. Such treatment is more effective the earlier it is started; therefore, prompt medical evaluation is critical. Recommended PEP for HBV, HCV, and HIV are discussed in the following paragraphs. General recommendations include –

- Offering women of childbearing age not known to be pregnant, a pregnancy test
- If viral resistance is suspected, seeking expert consultation
- During follow-up and testing, advising the exposed worker to seek medical evaluation for any acute illness during evaluation
- Providing counseling concerning infection status, including results and interpretations of all tests
- Providing post-exposure counseling if the worker needs help dealing with the emotional effect of the exposure

Exposures Posing Risk of HBV Infection Transmission

Table 15 describes recommended PEP for exposures posing risk of HBV infection. Recommended follow-up testing and counseling for the exposed worker includes –

- Performing follow-up antibody to Hepatitis B surface antigen (anti-HBs) testing in persons who receive Hepatitis B vaccine
- Testing for anti-HBs 1 to 2 months after last does of vaccine (Note: anti-HBs response to vaccine cannot be ascertained if Hepatitis B immune globulin (HBIG) was received in the previous 3 to 4 months)

Table 15. Recommended PEP for Exposure to HBV

Vaccination and Antibody Response Status of Exposed Workers[1]	Treatment		
	Source HBsAG[2] Positive	Source HBsAG[2] Negative	Source Unknown or Not Available for Testing
Unvaccinated	HBIG[3] x 1 and initiate HB vaccine series[4]	Initiate HB vaccine series	Initiate HB vaccine series
Previously Vaccinated			
Known Responder[5]	No treatment	No treatment	No treatment
Known Non Responder[6]	HBIG x 1 and initiate revaccination or HBIG x 2[7]	No treatment	If known high-risk source, treat as if source were HBsAG positive
Antibody Response Unknown	Test exposed person for anti-HBs[8] -If adequate[5], no treatment is necessary - If inadequate[6], administer HBIG X 1 and vaccine booster	No treatment	Test exposed person for anti-HBs -If adequate[8], no treatment is necessary - If inadequate[8], administer vaccine booster and recheck titer in 1-2 months

1 Persons who have previously been infected with HBV are immune to reinfection and do not require post exposure prophylaxis
2 Hepatitis B surface antigen
3 Hepatitis B immune globulin; dose is 0.06 mL/kg intramuscularly
4 Hepatitis B vaccine
5 A responder is a person with adequate levels of serum antibody to HBsAG (for example, anti-HBs ≥ 10 mlU/mL)
6 A nonresponder is a person with inadequate response to vaccination (for example, serum anti-HBS < 10 mlU/mL)
7 The option of giving one dose of HBIG and reinitiating the vaccine series is preferred for non-responders who have not completed a second 3-dose vaccine series. For persons who previously completed a second vaccine series but failed to respond, two doses of HBIG are preferred
8 Antibody to HBsAg

Exposures Posing Risk of HCV Infection Transmission

The USPHS does not recommend any PEP for exposures posing risk of HCV infection transmission, but it does recommend follow-up testing and counseling for the exposed worker that includes –

- Performing baseline and follow-up anti-HCV and alanine amino-tranferase (ALT) 4 to 6 months after exposure and performing HCV RNA at 4 to 6 weeks if earlier diagnosis of HCV infection is desired
- Confirming all anti-HCV results reported positive by enzyme immunoassays (EIAs) using supplemental anti-HCV tests
- Counseling exposed workers to refrain from donating blood, plasma, organs, tissue, or semen during the follow-up period
- Counseling exposed HCW on following all recommended infection control practices, including standard precautions, handwashing, protective barriers, and care in the use and disposal of sharps

Exposures Posing Risk of HIV Infection Transmission

If the source individual is seronegative for HIV, baseline testing or further follow-up of the exposed worker normally is not necessary. However, serologic testing should be made available to all workers who are concerned that they might have been occupationally infected with HIV.

Table 16 contains recommended PEP for percutaneous injuries posing risk of HIV infection transmission and Table 17 contains recommended PEP for mucous membrane and non-intact skin exposures. Because most occupational HIV exposures do not result in the transmission of HIV, potential toxicity must be carefully considered when prescribing PEP. Recommended follow-up, testing, and counseling includes –

- Starting PEP, if medically indicated, as soon as possible after exposure
- Reevaluating workers taking PEP, within 72 hours after exposure, especially as additional information about the source individual becomes available
- Administering PEP for 4 weeks if tolerated
- Discontinuing PEP if the source individual is determined HIV-negative
- Advising a pregnant exposed worker regarding the potential benefits and risks of PEP to her and her fetus

- Performing HIV-antibody testing for at least 6 months post exposure (for example at baseline, 6 weeks, 3 months, and 6 months)
- Performing extended HIV follow-up for 12 months when the exposed worker becomes infected with HCV
- Performing HIV antibody testing if illness compatible with an acute retroviral syndrome occurs
- Monitoring for drug toxicity (if PEP is used) by testing at baseline (within 72 hours) and again in 2 weeks after starting PEP
- Advising the exposed worker of the importance of completing the prescribed regimen
- Informing workers undergoing PEP, about possible drug toxicities, need for monitoring, and possible drug interactions
- Advising workers to use precautions to prevent secondary transmission (for example, sexual abstinence or condom use, avoid pregnancy, refrain from donating blood, plasma, organs, tissue, semen) during the follow-up period
- Advising women who are breast-feeding, of the risk of HIV transmission through breast milk and consideration of discontinuing breast-feeding, especially for high-risk exposures
- Referring the HIV-exposed worker to a specialist who is knowledgeable in HIV treatment and counseling for medical management

Table 16. PEP for Percutaneous Injuries Posing Risk of HIV Infection Transmission

Infection Status of Source	Exposure Type	
	Less Severe[4]	More Severe[7]
HIV-Positive Class 1[1]	Recommend basic 2-drug PEP	Recommend expanded 3-drug PEP
HIV-Positive Class 2[1]	Recommend expanded 3-drug PEP	Recommend expanded 3-drug PEP
Source of Unknown HIV Status[2]	Generally, no PEP warranted; however, consider basic 2-drug PEP for source with HIV risk factors	Generally, no PEP warranted; however, consider basic 2-drug PEP for source with HIV risk factors
Unknown Source[3]	Generally, no PEP warranted; however, consider basic 2-drug PEP[5] in settings where exposure to HIV-infected persons is likely[6]	Generally, no PEP warranted; however, consider basic 2-drug PEP[5] in settings where exposure to HIV-infected persons is likely
HIV-Negative	No PEP warranted	No PEP warranted

[1] HIV-Positive, Class 1 – asymptomatic HIV infection of known low viral load (for example, <1.500 RNA copies/mL). HIV-Positive, Class 2 – symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of PEP should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.
[2] Source of unknown HIV status (for example, deceased source person with no samples available for testing).
[3] Unknown source (for example, a needle from a sharps disposal container).
[4] Less severe (for example, solid needle and superficial injury).
[5] The designation "consider PEP" indicates that PEP is optional and should be based on individualized decision between the exposed person and the treating clinician.
[6] If PEP is offered and taken and the source is later determined to be HIV-negative, PEP should be discontinued.
[7] More severe (for example, large-bore, hollow needle, deep puncture, visible blood on device, or needle used in patient's artery or vein).

Table 17. Recommended PEP for Mucous Membrane and Non-intact Skin Exposures Posing Risk of HIV Infection Transmission

Infection Status of Source	Exposure Type	
	Small Volume[5]	Large Volume[8]
HIV-Positive Class 1[2]	Consider basic 2-drug PEP	Recommend expanded 3-drug PEP
HIV-Positive Class 2[2]	Recommend basic 2-drug PEP	Recommend expanded 3-drug PEP
Source of Unknown HIV Status[3]	Generally, no PEP warranted; however, consider basic 2-drug PEP for source with HIV risk factors	Generally, no PEP warranted; however, consider basic 2-drug PEP for source with HIV risk factors
Unknown Source[4]	Generally, no PEP warranted; however, consider basic 2-drug PEP[6] in settings where exposure to HIV-infected persons is likely[7]	Generally, no PEP warranted; however, consider basic 2-drug PEP[6] in settings where exposure to HIV-infected persons is likely
HIV-Negative	No PEP warranted	No PEP warranted

[1] For skin exposures, follow-up is indicated only if there is evidence of compromised skin integrity (for example, dermatitis, abrasion, or open wound).

[2] HIV-Positive, Class 1- asymptomatic HIV infection or known low viral load (for example, <1,500 RNA copies/mL). HIV-Positive, Class 2 symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of PEP should not be delayed pending expert consultation, and because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

[3] Source of unknown HIV status (for example, deceased source person with no samples available for testing).

[4] Unknown source (for example, splash from inappropriately disposed blood).

[5] Small volume (for example, a few drops).

[6] The designation "consider PEP" indicates that PEP is optional and should be based on individualized decision between the exposed person and the treating clinician.

[7] If PEP is offered and taken and the source is later determined to be HIV-negative, PEP should be discontinued.

[8] Large volume (for example, major blood splash).

Documenting Exposure Incidents

The exposure incident must be documented and at a minimum, include the following information –

- Route(s)of exposure
- Circumstances under which the exposure incident occurred
- Identification and documentation of the source individual, unless identification is infeasible or prohibited by state or local law

In addition, the USPHS guidelines recommend including the following information –

- Date and time of exposure
- Details of the procedure being performed, including where and how the exposure occurred; the type and brand of device; and how and when in the course of handling the device the exposure occurred
- Details of the exposure, including the type and amount of fluid or material and the severity of the exposure (for example, a percutaneous exposure, depth of injury, whether fluid was injected and for a skin or mucous membrane exposure, the estimated volume of material and the condition of the skin (for example, chapped, abraded, intact))
- Details about the exposure source (for example, whether the source material contained HBV, HCV, or HIV; if the source is HIV-infected, the stage of disease, history of antiretroviral therapy, viral load, and antiretroviral resistance information, if known)
- Details about the exposed person (for example, Hepatitis B vaccination and vaccine-response status)
- Details about counseling, post exposure management, and follow-up

Additional guidance on documenting exposure incidents is provided in the record keeping section of this technical guide.

Information Provided to the LHCP

After documenting the incident, send the following to the LHCP who is evaluating the exposed worker –

- A copy of the OSHA BBP standard

- A description of the exposed worker's job duties as they related to the exposure incident
- A report describing the routes and circumstances of exposure
- The source individual's HBV/HIV status (if obtainable or if known)
- The exposed worker's Hepatitis B vaccine status and all medical records relevant to the treatment of the worker (making sure those records remain confidential)

LHCP's Written Opinion

Within 15 days of completing the evaluation, the employers must obtain and provide the exposed worker with the LHCP's written opinion including –

- Documentation that the LHCP reported the test results and follow-up needs to the exposed worker (all other findings/diagnoses must remain confidential and must not be included in the written report)
- Whether vaccine evaluation or treatment was indicated and administered (Since the HBV vaccination is a vaccination series, the evaluating health care professional should develop a method to track and verify completion of the vaccination series)

Figure 4 contains a sample LHCP's Written Opinion, Figure 5 contains a sample Post-Exposure Evaluation and Follow-up Check points, and Figure 6 contains a sample transmittal form.

LICENSED HEALTH CARE PROFESSIONAL'S WRITTEN OPINION

DATE

OCCUPATIONAL EXPOSURE TO:

LICENSED HEALTH CARE PROFESSIONAL'S WRITTEN OPINION in the case of:

Name: _____ SSN: _____ Dept/Code: _____

1. The above noted individual was examined regarding exposure to blood and body fluids.

On the basis of this examination, the following comments are submitted:

2. A medical condition WAS or WAS NOT detected that would place the employee at an increased risk of material impairment of health from exposure to _____. Comments (if applicable):

3. The employee has been counseled regarding the results of this medical evaluation and of any medical conditions resulting from this exposure that require further evaluation or treatment.

_____
Date

_____
(Examiner's signature and stamp)

Original: employee's supervisor
Copies: employee health record

THIS LETTER IS PROTECTED BY THE PRIVACY ACT OF 1974

Figure 4.

POST-EXPOSURE EVALUATION AND FOLLOW-UP CHECKPOINTS

Activity	Completion Dates
1. Worker furnished with documentation regarding exposure incident.	_____
2. Source individual identified. Source individual:_____	_____
3. Source individual's blood tested and results given to exposed worker. Was consent obtained? Yes or No	_____
4. Exposed worker's blood collected and tested.	_____
5. Appointment arranged for worker with physician/LHCP.	_____

Figure 5.

TRANSMITTAL FORM

LICENSED HEALTH CARE PROFESSIONAL (LHCP):

_____

ADDRESS:

_____

_____

_____

DOCUMENTATION FORWARDED TO LHCP:

- BBP STANDARD
- DESCRIPTION OF EXPOSED EMPLOYEE'S DUTIES
- DESCRIPTION OF EXPOSURE INCIDENT, INCLUDING ROUTES OF EXPOSURE
- RESULT OF SOURCE INDIVIDUAL'S BLOOD TESTING (IF OBTAINABLE)
- COPY OF APPLICABLE MEDICAL RECORDS

SENT BY: _____

Figure 6.

COMMUNICATION OF HAZARDS TO EMPLOYEES –

29 CFR 1910.1030 (g)

Workers must receive sufficient warning through labels and signs to eliminate or minimize their exposure to blood or OPIM.

Labels and Signs

Labels

Labels must –

- Include the universal biohazard symbol and the word "BIOHAZARD"
- Be fluorescent orange or orange-red with contrasting symbols or lettering
- Be either an integral part of the container or affixed with a string, wire, adhesive, or other method that will prevent their loss or unintentional removal
- Be affixed to containers used for RMW; contaminated equipment; refrigerators and freezers containing blood or OPIM; clear sharps container liners and sharps container wall cabinets; and other containers used to store, transport, or ship blood or OPIM

Red bags or red containers may be substituted for labels. Employers must adopt either a single label or color-coded system. Multiple identification systems for the same hazard increase the chance for accidents.

Labels are not required for –

- Containers of blood, blood components, and blood products bearing an identifying label as specified by the FDA that have been screened for HBV and HIV antibodies and released for transfusion or other clinical use
- Individual containers of blood or OPIM that are placed in labeled secondary containers (for example, test tube rack) during storage, transport, shipment, or disposal
- Laundry bags in a facility that uses UP when handling all laundry
- RMW that has been decontaminated by incineration, autoclaving, or chemical means
- Specimen containers that stay in the facility, the content of which are recognizable as specimens, and UP are used by the facility to handle all specimens

These labeling requirements do not preempt either the U.S. Postal Service labeling requirements (39 CFR Part III) or the Department of Transportation's Hazardous Materials Regulation (49 CFR Parts 171-180).

Signs

Signs must be posted at the entrances to HIV and HBV research laboratories and production facilities. The signs must include –

- Biohazard symbol and the word "BIOHAZARD"
- Special requirements for entering the area
- Name of the infectious agent
- Name and telephone number of the laboratory director or other responsible person

These signs must be fluorescent orange-red with lettering or symbols in contrasting color.

Information and Training

Training for Occupationally Exposed Workers

All workers with occupational exposure must receive **initial** and **annual** training –

- On the hazards associated with blood and OPIM

- On protective measures to be taken to minimize the risk of occupational exposure
- Before placement in positions where occupational exposures may occur
- When tasks, responsibilities, procedures, or work station changes affect the worker's occupational exposure
- At no cost
- At a reasonable time
- At a convenient location
- By a subject matter expert

Additional training must be provided when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the worker's occupational exposure. This additional training may be limited to the modified or new tasks or procedures.

Training materials – including written materials, oral presentations, films, video, computer programs, or audiotapes – must be appropriate in content and vocabulary to the educational level, literacy, and language background of the workers. If a worker is only proficient in a foreign language, the trainer or interpreter must convey the information in that foreign language.

At a minimum, the training program must contain the following elements –

- An accessible copy of the regulatory text of this standard and an explanation of its contents
- A general explanation of the epidemiology and symptoms of bloodborne diseases (Note: The trainer must cover the commonly found BBPs in the MTF and other diseases of current events interest.)
- An explanation of the modes of transmission of BBP
- An explanation of the employer's ECP and the means by which the worker can obtain a copy of the written plan
- An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and OPIM
- An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and PPE
- Information on types, proper use, location, removal, handling, decontamination, and disposal of PPE
- An explanation of the basis for selection of PPE

- Information on the HBV vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and availability free of charge
- Information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM
- An explanation of the procedures to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that is available
- Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident
- An explanation of the labels and signs and/or color coding required by the standard
- An opportunity for interactive questions and answers with the person conducting the training session

All training elements must be covered; however, training is performance oriented, so flexibility is permitted to tailor the program to a worker's background and responsibilities. Site-specific training is therefore incorporated.

Training workers solely by film or video without a discussion period is insufficient. Also, a generic computer program, even an interactive one, is not considered appropriate unless the employer supplements the training with the site-specific information required (for example, the location of the ECP and the procedures to be followed in the event of an exposure incident, and an accessible contact person to clarify any issues of concern).

Sufficient time must be allocated to ensure the training –

- Adequately addresses all required training elements
- Allows for questions and a review of materials as needed

The Trainer

The individual conducting the training must –

- Be knowledgeable in all training program elements based on the completion of specialized courses, degree programs, or work experience

- Be familiar with the manner in which the training program elements relate to the particular workplace being addressed.

Possible qualified trainers include a variety of both health care professionals and non-health care professionals such as –

- Infection control practitioners
- Nurse practitioners
- Registered nurses
- Physicians
- Physician's assistants
- Emergency medical technicians
- Industrial hygienists
- Epidemiologists
- Occupational safety and health specialists or managers
- Professional trainers

In some workplaces, such as dental or physicians' offices, individual workers may conduct the training if they are familiar with blood and OPIM exposure control.

Additional Training for Workers in HIV and HBV Laboratories and Production Facilities

Workers of HIV and HBV laboratories and production facilities must receive the training outlined above. In addition, before working with HIV or HBV, they must –

- Demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to their facility prior to work assignment
- Have prior experience in the handling of human pathogens or tissue cultures

Employers must provide a training program for workers with no prior experience handling human pathogens prior to their participation in work activities involving infectious agents. Initial activities may not include the handling of infectious agents and the training program must include assignment of a progression of work activities as techniques are learned and proficiency is developed.

RECORDKEEPING - 29 CFR 1910.1030 (h)

Employers must maintain records related to BBPs including exposure incidents, post exposure follow-up, Hepatitis B vaccination status, and training attendance for all workers with occupational exposure.

Medical Records

Employers are required to maintain an accurate record for each worker with occupational exposure to BBPs. These records are required for training, medical evaluations, treatment, and surveillance and must include –

- The worker's name and social security number
- A copy of the worker's Hepatitis B vaccination status including the dates of all Hepatitis B vaccinations and any medical records relative to the worker's ability to receive vaccination or the vaccination declination statement
- A copy of all results of examinations, medical testing, and follow-up procedures related to post-exposure evaluation
- The employer's copy of the LHCP's written opinion
- A copy of the information provided to the LHCP

All records must be kept confidential unless –

- The worker expressly consents disclosure in writing
- Disclosure is required by the BBP standard or other Federal, state, or local regulations

Figure 7 contains a sample authorization letter for release of a worker's medical record information to a designated representative (non mandatory).

All medical records required by BBP standard must be made available to OSHA. In addition, workers must have access to their own individual records in accordance with 29 CFR 1910.1020.

Medical records must be retained for the duration of employment plus 30 years.

SAMPLE AUTHORIZATION LETTER FOR RELEASE OF AN EMPLOYEE'S MEDICAL RECORD INFORMATION TO A DESIGNATED REPRESENTATIVE (NONMANDATORY)

I, _____ (full name of worker/patient), hereby authorize _____ (Individual or organization holding the medical records) to release to _____ (individual or organization authorized to receive the medical information), the following medical information from my personal medical records:

_____

_____

(Describe generally the information desired to be released)

I give my permission to use this medical information for the following purpose:

_____

_____

I do not give my permission for any other use or redisclosure of this information.

Space is provided below so you can place additional restrictions on this authorization letter. You may leave these lines blank or you may want to (1) specify a particular expiration date for this letter (if less than one year); (2) describe medical information created in the future which you intend is covered by this authorization letter; or (3) describe portions of the medical information in your records which you do not intend for release as a result of this letter.

_____

_____

_____

Full Name of Employee or Legal Representative

_____ _____

Signature of Employee or Legal Representative Date of Signature

Figure 7.

Exposure Incident Records

OSHA's new record keeping rule, 29 CFR 1904.8 requires employers to record all work-related needlesticks, cuts, lacerations, punctures, and scratches from sharp objects contaminated with another blood or OPIM on OSHA Form 300, Log of Work-Related Injuries and Illnesses (or equivalent such as the Safety and Occupational Health Program Injury and Illness Log), as an injury. In addition, employers must complete an OSHA Form 301, Injury and Illness Incident Report (or equivalent form) for every recordable injury or illness.

The Installation Safety Office maintains the OSHA Form 300. In addition, the Occupational and Health Department, MTF Infection Control Officer, or MTF Safety Manager collects and evaluates sharps injury data for the MTF. The purpose of recording sharps injuries is to help employers quickly identify problem areas; therefore, records should be reviewed regularly and serve as a guide when updating the ECP.

Recorded entries must –

- Identify the type and brand of the device involved in the incident
- Identify the department or work area where the exposure incident occurred
- Include an explanation of how the incident occurred (for example, the procedure being performed, the body part affected, objects or substances involved and how they were involved)

To protect the confidentiality of the injured worker, the incident must be treated as a privacy case. Do not enter the worker's name on the OSHA Form 300.

If an injured worker is later diagnosed with an infectious bloodborne disease, the identity of the disease must be entered and the classification must be changed to an illness.

If a worker is splashed or exposed to blood or OPIM without being cut or punctured, the incident must be recorded on the OSHA Form 300, if it results in the diagnosis of a bloodborne illness or if it results in –

- Death
- Loss of consciousness
- Days away from work

- Restricted work activity or job transfer
- Medical treatment beyond first aid

First aid means –

- Using a non-prescription medication at nonprescription strength (for medications available in both prescription and non-prescription form, a recommendation by a physician or other licensed health care professional to use a non-prescription medication at prescription strength is considered medical treatment for recordkeeping purposes)
- Administering tetanus immunizations (other immunizations, such as Hepatitis B vaccine or rabies vaccine, are considered medical treatment)
- Cleaning, flushing or soaking wounds on the surface of the skin
- Using wound coverings such as bandages, Band-Aid® and gauze pads or using butterfly bandages or Steri-Strips™ (other wound closing devices such as sutures and staples are considered medical treatment)
- Using hot or cold therapy
- Using any non-rigid means of support, such as elastic bandages, wraps, non-rigid back belts, etc. (devices with rigid stays or other systems designed to immobilize parts of the body are considered medical treatment for recordkeeping purposes)
- Using temporary immobilization devices while transporting an accident victim (for example, splints, slings, neck collars, back boards, etc.)
- Drilling of a fingernail or toenail to relieve pressure, or draining fluid from a blister
- Using eye patches
- Removing foreign bodies from the eye using only irrigation or a cotton swab
- Removing splinters or foreign material from areas other than the eye by irrigation, tweezers, cotton swabs or other simple means
- Using finger guards
- Using massages (physical therapy or chiropractic treatment are considered medical treatment for recordkeeping purposes)
- Drinking fluids for relief of heat stress

The log may be maintained in hard copy or electronic formats. However, sharps injuries recorded on OSHA Form 300 must be easily separated from other types of work-related injuries.

Band-Aids® - is a registered trademark of Johnson & Johnson, New Brunswick, New Jersey
Steri-Strips™ is a registered trademark of 3M Coroporation, St. Paul, Minnesota

The OSHA Forms 300 and 301 must be maintained for five years following the end of the calendar year to which they cover. During the storage period, employers must update the stored OSHA 300 Logs to include newly discovered recordable injuries or illnesses and to show any changes that have occurred in the classification of previously recorded injuries and illnesses. If the description or outcome of a case changes, employers must remove or line out the original entry and enter the new information.

Training Records

The employer must fully document all training sessions accurately. Training records must include –

- The dates of the training sessions
- The contents or a summary of the training sessions
- The names and qualifications of the persons conducting the training
- The names and job titles of all persons attending the training sessions

Figure 8 contains a sample documented training session.

All training records must be made available to the Assistant Secretary and the Director upon request. Workers must have access to their own individual training records for examination and copying.

Training records are not considered to be confidential and may be maintained in any file in a location readily accessible for review by evaluators or inspectors. OSHA requires employers must retain training records for three years from the date on which the training occurred.

SAMPLE
INITIAL/ANNUAL TRAINING SESSION

Date: 2 February 2003

Topic: Labeling Requirements

Trainer: Mr. Henry, Occupational Safety and Health Manager

Attendees:

NAME	JOB TITLE
Mrs. Dean	Housekeeper/waste collector
MAJ Jones	Pathologist
Ms. Day	Contract Laundry Handler
CPT Largo	Chief, Patient Administration Department
Mr. Johnson	Food Service Supervisor

Figure 8.

Transfer of Records

If the employer ceases to do business, and there is no successive employer to receive and retain the medical and training records for the prescribed period, the employer must notify the Director at least three months prior to their disposal for a determination as to disposition.

APPENDIX A
29 CFR 1910.1030, BLOODBORNE PATHOGENS

29 CFR 1910.1030 Bloodborne pathogens.

(a) **Scope and Application**. This section applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b) of this section.

(b) **Definitions**. For purposes of this section, the following shall apply:

> **Assistant Secretary** means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.
>
> **Blood** means human blood, human blood components, and products made from human blood.
>
> **Bloodborne Pathogens** means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, Hepatitis B virus (HBV) and human immunodeficiency virus (HIV).
>
> **Clinical Laboratory** means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.
>
> **Contaminated** means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.
>
> **Contaminated Laundry** means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.
>
> **Contaminated Sharps** means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.
>
> **Decontamination** means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

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

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

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

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

HBV means Hepatitis B virus.

HIV means human immunodeficiency virus.

Needleless Systems means a device that does not use needles for (1) the collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (2) the administration of medication or fluids; or (3) any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

Occupational Exposure means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.

Other Potentially Infectious Materials means (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid,

pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Parenteral means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

Personal Protective Equipment is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

Production Facility means a facility engaged in industrial-scale, large-volume or high concentration production of HIV or HBV.

Regulated Waste means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

Research Laboratory means a laboratory producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in production facilities.

Sharps with Engineered Sharps Injury Protections means a nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

Source Individual means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

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

Universal Precautions is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

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

(c) **Exposure Control –**

(c)(1) **Exposure Control Plan**.

(c)(1)(i) Each employer having an employee(s) with occupational exposure as defined by paragraph (b) of this section shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure.

(c)(1)(ii) The Exposure Control Plan shall contain at least the following elements:

(c)(1)(ii)(A) The exposure determination required by paragraph (c)(2),

(c)(1)(ii)(B) The schedule and method of implementation for paragraphs (d) Methods of Compliance, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, (g) Communication of Hazards to Employees, and (h) Recordkeeping, of this standard, and

(c)(1)(ii)(C) The procedure for the evaluation of circumstances surrounding exposure incidents as required by paragraph (f)(3)(i) of this standard.

(c)(1)(iii) Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.1020(e).

(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:

(c)(1)(iv)(A) reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and

(c)(1)(iv)(B) document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.

(c)(1)(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.

(c)(1)(vi) The Exposure Control Plan shall be made available to the Assistant Secretary and the Director upon request for examination and copying.

(c)(2) **Exposure Determination**.

(c)(2)(i) Each employer who has an employee(s) with occupational exposure as defined by paragraph (b) of this section shall prepare an exposure determination. This exposure determination shall contain the following:

(c)(2)(i)(A) A list of all job classifications in which all employees in those job classifications have occupational exposure;

(c)(2)(i)(B) A list of job classifications in which some employees have occupational exposure, and

(c)(2)(i)(C) A list of all tasks and procedures or groups of closely related task and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in accordance with the provisions of paragraph (c)(2)(i)(B) of this standard.

(c)(2)(ii) This exposure determination shall be made without regard to the use of personal protective equipment.

(d) **Methods of Compliance -**

(d)(1) **General**. Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.

(d)(2) **Engineering and Work Practice Controls**.

(d)(2)(i) Engineering and work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after institution of these controls, personal protective equipment shall also be used.

(d)(2)(ii) Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.

(d)(2)(iii) Employers shall provide handwashing facilities which are readily accessible to employees.

(d)(2)(iv) When provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible.

(d)(2)(v) Employers shall ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.

(d)(2)(vi) Employers shall ensure that employees wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials.

(d)(2)(vii) Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B) below. Shearing or breaking of contaminated needles is prohibited.

(d)(2)(vii)(A) Contaminated needles and other contaminated sharps shall not be bent, recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure.

(d)(2)(vii)(B) Such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.

(d)(2)(viii) Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be:

(d)(2)(viii)(A) puncture resistant;

(d)(2)(viii)(B) labeled or color-coded in accordance with this standard;

(d)(2)(viii)(C) leakproof on the sides and bottom; and

(d)(2)(viii)(D) in accordance with the requirements set forth in paragraph (d)(4)(ii)(E) for reusable sharps.

(d)(2)(ix) Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure.

(d)(2)(x) Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials are present.

(d)(2)(xi) All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.

(d)(2)(xii) Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.

(d)(2)(xiii) Specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping.

(d)(2)(xiii)(A) The container for storage, transport, or shipping shall be labeled or color-coded according to paragraph (g)(1)(i) and closed prior to being stored, transported, or shipped. When a facility utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary provided containers are recognizable as containing specimens. This exemption only applies while such specimens/containers remain within the facility. Labeling or color-coding in accordance with paragraph (g)(1)(i) is required when such specimens/containers leave the facility.

(d)(2)(xiii)(B) If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of this standard.

(d)(2)(xiii)(C) If the specimen could puncture the primary container, the primary container shall be placed within a secondary container which is puncture-resistant in addition to the above characteristics.

(d)(2)(xiv) Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible.

(d)(2)(xiv)(A) A readily observable label in accordance with paragraph (g)(1)(i)(H) shall be attached to the equipment stating which portions remain contaminated.

(d)(2)(xiv)(B) The employer shall ensure that this information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken.

(d)(3) **Personal Protective Equipment -**

(d)(3)(i) **Provision**. When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Personal protective equipment will be considered "appropriate" only if it does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.

(d)(3)(ii) **Use**. The employer shall ensure that the employee uses appropriate personal protective equipment unless the employer shows that the employee temporarily and briefly declined to use personal protective equipment when, under rare and extraordinary circumstances, it was the employee's professional judgment that in the specific instance its use would have prevented the delivery of health care or public safety services or would have posed an increased hazard to the safety of the worker or co-worker. When the employee makes this judgement, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future.

(d)(3)(iii) **Accessibility**. The employer shall ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the worksite or is issued to employees. Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.

(d)(3)(iv) **Cleaning, Laundering, and Disposal**. The employer shall clean, launder, and dispose of personal protective equipment required by paragraphs (d) and (e) of this standard, at no cost to the employee.

(d)(3)(v) **Repair and Replacement**. The employer shall repair or replace personal protective equipment as needed to maintain its effectiveness, at no cost to the employee.

(d)(3)(vi) If a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible.

(d)(3)(vii) All personal protective equipment shall be removed prior to leaving the work area.

(d)(3)(viii) When personal protective equipment is removed it shall be placed in an appropriately designated area or container for storage, washing, decontamination or disposal.

(d)(3)(ix) **Gloves**. Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin; when performing vascular access procedures except as specified in paragraph (d)(3)(ix)(D); and when handling or touching contaminated items or surfaces.

(d)(3)(ix)(A) Disposable (single use) gloves such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.

(d)(3)(ix)(B) Disposable (single use) gloves shall not be washed or decontaminated for re-use.

(d)(3)(ix)(C) Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.

(d)(3)(ix)(D) If an employer in a volunteer blood donation center judges that routine gloving for all phlebotomies is not necessary then the employer shall:

(d)(3)(ix)(D)(**1**) Periodically reevaluate this policy;

(d)(3)(ix)(D)(**2**) Make gloves available to all employees who wish to use them for phlebotomy;

(d)(3)(ix)(D)(**3**) Not discourage the use of gloves for phlebotomy; and

(d)(3)(ix)(D)(**4**) Require that gloves be used for phlebotomy in the following circumstances:

(d)(3)(ix)(D)(**4**)(**i**) When the employee has cuts, scratches, or other breaks in his or her skin;

(d)(3)(ix)(D)(**4**)(**ii**) When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and

(d)(3)(ix)(D)(**4**)(**iii**) When the employee is receiving training in phlebotomy.

(d)(3)(x) **Masks, Eye Protection, and Face Shields**. Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

(d)(3)(xi) **Gowns, Aprons, and Other Protective Body Clothing**. Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments shall be worn in occupational exposure situations. The type and characteristics will depend upon the task and degree of exposure anticipated.

(d)(3)(xii) Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (e.g., autopsies, orthopaedic surgery).

(d)(4) **Housekeeping -**

(d)(4)(i) **General**. Employers shall ensure that the worksite is maintained in a clean and sanitary condition. The employer shall determine and implement an appropriate written schedule for cleaning and method of decontamination

based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area.

(d)(4)(ii) All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials.

(d)(4)(ii)(A) Contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning.

(d)(4)(ii)(B) Protective coverings, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the workshift if they may have become contaminated during the shift.

(d)(4)(ii)(C) All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination.

(d)(4)(ii)(D) Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dust pan, tongs, or forceps.

(d)(4)(ii)(E) Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed.

(d)(4)(iii) **Regulated Waste---**

(d)(4)(iii)(A) **Contaminated Sharps Discarding and Containment**.

(d)(4)(iii)(A)(**1**) Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:

(d)(4)(iii)(A)(**1**)(**i**) Closable;

(d)(4)(iii)(A)(**1**)(**ii**) Puncture resistant;

(d)(4)(iii)(A)(**1**)(**iii**) Leakproof on sides and bottom; and

(d)(4)(iii)(A)(**1**)(**iv**) Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard.

(d)(4)(iii)(A)(**2**) During use, containers for contaminated sharps shall be:

(d)(4)(iii)(A)(**2**)(**i**) Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries);

(d)(4)(iii)(A)(**2**)(**ii**) Maintained upright throughout use; and

(d)(4)(iii)(A)(**2**)(**iii**) Replaced routinely and not be allowed to overfill.

(d)(4)(iii)(A)(**3**) When moving containers of contaminated sharps from the area of use, the containers shall be:

(d)(4)(iii)(A)(**3**)(**i**) Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping;

(d)(4)(iii)(A)(**3**)(**ii**) Placed in a secondary container if leakage is possible. The second container shall be:

(d)(4)(iii)(A)(**3**)(**ii**)(**A**) Closable;

(d)(4)(iii)(A)(**3**)(**ii**)(**B**) Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and

(d)(4)(iii)(A)(**3**)(**ii**)(**C**) Labeled or color-coded according to paragraph (g)(1)(i) of this standard.

(d)(4)(iii)(A)(**4**) Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.

(d)(4)(iii)(B) **Other Regulated Waste Containment -**

(d)(4)(iii)(B)(1) Regulated waste shall be placed in containers which are:

(d)(4)(iii)(B)(1)(**i**) Closable;

(d)(4)(iii)(B)(1)(**ii**) Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;

(d)(4)(iii)(B)(1)(**iii**) Labeled or color-coded in accordance with paragraph (g)(1)(i) this standard; and

(d)(4)(iii)(B)(1)(**iv**) Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

(d)(4)(iii)(B)(**2**) If outside contamination of the regulated waste container occurs, it shall be placed in a second container. The second container shall be:

(d)(4)(iii)(B)(**2**)(**i**) Closable;

(d)(4)(iii)(B)(**2**)(**ii**) Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;

(d)(4)(iii)(B)(**2**)(**iii**) Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and

(d)(4)(iii)(B)(**2**)(**iv**) Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

(d)(4)(iii)(C) Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.

(d)(4)(iv) **Laundry**.

(d)(4)(iv)(A) Contaminated laundry shall be handled as little as possible with a minimum of agitation.

(d)(4)(iv)(A)(1) Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.

(d)(4)(iv)(A)(2) Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.

(d)(4)(iv)(A)(3) Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through of or leakage from the bag or container, the laundry shall be placed and transported in bags or containers which prevent soak-through and/or leakage of fluids to the exterior.

(d)(4)(iv)(B) The employer shall ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment.

(d)(4)(iv)(C) When a facility ships contaminated laundry off-site to a second facility which does not utilize Universal Precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded in accordance with paragraph (g)(1)(i).

(e) **HIV and HBV Research Laboratories and Production Facilities**.

(e)(1) This paragraph applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. It does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. These requirements apply in addition to the other requirements of the standard.

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

(e)(2)(i) **Standard Microbiological Practices**. All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

(e)(2)(ii) **Special Practices**.

(e)(2)(ii)(A) Laboratory doors shall be kept closed when work involving HIV or HBV is in progress.

(e)(2)(ii)(B) Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leakproof, labeled or color-coded container that is closed before being removed from the work area.

(e)(2)(ii)(C) Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms.

(e)(2)(ii)(D) When other potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The hazard warning sign shall comply with paragraph (g)(1)(ii) of this standard.

(e)(2)(ii)(E) All activities involving other potentially infectious materials shall be conducted in biological safety cabinets or other physical-containment devices within the containment module. No work with these other potentially infectious materials shall be conducted on the open bench.

(e)(2)(ii)(F) Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area and shall be decontaminated before being laundered.

(e)(2)(ii)(G) Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling

infected animals and when making hand contact with other potentially infectious materials is unavoidable.

(e)(2)(ii)(H) Before disposal all waste from work areas and from animal rooms shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

(e)(2)(ii)(I) Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency and which are checked routinely and maintained or replaced as necessary.

(e)(2)(ii)(J) Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of other potentially infectious materials. Extreme caution shall be used when handling needles and syringes. A needle shall not be bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture-resistant container and autoclaved or decontaminated before reuse or disposal.

(e)(2)(ii)(K) All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.

(e)(2)(ii)(L) A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or other responsible person.

(e)(2)(ii)(M) A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

(e)(2)(iii) **Containment Equipment**.

(e)(2)(iii)(A) Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment

devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols.

(e)(2)(iii)(B) Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually.

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

(e)(3)(i) Each laboratory shall contain a facility for hand washing and an eye wash facility which is readily available within the work area.

(e)(3)(ii) An autoclave for decontamination of regulated waste shall be available.

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

(e)(4)(i) The work areas shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors shall be the basic requirement for entry into the work area from access corridors or other contiguous areas. Physical separation of the high-containment work area from access corridors or other areas or activities may also be provided by a double-doored clothes-change room (showers may be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area.

(e)(4)(ii) The surfaces of doors, walls, floors and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.

(e)(4)(iii) Each work area shall contain a sink for washing hands and a readily available eye wash facility. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.

(e)(4)(iv) Access doors to the work area or containment module shall be self-closing.

(e)(4)(v) An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.

(e)(4)(vi) A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The proper direction of the airflow shall be verified (i.e., into the work area).

(e)(5) **Training Requirements**. Additional training requirements for employees in HIV and HBV research laboratories and HIV and HBV production facilities are specified in paragraph (g)(2)(ix).

(f) **Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up -**

(f)(1) **General**.

(f)(1)(i) The employer shall make available the Hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident.

(f)(1)(ii) The employer shall ensure that all medical evaluations and procedures including the Hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are:

(f)(1)(ii)(A) Made available at no cost to the employee;

(f)(1)(ii)(B) Made available to the employee at a reasonable time and place;

(f)(1)(ii)(C) Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed health care professional; and

(f)(1)(ii)(D) Provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place, except as specified by this paragraph (f).

(f)(1)(iii) The employer shall ensure that all laboratory tests are conducted by an accredited laboratory at no cost to the employee.

(f)(2) **Hepatitis B Vaccination**.

(f)(2)(i) Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii)(I) and within 10 working days of initial assignment to all employees who have occupational exposure unless the employee has previously received the complete Hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.

(f)(2)(ii) The employer shall not make participation in a prescreening program a prerequisite for receiving Hepatitis B vaccination.

(f)(2)(iii) If the employee initially declines Hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available Hepatitis B vaccination at that time.

(f)(2)(iv) The employer shall assure that employees who decline to accept Hepatitis B vaccination offered by the employer sign the statement in Appendix A.

(f)(2)(v) If a routine booster dose(s) of Hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii).

(f)(3) **Post-exposure Evaluation and Follow-up**. Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements:

(f)(3)(i) Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred;

(f)(3)(ii) Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;

(f)(3)(ii)(A) The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity.

If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.

(f)(3)(ii)(B) When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.

(f)(3)(ii)(C) Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

(f)(3)(iii) Collection and testing of blood for HBV and HIV serological status;

(f)(3)(iii)(A) The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

(f)(3)(iii)(B) If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

(f)(3)(iv) Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;

(f)(3)(v) Counseling; and

(f)(3)(vi) Evaluation of reported illnesses.

(f)(4) **Information Provided to the Health care Professional**.

(f)(4)(i) The employer shall ensure that the health care professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

(f)(4)(ii) The employer shall ensure that the health care professional evaluating an employee after an exposure incident is provided the following information:

(f)(4)(ii)(A) A copy of this regulation;

(f)(4)(ii)(B) A description of the exposed employee's duties as they relate to the exposure incident;

(f)(4)(ii)(C) Documentation of the route(s) of exposure and circumstances under which exposure occurred;

(f)(4)(ii)(D) Results of the source individual's blood testing, if available; and

(f)(4)(ii)(E) All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer's responsibility to maintain.

(f)(5) **Health care Professional's Written Opinion**. The employer shall obtain and provide the employee with a copy of the evaluating health care professional's written opinion within 15 days of the completion of the evaluation.

(f)(5)(i) The health care professional's written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.

(f)(5)(ii) The health care professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information:

(f)(5)(ii)(A) That the employee has been informed of the results of the evaluation; and

(f)(5)(ii)(B) That the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.

(f)(5)(iii) All other findings or diagnoses shall remain confidential and shall not be included in the written report.

(f)(6) **Medical Recordkeeping**. Medical records required by this standard shall be maintained in accordance with paragraph (h)(1) of this section.

(g) **Communication of Hazards to Employees -**

(g)(1) **Labels and Signs -**

(g)(1)(i) **Labels**.

(g)(1)(i)(A) Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F) and (G).

(g)(1)(i)(B) Labels required by this section shall include the following legend:

(g)(1)(i)(C) These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color.

(g)(1)(i)(D) Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

(g)(1)(i)(E) Red bags or red containers may be substituted for labels.

(g)(1)(i)(F) Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements of paragraph (g).

(g)(1)(i)(G) Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.

(g)(1)(i)(H) Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated.

(g)(1)(i)(I) Regulated waste that has been decontaminated need not be labeled or color-coded.

(g)(1)(ii) **Signs**.

(g)(1)(ii)(A) The employer shall post signs at the entrance to work areas specified in paragraph (e), HIV and HBV Research Laboratory and Production Facilities, which shall bear the following legend:

(Name of the Infectious Agent)
(Special requirements for entering the area)
(Name, telephone number of the laboratory director or other responsible person.)

(g)(1)(ii)(B) These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color.

(g)(2) **Information and Training**.

(g)(2)(i) Employers shall ensure that all employees with occupational exposure participate in a training program which must be provided at no cost to the employee and during working hours.

(g)(2)(ii) Training shall be provided as follows:

(g)(2)(ii)(A) At the time of initial assignment to tasks where occupational exposure may take place;

(g)(2)(ii)(B) Within 90 days after the effective date of the standard; and

(g)(2)(ii)(C) At least annually thereafter.

(g)(2)(iii) For employees who have received training on bloodborne pathogens in the year preceding the effective date of the standard, only training with respect to the provisions of the standard which were not included need be provided.

(g)(2)(iv) Annual training for all employees shall be provided within one year of their previous training.

(g)(2)(v) Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

(g)(2)(vi) Material appropriate in content and vocabulary to educational level, literacy, and language of employees shall be used.

(g)(2)(vii) The training program shall contain at a minimum the following elements:

(g)(2)(vii)(A) An accessible copy of the regulatory text of this standard and an explanation of its contents;

(g)(2)(vii)(B) A general explanation of the epidemiology and symptoms of bloodborne diseases;

(g)(2)(vii)(C) An explanation of the modes of transmission of bloodborne pathogens;

(g)(2)(vii)(D) An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan;

(g)(2)(vii)(E) An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;

(g)(2)(vii)(F) An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment;

(g)(2)(vii)(G) Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment;

(g)(2)(vii)(H) An explanation of the basis for selection of personal protective equipment;

(g)(2)(vii)(I) Information on the Hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;

(g)(2)(vii)(J) Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;

(g)(2)(vii)(K) An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available;

(g)(2)(vii)(L) Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;

(g)(2)(vii)(M) An explanation of the signs and labels and/or color coding required by paragraph (g)(1); and

(g)(2)(vii)(N) An opportunity for interactive questions and answers with the person conducting the training session.

(g)(2)(viii) The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.

(g)(2)(ix) Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements.

(g)(2)(ix)(A) The employer shall assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.

(g)(2)(ix)(B) The employer shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.

(g)(2)(ix)(C) The employer shall provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The employer shall assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.

(h) **Recordkeeping –**

(h)(1) **Medical Records**.

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

(h)(1)(ii) This record shall include:

(h)(1)(ii)(A) The name and social security number of the employee;

(h)(1)(ii)(B) A copy of the employee's Hepatitis B vaccination status including the dates of all the Hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination as required by paragraph (f)(2);

(h)(1)(ii)(C) A copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3);

(h)(1)(ii)(D) The employer's copy of the health care professional's written opinion as required by paragraph (f)(5); and

(h)(1)(ii)(E) A copy of the information provided to the health care professional as required by paragraphs (f)(4)(ii)(B)(C) and (D).

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

(h)(1)(iii)(A) Kept confidential; and

(h)(1)(iii)(B) Not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by this section or as may be required by law.

(h)(1)(iv) The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020.

(h)(2) **Training Records**.

(h)(2)(i) Training records shall include the following information:

(h)(2)(i)(A) The dates of the training sessions;

(h)(2)(i)(B) The contents or a summary of the training sessions;

(h)(2)(i)(C) The names and qualifications of persons conducting the training; and

(h)(2)(i)(D) The names and job titles of all persons attending the training sessions.

(h)(2)(ii) Training records shall be maintained for 3 years from the date on which the training occurred.

(h)(3) **Availability**.

(h)(3)(i) The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

(h)(3)(ii) Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee representatives, to the Director, and to the Assistant Secretary.

(h)(3)(iii) Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.1020.

(h)(4) **Transfer of Records**.

(h)(4)(i) The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h).

(h)(4)(ii) If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director, at least three months prior to their disposal and transmit them to the Director, if required by the Director to do so, within that three month period.

(h)(5) **Sharps Injury Log**.

(h)(5)(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:

(h)(5)(i)(A) the type and brand of device involved in the incident,

(h)(5)(i)(B) the department or work area where the exposure incident occurred, and

(h)(5)(i)(C) an explanation of how the incident occurred.

(h)(5)(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.

(h)(5)(iii) The sharps injury log shall be maintained for the period required by 29 CFR 1904.6.

(i) **Dates -**

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

(i)(2) The Exposure Control Plan required by paragraph (c) of this section shall be completed on or before May 5, 1992.

(i)(3) Paragraph (g)(2) Information and Training and (h) Recordkeeping shall take effect on or before June 4, 1992.

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

APPENDIX A TO SECTION 1910.1030 - HEPATITIS B DECLINATION (MANDATORY)

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring Hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with Hepatitis B vaccine, at no charge to myself. However, I decline Hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring Hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with Hepatitis B vaccine, I can receive the vaccination series at no charge to me.

APPENDIX B
NEEDLESTICK INJURY PREVENTION ACT

APPENDIX C
RELEVANT DOD AND MEDCOM POLICIES, INSTRUCTIONS, AND REGULATIONS

1. Policy Letter on Needlestick Safety for Health care Workers
http://www.ha.osd.mil/policies/2001/01_013.pdf

2. MEDCOM Regulation 40-35 Management of Regulated Medical Waste
http://chppm-www.apgea.army.mil/hmwp/

3. Change 1 to MEDCOM Regulation 40-35
http://chppm-www.apgea.army.mil/hmwp/

4. DODI Immunization Requirements
http://www.dtic.mil/whs/directives/corres/pdf/i62052_100986/i62052p.pdf

5. Hepatitis B Immunization Policy
http://www.tricare.osd.mil/policy/fy97/hepb9706.html

6. MEDCOM Memorandum MCHO-CL-W, Mandatory Hepatitis B Immunization Policy

7. MEDCOM Regulation No. 40-44, Latex Allergy Prevention
http://chppm-www.apgea.army.mil/IHMSM/ms/documents/R40-44.pdf

APPENDIX D
SAMPLE HOSPITAL BLOODBORNE PATHOGEN PROGRAM

Organization's Name

Office File Symbol

SOP No.
Disk File Name
Effective Date
Date Removed from Service

BLOODBORNE PATHOGEN EXPOSURE CONTROL PLAN (ECP)

1. PURPOSE. This ECP establishes policies and procedures for implementing a Bloodborne Pathogens (BBP) Prevention and Treatment Program within *(insert name of facility)*_____. The goal of this ECP is to eliminate or reduce the risk of injury or illness resulting from occupational exposure to BBP. Occupational exposure is defined as reasonably anticipated skin, eye, mucous membrane or parental contact with blood or other potentially infectious materials (OPIM) that may result from performance of a worker's duties. The primary methods used to prevent occupational exposure are engineering and administrative controls, safe work practices, and personal protective equipment (PPE).

2. SCOPE. This ECP applies to *(insert name of facility)* _____and all outlying health clinics.

3. REFERENCES. References are listed at Appendix A.

4. RESPONSIBILITIES.

a. The Commander ensures that an effective BBP ECP is developed and implemented according to 29 CFR 1910.1030.

b. The Safety/Infection Control Committees will monitor the ECP and approve all exceptions that require the need to recap or remove a needle.

c. Infection Control shall:

(1) Review the ECP annually and update it as required. The annual review must include changes in technology that eliminate or reduce exposure to BBPs, and consideration of implementation of safer medical devices.

(2) Coordinate the updating of infection control policies to ensure compliance with the ECP.

(3) Provide guidance and assistance regarding the use of equipment, interpretation and establishment of policies, and use of good work practices.

(4) Provide orientation and training to workers.

(5) Implement engineering controls when approved by the Regional Standardization Committee.

(6) Monitor the implementation and compliance with this regulation in conjunction with Safety and Preventive Medicine.

(7) In coordination with Occupational Health (OH) and Safety, analyze BBP incident data to identify trends and propose preventive measures. Data analysis will be presented to the appropriate department for implementation and action as indicated.

d. Safety shall:

(1) Collect data on all BBP exposure incidents and develop or recommend remedial actions to reduce exposures. Data shall be reported to the Safety Committee on a regular basis.

(2) Monitor compliance with the ECP during routine safety and health inspections.

(3) Ensure needlestick and sharps injuries are recorded on the Safety and Occupational Health Injury and Illness Log or OSHA 300 Log.

(4) Coordinate the identification and collection of safety devices as better products become available/approved by the Regional Standardization Committee.

e. Occupational Health shall:

(1) Manage the Hepatitis B vaccination, post-exposure evaluation and follow up provisions of this regulation.

(2) Provide initial orientation during in processing of workers covered under the ECP.

(3) Provide medical evaluation, treatment, referral and consultation to workers who sustain a BBP exposure.

(4) Record and follow up each BBP exposure incident.

(5) Maintain civilian worker health records.

(6) Upon request, provide a copy of all information that results from BBP exposure to consulting health care professionals.

(7) Maintain information concerning workers' exposure to BBP confidential.

(8) Report all BBP exposure incidents to Safety.

(9) For BBP exposure incidents involving contract workers, coordinate with the worker's contract representative to ensure the worker's records are forwarded to the contractor's health care provider.

f. Community Health Nurse or designee shall provide follow up counseling to all other health care beneficiaries (patients, volunteers, and visitors) involved in a BBP incident.

g. Patient Administration Division shall:

(1) Maintain military health records.

(2) Upon request, provide a copy of all information that results from BBP exposure to consulting health care professionals.

(3) Maintain information concerning workers' exposure to BBP confidential.

h. Plans, Training, Mobilization, and Security Division shall:

(1) Coordinate initial orientation training and birth month annual training.

(2) Maintain training records and provide verification of training to Infection Control and Nursing Education and Staff Development.

i. Emergency Room shall provide medical evaluation, treatment, referral and consultation to workers who sustain a BBP exposure.

j. Department Chiefs/supervisors shall:

(1) Implement this ECP in their respective departments/work areas.

(2) Develop and implement safe work practices for work area-unique BBP hazards.

(3) Investigate and document BBP exposures for workers.

(4) Promptly evaluate and take action as required to correct hazards reported by workers.

(5) Monitor work areas and verify engineering controls are functional and adequate supplies/appropriate sizes of PPE are available.

(6) Maintain a copy of the ECP in a location that is accessible to all workers on all shifts.

(7) Provide newly assigned workers orientation and training on the tasks with potential for occupational exposure; available engineering and work practice controls to prevent occupational exposure; availability, use, care, and disposal of PPE; and emergency spill response.

(8) Monitor workers' performance to verify that organization-wide and work area-specific orientation and training is effective, and provide refresher training whenever new procedures/equipment are introduced into the work area, work practices are modified, and whenever workers' performance is unsatisfactory.

k. Workers, determined to have occupational exposure to blood or OPIM, shall:

(1) Know the tasks they perform that have potential for exposure to blood and OPIM and the engineering and work practice controls to prevent occupational exposure.

(2) Follow all safety and health rules and regulations and properly use PPE to avoid contact with blood and OPIM.

(3) Immediately report unsafe or unhealthful conditions to their supervisor.

(4) Immediately report incidents involving actual or potential for occupational exposure to blood or OPIM to their supervisor.

l. Contracting officer representatives (CORs) shall:

(1) Ensure that contracts for personnel identified for having occupational exposure to BBP contain requirements to comply with all provisions of the ECP and 29 CFR 1910.1030.

(2) Monitor contractors and verify compliance with the ECP and 29 CFR 1910.1030.

5. EXPOSURE DETERMINATION.

a. The following table lists all job classifications in which all workers have occupational exposure to blood or other potentially infectious materials (OPIM):

Job classification	**Department/location**
Example: Phlebotomists	Clinical Lab

b. The following table lists the job classifications in which some workers have occupational exposure. Included is a list of tasks and procedures, or groups of closely related tasks and procedures, in which occupational exposure may occur for these individuals:

Job classification	**Department/location**	**Tasks and procedures**
Example: Housekeeper	Environmental Services	Handling regulated waste

6. METHODS OF IMPLEMENTATION AND CONTROL.

a. Standard precautions. All workers shall utilize standard precautions to prevent contact with blood or other potentially infectious materials (OPIM). All blood and OPIM is considered infectious regardless of the perceived status of the source individual. Standard precautions are outlined in *(insert name of local policy, regulation, or SOP)*_____.

b. Engineering and work practice controls.

(1) Use of engineering and work practice controls are the primary means to eliminate or minimize worker exposure to blood and OPIM. Workers shall be involved in the identification, evaluation, and selection of engineering and work practice controls.

(2) When occupational exposure remains after institution of engineering and work practice controls, workers shall wear appropriate PPE. At this facility the following engineering controls are utilized: *(list controls, such as sharps containers, biosafety cabinets, etc.)*

_____
_____
_____

(3) The above controls are examined and maintained on a regular schedule. The schedule for reviewing the effectiveness of the controls is as follows: *(list schedule such as daily, once/week, etc. as well as list who has the responsibility to review the effectiveness of the individual controls, such as the supervisor for each department, etc.)*

_____
_____
_____

(4) Workers shall follow hand hygiene policies and procedures outlined in *(insert name of local policy, regulation, or SOP)*_____. Hand washing facilities shall be readily accessible to workers and workers shall wash their hands and other skin surfaces with soap and water after any contact with blood, OPIM, or contaminated items or surfaces even if gloves were worn and after removing gloves and other PPE. In areas where sinks are not available, approved hand cleansers shall be readily accessible and workers shall wash their hands with soap and water as soon as feasible.

(5) Contaminated needles and other contaminated sharps shall not be bent, recapped, removed, sheared or purposely broken. OSHA allows an exception to this if the procedure would require that the contaminated needle be recapped or removed and no alternative is feasible and the action is required by the medical procedure. If such action is required then the recapping or removal of the needle must be done by the use of a mechanical device or a one-handed technique. At this facility recapping or removal is only permitted for the following procedures: *(List the procedures and also list the mechanical device to be used or alternately if a one-handed technique will be used.)*

_____

_____

_____

(6) Reusable contaminated sharps shall be placed immediately, or as soon as possible, after use into appropriate sharps containers. At this facility the sharps containers are puncture resistant, labeled with a biohazard label and are leak proof. *(List here where reusable sharps containers are located as well as who has responsibility for removing sharps from containers and how often the containers will be checked to remove the sharps.)*

(7) In work areas where there is a reasonable likelihood of exposure to blood or OPIM, workers shall not to eat, drink, apply cosmetics or lip balm, smoke, or handle contact lenses. Food and beverages shall not to be kept in refrigerators, freezers, shelves, cabinets, or on counter tops or bench tops where blood or other potentially infectious materials are present.

(8) Mouth pipetting/suctioning of blood or OPIM is prohibited.

(9) All procedures shall be conducted in a manner that minimizes splashing, spraying, splattering, and generation of droplets of blood or OPIM. Methods employed at this facility to accomplish this goal are: *(List methods, such as covers on centrifuges, usage of dental dams if appropriate, etc.)*

_____

_____

_____

(10) Specimens of blood or OPIM shall be placed in a container that prevents leakage during the collection, handling, processing, storage, and transport of the specimens. Containers used to store, transport, or ship blood or OPIM outside the

facility shall be labeled with a biohazard sign. Individual specimen containers that remain within the facility do not require labels.

(11) Any specimens that could puncture a primary container shall be placed within a secondary container that is puncture resistant.

(12) If outside contamination of the primary container occurs, the primary container shall be placed within a secondary container that prevents leakage during the handling, processing, storage, transport, or shipping of the specimen.

(13) Equipment that has become contaminated with blood or OPIM shall be examined prior to servicing or shipping and shall be decontaminated as necessary unless the decontamination of the equipment is not feasible. Equipment not decontaminated shall be tagged/labeled to indicate the portion of the equipment is contaminated and the name of the contaminant if known.

(14) All PPE used at this facility is provided without cost to workers. PPE is chosen based on the anticipated exposure to blood or OPIM. PPE is considered appropriate only if it does not permit blood or OPIM to pass through or reach the workers' clothing, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time that the PPE is used. *(Indicate how clothing is provided to workers, e.g., who has responsibility for distribution. Also list which procedures would require the protective clothing and the recommended type of protection required, this could also be listed as an appendix to the ECP.)*

(15) Workers shall use appropriate PPE unless the supervisor shows that worker temporarily and briefly declined to use PPE when under rare and extraordinary circumstances, it was the worker's professional judgment that in the specific instance its use would have prevented the delivery of health care or posed an increased hazard to the safety of the worker or co-worker. When the worker makes this judgment, the supervisor shall investigate and document the circumstances to determine whether changes can be instituted to prevent such occurrences in the future.

(16) Appropriate PPE in the appropriate sizes is readily accessible at the work site and is issued without cost to workers. Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives are readily accessible to those workers who are allergic to the gloves normally provided.

(17) All PPE is cleaned, laundered, and disposed of by this facility at no cost to the workers. All repairs and replacements are made at no cost to the workers.

(18) Workers shall remove all PPE before leaving their work areas. Workers shall remove immediately, or as soon as feasible, all garments that are penetrated by blood or OPIM.

(19) Workers shall place contaminated PPE in an appropriately designated area or container for storage, washing, decontamination or disposal.

(20) Workers shall wear gloves where it is reasonably anticipated that they will have hand contact with blood, OPIM, non-intact skin, and mucous membranes; when performing vascular access procedures; and when handling or touching contaminated items or surfaces.

(21) Workers shall not wash or decontaminate disposable gloves for re-use. Gloves shall be replaced as soon as practical when they become contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised. Utility gloves may be decontaminated for re-use provided that the integrity of the glove is not compromised. Utility gloves shall be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.

(22) Workers shall wear masks in combination with eye protection devices, such as goggles or glasses with solid side shield, or chin length face shields whenever splashes, splatters, or droplets of blood or OPIM may be generated and eye, nose, or mouth contamination can reasonably be anticipated. Situations at this facility that requires such protection are as follows:

_____

_____

_____

(23) Workers shall wear additional protective clothing (such as lab coats, gowns, aprons, clinic jackets, or similar outer garments) in instances when gross contamination can reasonably be anticipated (*such as autopsies and orthopedic surgery*). The following situations require that such protective clothing be utilized:

_____

_____

_____

(24) This facility is cleaned and decontaminated according to the following schedule: *(list area and schedule)*

AREA	Schedule	Cleaner
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

(25) Decontamination is accomplished by utilizing the following materials: *(list the materials that will be utilized, such as bleach solutions or EPA registered germicides)*

_____
_____
_____

(26) Workers shall decontaminate all contaminated work surfaces after completion of procedures and immediately or as soon as feasible after any spill of blood or other potentially infectious materials, as well as the end of the work shift if the surface may have become contaminated since the last cleaning. *(Add any information concerning the usage of protective coverings, such as plastic wrap that they may be using to assist in keeping surfaces free of contamination.)*

(27) Housekeeping inspects and decontaminates all bins, pails, cans, and similar receptacles on a regularly scheduled basis *(list frequency _____)*.

(28) Any broken glassware shall be picked up with mechanical means such as a brush and dustpan or tongs.

(29) Reusable sharps that are contaminated with blood or OPIM shall not be stored or processed in a manner that requires workers to reach by hand into the containers where these sharps have been placed.

(30) Contaminated sharps, including sharps with engineered sharps injury protection, shall be discarded immediately or as soon as feasible in containers that are closable, puncture resistant, leak proof on sides and bottom and labeled or color coded.

(31) During use, containers for contaminated sharps shall be easily accessible to workers and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries). Where no in-room sharps containers are available, workers shall carry a small sharps container into the room to immediately discard the sharps. The container shall be removed to a secure location after treatment/procedures are completed.

(32) Sharps containers shall be mounted on solid surfaces or in enclosed wall cabinets unless they are kept in constant observation.

(33) The containers shall be maintained upright throughout use and replaced routinely and not be allowed to overfill (no more than ¾ full).

(34) When moving containers of contaminated sharps from the area of use, the containers shall be closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

(35) The container shall be placed in a secondary container if leakage of the primary container is possible. The second container shall be closeable, constructed to contain all contents and prevent leakage during handling, storage and transport, or shipping. The second container shall be labeled or color-coded to identify its contents.

(36) Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner that would expose workers to the risk of percutaneous injury.

(37) Blood spills will be cleaned immediately following procedures outlined in (*list local policy, regulation or SOP)* _____.

(38) Regulated Medical Wastes (RMW) shall be placed in containers that are closeable, constructed to contain all contents and prevent leakage of fluids during handling, storage, transportation or shipping.

(39) RMW shall be labeled or color-coded and closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

(40) Disposal of all RMW waste shall be in accordance with applicable federal, state and local regulations and *(insert local RMW policy, regulation or SOP)* _____.

(41) RMW storage sites shall be secured and labeled with a biohazard symbol.

(42) Laundry contaminated with blood or OPIM shall be handled as little as possible. Such laundry shall be placed in appropriately marked (biohazard labeled, or color coded red bag) bags at the location where it was used. Such laundry shall not be sorted or rinsed in the area of use.

(43) Laundry at this facility is cleaned at _____. This facility also utilizes Standard Precautions in the handling of all contaminated laundry as required by contract.

7. HEPATITIS B VACCINE AND VACCINATION SERIES.

a. The Hepatitis B vaccine and vaccination series is available to all workers who have occupational exposure, and post exposure follow-up to workers who have had an exposure incident.

b. Medical evaluations and procedures including the Hepatitis B vaccine and vaccination series and post exposure follow-up, including prophylaxis are:

(1) Made available at no cost to the worker.

(2) Made available to the worker at a reasonable time and place.

(3) Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed health care professional.

(4) Provided according to the recommendations of the U.S. Public Health Service.

c. All laboratory tests shall be conducted by an accredited laboratory at no cost to the worker.

d. Hepatitis B vaccination shall be made available after the worker received the training in occupational exposure (see information and training) and within 10 working days of initial assignment to all workers who have occupational exposure unless the worker has previously received the complete Hepatitis B vaccination series, antibody testing has revealed that the worker is immune, or the vaccine is contraindicated for medical reasons.

e. Participation in a pre-screening program shall not be a prerequisite for receiving Hepatitis B vaccination.

f. The vaccination is made available to workers who initially decline the Hepatitis B vaccination but at a later date while still covered under the standard decide to accept the vaccination, the vaccination shall then be made available.

g. Workers who decline the Hepatitis B vaccination shall sign the OSHA required waiver indicating their refusal. A notation will be made in the worker's medical record when the worker refuses to sign the waiver. The following workers may not decline the Hepatitis B vaccination (the three exceptions listed in paragraph 7.d still apply):

(1) Military working in the medical and dental career fields.

(2) Civilians hired after 1 January 1997, assigned duties involving direct patient contact, and have Hepatitis B vaccination/immunization specifically mandated in their work agreement or job description.

h. If a routine booster dose of Hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster doses shall be made available to workers at no cost.

8. EXPOSURE INCIDENTS.

a. All exposure incidents shall be reported, investigated, and documented. When the worker incurs an exposure incident, it shall be reported to *(list who has responsibility for investigation of exposure incidents)*: _____

b. Following a report of an exposure incident, the exposed worker shall immediately receive a confidential medical treatment, evaluation, and follow-up, including at least the following elements:

(1) Documentation of the route of exposure, and the circumstances under which the exposure incident occurred.

(2) Identification and documentation of the source individual, unless it can be established that identification is infeasible or prohibited by state or local law.

(3) The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the (*insert name of position/person*) _____ shall establish that legally required consent cannot be obtained.

(4) When the source individual is known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.

(5) Results of the source individual's testing shall be made available to the exposed worker, and the worker shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

(6) Collection and testing of blood for HBV and HIV serological status will comply with the following:

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

(b) The worker shall be offered the option of having their blood collected for testing of the worker's HIV/HBV serological status. The blood sample will be preserved for up to 90 days to allow the worker to decide if the blood should be tested for HIV serological status.

(c) All workers who incur an exposure incident will be offered post-exposure evaluation and follow-up in accordance with the OSHA standard.

c. The health care professional responsible for the worker's Hepatitis B vaccination is provided with the following:

(1) A copy of 1910.1030.

(2) A written description of the exposed worker's duties as they relate to the exposure incident.

(3) Written documentation of the route of exposure and circumstances under which exposure occurred.

(4) Results of the source individuals blood testing, if available.

(5) All medical records relevant to the appropriate treatment of the worker including vaccination status.

d. The (*insert name of position/person*) _____ shall obtain and provide the worker with a copy of the evaluating health care professional's written opinion within 15 days of the completion of the evaluation.

e. The health care professional's written opinion for HBV vaccination shall be limited to whether HBV vaccination is indicated for a worker, and if the worker has received such vaccination.

f. The health care professional's written opinion for post exposure follow-up shall be limited to the following information:

(1) A statement that the worker has been informed of the results of the evaluation.

(2) A statement that the worker has been told about any medical conditions resulting from exposure to blood or OPIM which require further evaluation or treatment.

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

9. COMMUNICATION OF HAZARDS.

a. Biohazard labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or OPIM, and other containers used to store, transport or ship blood or OPIM.

b. The universal biohazard symbol shall be used. The label shall be fluorescent orange or orange-red.

c. Red bags or containers may be substituted for labels. However, RMW shall be handled in accordance with *(insert local RMW policy, regulation or SOP)* _____.

d. Blood products that have been released for transfusion or other clinical use are exempted from these labeling requirements.

10. EDUCATION AND TRAINING.

a. Training is provided at the time of initial assignment to tasks where occupational exposure may occur, and that it shall be repeated within twelve months of the previous training. Training shall be tailored to the education and language level of the worker, and offered during the normal work shift. The training will be interactive and cover the following:

(1) A copy of the standard and an explanation of its contents.

(2) A discussion of the epidemiology and symptoms of bloodborne diseases.

(3) An explanation of the modes of transmission of bloodborne pathogens.

(4) An explanation of the ECP and a method for obtaining a copy.

(5) The recognition of tasks that may involve exposure.

(6) An explanation of the use and limitations of methods to reduce exposure, for example engineering controls, work practices and PPE.

(7) Information on the types, use, location, removal, handling, decontamination, and disposal of PPE.

(8) An explanation of the basis of selection of PPE.

(9) Information on the Hepatitis B vaccination, including efficacy, safety, method of administration, benefits, and that it will be offered free of charge.

(10) Information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM.

(11) An explanation of the procedures to follow if an exposure incident occurs, including the method of reporting and medical follow-up.

(12) Information on the evaluation and follow-up required after a worker exposure incident.

(13) An explanation of the signs, labels, and color-coding systems.

b. The person conducting the training shall be knowledgeable in the subject matter.

c. Additional training is provided to workers when there are any changes of tasks or procedures affecting the worker's occupational exposure.

11. RECORDKEEPING.

a. Medical Records.

(1) _____ (*insert name of department*) is responsible for maintaining medical records as indicated below. These records will be kept (*insert location*) _____.

(2) Medical records shall be maintained in accordance with 29 CFR 1910.1020. These records shall be kept confidential, and must be maintained for at least the duration of employment plus 30 years. The records shall include the following:

(a) The name and social security number of the worker.

(b) A copy of the worker's HBV vaccination status, including the dates of vaccination.

(c) A copy of all results of examinations, medical testing, and follow-up procedures.

(d) A copy of the information provided to the health care professional, including a description of the worker's duties as they relate to the exposure incident, and documentation of the routes of exposure and circumstances of the exposure.

b. Training Records.

(1) _____ (*insert name of department*) is responsible for maintaining the following training records. These records will be kept (*insert location*) _____.

(2) Training records shall be maintained for three years from the date of training. The following information shall be documented:

(a) The dates of the training sessions.

(b) An outline describing the material presented.

(c) The names and qualifications of persons conducting the training.

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

c. All worker records shall be made available to the worker in accordance with 29 CFR 1910.1020.

d. All worker records shall 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 (NIOSH) upon request.

e. If this facility is closed or there is no successor employer to receive and retain the records for the prescribed period, the Director of the NIOSH shall be contacted for final disposition.

12. DATES. All provisions required by 29 CFR 1910.1030 were implemented by July 30 1992.

APPENDIX E
SAMPLE HIV/HBV RESEARCH LABORATORY BLOODBORNE PATHOGEN PROGRAM

Organization's Name

Office File Symbol

SOP No.
Disk File Name
Effective Date
Date Removed from Service

BLOODBORNE PATHOGEN EXPOSURE CONTROL PLAN (ECP)

1. PURPOSE. This ECP establishes policies and procedures for implementing a Bloodborne Pathogens (BBP) Prevention and Treatment Program within *(insert name of facility)*_____. The goal of this ECP is to eliminate or reduce the risk of injury or illness resulting from occupational exposure to BBP. Occupational exposure is defined as reasonably anticipated skin, eye, mucous membrane or parental contact with blood or other potentially infectious materials (OPIM) that may result from performance of a worker's duties. The primary methods used to prevent occupational exposure are engineering and administrative controls, safe work practices, and personal protective equipment (PPE).

2. SCOPE. This ECP applies to *(insert name of facility)* _____and all outlying research laboratories.

3. REFERENCES. References are listed at appendix A.

4. RESPONSIBILITIES.

a. The Commander ensures that an effective BBP ECP is developed and implemented according to 29 CFR 1910.1030.

b. The Safety/Biosafety Control Committees will monitor the ECP and approve all exceptions that require the need to recap or remove a needle.

c. Biosafety Officer shall:

(1) Review the ECP annually and update it as required. The annual review must include changes in technology that eliminate or reduce exposure to BBPs, and consideration of implementation of safer medical devices.

(2) Coordinate the updating of infection control policies to ensure compliance with the ECP.

(3) Provide guidance and assistance regarding the use of equipment, interpretation and establishment of policies, and use of good work practices.

(4) Provide orientation and training to workers.

(5) Implement engineering controls, including sharps with engineered sharps injury protection.

(6) Monitor the implementation and compliance with this regulation in conjunction with Safety and Preventive Medicine.

(7) In coordination with Occupational Health (OH) and Safety, analyze BBP incident data to identify trends and propose preventive measures. Data analysis will be presented to the appropriate department for implementation and action as indicated.

d. Safety shall:

(1) Collect data on all BBP exposure incidents and develop or recommend remedial actions to reduce exposures. Data shall be reported to the Safety Committee on a regular basis.

(2) Monitor compliance with the ECP during routine safety and health inspections.

(3) Ensure needlestick and sharps injuries are recorded on the Safety and Occupational Health Injury and Illness Log or OSHA 300 Log.

(4) Coordinate the identification and collection of safety devices as better products become available.

e. *(List name of supporting occupational health clinic)* _____ shall:

(1) Manage the Hepatitis B vaccination, post-exposure evaluation and follow up provisions of this regulation.

(2) Provide initial orientation during in processing of workers covered under the ECP.

(3) Provide medical evaluation, treatment, referral and consultation to workers who sustain a BBP exposure.

(4) Record and follow up each BBP exposure incident.

(5) Maintain civilian worker health records.

(6) Upon request, provide a copy of all information that results from BBP exposure to consulting health care professionals.

(7) Maintain information concerning workers' exposure to BBP confidential.

(8) Report all BBP exposure incidents to Safety.

(9) For BBP exposure incidents involving contract workers, coordinate with the worker's contract representative to ensure the worker's records are forwarded to the contractor's health care provider.

f. *(List name of supporting health clinic)* Patient Administration Division shall:

(1) Maintain military health records.

(2) Upon request, provide a copy of all information that results from BBP exposure to consulting health care professionals.

(3) Maintain information concerning workers' exposure to BBP confidential.

g. Facilities Management shall coordinate plans for all new laboratory construction and renovation with the Biosafety and Safety Officers.

h. Plans, Training, Mobilization, and Security Division shall:

(1) Coordinate initial orientation training and birth month annual training.

(2) Maintain training records and provide verification of training to the Biosafety Officer.

i. (*List name of supporting occupational health clinic)* shall provide medical evaluation, treatment, referral and consultation to workers who sustain a BBP exposure.

j. Department Chiefs/supervisors shall:

(1) Implement this ECP in their respective departments/work areas.

(2) Develop and implement safe work practices for work area-unique BBP hazards.

(3) Investigate and document BBP exposures for workers.

(4) Promptly evaluate and take action as required to correct hazards reported by workers.

(5) Monitor work areas and verify engineering controls are functional and adequate supplies/appropriate sizes of PPE are available.

(6) Maintain a copy of the ECP in a location that is accessible to all workers on all shifts.

(7) Provide newly assigned workers orientation and training on the tasks with potential for occupational exposure; available engineering and work practice controls to prevent occupational exposure; availability, use, care, and disposal of PPE; and emergency spill response.

(8) Monitor workers' performance to verify that organization-wide and work area-specific orientation and training is effective, and provide refresher training whenever new procedures/equipment are introduced into the work area, work practices are modified, and whenever workers' performance is unsatisfactory.

k. Workers, determined to have occupational exposure to blood or OPIM, shall:

(1) Know the tasks they perform that have potential for exposure to blood and OPIM and the engineering and work practice controls to prevent occupational exposure.

(2) Follow all safety and health rules and regulations and properly use PPE to avoid contact with blood and OPIM.

(3) Immediately report unsafe or unhealthful conditions to their supervisor.

(4) Immediately report incidents involving actual or potential for occupational exposure to blood or OPIM to their supervisor.

l. Contracting officer representatives (CORs) shall:

(1) Ensure that contracts for personnel identified for having occupational exposure to BBP contain requirements to comply with all provisions of the ECP and 29 CFR 1910.1030.

(2) Monitor contractors and verify compliance with the ECP and 29 CFR 1910.1030.

5. EXPOSURE DETERMINATION.

a. The following table lists all job classifications in which all workers have occupational exposure to blood or OPIM.

Job classification	**Department/location**
Example: Microbiologist	Clinical Lab

b. The following table lists the job classifications in which some workers have occupational exposure. Included is a list of tasks and procedures, or groups of closely related tasks and procedures, in which occupational exposure may occur for these individuals:

Job classification	Department/location	Tasks and procedures
Example: Housekeeper	Environmental Services	Handling regulated waste

6. METHODS OF IMPLEMENTATION AND CONTROL.

a. Universal precautions. All workers shall utilize universal precautions to prevent contact with blood or OPIM. All blood and OPIM is considered infectious regardless of the perceived status of the source individual. Universal precautions are outlined in *(insert name of local policy, regulation, or SOP)*_____.

b. Engineering and work practice controls.

(1) Use of engineering and work practice controls are the primary means to eliminate or minimize worker exposure to blood and OPIM. Workers shall be involved in the identification, evaluation, and selection of engineering and work practice controls.

(2) Laboratories producing research laboratory-scale amounts of HIV, manipulating concentrated virus preparations, and conducting procedures that may produce aerosols or droplets shall be carried out in a facility that meets Biosafety Level (BSL) 2 design criteria and laboratory workers shall follow BSL3 safe laboratory practices and use BSL3 containment equipment as outlined in the Department of Health and Human Services Centers for Disease Control and Prevention and National Institutes of health Biosafety in Microbiological and Biomedical Laboratories (BMBL), 4th Edition, May 1999 and *(insert facility Biosafety policy, regulation, or SOP).*

(3) Laboratories involved in industrial-scale, large-volume production or high concentration and manipulation of concentrated HIV shall be conducted in a facility that meets BSL3 design criteria and laboratory workers shall follow BLS3 safe laboratory practices and use BSL3 containment equipment as outlined in the BMBL and *(insert facility Biosafety policy, regulation, or SOP).*

(4) When occupational exposure remains after institution of engineering and work practice controls, workers shall wear appropriate PPE. At this facility the

following engineering controls are utilized: *(list controls, such as sharps containers, biosafety cabinets, etc.)*

_____
_____
_____

(5) The above controls are examined and maintained on a regular schedule. The schedule for reviewing the effectiveness of the controls is as follows: *(list schedule such as daily, once/week, etc. as well as list who has the responsibility to review the effectiveness of the individual controls, such as the supervisor for each department, etc.)*

_____
_____
_____

(6) Workers shall follow hand hygiene policies and procedures outlined in *(insert name of local policy, regulation, or SOP)*_____. Hand washing facilities shall be readily accessible to workers and workers shall wash their hands and other skin surfaces with soap and water after any contact with blood, OPIM, or contaminated items or surfaces even if gloves were worn and after removing gloves and other PPE. In areas where sinks are not available, approved hand cleansers shall be readily accessible and workers shall wash their hands with soap and water as soon as feasible.

(7) Contaminated needles and other contaminated sharps shall not be bent, recapped, removed, sheared or purposely broken. OSHA allows an exception to this if the procedure would require that the contaminated needle be recapped or removed and no alternative is feasible and the action is required by the medical procedure. If such action is required then the recapping or removal of the needle must be done by the use of a mechanical device or a one-handed technique. At this facility recapping or removal is only permitted for the following procedures: *(List the procedures and also list the mechanical device to be used or alternately if a one-handed technique will be used.)*

_____
_____
_____

(8) Reusable contaminated sharps shall be placed immediately, or as soon as possible, after use into appropriate sharps containers. At this facility the sharps containers are puncture resistant, labeled with a biohazard label and are leak proof.

(List here where reusable sharps containers are located as well as who has responsibility for removing sharps from containers and how often the containers will be checked to remove the sharps.)

(9) In work areas where there is a reasonable likelihood of exposure to blood or OPIM, workers shall not to eat, drink, apply cosmetics or lip balm, smoke, or handle contact lenses. Food and beverages shall not to be kept in refrigerators, freezers, shelves, cabinets, or on counter tops or bench tops where blood or OPIM are present.

(10) Mouth pipetting/suctioning of blood or OPIM is prohibited.

(11) All procedures shall be conducted in a manner that minimizes splashing, spraying, splattering, and generation of droplets of blood or OPIM. Methods that employed at this facility to accomplish this goal are: *(List methods, such as covers on centrifuges, splash shields, etc.)*

_____

_____

_____

(12) Specimens of blood or OPIM shall be placed in a container that prevents leakage during the collection, handling, processing, storage, and transport of the specimens. Containers used to store, transport, or ship blood or OPIM outside the facility shall be labeled with a biohazard sign. Individual specimen containers that remain within the facility do not require labels.

(13) Any specimens that could puncture a primary container shall be placed within a secondary container that is puncture resistant.

(14) If outside contamination of the primary container occurs, the primary container shall be placed within a secondary container that prevents leakage during the handling, processing, storage, transport, or shipping of the specimen.

(15) Equipment that has become contaminated with blood or OPIM shall be examined prior to servicing or shipping and shall be decontaminated as necessary unless the decontamination of the equipment is not feasible. Equipment not decontaminated shall be tagged/labeled to indicate the portion of the equipment is contaminated and the name of the contaminant if known.

(16) All PPE used at this facility is provided without cost to workers. PPE is chosen based on the anticipated exposure to blood or OPIM. PPE is considered appropriate only if it does not permit blood or OPIM to pass through or reach the workers' clothing, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time that the PPE is used. *(Indicate how clothing is provided to workers, e.g. who has responsibility for distribution. Also list which procedures would require the protective clothing and the recommended type of protection required, this could also be listed as an appendix to the ECP.)*

(17) Workers shall use appropriate PPE unless the supervisor shows that worker temporarily and briefly declined to use PPE when under rare and extraordinary circumstances, it was the worker's professional judgment that in the specific instance its use would have prevented the delivery of health care or posed an increased hazard to the safety of the worker or co-worker. When the worker makes this judgment, the supervisor shall investigate and document the circumstances to determine whether changes can be instituted to prevent such occurrences in the future.

(18) Appropriate PPE in the appropriate sizes is readily accessible at the work site and is issued without cost to workers. Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives are readily accessible to those workers who are allergic to the gloves normally provided.

(19) All PPE is cleaned, laundered, and disposed of by this facility at no cost to the workers. All repairs and replacements are made at no cost to the workers.

(20) Workers shall remove all PPE before leaving their work areas. Workers shall remove immediately, or as soon as feasible, all garments that are penetrated by blood or OPIM.

(21) Workers shall place contaminated PPE in an appropriately designated area or container for storage, washing, decontamination or disposal.

(22) Workers shall wear gloves where it is reasonably anticipated that they will have hand contact with blood, OPIM, non-intact skin, and mucous membranes; when performing vascular access procedures; and when handling or touching contaminated items or surfaces.

(23) Workers shall not wash or decontaminate disposable gloves for re-use. Gloves shall be replaced as soon as practical when they become contaminated or as

soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised. Utility gloves may be decontaminated for re-use provided that the integrity of the glove is not compromised. Utility gloves shall be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.

(24) Workers shall wear masks in combination with eye protection devices, such as goggles or glasses with solid side shield, or chin length face shields whenever splashes, splatters, or droplets of blood or OPIM may be generated and eye, nose, or mouth contamination can reasonably be anticipated. Situations at this facility that requires such protection are as follows:

_____
_____
_____

(25) Workers shall wear additional protective clothing (such as lab coats, gowns, aprons, clinic jackets, or similar outer garments) in instances when gross contamination can reasonably be anticipated (*such as autopsies and orthopedic surgery*). The following situations require that such protective clothing be utilized:

_____
_____
_____

(26) This facility is cleaned and decontaminated according to the following schedule: *(list area and schedule)*

AREA	Schedule	Cleaner
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

(27) Decontamination is accomplished by utilizing the following materials: *(list the materials that will be utilized, such as bleach solutions or EPA registered germicides)*

_____
_____
_____

(28) Workers shall decontaminate all contaminated work surfaces after completion of procedures and immediately or as soon as feasible after any spill of blood or OPIM, as well as the end of the work shift if the surface may have become contaminated since the last cleaning. *(Add any information concerning the usage of protective coverings, such as plastic wrap that they may be using to assist in keeping surfaces free of contamination.)*

(29) Housekeeping inspects and decontaminates all bins, pails, cans, and similar receptacles on a regularly scheduled basis *(list frequency _____)*.

(30) Any broken glassware shall be picked up with mechanical means such as a brush and dustpan or tongs.

(31) Reusable sharps that are contaminated with blood or OPIM shall not be stored or processed in a manner that requires workers to reach by hand into the containers where these sharps have been placed.

(32) Contaminated sharps, including sharps with engineered sharps injury protection, shall be discarded immediately or as soon as feasible in containers that are closable, puncture resistant, leak proof on sides and bottom and labeled or color coded.

(33) During use, containers for contaminated sharps shall be easily accessible to workers and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries). Where no in-room sharps containers are available, workers shall carry a small sharps container into the room to immediately discard the sharps. The container shall be removed to a secure location after treatment/procedures are completed.

(34) Sharps containers shall be shall be mounted on solid surfaces or in enclosed wall cabinets unless they are kept in constant observation.

(35) The containers shall be maintained upright throughout use and replaced routinely and not be allowed to overfill (no more than ¾ full).

(36) When moving containers of contaminated sharps from the area of use, the containers shall be closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

(37) The container shall be placed in a secondary container if leakage of the primary container is possible. The second container shall be closeable, constructed to contain all contents and prevent leakage during handling, storage and transport, or shipping. The second container shall be labeled or color-coded to identify its contents.

(38) Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner that would expose workers to the risk of percutaneous injury.

(39) Blood spills will be cleaned immediately following procedures outlined in (*list local policy, regulation or SOP)* _____.

(40) Regulated Medical Wastes (RMW) shall be placed in containers that are closeable, constructed to contain all contents and prevent leakage of fluids during handling, storage, transportation or shipping.

(41) RMW shall be labeled or color-coded and closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

(42) Disposal of all RMW waste shall be in accordance with applicable federal, state and local regulations and *(insert local RMW policy, regulation or SOP)* _____.

(43) RMW storage sites shall be secured and labeled with a biohazard symbol.

(44) Laundry contaminated with blood or OPIM shall be handled as little as possible. Such laundry shall be placed in appropriately marked (biohazard labeled, or color coded red bag) bags at the location where it was used. Such laundry shall not be sorted or rinsed in the area of use.

(45) Laundry at this facility is cleaned at _____. This facility also utilizes Universal Precautions in the handling of all contaminated laundry as required by contract.

7. HEPATITIS B VACCINE AND VACCINATION SERIES.

a. The Hepatitis B vaccine and vaccination series is available to all workers who have occupational exposure, and post exposure follow-up to workers who have had an exposure incident.

b. Medical evaluations and procedures including the Hepatitis B vaccine and vaccination series and post exposure follow-up, including prophylaxis are:

(1) Made available at no cost to the worker.

(2) Made available to the worker at a reasonable time and place.

(3) Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed health care professional.

(4) Provided according to the recommendations of the U.S. Public Health Service.

c. All laboratory tests shall be conducted by an accredited laboratory at no cost to the worker.

d. Hepatitis B vaccination shall be made available after the worker received the training in occupational exposure (see information and training) and within 10 working days of initial assignment to all workers who have occupational exposure unless the worker has previously received the complete Hepatitis B vaccination series, antibody testing has revealed that the worker is immune, or the vaccine is contraindicated for medical reasons.

e. Participation in a pre-screening program shall not be a prerequisite for receiving Hepatitis B vaccination.

f. The vaccination is made available to workers who initially decline the Hepatitis B vaccination but at a later date while still covered under the standard decide to accept the vaccination; the vaccination shall then be made available.

g. Workers who decline the Hepatitis B vaccination offered shall sign the OSHA required waiver indicating their refusal. A notation will be made in the worker's medical record when the worker refuses to sign the waiver. The following workers may not decline the Hepatitis B vaccination (exceptions listed in paragraph 7.d still apply):

(1) Military working in the medical and dental career fields.

(2) Civilians hired after 1 January 1997, assigned duties involving direct patient contact, and have Hepatitis B vaccination/immunization specifically mandated in their work agreement or job description.

h. If a routine booster dose of Hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster doses shall be made available to workers at no cost.

8. EXPOSURE INCIDENTS.

a. All exposure incidents shall be reported, investigated, and documented. When the worker incurs an exposure incident, it shall be reported to *(list who has responsibility for investigation of exposure incidents)*: _____

b. Following a report of an exposure incident, the exposed worker shall immediately receive a confidential medical treatment, evaluation, and follow-up, including at least the following elements:

(1) Documentation of the route of exposure, and the circumstances under which the exposure incident occurred.

(2) Identification and documentation of the source individual, unless it can be established that identification is infeasible or prohibited by state or local law.

(3) The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the (*insert name of position/person*) _____ shall establish that legally required consent cannot be obtained.

(4) When the source individual is known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.

(5) Results of the source individual's testing shall be made available to the exposed worker, and the worker shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

(6) Collection and testing of blood for HBV and HIV serological status will comply with the following:

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

(b) The worker shall be offered the option of having their blood collected for testing of the worker's HIV/HBV serological status. The blood sample will be preserved for up to 90 days to allow the worker to decide if the blood should be tested for HIV serological status.

(c) All workers who incur an exposure incident will be offered post-exposure evaluation and follow-up in accordance with the OSHA standard.

(c) The health care professional responsible for the worker's Hepatitis B vaccination is provided with the following:

(1) A copy of 1910.1030.

(2) A written description of the exposed worker's duties as they relate to the exposure incident.

(3) Written documentation of the route of exposure and circumstances under which exposure occurred.

(4) Results of the source individuals blood testing, if available.

(5) All medical records relevant to the appropriate treatment of the worker including vaccination status.

d. The (*insert name of position/person*) _____ shall obtain and provide the worker with a copy of the evaluating health care professional's written opinion within 15 days of the completion of the evaluation.

e. The health care professionals written opinion for HBV vaccination shall be limited to whether HBV vaccination is indicated for a worker, and if the worker has received such vaccination.

f. The health care professional's written opinion for post exposure follow-up shall be limited to the following information:

(1) A statement that the worker has been informed of the results of the evaluation.

(2) A statement that the worker has been told about any medical conditions resulting from exposure to blood or OPIM which require further evaluation or treatment.

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

9. COMMUNICATION OF HAZARDS.

a. Biohazard labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or OPIM, and other containers used to store, transport or ship blood or OPIM.

b. The universal biohazard symbol shall be used. The label shall be fluorescent orange or orange-red.

c. Red bags or containers may be substituted for labels. However, RMW shall be handled in accordance with *(insert local RMW policy, regulation or SOP)* _____.

d. Blood products that have been released for transfusion or other clinical use are exempted from these labeling requirements.

10. EDUCATION AND TRAINING.

a. Training is provided at the time of initial assignment to tasks where occupational exposure may occur, and that it shall be repeated within twelve months of the previous training. Training shall be tailored to the education and language level of the worker, and offered during the normal work shift. The training will be interactive and cover the following:

(1) A copy of the standard and an explanation of its contents.

(2) A discussion of the epidemiology and symptoms of bloodborne diseases.

(3) An explanation of the modes of transmission of bloodborne pathogens.

(4) An explanation of the ECP and a method for obtaining a copy.

(5) The recognition of tasks that may involve exposure.

(6) An explanation of the use and limitations of methods to reduce exposure, for example engineering controls, work practices and PPE.

(7) Information on the types, use, location, removal, handling, decontamination, and disposal of PPE.

(8) An explanation of the basis of selection of PPE.

(9) Information on the Hepatitis B vaccination, including efficacy, safety, method of administration, benefits, and that it will be offered free of charge.

(10) Information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM.

(11) An explanation of the procedures to follow if an exposure incident occurs, including the method of reporting and medical follow-up.

(12) Information on the evaluation and follow-up required after a worker exposure incident.

(13) An explanation of the signs, labels, and color-coding systems.

b. The person conducting the training shall be knowledgeable in the subject matter.

c. Additional training is provided to workers when there are any changes of tasks or procedures affecting the worker's occupational exposure.

11. RECORDKEEPING.

a. Medical Records.

(1) _____ (*insert name of department*) is responsible for maintaining medical records as indicated below. These records will be kept (*insert location*) _____.

(2) Medical records shall be maintained in accordance with OSHA Standard 1910.1020. These records shall be kept confidential, and must be maintained for at least the duration of employment plus 30 years. The records shall include the following:

(a) The name and social security number of the worker.

(b) A copy of the worker's HBV vaccination status, including the dates of vaccination.

(c) A copy of all results of examinations, medical testing, and follow-up procedures.

(d) A copy of the information provided to the health care professional, including a description of the worker's duties as they relate to the exposure incident, and documentation of the routes of exposure and circumstances of the exposure.

b. Training Records.

(1) _____ (*insert name of department*) is responsible for maintaining the following training records. These records will be kept (*insert location*) _____.

(2) Training records shall be maintained for three years from the date of training. The following information shall be documented:

(a) The dates of the training sessions.

(b) An outline describing the material presented.

(c) The names and qualifications of persons conducting the training.

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

c. All worker records shall be made available to the worker in accordance with 1910.1020.

d. All worker records shall 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 (NIOSH) upon request.

e. If this facility is closed or there is no successor employer to receive and retain the records for the prescribed period, the Director of the NIOSH shall be contacted for final disposition.

12. DATES. All provisions required by 29 CFR 1910.1030 were implemented by July 30 1992.

APPENDIX F
SELF-INSPECTION CHECKLIST

EXPOSURE CONTROL PLAN: SELF-INSPECTION CHECKLIST

Exposure Control	Yes	No
1. Documentation exists that identifies job classifications where:		
• All workers are occupationally exposed to bloodborne pathogens.	☐	☐
• Some workers are occupationally exposed to bloodborne pathogens.	☐	☐
• For those job classifications where some, but not all workers are occupationally exposed, a list had been developed which identifies tasks and procedures, or groups of closely related procedures, that may result in exposure.	☐	☐
• Workers assist in identifying, evaluating, and selecting engineering and work practice controls.	☐	☐
• The exposure control plan (ECP) is accessible to workers.	☐	☐
• The ECP is updated when necessary to reflect new or modified tasks that affect occupational exposure, new or revised worker positions, and changes in technology that will reduce or eliminate exposure.	☐	☐
• The ECP is reviewed at least annually.	☐	☐
Methods of Compliance		
2. Engineering and work practice controls are used to eliminate or minimize worker exposure.	☐	☐
3. Engineering controls are examined, maintained, or replaced on a regular schedule to ensure their continued effectiveness.	☐	☐
4. Eating, drinking, smoking, application of cosmetics, and handling of contact lenses is prohibited in areas where there is reasonable likelihood of occupational exposure.	☐	☐
5. Food and drink are not kept in refrigerators, freezers, shelves, cabinets, counter tops or bench tops, or other areas where potentially infectious materials are present.	☐	☐
6. Containers used for storage, transport, or shipping of regulated medical waste are properly labeled.	☐	☐

7. Procedures involving blood or other potentially infectious materials (OPIM) are performed in a manner that minimizes spraying, splashing, and spattering.	☐	☐
8. Mouth pipetting is prohibited.	☐	☐
9. Handwashing facilities are readily accessible, or if they are infeasible, antiseptic hand cleaner and paper towels are provided.	☐	☐
10. When antiseptic cleaners are used, workers are required to wash their hands in running water as soon as practical.	☐	☐
11. Workers are required to wash their hands as soon as practical after removing gloves and other personal protective equipment (PPE).	☐	☐
12. Workers are required to wash skin or flush mucous membranes as soon as feasible after contact with blood and OPIM.	☐	☐
13. Sharps disposal containers are properly labeled or color-coded.	☐	☐
14. Contaminated needles are not bent or recapped by hand.	☐	☐
15. Contaminated sharps are placed in appropriate sharps disposal containers as soon as feasible.	☐	☐
16. Sharps disposal containers are located as close as practical to locations where sharps are being used or likely to be encountered (laundries, examination rooms, emergency room, etc.)	☐	☐
17. Sharps disposal containers are puncture resistant, have leak-proof sides and bottoms, and are labeled or color-coded to indicate a biohazard.	☐	☐
18. Reusable sharps that are contaminated with blood or OPIM are not stored or handled in a manner that requires workers to reach into containers.	☐	☐
19. Sharps disposal containers are maintained upright throughout their use.	☐	☐
20. Sharps disposal containers are replaced routinely and not allowed to overfill.	☐	☐
21. Shipping containers are closed before being moved to prevent spillage of contents during handling.	☐	☐
22. Reusable containers are not opened, emptied, or cleaned in a manner that exposes workers to risk percutaneous injury.	☐	☐
23. Specimens of blood or OPIM are placed in containers that prevent leakage during collection, transport, handling, storage, or shipping.	☐	☐
24. Specimen containers are labeled as biohazardous (except when handling in house if universal precautions are used and containers are recognizable to everyone as containing specimens.	☐	☐

25. If the exterior of a specimen container is contaminated, it is placed in a labeled or color-coded secondary container that prevents leakage.	☐	☐
26. Specimens that can puncture primary containers are placed in a puncture resistant secondary container.	☐	☐
27. Equipment contaminated with blood or OPIM is decontaminated before shipping or servicing.	☐	☐
28. Portions of equipment that cannot be decontaminated are noted on a readily observable label with a biohazard symbol attached.	☐	☐
29. Information concerning portions of equipment that are not decontaminated is conveyed to affected workers, service representatives, and manufacturers as appropriate, to ensure necessary precautions will be taken during handling, shipping and servicing.	☐	☐
30. Universal precautions are followed in situations where workers are exposed to blood or OPIM.	☐	☐
31. PPE is provided at not cost to workers.	☐	☐
32. PPE prevents blood and OPIM from passing through workers' street clothes, undergarments, skin, eyes, or mouth for the duration of time for which the equipment must be worn.	☐	☐
33. PPE is used (except in rare and extraordinary circumstances where it is temporarily and briefly waived by the worker because it could compromise the delivery of health services or public safety).	☐	☐
34. In cases where PPE is not used, the circumstances are investigated and documented to determine if changes can be made to prevent future occurrences.	☐	☐
35. PPE in appropriate sizes is readily available (readily available means not having to ask for it or get a key from another worker).	☐	☐
36. Hypoallergenic gloves or other alternatives are provided or workers who are latex sensitive.	☐	☐
37. PPE is inspected, decontaminated, repaired, and replaced as needed.	☐	☐
38. Garments penetrated by blood or OPIM are removed as soon as feasible.	☐	☐
39. All PPE is taken off before leaving the work area.	☐	☐
40. PPE is placed in a designated area or container after removal.	☐	☐
41. Single-use gloves are not washed or decontaminated for reuse.	☐	☐
42. Utility gloves are discarded when they show signs of deterioration.	☐	☐

43. Masks and eye protection are worn when splash to the eyes, mouth, or mucous membranes is reasonably anticipated.	☐	☐
44. Gowns, aprons, and other protective body clothing are worn when dictated by the exposure situation.	☐	☐
45. Work sites are maintained in a clean and sanitary condition.	☐	☐
46. A written cleaning schedule is established.	☐	☐
47. The methods of cleaning are based on the type of surface to be cleaned, type of soil present, and tasks and procedures performed.	☐	☐
48. Equipment and surfaces shall be cleaned and decontaminated after contact with blood or OPIM.	☐	☐
49. Protective materials used to cover equipment and environmental surfaces are removed and replaced as soon as feasible after becoming overtly contaminated, or are replaced at the end of the shift if they have become contaminated during the shift.	☐	☐
50. Refuse receptacles reasonably likely to be contaminated with blood or OPIM, are inspected and decontaminated on a regularly scheduled basis.	☐	☐
51. Refuse receptacles are decontaminated as soon as feasible after they become visibly contaminated.	☐	☐
52. Contaminated broken glassware is cleaned up using mechanical means such as tongs or dustpan and brush rather than picked up with the hands.	☐	☐
53. RMW is placed in closeable containers that prevent spillage during transport and handling.	☐	☐
54. Waste containers are closed before handling, transport, or storage.	☐	☐
55. Contaminated RMW containers whose exteriors are contaminated are placed in collapsible, leak resistant secondary containers before handling, shipping or storage.	☐	☐
56. RMW is disposed according to local, state, and federal regulations.	☐	☐
57. Contaminated laundry is handled with as little agitation as possible.	☐	☐
58. Contaminated laundry is bagged and containerized where it was used.	☐	☐
59. Contaminated laundry is not sorted or rinsed where it was used.	☐	☐
60. Contaminated laundry is placed in labeled or color-coded bags or containers.	☐	☐
61. Wet laundry that poses a hazard of soak-through is placed in a container that prevents the liquid flow-through.	☐	☐

62. Workers who contact contaminated laundry wear PPE. ☐ ☐
63. Contaminated laundry shipped off-site is marked labeled. ☐ ☐

Hepatitis B Vaccination

64. Hepatitis B vaccination is available to all occupationally exposed workers at not cost, and is provided according to the US Public Health Service guidelines. ☐ ☐
65. Hepatitis B vaccination is made available to all workers that have had an exposure incident. ☐ ☐
66. Hepatitis B vaccination is available at no cost to workers, and at reasonable places and times. ☐ ☐
67. The vaccination is performed under the supervision of a licensed health care professional. ☐ ☐
68. Workers are offered Hepatitis B vaccination within 10 working days of initial assignment and after receiving training. ☐ ☐
69. Workers who decline the Hepatitis B vaccination are required to sign the waiver provided in Appendix A of the standard. ☐ ☐
69. Hepatitis B vaccination is made available to workers who initially decline vaccination but request it at a later date. ☐ ☐
70. A copy of the OSHA standard, 29 CFR 1910.1030, has been provided to the health care professional who administers the vaccine. ☐ ☐

Communication of Hazards to Workers

71. All workers who are occupationally exposed to BBP have participated in a training program that was:
- Conducted by a person knowledgeable on the subject matter. ☐ ☐
- Provided at no cost to the worker and conducted during working hours. ☐ ☐
- Provided an opportunity for interactive questions and answers. ☐ ☐
- Provided at appropriate levels of literacy and language for workers. ☐ ☐

72. Information and training included the following items:
- A copy of the standard, an explanation of its contents, and where it may be read and reviewed by workers. ☐ ☐
- A general explanation of the epidemiology, modes of transmission, and symptoms of BBPs. ☐ ☐

- An explanation of the ECP and means by which a copy can be obtained. ☐ ☐
- An explanation of the methods for recognizing tasks and activities that may involve exposure to potentially infectious materials. ☐ ☐
- An explanation of the use and limitations of methods that are used in the facility to prevent or reduce exposure, such as engineering controls, PPE, and work practices. ☐ ☐
- Information on the types, use, location, removal, handling, decontamination, and disposal of PPE. ☐ ☐
- An explanation of the basis for selection of PPE. ☐ ☐
- Information about the Hepatitis B vaccination including information on its efficacy, safety, method of administration, benefits of being vaccinated and that the vaccination is offered free of charge. ☐ ☐
- Information on appropriate actions to take and persons to contact in the event of an emergency involving blood or OPIM. ☐ ☐
- An explanation of the procedure to follow if an exposure incident occurs including the method of reporting the incident and the medical follow-up. ☐ ☐
- Information on the post-exposure evaluation and follow-up, provided by the employer, following an exposure incident. ☐ ☐
- An explanation of the signs and labels and/or color-coding in use. ☐ ☐

<u>Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up</u>

73. A confidential medical exam is made available to workers immediately following an exposure incident. ☐ ☐

74. The circumstances of the incident and route of exposure are documented. ☐ ☐

75. When feasible, the identity of the source individual is documented. ☐ ☐

76. The source individual's blood is tested for HIV and HBV as soon as feasible, after consent is obtained. ☐ ☐

77. The results of the source individual's blood test are made available to the exposed worker. ☐ ☐

78. The exposed worker is informed of laws and regulations concerning disclosure of the source individual's identity and infection status. ☐ ☐

79. The exposed worker's blood is collected as soon as practical and tested after consent is obtained. ☐ ☐

80. If the exposed worker does not consent to HIV testing, the blood sample is retained for 90 days in the event the worker reconsiders. ☐ ☐

81. The following information is provided to the health care provider who conducts the post-exposure evaluation and follow-up:

- A copy of the OSHA BBP standard, 29 CFR 1910.1030. ☐ ☐
- A description of the worker's duties and responsibilities as they relate to the exposure. ☐ ☐
- Documentation concerning the routes of entry and circumstances under which the exposure incident occurred. ☐ ☐
- Results of the source individual's blood testing, if available. ☐ ☐
- All other relevant medical records including vaccination status, which the employer maintains. ☐ ☐
- The exposed worker is provided post-exposure prophylaxis when medically indicated according to the US Public Health Service guidelines. ☐ ☐
- Counseling for the exposed worker is provided. ☐ ☐
- The health care professional's written opinion is obtained and provided to the exposed worker within 15 days. ☐ ☐
- Subsequent illnesses for exposed workers are evaluated. ☐ ☐

Recordkeeping

82. Medical records are established and maintained for each worker in accordance with 29 CFR 1910.1020. ☐ ☐

83. Medical records include:

- Name and social security number of the worker. ☐ ☐
- Copy of the worker's HBV vaccination status, including all dates of all vaccinations, any medical records relative to the worker's ability to receive vaccination. ☐ ☐
- Copies of all results of examinations, testing, and follow-up as required by the standard. ☐ ☐
- Employer's copy of the health care professional's written opinion. ☐ ☐
- Copy of the information provided to the health care professional. ☐ ☐

84. Medical records are:

- Kept confidential. ☐ ☐
- Not disclosed or reported without the worker's written consent. ☐ ☐

85. Medical records are maintained for the duration of employment plus 30 years. ☐ ☐

86. A worker's medical record is made available to that worker, or anyone with that worker's written consent, for examination or copying. ☐ ☐

87. Training records include:

- Dates of training sessions. ☐ ☐
- Contents or summary of training. ☐ ☐
- Name(s) and qualification of trainer(s). ☐ ☐
- Names and job titles of attendees. ☐ ☐

88. Training records are made available to MOSH Inspectors and NIOSH. ☐ ☐

89. Training records are made available to workers, or an authorized representative of the worker, for examination and copying. ☐ ☐

90. Safety and Occupational Health Program Injury and Illness Log (or OSHA 300 log) includes:

- Type and brand of device involved in the incident. ☐ ☐
- Department or work area where the incident occurred. ☐ ☐
- Explanation of how the incident occurred. ☐ ☐

91. Entries recorded on the log are treated as privacy cases. ☐ ☐

APPENDIX G
GLOSSARY

AIA	American Institute of Architects
AIDS	Acquired immunodeficiency syndrome
BBP	Bloodborne pathogens
BMBL	Biosafety in Microbiological Biomedical Laboratories
BSC	Biological safety cabinet
BSI	Body substance isolation
BSL	Biosafety level
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CPR	Cardiopulmonary resuscitation
CMS	Central Material Services
COR	Contracting Officer Representatives
DOD	Department of Defense
ECP	Exposure Control Plan
EIA	Enzyme immunoassays
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
HBIG	Hepatitis B immune globulin
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HCW	Health care workers
HDV	Hepatitis D virus
HEPA	High efficiency particulate air
HIV	Human immunodeficiency virus
HMO	Health maintenance organization
HVAC	Heating, ventilation, air conditioning
IV	Intravenous
LHCP	Licensed health care professional
MRI	Magnetic resonance imaging
MTF	Military treatment facility
NIOSH	National Institute for Occupational Safety and Health
OPIM	Other potentially infectious materials
OSHA	Occupational Safety and Health Administration
PEP	Post exposure prophylaxis
PPE	Personal protective equipment

RMW	Regulated medical waste
SESIP	Sharps with engineered sharps injury protection
SJA	Staff Judge Advocate
SP	Standard precautions
TG	Technical guide
UP	Universal precautions
USACHPPM	U.S. Army Center for Health Promotion and Preventive Medicine
USPHS	U.S. Public Health Service

APPENDIX H
REFERENCES

Department of Defense Instructions

DOD Policy Letter on Needlestick Safety

DODI Immunization Requirements

Army Regulations and Policies

AR 40-5	Preventive Medicine
AR 385-10	The Army Safety Program
AR 385-40	Accident Reporting and Records

U.S. Army Medical Command Regulations and Memorandums

MEDCOM Regulation 40-35 & Change 1	Management of Regulated Medical Waste
MEDCOM Regulation 40-44	Latex Allergy Prevention
MEDCOM Memorandum MCHO-CL-W (OASD/5 Nov 96) 27 Mar 1997	Hepatitis B Immunization Policy for Department of Defense Medical and Dental Personnel

Other Publications

CDC MMWR Vol.51, No.RR16 Oct 25, 2002	Guideline for Hand Hygiene in Health-Care Settings

DHHS Publication No. 017-040-00547-4	Biosafety in Microbiological and Biomedical Laboratories
OSHA Instruction CPL 2-0.131	Record Keeping and Procedures Manual
OSHA Instruction CPL 2-2.69	Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens
29 CFR 1910	Occupational Safety and Health Standards
39 CFR	Postal Service
49 CFR 171-180	Transportation

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THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

JUN 4 2001

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (SAF/MI)

SUBJECT: Policy Letter on Needlestick Safety for Health Care Workers

Needlesticks and other percutaneous injuries resulting in exposure to blood or other potentially infectious materials are a serious concern for health care workers. Newer, safer medical devices can reduce the risk of needlesticks and the chance of contracting deadly bloodborne diseases including human immunodeficiency virus (HIV), hepatitis B virus, hepatitis C virus and others. The Needlestick Safety and Prevention Act, Public Law 106-430, signed November 6, 2000, mandated specific revisions of the Occupational Safety and Health Administration Bloodborne Pathogens standard (29 CFR 1910.1030) with an effective date of April 18, 2001. This revision was intended to ensure widespread use of safer medical devices to prevent dangerous needlesticks.

Effective immediately, it is Department of Defense policy that Medical and Dental Treatment Facilities will comply with newly revised OSHA 29 CFR Part 1910 and all applicable state regulations with respect to needlestick safety. All decisions concerning safety devices will be coordinated with the Regional Tri-Service Product Standardization Boards. The Clinical Product Teams for needlestick safety devices should include employees representing the range of exposure situations encountered in the workplace. The Services will include information on any cost increases associated with this policy in their quarterly product standardization report to the TRICARE Management Activity.

I am confident that adherence to this guidance will afford our healthcare providers greater protection against deadly and debilitating bloodborne diseases. I request you direct immediate implementation within your Service and provide a copy of your implementation instructions to my office.

My point of contact is Gail Sanftleben, Deputy Director for Medical Logistics, at (703) 681-0039, and email, Gail.Sanftleben@tma.osd.mil.

J. Jarrett Clinton, MD, MPH
Acting Assistant Secretary

cc:
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force

HA POLICY: 0000013

PCDocs No.: 22590/226.04
Due Date:

April 10, 2001

MEMORANDUM FOR ASSISTANT SECRETARY OF DEFENSE (HEALTH AFFAIRS)

THROUGH: H. James T. Sears, M.D., Executive Director, TMA

FROM: Gail Sanftleben, POD, HS&OS, (703) 681-0039

SUBJECT: Policy Letter on Needlestick Safety

DISCUSSION: Needlesticks and other percutaneous injuries resulting in exposure to blood and other potentially infectious material are a serious concern for healthcare workers. The Center for Disease Control estimates more than 800,000 needlestick injuries occur to healthcare workers in the U.S. each year. These workers are at risk for exposure to bloodborne pathogens such as the human immunodeficiency virus (HIV) and the hepatitis B virus (HBV). Recent changes to Occupational Health and Safety Administration standards require increased emphasis on the prevention of needlesticks to include use of safer medical devices. The Services will require additional resources to achieve this standard. Product decisions must be based upon the safety of our employees rather than product costs. The Tri-Service Logistics Chiefs recommend the product standardization decisions and associated costs be documented by the regional Tri-Service Product Standardization Boards.

RECOMMENDATION: The ASD (HA) sign the policy letter.

COORDINATION:

Director, Dental Ops
Director, Clin Ops
Director, HS&OS
TMA OGC
Dep Dir, (POD)
Director (POD)
Chief of Staff (TMA)
DoD TMA
Chief of Staff (HA)

Public Law 106–430
106th Congress

An Act

To require changes in the bloodborne pathogens standard in effect under the Occupational Safety and Health Act of 1970.

Nov. 6, 2000
[H.R. 5178]

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Needlestick Safety and Prevention Act.

SECTION 1. SHORT TITLE.

This Act may be cited as the "Needlestick Safety and Prevention Act".

SEC. 2. FINDINGS.

The Congress finds the following:

(1) Numerous workers who are occupationally exposed to bloodborne pathogens have contracted fatal and other serious viruses and diseases, including the human immunodeficiency virus (HIV), hepatitis B, and hepatitis C from exposure to blood and other potentially infectious materials in their workplace.

(2) In 1991 the Occupational Safety and Health Administration issued a standard regulating occupational exposure to bloodborne pathogens, including the human immunodeficiency virus, (HIV), the hepatitis B virus (HBV), and the hepatitis C virus (HCV).

(3) Compliance with the bloodborne pathogens standard has significantly reduced the risk that workers will contract a bloodborne disease in the course of their work.

(4) Nevertheless, occupational exposure to bloodborne pathogens from accidental sharps injuries in health care settings continues to be a serious problem. In March 2000, the Centers for Disease Control and Prevention estimated that more than 380,000 percutaneous injuries from contaminated sharps occur annually among health care workers in United States hospital settings. Estimates for all health care settings are that 600,000 to 800,000 needlestick and other percutaneous injuries occur among health care workers annually. Such injuries can involve needles or other sharps contaminated with bloodborne pathogens, such as HIV, HBV, or HCV.

(5) Since publication of the bloodborne pathogens standard in 1991 there has been a substantial increase in the number and assortment of effective engineering controls available to employers. There is now a large body of research and data concerning the effectiveness of newer engineering controls, including safer medical devices.

(6) 396 interested parties responded to a Request for Information (in this section referred to as the "RFI") conducted

by the Occupational Safety and Health Administration in 1998 on engineering and work practice controls used to eliminate or minimize the risk of occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps. Comments were provided by health care facilities, groups representing healthcare workers, researchers, educational institutions, professional and industry associations, and manufacturers of medical devices.

(7) Numerous studies have demonstrated that the use of safer medical devices, such as needleless systems and sharps with engineered sharps injury protections, when they are part of an overall bloodborne pathogens risk-reduction program, can be extremely effective in reducing accidental sharps injuries.

(8) In March 2000, the Centers for Disease Control and Prevention estimated that, depending on the type of device used and the procedure involved, 62 to 88 percent of sharps injuries can potentially be prevented by the use of safer medical devices.

(9) The OSHA 200 Log, as it is currently maintained, does not sufficiently reflect injuries that may involve exposure to bloodborne pathogens in healthcare facilities. More than 98 percent of healthcare facilities responding to the RFI have adopted surveillance systems in addition to the OSHA 200 Log. Information gathered through these surveillance systems is commonly used for hazard identification and evaluation of program and device effectiveness.

(10) Training and education in the use of safer medical devices and safer work practices are significant elements in the prevention of percutaneous exposure incidents. Staff involvement in the device selection and evaluation process is also an important element to achieving a reduction in sharps injuries, particularly as new safer devices are introduced into the work setting.

(11) Modification of the bloodborne pathogens standard is appropriate to set forth in greater detail its requirement that employers identify, evaluate, and make use of effective safer medical devices.

SEC. 3. BLOODBORNE PATHOGENS STANDARD.

The bloodborne pathogens standard published at 29 CFR 1910.1030 shall be revised as follows:

(1) The definition of "Engineering Controls" (at 29 CFR 1910.1030(b)) shall include as additional examples of controls the following: "safer medical devices, such as sharps with engineered sharps injury protections and needleless systems".

(2) The term "Sharps with Engineered Sharps Injury Protections" shall be added to the definitions (at 29 CFR 1910.1030(b)) and defined 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".

(3) The term "Needleless Systems" shall be added to the definitions (at 29 CFR 1910.1030(b)) and 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".

(4) In addition to the existing requirements concerning exposure control plans (29 CFR 1910.1030(c)(1)(iv)), the review and update of such plans shall be required to 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".

(5) The following additional recordkeeping requirement shall be added to the bloodborne pathogens standard at 29 CFR 1910.1030(h): "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— Records.

"(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 requirement for such sharps injury log shall not apply to any employer who is not required to maintain a log of occupational injuries and illnesses under 29 CFR 1904 and the sharps injury log shall be maintained for the period required by 29 CFR 1904.6.

(6) The following new section shall be added to the bloodborne pathogens standard: "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.".

SEC. 4. EFFECT OF MODIFICATIONS.

The modifications under section 3 shall be in force until superseded in whole or in part by regulations promulgated by the Secretary of Labor under section 6(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655(b)) and shall be enforced in the same manner and to the same extent as any rule or regulation promulgated under section 6(b).

SEC. 5. PROCEDURE AND EFFECTIVE DATE.

(a) PROCEDURE.—The modifications of the bloodborne pathogens standard prescribed by section 3 shall take effect without regard to the procedural requirements applicable to regulations promulgated under section 6(b) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655(b)) or the procedural requirements of chapter 5 of title 5, United States Code.

(b) EFFECTIVE DATE.—The modifications to the bloodborne pathogens standard required by section 3 shall—

(1) within 6 months of the date of the enactment of this Act, be made and published in the Federal Register by the Deadline. Federal Register, publication.

Secretary of Labor acting through the Occupational Safety and Health Administration; and

(2) at the end of 90 days after such publication, take effect.

Approved November 6, 2000.

LEGISLATIVE HISTORY—H.R. 5178:

CONGRESSIONAL RECORD, Vol. 146 (2000):
Oct. 3, considered and passed House.
Oct. 26, considered and passed Senate.
WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 36 (2000):
Nov. 6, Presidential statement.

○

INFORMATION ON NEEDLE STICKS

1. **Step (1) to comply with Legislation**

    a. Understand the Law
    b. Develop an Action Plan
    c. Select and Evaluate Safety Devices
    d. Establish Safer Work Practices
    e. Document Sharp Injuries
    f. Develop an Exposure Control Plan

2. What Bloodborne Pathogen are covered

    a. Human Immunodeficiency Virus (HIV)
    b. Hepatitis B Virus (HBV)
    c. Hepatitis C Virus (HCV)

3. General Provision of Bloodborne Pathogen Control Law.

    a. Develop an exposure control plan that includes employee exposure determination. Training, and education, vaccination, post exposure evaluation and follow-up, record keeping, housekeeping and laundry guidelines and the use of personal protective equipment to limit exposure to bloodborne pathogens
    b. Use needless systems or devices with engineered sharp injury protection for all venous/arterial access, body fluid withdrawal, fluid administration and injections, with limited exceptions.
    c. Keep a sharp injury log that records the date and time of exposure, the type and brand of sharp involved, details of the incident and other pertinent information as mandated by law.
    d. Annually review and update the exposure control plan to reflect current risk reduction strategies in place to further reduce exposure to bloodborne pathogens. The plan should be updated more frequently if safer work practices and devices become available

4. **Sharp is defined:** as any object used or encountered in a healthcare setting that can be reasonably anticipated to penetrate the skin, or any other part of the body. Resulting in an exposure incident, including a needle device, a scalpel, a lancet, a piece of broken glass, a broken capillary tube, an exposed end of a dental wire or a dental knife, drill or bur.

5. **Sharp Injury:** an injury caused by a sharp including cuts, abrasions or needle stick.

6. **Needless systems:** are those used to withdraw body fluids after initial venous or arterial access is established, to administer medications or fluids, or for any other procedure involving the potential of an exposure incident.

7. **Alternative to needless systems,** a device with engineered sharps injury protection should be used. A physical attribute that is built into the needle device, that effectively reduces the risk of an exposure incident by a mechanism, such as barrier creation blunting, encapsulation, withdrawal, retraction, destruction or another effective mechanism. One that is built into any other type of needle device, into a non-needle sharp, or into a non-needle infusion safety securement device that effectively reduces the risk of an exposure incident.

8. Devices with engineered sharps injury protection are to be used:

   - to withdraw body fluids
   - to access a vein or artery or
   - to administer medications or fluids

9. Exceptions to the Engineered Sharps Requirement:
   - **Patient Safety**. An evaluation committee at least half of whose members are direct care givers or provide services on a regular basis, must establish that a needless system or engineered sharps injury protection device would jeopardize patient safety with regards to a specific medical procedure.
   - **Employee Safety**. An evaluation committee at least half of whose members are direct care givers or provide services on a regular basis, must establish that a needless system or engineered sharps injury protection device would jeopardize employee safety with regards to a specific medical procedure.
   - **Undue Burden.** The evaluation committee must establish that obtaining a needless system or engineered sharps injury.

10. **Step (2) Develop an action plan:** an action plan is your road map. It outlines what needs to be done, who is going to do tit, and by when. The action plan is the framework that surrounds the bloodborne pathogens exposure control plan.

11. What's important is that the plan clearly:

    - establish the need for the action
    - set goals and strategies
    - defines roles and responsibilities
    - allow for input and involvement from pertinent stakeholders,
    - is consistent with the requirement of the exposure control plan and
    - is a documented from which everyone works

12. The sample plan should include these components:

    - Background
    - Issues
    - Assumptions
    - Needle stick reduction

- Goals and strategies

13. **Background:** CDC estimates more than 800,000 needlestick injuries occur to health care worker I n the U.S. each year. These workers are at risk from blood borne pathogens such as HIV, HBV, and HCV.
14. **Issues:** Professional and labor organizations support mandating the use of needleless and safer needle devices ie ANA, ACCN, APRN, AAOHN.
15. **Assumptions:** Needlestick injuries pose a serious risk to health care workers. We will make all reasonable efforts to provide the training and tools to prevent and reduce employee occupational needlestick injuries. Strive to maintain a safe environment for employees. It is the intent and desire to be a good citizen of the community. Facility will make all reasonable efforts to design and implement needlestick reduction strategies that comply with legal standards.
16. Needlestick Reduction: The following efforts have been made to reduce needlestick injuries and prevent infection by bloodborne pathogens.

    - An exposure control plan has been developed
    - Health care workers are educated regarding the safe handling of sharps.
    - A hepatitis B vaccine is offered to all at-risk employees at no cost to employees.
    - Sharps disposal systems are correctly installed, easily accessible, conveniently located and routinely replaced.
    - A needleless IV fluid/medication administration system is in place.
    - Safer IV insertion catheter devices are in place and appropriately used by staff.
    - Safer syringe devices are in place and properly used by staff.
    - Safer blood collection devices are in place and safely used by staff.

17. Goals and Strategies:

18. **Plan Approval**: Infection Control Committee, Executive Control Committees, Safety, Occupational Health Etc.

19. **Suggested Committees:**

    - Guidance Committee. The guidance committee develops and oversees the sharps safety action plan, which includes the exposure control plan. Primary function include review, modify and approve the sharps safety action plan, ensure effective implementation of the sharps safety action plan, support and assist the evaluation committee and any action work group as needed, review and revise the exposrue control plan at least once a year.
    - **Suggested Members**:
        1. Anesthesiology director
        2. Chief financial officer
        3. Chief operations office
        4. Employee health director
        5. Human resource personnel
        6. Infection control director

7. Legal counsel
8. Materials management/purchasing
9. Medical staff director
10. Nursing administration
11. Quality management director
12. Safety director
13. Risk manager

20. **Evaluation Committee:** Develop standardizes criteria to review and select available safety products, develop product evaluation forms based on the standardize criteria. Establish a test protocol to ensure that each product is adequately and fairly evaluated. Consults with materials management/purchasing and administration during the product selection processes. Submit data from the tests to guidance committee with recommendation for purchase. Review performance of existing safety devices and evaluating new devices annually or as appropriate. Submit annual reports, and requesting waivers.
21. **Work groups:** may research and provide information on best practices, products, policies and procedures. Work groups collect review and discuss information obtained from literature searches, employee practices and other health care facilities.

- Education Work Group
- Safer Work Practice Group
- Post exposure Prophylaxis work group
- Data collection work group

22. **Step (3) Select and Evaluate Safety Devices:** Federal units use needleless systems and devices with engineered sharp injury protection to reduce employee exposure to bloodborne pathogens. Ongoing evaluation of these products is necessary.

23. Select Safety products for testing: Start the process by documenting all sharp devices currently in use, all procedures performed where sharps are used to deliver medications or access veins or arteries.

- **Focus on high Risk procedures first. The highest risk devices are hollow-bore needles used to access veins or arteries, including devices used for**
  1. Phlebotomy
  2. To draw arterial gas and
  3. To start intravenous lines

- **Search for Safety Devices**
  1. Gather information on devices currently available in the marketplace, There are a number of ways to find this information
  2. A list of safety devices and manufacturers from the international Healthcare Worker Safety Center of the University of Virginia can be accessed via the Internet at www.hsc.virginia.edu/epinet
  3. Look for safety devices advertised in nursing and health care publications.

4. Call manufacturers of devices you currently use and ask whether they make a safety product.
5. Contact the customer service department of manufacturers and request written information and product samples.
6. Work groups members may suggest safety devices they have used elsewhere or learned about at professional conferences.

24. Establish Criteria for screening Products:

- Quantity of product to be tested
- Length of test period
- Test sites
- Evaluation forms to be used and
- Feedback mechanism to vendor after decision is made

25. Test Products:

- Test only devices that meet the criteria established by the evaluation committee
- All test projects will be coordinated through the project coordinator or designee
- Devices will not be tested in all areas of the facility. The project coordinator will select individual units/areas that represent the spectrum of the expected product use.
- Tests are expected to run for a period of one to two weeks.

26. Educate Staff on New Safety Devices and Products:

27. Evaluate Existing And New Products

28. Product Specific Forms Aid Evaluation

29. Step (4) Establish Safer Work Practices. These practices include the way we do our work, the tools we choose to work with, and the protective equipment we take time to put on and our willingness to help each other.

30. Step (5) Document Sharps Injuries. Establish and maintain a sharps injury log, either paper or electronically. The log must document all contaminated sharps injuries occurring in the facility or while employees are on duty outside the facility (EMS service, Home health care) record the following information.

- Name and address of the facility where the injury occurred
- Name and phone number of the chief administrative officer or reporting officer.
- Date and time of injury
- Age and sex of the injured employee
- Type and brand of sharp involved
- Original intended use of the sharp

- Whether the injury occurred before, during or after the sharp was used for its original intended purpose.
- Whether the exposure was during or after the sharp was used
- Whether the device had engineered sharps injury protection
- If the device had engineered sharps injury protection, whether the protective mechanism was activated and whether the exposure incident occurred before, during or after activation of the protective mechanism.
- Whether the injured person was wearing gloves at the time of the injury
- Whether the injured person had completed a hepatitis B vaccination series
- Whether a sharps container was readily available for disposal of the sharp
- Whether the injured person received training on the exposure control plan during the 12 months prior to the incident,
- The involved body part
- The employment status of the injured person, and
- The location/facility/agency and the work area where the sharps injury occurred.

31. Reporting Requirements:

32. Post-Exposure Evaluation And follow-up Requirements:

33. Information provided to the health care Professional

34. Obtaining a Written Medical Opinion

35. Using the injury log to improve safety

36. Step (6) developing an Exposure Control Plan: the guidance committee, which includes representatives from infection control, nursing, housekeeping, materials management and administration, should develop the exposure control plan. By law the plan must be reviewed annually and updated as necessary with revision documented. At a minimum, the, plan should specify the following

- Determination of occupational risk exposure
- Implementation schedule for the plan
- Effective procedures for protecting employees through training, safer devices, personal protective equipment, work habits, cleaning and disposal practices, and vaccines;
- Post-exposure evaluation and follow-up procedures and
- Documentation of record keeping responsibilities.

37. Sample Exposure Control Plan:

- **Definitions**
- **Exposure determinations (What jobs put workers at risk)**
- **Methods of compliance and protocols for:**

1. **Universal Precautions/Standards Precautions**
2. **Engineered Controls**
3. **Work practice controls**
4. **Personal protective equipment**
5. **Cleaning and decontaminating the work site**
6. **Waste disposal**
7. **Hepatitis B vaccine program**
8. **Biohazard labeling**
9. **Reporting and documenting sharps injuries**
10. **Post exposure evaluation and follow-up**
11. **Training**
12. **Record keeping**
13. **Annual review**

38. Other plan attachments.

- Hepatitis B vaccine declination statement
- Confirmation of post exposure evaluation
- Sample letter for obtaining waivers based on patient/employee safety or undue burden
- Checklist for assisting the exposure control plan

From: Sass, Melinda L MAJ FSHTX
Sent: Friday, February 02, 2001 8:07 AM
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Cc: Powers, Judith L COL FSHTX
Subject: Needle Safety Info for Standardization

All,

This all pertains to standardization for needle safety. The recently signed Needlestick Safety and Prevention Act gives health care workers the legal guidelines for protection. This Act directly affects the types of products purchased within the needle saftey arena.

A. The 3 relevant product groups getting the main focus are:
   1. IV safety catheters and infusion therapy
   2. Blood collection products/blood-drawing devices
   3. Syringes

B. The Public Citizen petition to FDA to immediately ban (remove from market) unsafe medical needles include:
   1. All unsafe intravenous catheters
   2. Blood collection devices
   3. Blood collection needle sets (butterfly syringes)
   4. Glass capillary tubes and intravenous infusion equipment

C. The 5 standards for medical devices by FDA specific to needles are:

1. A fixed safety feature allows or requires provides a barrier between the hands and the needle after use

2. The safety feature is an integral part of the device, and not an accessory

3. The safety feature allows or requires the worker's hands to remain behind the needle at all times

4. The safety feature is in effect before disassembly, is any, and remains in effect after disposal; and

5. The device should be simple and easy to use, requiring little training

D. OSHA Bloodborne Pathogen Standard, CFR 1910.1030 (Jan 18,01) relates:

> Paragraph (c) (1) (v) (NEW). Employers must involve potentially exposed HCWs in the identification, evaluation, and selection of engineering and work practice controls. HCW involvement must be documented in the Exposure Control Plan.

This was added so that employees had a voice in choosing

effective sharps safety devices and that it wasn't just a health facility's management decision to go with the cheapest product. As we continue to conduct our regional standardization efforts, as it pertains to sharps safety devices, our health care facilities will need to come up with a mechanism that demonstrates that employees with potential exposure had involvement in choosing the regionally selected products. Further coordination should be clarified from OSHA and our Safety POCs, e.g., Larry Whisenhut and Rose Overturf concerning OSHA acceptance of trial results or synopsis from the regional standardization committees.

Check out the OSHA web site, specifically the Federal Register published Jan 18, 01.

http://www.osha-slc.gov/needlesticks/index.html

MAJ Sass, MEDCOM
Ms. Paula Valentino, Reg 1
MAJ Anderson, Redstone Arsenal MEDDAC

Information Paper

MCLO-O
19 March 2001

SUBJECT: Needle Safety Program Initiatives Summary

1. Purpose. To provide a status update on the needle safety program initiatives in each of the Tri-service regions.
2. Facts.

a. A written summary on the Needlestick Safety and Prevention Act with provisions of OSHA's compliance directive on sharp safety was provided to the logistics chiefs on February 2 (See Encl 1). The intent was to provide a brief overview to ensure that the medical activities are aware of the new requirements.

b. A Tri-service Regional Data Call was conducted to collect the regions current standardization initiatives involving needle safety and current accomplishments (See Encl 2).

c. Primary key areas for immediate consideration:

(1) Regions/Facilities must develop an Exposure Control Plan as required by OSHA Bloodborne Pathogen Standard CFR 1910.1030 by April 18, 2001.

(2) Identify a list of all products or items pertaining to or associated with needlesticks or sharp injury for a complete review and analysis. Identify and prioritize clinical service areas (In-patient, Outpatient) that have employees with the highest risk of sharp injury.

(3) Regions/Facilities should coordinate all needle safety related products with the infectious control nurse before, during, and after standardization efforts, and identify other critical care representatives for involvement with the hospital clinical trials of these products. The clinical product team should develop a timeline to complete standardization of these products.

(4) Conduct a cost comparison of the associated costs estimated for each product identified for possible standardization from the current product to potential

replacement products available that comply with OSHA standards.

d. There is a more comprehensive plan outlining important steps that a facility should review when developing a strategy compliance to meet the new requirements (See Encl 3).

e. A list of safety devices and manufacturers from the International Healthcare Worker Safety Center of the University of Virginia can be accessed via the Internet at www.hsc.virginia.edu/epinet. The web site contains over 15 types of products associated with sharp injury and includes a company directory of manufacturers for these products.

MAJ Melinda Sass/MCLO-O/DSN: 471-7877
Approved By: COL Michael G. Johnson

DEPARTMENT OF THE ARMY
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MEDCOM Regulation
No. 40-35

22 November 1999

Medical Services

MANAGEMENT OF REGULATED MEDICAL WASTE (RMW)

Supplementation of this regulation and establishment of forms other than MEDCOM forms are prohibited without prior approval from HQ MEDCOM, ATTN: MCHO-CL-W.

1. **HISTORY.** This issue publishes a revision of this publication. Because the publication has been extensively revised, the changed portions have not been highlighted.

2. **PURPOSE.**

a. To provide guidance to U.S. Army Medical Command (MEDCOM) organizations on the management of regulated medical waste (RMW).

b. To manage RMW in a manner which minimizes occupational exposure, protects both the environment and the public, and ensures compliance with appropriate Federal and Department of the Army (DA) Regulations.

c. This regulation does not purport to reflect regulatory variations found in many State or overseas jurisdictions. The user of this regulation must ascertain and adhere to State and local requirements.

3. **REFERENCES.** References are listed in appendix A.

4. **EXPLANATION OF ABBREVIATIONS AND TERMS.** Abbreviations and special terms used in this publication are explained in the glossary.

5. **SCOPE.**

a. This regulation applies to all personnel assigned, attached, or otherwise employed by the MEDCOM and its subordinate activities/medical treatment facilities (MTF).

b. This regulation implies that management requires implementing all engineering and administrative controls for bloodborne pathogens, and that employees use standard precautions and wear required Personal Protective Equipment (PPE). (The use of standard precautions does not change waste management programs recommended by the Centers for Disease Control and Prevention (CDC) for health-care settings nor does using standard precautions define the classification of waste.)

c. All waste generated within the U.S. Army Medical Center (MEDCEN)/ medical department activity (MEDDAC)/dental activity (DENTAC) and U.S. Army Veterinary Command (VETCOM) activities will be disposed of according to State and local regulations.

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*This regulation supersedes HSC Regulation 40-35, 27 December 1993.

NOTE: When implementing this regulation, specify State and local requirements. Include contingency plans for backup if primary means of disposal is inoperable.

6. DEFINITIONS.

a. General Waste - waste that is disposed of by normal waste disposal methods without pretreatment. This includes garbage, rubbish, and nonregulated medical waste.

(1) Garbage - putrescible solid waste resulting from handling, preparation, cooking, or serving of food.

(2) Rubbish - nonputrescible solid waste comprising two categories:

(a) Organic material. Examples include paper, plastics, cardboard, wood, rubber, and bedding.

(b) Inorganic material. Examples include glass, ceramics, and metal.

(3) Nonregulated Medical Waste - solid material intended for disposal which is produced as the direct result of patient diagnosis, treatment, or therapy. Such waste is generated in patients' sleeping, treatment, therapy, or isolation rooms (except where the patient is isolated for a CDC Class 4) (see appendix B), and rooms used for diagnostic procedures, doctors' offices, and nursing units. Examples of items included in this category are soiled dressings, bandages, disposable catheters, swabs, used disposable drapes, gowns, masks, gloves, and empty used specimen containers. This waste requires no further treatment and is disposed of as general waste.

b. Regulated Medical Waste - waste which is potentially capable of causing disease in man and may pose a risk to both individuals or community health if not handled or treated properly. Sometimes called "Infectious Waste," "Biohazardous Waste," or "Medical Waste." State or local regulations may vary. Consists of the following classes:

(1) Class 1 - Cultures, Stocks, and Vaccines. Examples include cultures and stocks of infectious agents and associated biologicals, including cultures from medical and pathological laboratories; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures. (All other lab waste except Class 2 and Class 3 is considered general waste.)

(2) Class 2 - Pathological Waste. Examples are human pathological wastes, including tissues, organs, body parts, extracted human teeth, and body fluids that are removed during surgery or autopsy, or other medical procedures, and specimens of body fluids.

(3) Class 3 - Blood and Blood Products. Examples include:

(a) Free flowing liquid human blood, plasma, serum, and other blood derivatives that are waste (e.g., blood in blood bags, blood and/or bloody drainage in suction containers).

(b) Items such as gauze or bandages, saturated or dripping with human blood, including items produced in dental procedures, such as gauze or cotton rolls saturated or dripping with saliva. Included are contaminated items that could release blood or related fluids if compressed.

NOTE: The following items saturated or dripping with blood are not subject to the requirements of this regulation: Products used for personal hygiene, such as diapers, facial tissues, and sanitary napkins/tampons (or feminine hygiene products). There was never an intent in law or by implementing regulations to manage as RMW the contents of trash receptacles in public areas. MTF personnel need to use judgement in deciding when and where these items, from patients, need to be managed as RMW.

(c) Items caked with dried blood and capable of releasing the blood during normal handling procedures.

(4) Class 4 and Class 7 - All Used (Class 4) and Unused (Class 7) Sharps. Examples include sharps used in animal or human patient care or treatment in medical, research, or support laboratories [including hypodermic needles, syringes (with or without the attached needle)], Pasteur pipettes, scalpel blades, blood collection tubes and vials, test tubes, needles attached to tubing, and culture dishes (regardless of presence of infectious agents). Other examples include broken or unbroken glassware that was in contact with infectious agents (i.e., used slides and cover slips).

NOTE: Unused glassware may be discarded in designated and labeled "broken glass" boxes usually found in laboratories.

(5) Class 5 - Animal Waste. Examples include contaminated animal carcasses, body parts, and bedding of animals known to have been exposed to infectious agents[1] during research (including those produced in veterinary facilities), production of biologicals, or testing of pharmaceuticals.

NOTE: Carcasses of road kills, euthanized animals, animals dying of natural causes, and waste produced by general veterinary practices are not considered Class 5 animal waste.

(6) Class 6 - Isolation wastes, including bedding, from patients or animals with etiologic agents classified by the CDC as Class 4. Examples include biological waste and discarded materials contaminated with blood, excretion exudates, or secretions from humans who are isolated to protect others from highly communicable diseases, or isolated animals known to be infected with highly communicable diseases caused by agents designated by the CDC as Class 4 in Classification of Etiologic Agents on the Basis of Hazard (1974) and Biosafety in Microbiological and Biomedical Laboratories (1999). This category includes pox viruses and arboviruses (shown at appendix B).

(7) Other - Fluids that are designated by the local Infection Control authority. They may include but are not limited to semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid. These designated fluids are RMW when free flowing, dripping, or saturated on substrates.

7. **GENERAL.**

a. MTF personnel will adhere to the principles of pollution prevention by minimizing the use of disposable items, encouraging the use of reusable materials, and recycling to the maximum extent.

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[1]To obtain an interpretation about how this term applies at your MTF, consult with your Veterinary, Infection Control, and PVNTMED authorities.

b. The MTF waste management system includes the segregation, by categories, of waste at the point of origin and the appropriate packaging, transporting, and treatment/disposal of waste in each category. A combination of three basic approaches is used to define regulated medical waste (i.e., the infectious characteristics of the waste, the types or categories of waste, and sources of generation).

c. The facility will assess its entire waste stream to identify areas and processes that generate RMW. A suggested list of areas that normally do and do not generate RMW is shown at appendix C.

d. The following items shall NOT be placed into hospital trash compaction systems: liquids, RMW, semi-solid waste (food service), empty containers from hazardous laboratory chemicals, aerosol cans, chemotherapy and antineoplastic agents, and radioactive substances.

e. RMW and hazardous waste (HW) are different categories of waste and are classified and managed by separate and distinct regulations. RMW will not be mixed with HW and, conversely, HW will not be mixed with RMW for purposes of disposal.

8. RESPONSIBILITIES.

a. The MEDCEN/MEDDAC/DENTAC/VETCOM commanders will ensure that RMW is identified and disposed of following the procedures established in this and local regulations.

b. The Preventive Medicine (PVNTMED) Service has joint responsibility with other organizational staff offices within the MEDCEN/MEDDAC/DENTAC/VETCOM for the effective management of the RMW program. The PVNTMED Service is responsible for preparation of local regulations, monitoring all aspects of RMW management including the timely collection, transportation, treatment, storage, and disposal of regulated medical waste. The PVNTMED Service is jointly responsible with Infection Control, Logistics, and Safety for identifying and characterizing RMW properly and for providing training.

c. The Infection Control Committee (ICC) provides guidance and technical consultation to departments responsible for RMW, and approves policies and procedures related to RMW.

d. Logistics Division supervises the collection, storage, transportation, and disposal of RMW.

e. Housekeeping personnel collect and transport RMW to the appropriate holding area. Housekeeping ensures that RMW bags are available to the staff after normal duty hours in the event of a spill.

f. The MEDCEN/MEDDAC/DENTAC/VETCOM supervisors will ensure compliance through proper management controls and periodic inspections. Supervisors will provide, as needed, in-service or other training to ensure that safe practices and regulatory compliance are achieved.

g. The Safety Manager or Collateral-Duty Safety Officer monitors worksites for compliance with applicable safety standards for the commander, MEDCEN/MEDDAC/DENTAC/VETCOM and participates, as needed, in providing relevant training on RMW practices.

9. WASTE MANAGEMENT PROCEDURES.

a. Manage and dispose of general waste according to existing published regulations (i.e., AR 40-5 and AR 420-49).

b. Regulated Medical Waste:

(1) Packaging, Collecting, Marking, and Handling of RMW.

(a) Segregate RMW from general waste at its point of origin. Tie the bag securely to provide a barrier between waste and worker. The bag is the primary barrier for bagged medical waste, and the sharps container is the primary barrier for sharps waste.

(b) Put regular trash and recycling containers at appropriate locations in the workplace to aid convenience and to minimize improper segregation. Use RMW bags on an "as needed" basis. In most instances, they are not placed in clinic/patient rooms unless they are required for a specific procedure or case. See appendix E for guidance.

(c) Deposit RMW in leakproof, puncture resistant, plastic bag lined receptacles. Bags used must be sturdy, tear resistant, 3 mils in thickness, and of an installation-specific color that denotes RMW (generally red). Bags less than 3 mil may be used as interim bags at selected work locations when RMW is not heavy or is rarely generated (e.g., some lab activities and some clinics) **provided** that these thinner bags are collected in 3-mil bags prior to being transported within the MTF.

NOTE: Any State requirement regarding the thickness or strength of the RMW bag must be met. Meeting the State requirement takes precedence over the thickness and strength requirement of this regulation.

(d) When sealing, the bag will not be shaken or squeezed in an attempt to reduce volume. RMW will never be compacted prior to disposal. Sealed bags (or containers) of RMW should be marked at the point of generation with the location of generation, date when sealed, and point of contact (POC).

(e) Carry sealed bags by their necks to the transportation cart. Do not lift or hold bags by the bottom or sides. Carry bags away from the body.

(f) Ensure bags are not broken, opened, or dropped. Never throw bags into carts or from one individual to another.

(g) Wear gloves appropriate for the task when handling bagged RMW. If necessary, obtain guidance from Infection Control, PVNTMED Service, and Safety.

(h) Class 1 - Cultures and Stocks. Separate microbiologic waste (cultures and stocks of etiologic agents) from general waste for decontamination. Liquid Class 1 RMW (e.g., liquid culture media) may be either steam sterilized and disposed of in the sanitary sewer system or kept in its original glass container and placed in the sharps container for treatment and disposal without using the sanitary sewer system.

(i) Class 1 - Vaccines. Deposit full, partially full, or empty vials of vaccine in sharps containers. Carpules from dental procedures may also be placed in sharps containers.

(j) Class 2 - Pathological Waste. Dispose of pathological waste inside an RMW container lined with a plastic bag or double bagged in RMW bags.

(k) Class 3 - Blood and Blood Products. Dispose of breakable containers of bulk blood or blood products in rigid, puncture-resistant, leakproof containers. Use plastic RMW bags to dispose of bulk blood or blood products, such as blood bags and blood filter tubing, and items saturated, dripping, or caked with blood. Remove needles from the tubing (avoiding unsafe manipulation) and place in a sharps container for disposal.

(l) Class 4 and 7 - Sharps. Discard all sharps directly into a rigid puncture-resistant, plastic sharps container immediately after use. Discard disposable needles and syringes intact, and do not cut, break, bend by hand, or recap using a two-hand method. To prevent unauthorized removal of its contents, the containers must be of a tamper-resistant design and will either be locked to a mounting device which is securely fastened to the building structure, or be located in a room or area which is under continuous supervision of ward or clinic personnel. Locate sharps containers as close as practical to the use area. The size (volume) of the sharps container will be determined by the activity serviced by that container and must meet the requirements of paragraph 9b(3)(e). Remove and seal the sharps container when it either is 3/4 full or is filled to the line indicated by the manufacturer. Sharps containers mounted on the wall will be positioned at a height to reflect safe use and safety standards for patients and visitors.

(m) Class 5 - Animal Waste. Contaminated animal carcasses, body parts, and bedding of animals that are known to have been exposed to infectious agents during research (including those produced in veterinary facilities), production of biologicals, or testing of pharmaceuticals must be incinerated.

NOTE: When implementing this regulation, specify if this type of animal waste is generated at the facility.

(n) Class 6 - Isolation Waste (CDC Class 4). Consult the Infection Control Officer (ICO) for specific instructions on handling waste with etiologic agents in CDC Class 4 (shown at appendix B).

(2) Transportation of RMW within the MTF:

(a) Carts used to transport RMW will be constructed of readily cleanable material, plastic, or stainless steel. Carts will be closed whenever possible.

(b) Clean carts and any other reusable containers used to transfer RMW using an Environmental Protection Agency (EPA)-registered hospital detergent-disinfectant. Housekeeping personnel will be responsible for timely transportation of waste within the MTF, maintenance of carts, and the cleaning on a weekly basis, or more frequently if needed. If a spill occurs, the cart will be cleaned immediately.

(c) Put bags of RMW in leakproof, rigid containers and mark the containers with the universal biohazard symbol. Red bags do not need to be marked with the universal biohazard symbol unless required by State or local regulations.

(d) RMW from outlying medical, dental, and veterinary service buildings within the health service area will be collected on a schedule approved by the MTF's environmental, infection control, and safety officials. See paragraph 9b(4)(b) for guidance.

(3) Transportation of RMW outside the MTF:

(a) RMW destined for disposal will be transported in a government-owned or contractor-owned vehicle. The use of privately owned vehicles for transporting RMW is not authorized. The transporting vehicle must be disinfected if a leak or spill occurs during transportation. The local MTF may be able to provide transportation support to the Veterinary Treatment Facility.

(b) A spill containment and cleanup kit will be maintained in each vehicle transporting RMW. The kit will include appropriate PPE, a disinfectant approved by the MTF, and appropriate absorbent and housekeeping equipment for cleaning up a spill. The kit may either be developed and assembled locally or be commercially procured.

(c) RMW is defined by the U.S. Department of Transportation (DOT) as a hazardous material. When transported in commerce (e.g., over public roads), RMW will be prepared for shipment following the requirements in Title 49, Code of Federal Regulations (CFR) Parts 172, 173, and 177.

(d) Shipping papers will be prepared IAW 49 CFR 172.200 and carried IAW 49 CFR 177.817. They will be signed by a DOD certifying official IAW DOD 4500.9-R, Defense Transportation Regulations, Part II, Chapter 204. The person signing the shipping papers must successfully complete an approved DOD hazardous materials certification course and shall be appointed in writing by the activity or unit Commander, to include scope of authority. Shipping papers must include a shipping description [i.e., Regulated Medical Waste,6.2,UN3291,PGII, *(Quantity being shipped)*] and other transportation information. The DD Form 836 (Sep 98 or later) is the standard shipping paper used for transporting hazardous materials on government vehicles. See appendix D for an example pertaining to RMW. When using DD Form 836, adhere to instructions that accompany the form, including filling out DD Form 626 for vehicle inspection. Alternative shipping papers may be used if they meet transportation requirements.

(e) Packagings (i.e., outer containers) must be rigid, leak resistant, impervious to moisture, strong enough to prevent bursting during handling, and sealed to prevent leakage during transport. Sharps containers must be able to fit within the outer packaging when off-post transport is involved. Outer containers must meet the DOT requirements for Performance Oriented Packaging as required by 49 CFR 173.197. The outer container will display the DOT Infectious Substance label whenever the military uses in-house personnel and equipment (i.e., not contractors) to transport RMW over public roads. An example is when medical personnel move RMW from outlying clinics to the main hospital using State or Interstate highways. The requirements of this paragraph are optional when moving RMW between buildings that are within the boundaries of the installation (i.e., "on post").

(f) Persons who transport RMW over public roads will receive the driver training specified in 49 CFR 177.816 and AR 600-55. A commercial driver's license (CDL) is not required provided the gross weight of the vehicle used is less than 26,001 pounds. All military and civilian drivers of U.S. government-owned vehicles must have a valid State driver's license and a military driver's license (OF 346).

(4) Storage of RMW:

(a) Store RMW, excluding pathological waste, in the RMW storage area. The main holding area for the MTF will be secured, properly identified, and kept clean and free from pests (e.g., insects, rats, and animals). Soiled utility rooms do not need to be secured when RMW is collected there.

(b) Storage of RMW should not exceed 5 days: point of generation 1 day, storage area 3 days, and transport vehicle 1 day. Sharps containers are exempt from these time guidelines. Seal the sharps containers when they are 3/4 full and/or picked up for disposal. Unusual or extenuating circumstances will be taken into consideration to allow brief or minor variances from these times.

(c) Refrigerate pathological waste generated at the hospital in the morgue freezer prior to pick up for disposal. Keep pathological waste generated at the Veterinary Clinic in the clinic freezer prior to pick up for disposal. The usual time for freezer storage of any RMW is approximately 30 days.

(5) Management of RMW spills:

(a) The ICC and Safety Committee will approve policies and procedures that govern the management of RMW spills.

(b) Clean RMW spills immediately with an EPA-registered hospital grade detergent-disinfectant which acts as a mycobacteriacide. Use higher level disinfection when advised by the local or RMC infection control authority. Carefully follow the manufacturer's instruction regarding the dilution of the detergent-disinfectant. Minimum contact time for the disinfectant is 10 minutes.

(c) Aerosolization of RMW is rare. If it should occur, allow the aerosol to settle and isolate the spill until it is safe to begin the cleanup.

(d) PPE for cleanup workers:

1 Wear disposable, waterproof gloves as a minimum.

2 Wear fluid-impervious gowns or other protective clothing when there is danger of soiling the workers' clothes.

3 Wear a mask and protective eyewear when there is danger of splashes or aerosols coming in contact with the workers' face and eyes.

4 Use engineering controls to pick-up and dispose of any broken glass and larger volumes of RMW.

(e) Report spills, when required, by following local procedures.

(6) Treatment/disposal of RMW:

(a) Liquid microbiological waste will be rendered noninfectious by steam sterilization prior to disposal into the sanitary sewer system.

(b) Steam sterilize or incinerate solid microbiological waste prior to disposal in the general waste stream.

(c) Blood and blood products require no treatment prior to disposal in the sanitary sewer system. Blood and blood products in containers may be disposed of without pretreatment either in RMW bags or sharps containers (depending on whether the container is breakable or nonbreakable). They may be treated by steam sterilization or incineration when sanitary sewer disposal is not allowed by local ordinance.

(d) Refrigerate or freeze pathological waste prior to incineration if not picked up immediately for disposal.

(e) Decontaminate wastes with CDC Class 4 etiologic agents (appendix B) by steam sterilization, incineration, or other approved disposal technologies prior to disposal. Consult the ICO for further guidance.

(f) Vaccine waste requires no treatment prior to steam sterilization or incineration.

(g) Sharps containers require no treatment prior to incineration (or other approved disposal technologies) unless required by the State.

10. CONTINGENCY PLANNING.

a. MTFs will write detailed contingency plans for RMW disposal in case the primary means of disposal becomes inoperable. These plans will be revised and updated frequently (yearly at least). Contingency plans will meet all local, State, and Federal regulations.

b. Optional methods of disposal are shown at appendix E.

11. GENERATOR FEES.

a. The MTF will keep records on the rate of generation and the weight of the RMW produced.

b. All MTFs, regardless of the amount of RMW produced, must determine whether or not generator, transporter, disposal fees, and other appropriate fees will be paid according to local and State regulatory requirements. MTFs must coordinate this determination with the local Judge Advocate General's Office.

c. The funding requirements for fees related to permits and for expenses due to the need to comply with environmental regulations should be reflected on the Environmental Program Requirements (EPR) submission. Obtain guidance from the PVNTMED Service.

12. TRAINING REQUIREMENTS.

a. Commanders will ensure that all employees are adequately trained to perform their duties.

b. All employees of the MTF in direct contact with patients, or who segregate, package, store, transport, treat, dispose of RMW, will be provided training in RMW that is pertinent to the employee's primary job. Consult the ICO, Safety Manager, or Collateral-Duty Safety Officer at the MTF for technical assistance in determining pertinent information to be included in the training. The training will include topics related to general awareness, specific functions, and safety. Persons who sign shipping papers will receive specific training [see paragraph 9b(3)(d)]. Drivers will have driver training [see paragraph 9b(3)(f)]. Contractors whose duties involve handling or transporting RMW will have training that includes the topics discussed in this paragraph.

c. Initial training will include an orientation to local RMW work site policies and procedures before the employee begins work. Recurrent training will be conducted at least every 2 years and will include a report of work site policies, procedures, and new technologies.

d. The department/service/activity managers/leaders will maintain written documentation of all training for 3 years. Documentation will include

topic(s), content summary, date, speaker, number of hours, printed name and signatures of attendees.

e. Department/service/activity managers/leaders will monitor and evaluate the training. Training topics will reflect assessment of the needs of the work center. For example, an increase in needle sticks may indicate a need to increase training in use of sharps disposal systems.

f. The instructor for the training classes will be recognized by title and will be qualified to instruct classes based on experience, demonstrated performance excellence, and communication skills.

APPENDIX A

REFERENCES

AR 40-5, Preventive Medicine (under revision).

AR 40-61, Medical Logistics Policies and Procedures (under revision).

AR 190-51, Security of Unclassified Army Property (Sensitive and Nonsensitive).

AR 200-1, Environmental Protection and Enhancement.

AR 385-10, The Army Safety Program.

AR 420-49, Utility Services.

AR 600-55, The Army Driver and Operator Standardization Program (Selection, Training, and Licensing).

MEDCOM Suppl 1 to AR 40-61 (under revision).

TB MED 530, Occupational and Environmental Health Food Service Sanitation, (under revision).

Title 49, Code of Federal Regulations, Transportation, Parts 100-185, latest edition.

DOD 4500.9-R, Defense Transportation Regulation - Part II, Cargo Movement, August 1998.

CDC Guidelines for Handwashing and Hospital Environmental Control, 1985. Source: http://wonder.cdc.gov/wonder/prevguid

CDC Guidelines for Isolation Precautions in Hospitals January 1996. Source: http://wonder.cdc.gov/wonder/prevguid

Biosafety in Microbiological and Biomedical Laboratories, 4th Edition, Centers for Disease Control and Prevention, Atlanta, Georgia, May 99. Source: http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm)

EPA Guide for Infectious Waste Management, U.S. Environmental Protection Agency, May 1986. (EPA530-SW-86-014)

Military Item Disposal Instructions, U.S. Army Center for Health Promotion and Preventive Medicine.

APPENDIX B

CDC Classification of Etiologic Agents on the Basis of Hazard: Class 4 (listing not all inclusive).

Junin
Congo-Crimean hemorrhagic fever
Marburg
Machupo virus
Ebola
Anthrax
Lassa virus
Smallpox (and smallpox-like cases)
Herpesvirus simiae (Monkey B virus)
Tick-borne encephalitis virus complex
- Absettarov virus
- Hanzalova
- Hypr
- Kumlinge virus
- Kyasanur forest disease
- Omsk hemorrhagic fever
- Russian Spring-Summer encephalitis
- Central European encephalitis viruses
- Far Eastern subtypes

Sabia virus

[plus other emerging pathogenic microorganisms when designated by CDC or other Public Health officials]

SOURCE:
Biosafety in Microbiologic and Biomedical Laboratories, Centers for Disease Control and Prevention, Atlanta, Georgia, May 99. Source: http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm)

APPENDIX C

Suggested Examples of Generation Sites.

1. All areas must use a rigid, puncture resistant, sharps container for disposal if they generate sharps [sharps used in animal or human patient care, or treatment in medical, research, or support laboratories (including hypodermic needles, syringes (with or without the attached needle)], Pasteur pipettes, scalpel blades, blood collection tubes and vials, test tubes, needles attached to tubing, and culture dishes (regardless of presence of infectious agents). Other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips, are also included in this category.

2. All administrative areas that have a direct or indirect patient contact and generate nonregulated medical waste. The waste generated is general waste and will be disposed of as such.

a. Headquarters.

b. Patient Administration.

c. Personnel.

d. Logistics.

e. Plans, Training, Mobilization and Security.

f. Nutrition Care.

g. Resource Management.

h. Information Management.

i. Nursing Education and Staff Development.

3. The following areas with direct and indirect patient contact generally generate nonregulated medical waste. The waste generated is general waste and will be disposed of as such. Sharps generated in these areas are always considered RMW.

a. Allergy/Immunization clinics.

b. Social Work Service.

c. General outpatient clinics.

d. Pediatric clinics.

e. Optometry/Ophthalmology clinics.

f. Orthopedic clinic including brace shop.

g. Radiology including ultrasound.

h. Pharmacy service.

i. Occupational Health clinic.

j. Physical Examination.

k. Community Mental Health clinic.

l. Veterinary Service if not engaged in research.

m. Urology clinic.

n. Neurology/Neurosurgical clinic.

o. Ear, Nose and Throat (verify if free flowing/saturated/dripping/caked blood).

p. Central Material section.

q. General patient units.

4. The following areas with direct patient care contact generate regulated medical waste (selected items) and will be disposed of as such. Sharps generated in these areas are always considered RMW.

a. Operating room.

b. Pathology service.

c. Laboratory services.

d. Blood donor centers (only in draw areas).

e. Critical care areas.

f. Recovery room.

g. Dental clinics.

APPENDIX D

Shipping Paper and Emergency Response Information for Hazardous Materials Transported by Government Vehicles (DD Form 836)

1. NOMENCLATURE: TCN NUMBER:
MODEL NO.: SERIAL NO.: BUMPER NO.

SHIPPING PAPER AND EMERGENCY RESPONSE INFORMATION FOR HAZARDOUS MATERIALS TRANSPORTED BY GOVERNMENT VEHICLES

THIS VEHICLE IS TRANSPORTING HAZARDOUS MATERIALS

2a. LOCATION AND DATE PREPARED	b. DATE OF TRAVEL	c. PAGE OF PAGES

TO BE COMPLETED BY THE UNIT OR SHIPPER T.O. OFFICE.

3. CARGO

PACKAGES NUMBER a.	PACKAGES KIND b.	PROPER SHIPPING NAME (Include RQ, Technical Names, Additional information per §172.203 as required.) c.	HC d.	UN OR ID NO. e.	PG f.	NET TOTAL QTY. g.	TOTAL AMMO (NEW) h.
		Regulated Medical Waste	6.2	3291	II		

4. EMERGENCY NOTIFICATION. IN ALL CASES OF ACCIDENT, INCIDENT, BREAKDOWN OR FIRE, PROMPT NOTIFICATION MUST BE GIVEN TO:

a. SHIPPER'S ADDRESS AND TELEPHONE NO. (List 24-hour telephone number(s)):	b. CONSIGNEE

FOR SAFE HAVEN/REFUGE, IMMEDIATELY CALL APPROPRIATE ATLANTIC AREA HOTLINE LISTED BELOW:
EASTERN/WESTERN UNITED STATES: 1-800-524-0331
NEW JERSEY ONLY: 1-800-642-1381

24-HOUR EMERGENCY ASSISTANCE TELEPHONE NUMBERS:		
DOD NON-EXPLOSIVE HAZARD CLASS MATERIALS ONLY: 1-800-851-8061 TO CALL FROM A SHIP: 804-279-3166 (COLLECT)	DOD HAZARD CLASS 1 (EXPLOSIVES) ONLY CALL ARMY OPERATIONS CENTER - COLLECT 703-697-0216/0219 ASK FOR THE WATCH OFFICER	NATIONAL RESPONSE CENTER (NRC) 1-800-424-8802 TO CALL FROM A SHIP: 202-267-2675 (COLLECT) DOD RADIOACTIVE MATERIAL ONLY - COLLECT: 309-782-3510 ASK FOR STAFF DUTY OFFICER

4c. COPY OF EMERGENCY GUIDE NUMBER(S) _____ ATTACHED.

5. REMARKS

6. CERTIFICATION
THIS IS TO CERTIFY THAT THE HEREIN NAMED MATERIALS ARE PROPERLY CLASSIFIED, DESCRIBED, PACKAGED, MARKED, AND LABELED, AND ARE IN PROPER CONDITION FOR TRANSPORTATION ACCORDING TO THE APPLICABLE REGULATIONS OF THE DEPARTMENT OF TRANSPORTATION.

a. SIGNATURE OF SHIPPER CERTIFIER	c. SIGNATURE(S) OF VEHICLE OPERATOR(S)
b. PRINT NAME OF SHIPPER CERTIFIER	

DD FORM 836, SEP 1998 (EG) PREVIOUS EDITION IS OBSOLETE. Designed using Perform Pro, WHS/DIOR, Sep 98

APPENDIX E

Disposal/Treatment Methods**

Source/Type of Medical Waste	Regulated	Treatment/Disposal Method
Microbiologic Cultures/stocks	Yes	Steam sterilization Incineration Thermal inactivation Chemical disinfection (for liquids only) Steam sterilization followed by incineration or grinding (check with state/local regulations if end product should be unrecognizable)
Pathological waste includes surgery and autopsy waste	Yes	Incineration Steam sterilization followed by incineration or grinding (check with state/local regulations if end product should be unrecognizable)
Blood. Blood products caked blood including blood bags and tubing	Yes. Only if free flowing saturated, dripping or caked	Steam Sterilization Incineration Sanitary sewer system for liquids
"Sharps" both used and unused	Yes	Incineration Steam sterilization followed by incineration or grinding (check with state/local regulations if end product should be unrecognizable)
Vaccine	Yes	Incineration Steam sterilization followed by incineration or grinding (check with state/local regulations if end product should be unrecognizable)

Source/Type of Medical Waste	Regulated	Treatment/Disposal Method
Contaminated animal carcasses, body parts, and bedding	Yes	Incineration Steam sterilization followed by incineration or grinding (check with state/local regulations if end product should be unrecognizable)
Communicable Disease Isolation	No, Except for CDC Risk Group IV	Check with ICO for guidance Steam sterilization Incineration
Dialysis Waste	Optional	Steam sterilization
*Treatment/ Examination Room	No	General waste
*General Patient care areas	No	General waste
*Dental Operatory	Yes, only if free flowing item saturated, dripping, or caked with blood	Steam sterilization Incineration Sanitary sewer system for liquids
Intravenous bags and intravenous tubing	Check with state regulation	Steam sterilization Incineration

* Unless the wastes fall into one of the categories above.

**More stringent state codes may require more stringent treatment/disposal methods.

NOTE: When the treatment/disposal methods shown above are not appropriate or feasible for the local situation, CONTRACTING for the transport and disposal of RMW is strongly recommended.

GLOSSARY

ABBREVIATIONS

CDC . . . . . Centers for Disease Control and Prevention

CDL . . . . . Commerical Driver's License

CFR . . . . . Code of Federal Regulations

DA . . . . . Department of the Army

DENTAC . . . . . .Dental Activity

DOD . . . . . Department of Defense

DOT . . . . . Department of Transportation

EPA . . . . . .Environmental Protection Agency

EPR . . . . . Environmental Program Requirements

HW . . . .Hazardous Waste

IAW . . . . . .In Accordance With

ICC . . . . . Infection Control Committee

ICO . . . . . Infection Control Officer

MEDCEN . . . . . U.S. Army Medical Center

MEDCOM . . . . . .U.S. Army Medical Command

MEDDAC . . . . . .Medical Department Activity

MTF . . . . . Medical Treatment Facility

POC . . . . . point of contact

PPE . . . . . personal protective equipment

PVNTMED . . . . . .Preventive Medicine

RMC . . . . . .Regional Medical Command

RMW . . . . . .Regulated Medical Waste

SOP . . . . . Standing Operating Procedure

USACHPPM . . . . U.S. Army Center for Health Promotion and Preventive Medicine

VETCOM. . . . . U.S. Army Veterinary Command

The proponent of this publication is the U.S. Army Center for Health Promotion and Preventive Medicine. Users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) to Commander, U.S. Army Medical Command, ATTN: MCHO-CL-W, 2050 Worth Road, Fort Sam Houston, TX 78234-6000.

FOR THE COMMANDER:

PATRICK D. SCULLEY
Major General
Chief of Staff

OFFICIAL:
CARL E. HENDRICKS
Colonel, MS
Assistant Chief of Staff for
Information Management

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DEPARTMENT OF THE ARMY
HEADQUARTERS, UNITED STATES ARMY MEDICAL COMMAND
2050 Worth Road
Fort Sam Houston, Texas 78234-6000

MEDCOM Regulation No. 40-35 11 June 2001
Change 1

Medical Services
MANAGEMENT OF REGULATED MEDICAL WASTE (RMW)

Supplementation of this regulation and establishment of forms other than MEDCOM forms are prohibited without prior approval from HQ MEDCOM, ATTN: MCHO-CL-W.

MEDCOM Regulation 40-35, 22 November 1999, is changed as follows:

1. HISTORY. This publication was originally printed on 22 November 1999. This printing publishes Change 1.

2. Page 2. Paragraph 6a(3) . Change the word "Class" to read "Category."

Pages 2 and 3. Paragraphs 6b(1) through 6b(6) . Change the word "Class" to read "Category."

Pages 5 and 6. Paragraphs 9b(1)(h) through 9b(1)(n) . Change the word "Class" to read "Category."

Page 7. Paragraph 9b(3)(d) . Change the dates on line 9 "(Sep 98 or later)" to read "(Jan 01 or later)."

Page 9. Paragraph 9b(6)(e) . Change the word "Class" to read "Category."

Page 16. APPENDIX D . Remove old page of DD Form 836 dated Sep 98 and insert new page dated Jan 01.

3. File this change in front of publication for reference purposes.

The proponent of this publication is the U.S. Army Center for Health Promotion and Preventive Medicine. Users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) to Commander, U.S. Army Medical Command, ATTN: MCHO-CL-W, 2050 Worth Road, Fort Sam Houston, TX 78234-6010.

FOR THE COMMANDER:

OFFICIAL:

PATRICK D. SCULLEY
Major General
Chief of Staff

BARCLAY P. BUTLER
Lieutenant Colonel (P), MS
Assistant Chief of Staff for
Information Management

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MCHS-AS (Editor) (2 cy)

HAZMAT//HAZMAT//HAZMAT//HAZMAT//HAZMAT//HAZMAT

1.a. NOMENCLATURE:	c. CONTAINER SEAL NO.:	e. TCN NUMBER:
b. MODEL NO.:	d. SERIAL NO.:	f. BUMPER NO.

DANGEROUS GOODS SHIPPING PAPER/DECLARATION AND EMERGENCY RESPONSE INFORMATION FOR HAZARDOUS MATERIALS TRANSPORTED BY GOVERNMENT VEHICLES/CONTAINERS OR VESSEL

2. SHIPPER/ADDRESS/TELEPHONE NO.	3. LOCATION AND DATE SHIPMENT PREPARED	4. DATE OF TRAVEL	5. PAGE 1 OF ____ PAGES

6. CARGO *(To be completed by the unit or shipper Transportation Office (T.O.))*

PROPER SHIPPING NAME *(Include RQ, Technical Names, Additional Information per 49 CFR172.203, as required.)* a.	HAZARD CLASS/ DIVISION b.	UN/ID NUMBER c.	PACKING GROUP d.	PACKAGES NUMBER e.	PACKAGES KIND f.	NET TOTAL QUANTITY & GROSS WT. *(kg)* g.	TOTAL AMMO (NEW) h.
Regulated Medical Waste	6.2	UN 3291	II				

SAMPLE

(Port personnel complete Items 7 and 8.)

7. PORT OF EMBARKATION *(OCONUS only)*	8a. SHIP NAME *(OCONUS only)*	b. VOYAGE NUMBER

9. CONSIGNEE

10. REMARKS

11a. COPY OF EMERGENCY GUIDE NUMBER(S) _____ ATTACHED *(See back of this form.)*

b. EMERGENCY NOTIFICATION. In all cases of accident, breakdown or fire, prompt notification must be given to shipper as noted in Item 2.

c. 24-HOUR EMERGENCY ASSISTANCE TELEPHONE NUMBERS:

DOD NON-EXPLOSIVE HAZMAT: 1-800-851-8061 AT SEA: 804-279-3131 (COLLECT)	DOD HAZ CLASS 1 (EXPLOSIVES) ONLY: 703-697-0218/0219 (COLLECT) (WATCH OFFICER)	SAFE HAVEN: 1-800-524-0331 NATIONAL RESPONSE CENTER (NRC): 1-800-424-8802 AT SEA: 202-267-2675 (COLLECT)	DOD RADIOACTIVE MATERIALS: ARMY: (703) 697-0218 (COLLECT) USAF: (202) 767-4011 USN/MC: (757) 887-4692/ 1-888/528-0148 DLA: (717) 770-5283

12. CONTAINER PACKING CERTIFICATE OR VEHICLE PACKING DECLARATION

It is hereby declared that the goods described above have been packed/loaded into the container/vehicle identified above in accordance with applicable provisions. *(Must be completed and signed for all container/vehicle loads by person responsible for packing/loading.)*

☐ CONTAINER NO. _____ ☐ VEHICLE NO. _____

a. TYPE OR PRINT NAME	b. SIGNATURE	c. DATE *(YYYYMMDD)*

13. SHIPPER'S CERTIFICATION

This is to certify that the above named materials are properly classified, described, packaged, marked and labeled, and are in proper condition for transportation according to the applicable regulations of the Department of Transportation, international and national governmental regulations.

a. TYPE OR PRINT NAME OF SHIPPER CERTIFIER	c. SIGNATURE(S) OF VEHICLE OPERATOR(S)
b. SIGNATURE OF SHIPPER CERTIFIER	

14. *(X as appropriate)* PREPARED IN ACCORDANCE WITH:	☐	49 CFR	☐	IMDGC

DD FORM 836, JAN 2001 PREVIOUS EDITION IS OBSOLETE.

This form meets the requirements of SOLAS 74 Chapter VII, Regulation 5: MARPOL 73/78 Annex III, Regulation 4 and IMDG Code, General Introduction, Section 9.

HAZMAT//HAZMAT//HAZMAT//HAZMAT//HAZMAT//HAZMAT

[Categorical Listing] [Numerical Listing]

THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

23 Oct 1996

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (MRAI&E

SUBJECT: Hepatitis B Immunization Policy for Department of Defense Medical and Dental Personnel

This memorandum prescribes interim policy for hepatitis B immunization of medical and dental personnel, pending issuance of a revision of Department of Defense Instruction 6205.2, Immunization Requirements, dated October 9, 1986.

All Service members who hold qualification or assignment in medical or dental career fields shall be required to complete a series of three immunizations against hepatitis B, or to show evidence of prior completion of three immunizations.

There is no requirement to screen Service members by testing for hepatitis B surface antigen or antibody in order to implement this policy. Existing hepatitis B serologic information documented in health records may permit exemption from immunization, or may require evaluation of clinical privileging, as described below.

Service members who have any of the three conditions below are exempt from the immunization requirement:

(1) Known positive serum hepatitis B surface antigen. Such personnel who are clinically privileged shall have documentation at each renewal of privileging that their Military Treatment Facility Credentials Committee has evaluated their potential for transmitting hepatitis B during invasive procedures. In delineating privileges, the privileging authority shall fully consider the clinical status of each individual, based on his or her specific situation and scope of practice. It is Department of Defense policy that Credentials Committees shall recommend curtailment of the privileges of providers who are at high risk for transmitting hepatitis B, as shown by positive serum hepatitis B E antigen or positive serum hepatitis B DNA, in such invasive procedures as cardiac surgery. In situations where a question of defining a provider's scope of privileges arises, Credentials Committees shall seek expert assistance from the facility's parent Service Consultant in Preventive Medicine. Limitation of clinical privileges under this policy is medical rather than administrative, and shall not be considered as an adverse action against the individual.

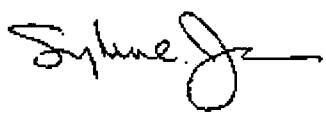
(2) A past history of recovery from hepatitis B, with known positive serum antibody to hepatitis B surface antigen. There is no requirement for Credentials Committee evaluation of this status.

(3) A disease or medical condition that would make hepatitis B immunization inadvisable in the

judgement of the Service member's physician. Such a condition shall be adequately documented in the individual's medical record.

The same requirement, with the same provisions and exemptions, shall apply to all Department of Defense civilian personnel, including trainees, volunteers, and other temporary staff, with duties involving direct patient contact who are hired or begin activity on or after January 1, 1997. Currently employed civilian personnel involved in direct patient contact are strongly encouraged to have hepatitis B immunization. The same requirement, with the same provisions and exemptions, shall be incorporated into contracts for civilian medical personnel who provide care within Department of Defense medical and dental treatment facilities.

This policy is effective immediately. Forward two copies of implementing documents to the Assistant Secretary of Defense (Health Affairs) within 120 days.



Stephen C. Joseph, M.D., M.P.H.

[Top]

Last update: 1/5/1999

Department of Defense

INSTRUCTION

NUMBER 6205.2

October 9, 1986

ASD(FM&P/HA)

SUBJECT: Immunization Requirements

References: (a) DoD Directive 5136.1, "Assistant Secretary of Defense (Health Affairs)," October 5, 1984
(b) DoD Instruction 6205.1, "Immunization Requirements for DoD Dependents Schools, Section 6 Schools, and Day Care Centers Operated by the Department of Defense," May 29, 1985
(c) DoD Directive 6420.1, "Armed Forces Medical Intelligence Center," December 9, 1982
(d) through (k), see enclosure 1

1. PURPOSE

This Instruction addresses immunization policies for all members of the Armed Forces, civilian employees of the Department of Defense, and all eligible beneficiaries of the military health care system as established by reference (a). It requires implementation of programs that minimize individual illness and disability, days lost from work, and impairment of operational capabilities from conditions that are preventable through immunization. Immunization requirements contained in this Instruction complement immunization, preventive medicine, and health promotion requirements listed in references (a) through (j) and implement the Public Health Service plans for attaining the immunization objectives for the nation.

2. APPLICABILITY AND SCOPE

This Instruction:

2.1. Applies to the Office of the Secretary of Defense (OSD), the Military Departments (including their National Guard and Reserve components), the

Organization of the Joint Chiefs of Staff (OJCS), and the Defense Agencies (hereafter referred to collectively as "DoD Components").

2.2. Addresses military-unique peacetime and contingency requirements such as global deployment and defense against potential biological warfare agents.

2.3. Provides protection for all eligible beneficiaries against vaccine preventable diseases.

3. POLICY

It is DoD policy that:

3.1. The general recommendations of the U.S. Public Health Service, as promulgated by the Centers for Disease Control (CDC) Immunization Practices Advisory Committee (ACIP) and published in CDC's Morbidity and Mortality Weekly Report (MMWR) shall be followed.

3.2. For those activities that are unique to the Military, the Military Departments shall develop appropriate immunization procedures in consultation with the Armed Forces Epidemiological Board, Armed Forces Medical Intelligence Center, and Armed Forces Pest Management Board, as required.

3.3. Health care beneficiaries shall be advised of the availability and indications for use of immunizing agents for vaccine preventable diseases. Particular emphasis shall be given to those conditions that affect operational readiness, pose a risk in the community and occupational environment, or are unique to a particular geographic or cultural setting.

3.4. Communicable disease reporting requirements and adverse vaccine reaction reporting requirements of civil authorities shall be complied with through liaison between the military public health jurisdiction and the appropriate local, state, or federal health jurisdiction.

3.5. Persons in specific occupations may need selected vaccines and toxoids in addition to those routinely recommended. Vaccinations shall be provided to all military and civilian employees when it is in the best interest of the Government.

4. RESPONSIBILITIES

4.1. The Assistant Secretary of Defense (Health Affairs) (ASD(HA)) shall:

4.1.1. Monitor and evaluate the implementation and effectiveness of the immunization program, and make appropriate recommendations to the Secretary of Defense and the Secretaries of the Military Departments concerning changes or improvements in the program.

4.1.2. Establish a Disease Prevention and Control Coordinating Committee that shall:

4.1.2.1. Provide a forum for discussion and review of procedures developed concerning the prevention and control of infectious diseases in military and civilian personnel and their dependents worldwide; the epidemiologic aspects of military mustering, training, and deployment activities; and the civilian community and public health implications of unique military activities.

4.1.2.2. Identify military-unique requirements for vaccine research, development, and production in consultation with the Armed Forces Medical Intelligence Center, Armed Forces Epidemiological Board, and the Armed Forces Pest Management Board.

4.1.2.3. Review Service implementation of DoD policies stated herein and recommend changes, as needed, to the ASD(HA).

4.2. The Assistant Secretary of Defense (Force Management and Personnel) shall promulgate policy for the use of immunizations in the prevention and/or amelioration of occupationally related diseases under DoD Instruction 6055.5 (reference (k)). Coordination shall be maintained between the DoD Disease Prevention and Control Coordinating Committee and the DoD Safety and Occupational Health Policy Council.

4.3. The Secretaries of the Military Departments shall:

4.3.1. Develop and implement general principles and specific procedures to be followed in the prophylactic immunization programs of the Armed Forces. Prophylactic immunization includes the use of any vaccine, toxoid, or other immunizing agent for the prevention of disease, including the maintenance of immune status by reimmunization.

4.3.2. Maintain a medical consultation capability to promulgate the requirements and recommendations herein, as applicable.

4.3.3. Consistent with the policies of DoD Directive 5000.19 (reference (h)), establish and implement uniform procedures for:

4.3.3.1. The identification, reporting, and epidemiologic evaluation of vaccine-associated adverse reactions and illnesses.

4.3.3.2. The identification, reporting, epidemiologic evaluation, and prevention of all cases of vaccine preventable illness.

5. EFFECTIVE DATE AND IMPLEMENTATION

This Instruction is effective immediately. Forward two copies of implementing documents to the Assistant Secretary of Defense (Health Affairs) within 120 days.

Chapman B. Cox
Assistant Secretary of Defense
(Force Management & Personnel)

By William Mayer, M.D.
Assistant Secretary of Defense
(Health Affairs)

Enclosures - 1
1. References

E1. ENCLOSURE 1

REFERENCES, continued

(d) DoD Directive 6015.5, "Joint Use of Military Health and Medical Facilities and Services," February 5, 1981
(e) DoD Instruction 6040.33, "Medical Diagnoses and Surgical Operations Nomenclature and Statistical Classification," May 12, 1986
(f) DoD Directive 5154.8, "Armed Forces Epidemiological Board," November 6, 1978
(g) OMB Form No. 68-R1681, "Report of Illness Following Vaccination," 1979
(h) DoD Directive 5000.19, "Policies for the Management and Control of Information Requirements," March 12, 1976
(i) Assistant Secretary of Defense (Health Affairs) Memorandum, "DoD Immunization and Infectious Disease Control Coordinating Committee," March 22, 1985
(j) Assistant Secretary of Defense (Health Affairs) Memorandum, "Protection Against Hepatitis B Virus Infection," April 3, 1985
(k) DoD Instruction 6055.5, "Industrial Hygiene and Occupational Health," April 30, 1980

DEPARTMENT OF THE ARMY
U.S. ARMY HEALTH PROFESSIONAL SUPPORT AGENCY
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF

SGPS-PSP (40)

19 APR 1989

MEMORANDUM FOR ALL U.S. ARMY PREVENTIVE MEDICINE PHYSICIANS

SUBJECT: Mandatory Hepatitis B Immunization Policy

1. Reference TSG letter, 17 April 89, SAB (Enclosure).

2. The enclosed letter from The Surgeon General outlines an extremely important program which we all must support fully. Hepatitis B is preventable and we will protect all Army Medical Department active duty members according to the milestones given by LTG Ledford. Hopefully, our civilian employees also will participate. This program is a major step toward immunizing the total Army. The Army Preventive Medicine community is taking the lead in what will eventually become a national program to significantly reduce, and possibly even eradicate, hepatitis B within the United States.

3. As your consultant, I sincerely ask for your support and resolute commitment to this historic undertaking. We have a tremendous opportunity to make a significant, positive impact on the health of the Army and the health of our Nation. I am certain your efforts will be rewarded by an unmatched sense of professional satisfaction and accomplishment.

4. This program will generate many questions. Please direct these to your regional or major command Preventive Medicine Office. I wish you the very best. Thanks for your continued good work and support of the soldier and the total Army community.

Encl

Joel C. Gaydos, M.D.
JOEL C. GAYDOS, M.D.
Colonel, MC
Chief, Preventive and Military
Medicine Consultants Division

CF:
CDR, I CORPS, ATTN: SURGEON
CDR, V CORPS, ATTN: SURGEON
CDR, III CORPS, ATTN: SURGEON
CDR, XVIII ABN CORPS, ATTN: SURGEON
CHIEF, NATIONAL GUARD BUREAU, ATTN: NGB-DA
ASA (MANPOWER AND RESERVE AFFAIRS)

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO ATTENTION OF

SGPS-PSP (40)

17 APR 1989

MEMORANDUM FOR

COMMANDER, U.S. ARMY HEALTH SERVICES COMMAND, ATTN: HSCL, FORT SAM HOUSTON, TX 78234-6000
COMMANDER, 7TH MEDICAL COMMAND, ATTN: AEMCL-PM, APO NEW YORK 09102-3304
COMMANDER, 18TH MEDICAL COMMAND, ATTN: EAMC-PM, APO SAN FRANCISCO 96301
COMMANDER, U.S. ARMY JAPAN, ATTN: SURG, CAMP ZAMA (SAGAMIHARA), APO SAN FRANCISCO 96343

SUBJECT: Mandatory Hepatitis B Immunization Policy

1. Hepatitis B virus (HBV) causes a vaccine-preventable disease that accounts for approximately 200,000 cases of infection in the United States annually. About 6-10% of cases become chronic carriers, and about 25% of carriers develop chronic active hepatitis. As much as 80% of all cases of primary liver cancer are due to HBV infection. The U.S. Public Health Service estimates that at least 250 health care workers die annually from HBV infection.

2. The Occupational Safety and Health Administration (OSHA) identified HBV vaccination as an issue of concern in OSHA inspections of health care facilities. In a 19 April 1988 memorandum, this office strongly recommended vaccination of all military and civilian health-care workers at occupational risk of acquiring HBV. In response, several Army hospitals began highly commendable and aggressive immunization programs, and have already immunized the majority of their workers at greatest risk. Others have immunized selected personnel, but have been hampered by high-vaccine costs.

3. All active duty members of the Army Medical Department (AMEDD) will be immunized against HBV. It is my goal to have all susceptible active duty AMEDD personnel receive at least two doses of the HBV vaccine by 31 December 1989, and 100% to be fully immunized by 1 July 1990. It is essential that all uniformed AMEDD personnel be immunized because every one of us may be called upon to administer to the injured during peacetime or on the battlefield.

4. Civilian health-care workers at risk will be approached individually and encouraged to be immunized, unless immunization

is specifically mandated in their work agreement or job description. Army reservists serving in Army hospitals will be offered the vaccine also. Volunteer workers will be provided the immunization only if it has been determined that they are at risk of contracting HBV as part of their services.

5. AMEDD personnel who provide evidence of having had HBV infection previously, having serologic evidence of immunity, or having received at least three intramuscular doses of HBV vaccine will be exempted from the program. Personnel who have received HBV vaccine intradermally in the past cannot be assured of long-term protection, and are, therefore, recommended to receive one additional booster dose intramuscularly. As an alternative, these people can be tested for serologic evidence of immunity and should receive an intramuscular booster dose if titers are low (below 10 IU/l). Additional information about this program is in the enclosure.

6. Either plasma-derived or recombinant HBV vaccine produces immunity. However, use of the plasma-derived vaccine is encouraged since the Army is procuring this vaccine at considerable cost reduction. My office will centrally fund plasma-derived HBV vaccine requirements for initiation of the AMEDD program this fiscal year.

7. HBV infection is a serious threat to health-care workers. This expanded mandatory policy is clearly indicated. I greatly appreciate your assistance in reaching the very important goals I have outlined above.

Encl

FRANK F. LEDFORD, JR.
Lieutenant General
The Surgeon General

CF:
CDR, FORCES COMMAND, ATTN: FCMD
CDR, U.S. ARMY TRAINING AND DOCTRINE COMMAND, ATTN: ATMD
COMDT, ACADEMY OF HEALTH SCIENCES, U.S. ARMY
CDR, U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
CDR, U.S. ARMY MEDICAL MATERIEL DEVELOPMENT AGENCY
CDR, U.S. ARMY MEDICAL MATERIEL AGENCY, ATTN: SGMMA
CDR, U.S. ARMY MATERIEL COMMAND, ATTN: AMCSG
CDR, NAVAL MEDICAL COMMAND, ATTN: NMC 241
SURGEON GENERAL, U.S. AIR FORCE, ATTN: SGPA
COMDT, MARINE CORPS, ATTN: MED
CHIEF, COAST GUARD HEALTH SERVICES, ATTN: GKOM

HEPATITIS B (HBV) IMMUNIZATION OF THE ARMY MEDICAL DEPARTMENT

1. Scope of Program. This mandatory program applies to active duty Army personnel. It is estimated that as much as 90% of active duty AMEDD personnel may need HBV immunization. The program is strongly encouraged for civilian health-care workers and reservists serving in Army hospitals.

2. Dates. The AMEDD program will begin on or about 1 June 1989. Target date for completion of all active duty personnel in the AMEDD is 1 July 1990.

3. Dosage Schedule. The immunization schedule for active duty AMEDD personnel will consist of a three-dose 1.0 ml intramuscular (IM) series of either the plasma-derived or recombinant HBV vaccine. However, the plasma-derived vaccine is strongly encouraged and will be centrally procured for this program. Vaccine will be administered at 0, 30, and at least 180 days following initial vaccination. The decision to initiate this mandatory program now and use a 1.0 ml dosage regimen for AMEDD personnel is based on the need to maintain a high level of readiness to respond to crises, the need to provide the best possible long-term protection to health-care workers, and the need to ensure the most optimal antibody response in all individuals, regardless of age.

4. Intradermal Admininstration. The intradermal (ID) HBV immunization program with the plasma-derived vaccine in Korea has been highly successful, but no data are yet available on long-term protection over several years. Therefore, AMEDD personnel who have completed a 3-dose (0.1 ml) ID series should receive an additional 1.0 ml IM dose. Prior screening for HBV antibody is not required, but can be performed if laboratory resources permit. Individuals with titers less than 10 IU/l should receive a 1.0 ml IM booster dose. Individuals need not be vaccinated if they have serological confirmation (presence of HBV antibody) in their medical records as a result of past HBV infection or previous immunization. AMEDD personnel who have recently begun receiving the vaccine ID should be changed to an IM schedule of vaccine administration to ensure the best possible long-term protection. Titers should be drawn at least one month following the third dose.

5. Prior Screening. Prior testing for HBV antibody (or HBV antigen) is not required. However, health-care workers with a past history of HBV are encouraged to be tested for HBV antigen. Should they be identified as being a carrier of HBV virus, they should be medically evaluated and counseled as to risks of transmission and chronicity of infection.

6. New Personnel. Army MTFs should have well defined procedures for records screening and counseling of all AMEDD personnel reporting to supported TOE and TDA units and organizations. This counseling must provide information concerning the occupational risks of blood-borne infections such as HBV and HIV infections. This should be an integral part of the occupational health program for all medical personnel. HBV vaccine will be provided at this time to all appropriate AMEDD personnel who have not begun immunization or have no evidence of antibody to HBV.

7. Program Guidelines. USAMMA will publish logistical guidance, which will include instructions for requisition submission. Activities should immediately compute their requirements in order to comply with a short-notice call for unfunded requisitions. Success of this program depends upon expeditious and accurate submission of unfunded requisitions to USAMMA during rigidly defined submission windows, which will be identified by USAMMA in forthcoming logistical implementation instructions. (Logistics POC: CPT LoSardo at AV 343-7161)

8. Funding. OTSG will centrally fund MTF requirements for plasma-derived HBV vaccine for the AMEDD. OTSG will not centrally fund recombinant vaccine requests. Army medical commands are requested to fund the expendable costs; i.e., syringes, gauzes, and alcohol.

9. Program Inquiries. Questions on the program should be directed to COL Takafuji or MAJ(P) Driggers at AV 289-0125.

UNCLASSIFIED

RCV MSG # 00802 TIME 1934 RADAY 207/89 RET MSG # 09148 ROUTINE

ACTION/Meddac /INFO SGS G1 G2 G3 G4 G5 AG DRM DOL DOIM DOC DPCA DRC
AFLO C-SIG C-CHAP C-CHEM C-AVN PMO SJA RPG CPO IG 1CAV 2AD 3CS 6CAV
3SIG 31ADA 89MP 504MI 3DFG ATB DENTAC MEDDAC TEXCOM MSE CID 546PSC

RTTUZYUW RUEORDB0456 2071929-UUUU--RUCLBFA.
ZNR UUUUU
R 251805Z JUL 89
FM CDRUSAMMA FTDETRICKMD //SGMMA-RMM//
TO AIG 6629
AIG 7485
RUFDAAA/CDR7THMEDCOM HEIDELBERG GE //AEMLO-SL//
RUAGAAA/CDR18THMEDCOM SEOUL KOR //EAMC-H-SS//
RUHHHMA/CDRWESTCOM FT SHAFTER HI //APMD//
RUADJHA/CDRUSARJ CP ZAMA JA //AJMD//
INFO RUWTNFH/CDRUSAHSC FT SAM HOUSTON TX //HSLO//
RUFTFBD/CDRUSAMMCE PIRMASENSGE //AEMMM-IM-DC//
RUAGAAA/CDR6THMEDSOM SEOUL KOR //EAMC-MSO//
RHCGSRB/CDRFORSCOM FTMCPHERSONGA //FCMO//
RUEADWD/DA WASHDC //SGPS-PSP-D//
BT
UNCLAS SGMMA-RMM MSG NO. 2657
SUBJECT: ADDITIONAL LOGISTICAL GUIDANCE FOR MANDATORY HEPATITIS IMMUNIZATION POLICY
A. MSG, SGMMA-RMM, 271805Z APR 89, SUBJ: LOGISTICAL GUIDANCE FOR MANDATORY HEPATITIS B IMMUNIZATION POLICY.
B. MEMO, SGPS-PSP, 17 APRIL 89, SUBJECT: MANDATORY HEPATITIS B

PAGE 02 RUEORDB0456 UNCLAS SGMMA-RMM MSG NO. 2657
IMMUNIZATION POLICY.
1. THIS MSG SUPPLEMENTS INFORMATION PROVIDED IN REF A CONCERNING THE SURGEON GENERAL'S MANDATORY HEPATITIS B IMMUNIZATION PROGRAM. REQUEST DISSEMINATION OF THIS MSG TO ALL PREVENTIVE MEDICINE AND MEDICAL SUPPLY SECTIONS.
2. IAW REF A AND B, USAMMA IS IN RECEIPT OF UNFUNDED REQUISITIONS FROM ARMY ACTIVITIES FOR HEPATITIS B VACCINE. QUANTITIES ARE SIGNIFICANTLY MORE THAN ORIGINALLY FORECASTED. THEREFORE, THESE ADDITIONAL REQUIREMENTS WILL BE SATISFIED WITH A CENTRALIZED PROCUREMENT OF RECOMBINANT HEPATITIS B VACCINE. IN ORDER TO FACILITATE THE DELIVERY OF VACCINE TO MEDICAL FACILITIES, MEDICAL SUPPLY OFFICERS SHOULD READ CAREFULLY THE INFORMATION AND INSTRUCTIONS BELOW:
A. ACTIVITIES WILL INITIALLY RECEIVE APPROXIMATELY 60 PERCENT OF THEIR ORIGINALLY REQUISITIONED QUANTITY OF PLASMA-DERIVED HEPATITIS B VACCINE, NSN 6505-01-139-5000 (HEPTAVAX). VACCINE WILL BE SHIPPED UNDER EACH ACTIVITY'S ORIGINAL REQUISITION. USAMMA WILL PROCESS A PARTIAL CANCELLATION TO EACH ACTIVITY FOR THE UNDELIVERED AMOUNT OF THE VACCINE. ESTIMATED DELIVERY DATE FOR HEPTAVAX IS 31 JULY 89.
B. ACTIVITIES WILL SUBSEQUENTLY RECEIVE RECOMBINANT HEPATITIS B

PAGE 03 RUEORDB0456 UNCLAS SGMMA-RMM MSG NO. 2657
VACCINE (RECOMBOVAX) TO SATISFY THEIR REMAINING VACCINE

UNCLASSIFIED

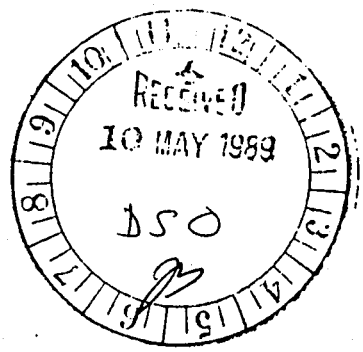
REQUIREMENT. DELIVERY IS CONTINGENT UPON THE CENTRALIZED PROCUREMENT THAT IS CURRENTLY IN PROGRESS FOR THIS VACCINE. ESTIMATED DELIVERY DATE FOR RECOMBOVAX IS EARLY 1QTR FY90. RECOMBOVAX WILL BE CENTRALLY FUNDED AND FREE-ISSUED TO ALL ARMY ACTIVITIES. VACCINE WILL BE PUSH-ISSUED AND SHIPPED FROM VENDOR TO ACTIVITIES UNDER USAMMA DOCUMENT NUMBER. USAMMA WILL PROVIDE CONTRACT NUMBER UNDER SEPARATE MSG TO FACILITATE IDENTIFICATION OF SHIPMENT.

C. IT IS IMPERATIVE THAT ACTIVITIES CONFIRM BACK TO USAMMA RECEIPT OF SHIPMENT AND QUANTITY OF BOTH VACCINES. RECEIPT OF HEPTAVAX SHIPMENTS CAN BE CONFIRMED TELEPHONICALLY WITH SGMMA-RMM. SUBSEQUENT RECOMBOVAX SHIPMENTS MUST BE CONFIRMED BOTH TELEPHONICALLY AND IN WRITING.

3. QUESTIONS SHOULD BE DIRECTED TO CPT LOSARDO OR MS MEADOWS, SGMMA-RMM, AV 343-7161.

BT

#0456 NNNN



HSXI-PMS

8 May 1989

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Hepatitis B Vaccination

1. The Surgeon General has directed that all active duty members of the Army Medical Department be immunized against Hepatitis B virus (HBV). Civilian health-care workers at risk will be approached individually and encouraged to be immunized unless immunization is already mandated in their work agreement or job description. Army Reservists serving in Army hospitals will be offered the vaccine also. Volunteer workers will be provided the immunization if they are at occupational risk of acquiring HBV while providing their service.

2. Those who can provide serologic evidence of immunity or of having three intramuscular doses of HBV will be exempted. Personnel who received intradermal HBV vaccine shall have an IM booster.

3. The OTSG is funding plasma-derived HBV vaccine for the initiation of this AMEDD program this fiscal year. This vaccine is totally safe based on processing techniques. This has been verified by the Centers for Disease Control.

4. Request you supply the total number of AMEDD personnel assigned to you and the number of civilians at risk of acquiring HBV to the C, Preventive Medicine Service by 22 May 1989.

5. An order for administering three 1.0 ml doses for your personnel will be placed. When the shipment is received the below POCs will be contacted for pick-up and appropriate vaccination of AMEDD and appropriate civilians. Vaccine 1.0 ml IM should be given on days 0, 30, and 180.

6. Also, request the name and telephone number for the POC and alternate who will pick up the vaccine from the warehouse for your unit.

JAMES W. SMALL
MAJ, MC
C, Preventive Medicine Service

DISTRIBUTION:

RRAD
DENTAC
6th CAV
1 CD
2 AD

2501 x3 = 7503

DEPARTMENT OF THE ARMY
HEADQUARTERS, UNITED STATES ARMY HEALTH SERVICES COMMAND
FORT SAM HOUSTON, TEXAS 78234-6000

REPLY TO
ATTENTION OF:

HSIO (360-5d)

14 June 1989

MEMORANDUM FOR: Public Affairs Officers, HSC Activities

SUBJECT: Boilerplate News Article On Mandatory HBV Vaccinations

1. The Army Surgeon General has ordered all Army Medical Department active-duty people to be immunized against Hepatitis B virus. Later many other soldiers likely to encounter this virus will also be immunized.

2. The attached article addresses this issue, which concerns not only your own medical personnel but other soldiers at your host installation. Please contact the appropriate official at your MTF for quotations to fill in the blanks in the attached draft. Make sure your source is aware of and concurs in all the information attributed to him, including the indirect quotations on general background information.

3. The article is suitable for use in your own MTF newspaper, if any. It should also be provided to your post PAO for use in the post newspaper and (where suitable) for release to civilian media.

Michael P. Kehoe

MICHAEL P. KEHOE
LTC, Armor
Chief of Public Affairs

U.S. ARMY HEALTH SERVICES COMMAND **News Release**

Office of the Chief, Public Affairs, Headquarters, U.S. Army Health Services Command
Fort Sam Houston, Texas 78234-6000

No. 53
FOR IMMEDIATE RELEASE

CONTACT: Harry Noyes
(512) 221-6213
AV 471-6213

ARMY MANDATES HEPATITIS B VACCINATIONS FOR MEDICS, OTHERS

Vaccination against Hepatitis B virus (HBV), previously offered to Army health-care workers on a voluntary basis, is now mandatory for active-duty Army Medical Department (AMEDD) people.

The new policy -- set by Army Surgeon General Lt. Gen. Frank F. Ledford, Jr., in April -- will initially affect (number of soldiers) at (name of facility and post), according to local medical officials.

"(Insert quotation from local MTF commander or appropriate medical officer about vaccination schedule)," said (individual's grade, name, position). "(Here add additional remarks)."

Eventually many more soldiers are expected to be affected.

The Army's ultimate goal is to immunize all soldiers against HBV, said (last name of individual quoted above). Some non-medical groups, such as soldiers going to Korea, are already being immunized this year.

After AMEDD people are vaccinated, health officials will look at other Army occupations at potential risk for HBV, e.g., military

-- more --

police, corrections workers and graves-registration troops.

"It is my goal to have all susceptible active-duty AMEDD personnel...fully immunized by July 1, 1990," said Ledford. "Every one of us may be called upon to administer to the injured during peacetime or on the battlefield."

Three intramuscular injections are required. Priority will be given to health-care workers. (Individual quoted above) said AMEDD civilian health-care workers in jobs that involve exposure to patients' blood are also encouraged to take the immunizations voluntarily, at no cost to themselves.

Many Army health workers have already been vaccinated, but some medical-treatment facilities (MTFs) were stymied by high vaccine costs. Under the new program, vaccine is centrally procured: MTFs bear only the cost of disposables, such as syringes.

(Insert MTF's name) is scheduled to receive its vaccine supply by July 15, and immunizations will begin soon afterwards.

"We have a very safe and effective HBV vaccine which provides lifelong immunity without boosters," said Col. James Nelson, chief of Preventive Medicine Division at the U.S. Army Health Services Command. "Hepatitis B is a major occupational risk for our health-care workers who are exposed to patient blood."

The U.S. Public Health Service estimates at least 250 health-care workers die each year from HBV infection. Of those infected, some become chronic carriers and many develop liver cancer.

MCHO-CL-W (OASD/5 Nov 96) (40) 2d End COL Oliverson/jf/
DSN 471-6612
SUBJECT: Hepatitis B Immunization Policy for Department of Defense Medical and Dental Personnel

HQ, U.S. Army Medical Command, 2050 Worth Road, Suite 10, Fort Sam Houston, TX 78234-6010 27 MAR 1997

FOR Commanders, MEDCOM RMCs

1. Reference memorandum, HQDA, SGPS-PSP, 17 April 1989, subject: Mandatory Hepatitis B Immunization Policy, with 1st Endorsement.

2. The Hepatitis B immunization policy (attachment) is forwarded for immediate implementation.

3. Federal regulations of the Occupational Safety and Health Administration (OSHA), Department of Labor (29 Code of Federal Regulations 1910.1030, Occupational Exposure to Bloodborne Pathogens) requires all employers who are subject to the regulations to offer Hepatitis B immunization to their employees, but makes it voluntary on the employee's part.

4. Policy directs that Department of Defense civilian personnel, including trainees, volunteers, and other temporary staff, with duties involving direct patient contact, who were hired or began activity on or after 1 January 1997 be covered on a mandatory basis. This condition of employment must be made clear in job announcements, job descriptions, and contracts. The new policy goes beyond the Department of Labor, OSHA regulations, and provides more secure protection.

5. Our points of contact are COL Forrest Oliverson, Directorate of Clinical Operations, Headquarters, U.S. Army Medical Command, DSN 471-6612 or Commercial (210) 221-6612; and MAJ Roberto N. Nang, Directorate of Clinical Preventive Medicine, U.S. Army Center for Health Promotion and Preventive Medicine, DSN 584-2714 or Commercial (410) 671-2714.

FOR THE COMMANDER:

JAMES B. PEAKE
Major General, MC
Deputy Commander

Atch
nc

MCHO-CL-W
SUBJECT: Hepatitis B Immunization Policy for Department of Defense Medical and Dental Personnel

CF (w/atch):
HQDA (DASG-HS-PM), 5109 Leesburg Pike, Falls Church, VA 22041-3258
Commander, U.S. Army Center for Health Promotion and Preventive Medicine, 5158 Blackhawk Road, Aberdeen Proving Ground, MD 21010-5422
Commander, U.S. Army Dental Command, 2050 worth Road, Suite 4, Fort Sam Houston, TX 78234-6004
Commander, U.S. Army Medical Research and Material Command, Fort Detrick, MD 21702-5012
Commander, U.S. Army Medical Department Center and School, 2250 Stanley Road, Fort Sam Houston, TX 78234-6100

DEPARTMENT OF THE ARMY
HEADQUARTERS, UNITED STATES ARMY MEDICAL COMMAND
2050 Worth Road
Fort Sam Houston, TX 78234-6000

MEDCOM Regulation
No. 40-44

6 June 2002

Medical Services

LATEX ALLERGY PREVENTION

Supplementation of this regulation and establishment of forms other than MEDCOM forms are prohibited without prior approval from HQ MEDCOM, ATTN: MCPO-NC.

1. HISTORY. This is the first printing of this publication.

2. PURPOSE. This policy prescribes the policies and procedures for identifying, reducing, and/or eliminating health risks associated with latex exposures in the health care setting. It prescribes the use of U.S. Army Medical Command (MEDCOM) Form 736-R (Occupational Health Surveillance for Latex Sensitivity) at appendix D. The goal of this policy is to protect patients and staffs from unnecessary exposures to latex.

3. REFERENCES.

a. AR 40-3, Medical, Dental, and Veterinary Care.

b. AR 40-5, Preventive Medicine.

c. AR 40-66, Medical Record Administration and Health Care Documentation.

d. AR 385-10, The Army Safety Program.

e. National Institute for Occupational Safety and Health (NIOSH) Alert: Preventing Allergic Reactions to Natural Rubber Latex in the Workplace, Publication No 97-135.

f. Title 29, Code of Federal Regulations, Part 1910 (29 CFR 1910), Occupational Safety and Health Standards.

4. EXPLANATION OF ABBREVIATIONS AND TERMS. Abbreviations and special terms used in this regulation are explained in the glossary.

5. APPLICABILITY. This policy applies to all MEDCOM Major Subordinate Commands, U.S. Army Medical Centers, U.S. Army Medical Department Activities, and Military Treatment Facilities (MTFs), including U.S. Army Dental Command and U.S. Army Veterinary Command activities. This policy covers patients, soldiers, and employees who work in MTFs.

6. BACKGROUND.

a. Latex allergy has increased over the past 10 years, and occurs with relatively high frequency in certain at-risk populations, especially health care workers (HCWs), certain patients, and workers who may be required to use latex products in their day-to-day work environment. Once sensitized, latex-allergic individuals are at risk for potentially life-threatening reactions to latex exposure. Reducing latex exposure to the maximum extent possible minimizes sensitization and development of new latex allergy cases.

b. Latex allergy development has been attributed to a high molecular weight (greater than 30,000 daltons) trypsin-sensitive protein derived from the rubber tree Hevea brasiliensis. This protein may leach out of latex gloves onto skin, mucous membranes, or surrounding powder and thus becomes airborne.

c. Latex products have been widely used during the 20th century and the existence of latex-induced irritant dermatitis has been well documented in the medical literature. In the last decade, a new emergence of latex hypersensitivity has been reported.

d. Between 1988 and 1992, the Food and Drug Administration (FDA) received reports of more than 1,000 systemic allergic reactions to latex, 15 of which were fatal. The prevalence of latex allergy in HCWs ranges from 5 to 10 percent, however, it may be as high as 24 percent in those with an atopic history.

7. RESPONSIBILITIES. Commanders are responsible for the establishment, implementation, and overall supervision of a latex allergy detection and exposure control program.

8. POLICY. Prevention and control measures to prevent latex sensitization and latex allergies will include the following:

a. Identification of where latex is utilized in the MTF.

b. Surgical and examination gloves must be powder free if made of natural rubber latex with low latex protein release attributes (<50 mcg-protein/gram latex). Refer to appendix A for a list of latex-containing products and substitutes. These efforts may prevent latex sensitization.

c. Mandatory education of HCWs and patients regarding the hazards of latex exposure, a requirement for personnel protective equipment and control measures.

d. Ensure all patients, soldiers, and civilian employees who work with latex are screened using MEDCOM Form 736-R to identify high risk individuals who may be latex sensitized or latex allergic, or who are already allergic and taking appropriate precautions. Providers should be aware that many glove reactions are due to the accelerators used in glove manufacture (usually thiourams and carbamates). These reactions usually manifest as a contact dermatitis. They may be treated and controlled with steroid creams, cotton glove inserts, and substitution of gloves. These workers should be evaluated and followed by a dermatologist. They are at higher risk of sensitization to latex proteins and should be closely followed and routinely evaluated for latex sensitization.

e. Refer to appendix B for guidelines on how to prevent latex sensitization and latex allergy. Latex use will be reduced or eliminated by substituting non-latex containing products, pharmaceuticals, and equipment. Use non-latex products whenever practical. Focus on latex safe rather than latex free.

f. Once patients and HCWs are identified as high risk for latex sensitization, every effort will be made to make the immediate work area and patient rooms latex safe avoiding direct latex contact for the patient or affected employee.

g. Commanders should consult Allergy and Immunology, Dermatology, Occupational Medicine, Logistics, and Department of Nursing personnel in designing a latex reduction and control program.

h. Latex allergic soldiers and civilian employees will be managed utilizing the procedures outlined in appendix C.

Appendix A

Latex Alternatives

Disclaimer: This list is NOT comprehensive and is subject to change over time. It is provided as a means to start a latex inventory for your institution. Institutions should validate the accuracy of what is latex safe or free prior to use with patients manifesting hypersensitivity.

FREQUENTLY CONTAIN LATEX	EXAMPLES OF LATEX-SAFE ALTERNATIVES/BARRIERS
Anesthesia,ventilator circuits, bags	Neoprene (Anesthesia Associates, Ohmeda adult) well-washed systems
Band-aids	Active Strips (3M-latex in package), Snippy Band (Quantasia), Readi-Bandages
Bed protectors (washable rubber)	Disposable underpads
Blood pressure cuff, tubing	Cleen Cuff (Vital Signs), Dinamap, Critikon, over clothing or stockinette
Bulb syringe	PVC (Davol)
Casts: Delta-Lite Conformable (J&J)	Scotchcast soft cast, Delta-Lite S, Fiberglass, Fabric (J&J)
Catheters, condom	Silicone (Coloplast, Mentor, Rochester)
Catheters, indwelling	Silicone (Argyle, Bard, Kendall, Rochester, Vitaid)
Catheters, leg bags, drainage systems	Velcro, nylon (Dale, Mentor), Bard systems
Catheters, straight, coude	Bard, Coloplast, Mentor, RobNel (Sherwood)
Catheters, Urodynamics	Bard, Cook, Lifetech, Rusch
Catheters, rectal pressure	Cook, Lifetech
Dressings: Moleskin (J&J), Action Wrap, Coban (3M), BDF Elastoplast	Duoderm (Squibb), reston foam (3M), Opsite. Venigard, Comfeel (Coloplast), Xerofoam (Sherwood), PinCare (Hollister), Bioclusive, Mongomery straps (J&J), Webrill (Kendall). NOTE: Steri-strips, Tegaderm, Tegasorb (3M) have latex in package
Elastic wrap: ACE, Esmarch, Zimmer Dyna-flex, Elastikon (J&J)	Adban Adhesive Compression Bandage (Avcor). Cover skin with cotton barrier
Electrode bulbs, pads, grounding	Baxter, Dantec EMG, Conmed, ValleyLab, Vermont Med
Endotracheal tubes, airways	Berman, Mallinckrodt, Polamedco, Portex, Sheridan, Shiley
Enemas, Reay-use (Fleet-latex valve)	Glycerin, BabyLax (Fleet), Theravac, Bowel Management Tube (MIC)
G-tubes, buttons	Silicone (Bard, MIC, Stomate)

Gloves, sterile, clean, surgical	Vinyl, neoprene, polymer gloves: Allergard (J&J), dermaprene (Ansell), Neolon, SensiCare, Tru-touch (B-D), Nitrex, Tactyl 1.2 (SmartPractice), Duraprene, Tritlex (Baxter)
IV access: injection ports. Y-sites, bags buretrol ports, PRN adapters, Needleless systems	Cover Y-sites and do not puncture: Use stopcocks for meds. Do not puncture bag ports to add meds. Flush all tubing. Abbot nitroglycerin tubing: Walrus, Gemini (IMED), some Baxter systems. Braun burettes: Braun, Clave, Abbott needleless systems
Jobst spandex products	Jobst has a non-latex material available
OR masks, hats, shoe covers	Replace elastic bands with twill tape ties
Oxygen masks, cannulas	Remove elastic bands: check content of valves
Medication vial stoppers	Eli Lilly, Fujisawa: if not certain, remove stopper
Penrose drains	Jackson-Pratt, Zimmer Hemovac
Pulse oximeters	Certain Oxisensor (Nellcor), cover digit with Tegaderm
Reflex hammers	Cover with baggie
Respirators – tb (3M 9970)	Advantage (MSA), HEPA-Tech (uvex)
Resuscitators, manual	Silicone: PMR 2 (Puriton Bennett), SPUR (Ambu) ,Vital Blue, Respironics, Laerdal, Armstrong
Stethoscope tubing	PVC tubing, cover with stockinette or ScopeCoat
Suction tubing	PVC (Davol, Laerdal, Mallinckrodt, Superior, Yankauer)
Syringes, disposable	Draw up medication in syringe right before use: Abboject, PCA (Abbott), Terumo syringe latex-free
Tapes: adhesive, porous, pink, Waterproof (3M)	Dermaclear, Dermicel, Waterproof (J&J), Durapore, Microfoam, Micropore, Transpre (3M)
Tourniquet	Children's Med Ventures, Grafco, VelcroPedic, or over clothes
Theraband, Therastrip, Theratube	Cover with cloth, exercise putty (Rolyan)
Tubing, sheeting	Plastic tubing, Tygon LR-40 (Norton), elastic thread, sheets (JPS), Elastomerics

Appendix B

Guidelines for Preventing Latex Sensitization and Latex Allergy in MTF Staff and Patients

B-1. Provide workers with non-latex gloves when there is little potential for contact with infectious materials (such as food preparation, routine housekeeping and maintenance, etc.)

B-2. Appropriate barrier protection is necessary when handling infectious materials. If latex gloves are chosen, provide powder-free gloves to protect workers from the latex protein particles bound to the powder.

B-3. Good housekeeping practices must be utilized to identify and remove latex containing dust from the workplace.

a. Identify areas contaminated by latex dust for frequent cleaning.

b. Change ventilation filters and vacuum bags frequently in latex contaminated areas.

B-4. Provide workers with education programs and training materials about latex allergy. Training should be documented as required by the Occupational Safety and Health Administration, and the Joint Commission on Accreditation of Healthcare Organizations.

B-5. Screen all HCWs and others working with latex using MEDCOM Form 736-R to identify high risk individuals.

a. When new patients are admitted and when outpatient invasive procedures are performed, patients must be screened.

b. In addition, soldiers and employees will be screened using MEDCOM Form 736-R at in-processing and during periodic health assessments.

B-6. Once high risk individuals are identified, they should receive IGE RAST blood testing. Two commercially available serologic tests for IgE have been approved by the FDA to test for latex sensitization. Healthcare providers should be aware of the fact that up to 15-20% of such tests will be negative in challenge positive hypersensitive individuals. Therefore, a positive test is helpful, a negative is NOT and patients with positive histories should be evaluated by a specialist.

B-7. Periodically screen high-risk workers for latex allergy symptoms. Detecting symptoms early and removing symptomatic workers from latex exposure are essential for preventing long-term health effects.

B-8. Reduce or eliminate latex exposure in the healthcare facility as much as feasible.

B-9. Perform surgical procedures in a latex-free area on all patients with spina bifida, regardless of history, and on all patients with positive history of latex allergy.

Appendix C

Management of Latex Sensitized Patients and Staff

C-1. The clinical management of individuals with latex hypersensitivity requires early identification and reducing or eliminating latex exposures. Interventions should be tailored according to the severity of the symptoms.

C-2. Individuals with irritant dermatitis may be educated regarding the risk of latex allergy and advised to use cotton liners in their gloves and/or eliminate the unnecessary use of gloves. In addition, attempts must be made to identify the irritant and eliminate the risk with good hand care techniques such as thorough and frequent hand washing.

C-3. Individuals who have been identified with allergic dermatitis/delayed hypersensitivity should be referred for skin testing and advised to use powder free or non-latex gloves when possible.

C-4. Individuals who suffer local allergic reactions, such as contact urticaria, should be referred to a dermatologist or allergist for follow-up evaluation and treatment that may include antihistamines and oral or topical corticosteroids. These individuals should work in a latex-free environment when possible.

C-5. The highest risk category includes those who have sustained systemic allergic reactions to latex. These individuals should be evaluated by dermatology or allergy and immunology.

a. In only the most severe cases should affected soldiers be considered for a medical board.

b. Civilian employees should be considered for placement in a latex-free work area or job retraining when no other alternatives are available.

C-6. Patients with a positive history of atopy, multiple allergies, latex glove intolerance, allergies to medical products, i.e., catheters, should receive a RAST blood test for IGE.

C-7. If blood testing confirms the presence of latex allergy, then the operating suite will be made latex safe and the latex allergic patient should be scheduled as the first case in the day and should wear a Medic-Alert bracelet at all times.

C-8. Further, patients scheduled for surgery who are latex allergic must be managed with a latex-free cart.

Appendix D

MEDCOM Form 736-R
(Occupational Health Surveillance for Latex Sensitivity)

MEDICAL RECORD - OCCUPATIONAL HEALTH SURVEILLANCE FOR LATEX SENSITIVITY For use of this form see MEDCOM Reg 40-44			OTSG APPROVED (Date)
DEPARTMENT	OCCUPATION	NUMBER OF YEARS IN OCCUPATION	WORK PHONE

1. Has a doctor ever told you that you have an allergy to any latex products? ☐ Yes ☐ No

If YES, to what specifically did the doctor say you were _____

2. Do you have a history of :
☐ Contact Dermatitis ☐ Rhinitis or Conjuctivitis ☐ Eczema
☐ Spina Bifida ☐ Hay Fever ☐ Asthma
☐ Auto Immune Disease (i.e., thyroid disease, diabetes, lupus)

3. Please check product(s) to which you have a noted reaction:

☐ Surgical Gloves	☐ Enema Cuffs	☐ Rubber Bands/Binders	☐ Ostomy Bags
☐ Catheters	☐ Dental Darns	☐ Anesthetic Mask	☐ Intestinal Tubes
☐ Buretrols	☐ Condoms	☐ Rebreather Bags	☐ Ostomy Tubes
☐ Diaphragm	☐ Elastic Adhesives (bandaids)	☐ Power in Latex Gloves	☐ Other _____
☐ Intubation Tubes	☐ Vial with Latex Tops	☐ Elastic Threads	
☐ Blood Pressure Cuffs	☐ Tubing (Latex Ports)	☐ Ballons	

4. Type of reaction noted:

☐ Sneezing	☐ Itchy Skin	☐ Chapped/Cracking Hands	☐ Stuffy Nose
☐ Low Blood Pressure	☐ Itchy Throat	☐ Shortness of Breath	☐ Runny Nose
☐ Wheezing	☐ Itchy Ears	☐ Lost of Consciousness	☐ Watery Eyes
☐ Tight Chest	☐ Itchy Eyes	☐ Rash	
☐ Other _____			

5. Do you have any food allergies? ☐ Yes ☐ No If YES, are you allergic to any of the following?

☐ Kiwi	☐ Banana	☐ Chestnut	☐ Avocado
☐ Passion Fruit	☐ Tomato	☐ Papaya	☐ Peaches
☐ Potato	☐ Milk	☐ Grape	☐ Other _____

6. Have you had any previous surgery? ☐ Yes ☐ No If YES, how many? _____

What types? _____

7. Have you ever had any allergic or unusual symptoms following a dental, gynecological or rectal ☐ Yes ☐ No

If YES, explain: _____

8. Have you ever had hives, asthma, swelling and tightness in the throat or other unusual reaction to latex products or devices? ☐ Yes ☐ No

If YES, explain: _____

OCCUPATIONAL HEALTH NURSE COMMENTS:

☐ List of products containing latex issued ☐ Educational material reviewed and issued
☐ Aware of available powerless latex gloves and non-latex supplies at CMS

PREPARED BY (Signature and Title)	DEPARTMENT/SERVICE/CLINIC	DATE

PATIENT IDENTIFICATION		
	☐ HISTORY/PHYSICAL	☐ FLOW CHART
	☐ OTHER EXAMINATION OR EVALUATION	☐ OTHER (Specify)
	☐ DIAGNOSTIC STUDIES	_____
	☐ TREATMENT	_____

Glossary

Section I
Abbreviations

FDA.....Food and Drug Administration
HCW.....health care worker
MEDCOM.....U.S. Army Medical Command
MTF.....Military Treatment Facility

Section II
Terms

Anergy
The absence of the capacity to express delayed type hypersensitivity skin test reactivity to common antigens such as tetanus, candida, and mumps. The state of anergy reflects a depressed functional capacity of the cellular immune system.

Employee
DA civilian employees, students, or volunteers who work in health care facilities or perform other tasks where blood and body fluids of patients may be encountered.

High risk populations:

a. HCWs are at greatest risk for latex hypersensitivity because of frequent exposure to latex gloves.

b. Workers in other occupations including firefighters, police, security personnel, rescue workers, correctional workers, emergency response personnel, day care workers, and food handlers are also are at risk.

c. Patients who have multiple surgical, dental, and radiological procedures as well as vaginal and rectal examinations may be at high risk. Patients with neural tube defects such as meningomyelocele and spina bifida or congenital urologic abnormalities requiring multiple catheterizations and/ or surgeries at an early age are at a particularly high risk for sensitization.

d. Subgroups of individuals which merit particular attention are those with:

(1) Atopic disease.

(2) Pre-existing hand eczema.

(3) Prior reactions to latex.

(4) Allergies to certain foods including bananas, avocados, chestnuts, and kiwi fruits.

High hazard procedures
Procedures that involve mucous membrane contact with latex and donning of powdered latex gloves, which produces aerosolized particles of powder covered with latex proteins.

Latex
Refers to natural rubber produced from the coagulating sap of the rubber tree Hevea brasiliensis, the proteins of which produce a number of water-soluble allergens. See appendix A for a list of equipment and supplies that may contain latex.

Latex-free area
Work area where latex free gloves, pharmaceuticals, and equipment are utilized.

Latex routes of exposure
There are five recognized routes of latex exposure: cutaneous, percutaneous, mucosal, parenteral, and inhalation.

a. HCWs are most commonly exposed to latex through direct contact with latex gloves.

b. Patients can be exposed to latex by the direct contact of latex gloves and latex containing medical equipment with the skin and mucosal surfaces.

c. Both patients and HCWs can be exposed to latex proteins bound to glove powder particles aerosolized when donning and removing latex gloves.

Types of latex reactions

a. Irritant contact dermatitis. The most common reaction to protective gloves is irritant contact dermatitis. It usually produces a dry, crusty and irritated contact area on the skin, usually the hands. This non-allergic condition is caused by skin irritation from using gloves, repeated hand-washing, incomplete drying, and possibly by exposure to other workplace products and chemicals. It typically resolves upon removal of exposure and may and may be a risk factor for developing a true latex allergy.

b. Allergic contact dermatitis. A delayed (Type IV) cell mediated hypersensitivity reaction which manifests acutely as an eczematous rash over the affected area during the first 6 to 48 hours following contact. This reaction is similar to poison ivy. This is the most common allergy resulting from exposure to chemicals added to latex during harvesting, processing or manufacturing. Repeated exposure causes extension of the rash into non-contact areas and oozing skin blisters.

c. Immediate (type I) hypersensitivity reactions. Both local and systemic latex allergic reactions are IgE mediated and can occur within minutes, but can also occur hours later. In HCWs sensitized to aeroallergens from powdered latex gloves, as many as 30 percent develop allergic respiratory symptoms. Unfortunately, it is difficult to predict the severity of the reaction from IgE serum levels, skin testing or types of exposure. Some individuals have repeated mild reactions, while others with minor responses may unexpectedly react severely. The degrees of reaction are:

(1) Mild–Urticaria, rhinoconjunctivitis, cough, dyspnea, and hives. Providers should be aware that these patients are at risk for life-threatening hypersensitivity reactions. Cough and dyspnea ARE SYMPTOMS of upper respiratory reactions and may be associated with abnormal spirometry or early laryngeal edema.

(2) More severe–Upper respiratory symptoms such as runny nose, sneezing, itchy eyes, scratchy throat; bronchial asthma, abdominal pain, and nausea.

(3) Severe–May include hypotension, shock and death but is seldom the first sign of latex allergy. In these cases, massive release of histamine and other mediators results from the cross-linking of mast cell and/or basophil surface bound IgE by latex allergens.

The proponent of this publication is the Proponency Office for Preventive Medicine. Users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) to Commander, U.S. Army Medical Command, ATTN: MCPO-NC, 2050 Worth Road, Fort Sam Houston, TX 78234-6010.

JAMES B. PEAKE
Lieutenant General
Commanding

BARCLAY P. BUTLER
Colonel, MS
Assistant Chief of Staff for
Information Management

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DEPARTMENT OF THE ARMY
OFFICE OF THE ASSISTANT SECRETARY
MANPOWER AND RESERVE AFFAIRS
111 ARMY PENTAGON
WASHINGTON DC 20310-0111

REPLY TO
ATTENTION OF

November 5, 1996

MEMORANDUM THRU ~~DIRECTOR OF THE ARMY STAFF~~ KM LINDAHL, MAJ, GS, ARNG 6/11

FOR THE SURGEON GENERAL

SUBJECT: Hepatitis B Immunization Policy for Department of Defense Medical and Dental Personnel

Reference memorandum, Assistant Secretary of Defense (Health Affairs), October 23, 1996, subject as above (attached).

Please ensure this policy is implemented and forward a copy of your implementing instruction through this office to the Office of the Assistant Secretary of Defense (Health Affairs).

Sara Lister

Sara E. Lister
Assistant Secretary of the Army
(Manpower and Reserve Affairs)

Attachment

CF: Dr. Joseph

OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

OCT 2 3 1996

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (MRAI&E)

SUBJECT: Hepatitis B Immunization Policy for Department of Defense Medical and Dental Personnel

This memorandum prescribes interim policy for hepatitis B immunization of medical and dental personnel, pending issuance of a revision of Department of Defense Instruction 6205.2, Immunization Requirements, dated October 9, 1986.

All Service members who hold qualification or assignment in medical or dental career fields shall be required to complete a series of three immunizations against hepatitis B, or to show evidence of prior completion of three immunizations.

There is no requirement to screen Service members by testing for hepatitis B surface antigen or antibody in order to implement this policy. Existing hepatitis B serologic information documented in health records may permit exemption from immunization, or may require evaluation of clinical privileging, as described below.

Service members who have any of the three conditions below are exempt from the immunization requirement:

(1) Known positive serum hepatitis B surface antigen. Such personnel who are clinically privileged shall have documentation at each renewal of privileging that their Military Treatment Facility Credentials Committee has evaluated their potential for transmitting hepatitis B during invasive procedures. In delineating privileges, the privileging authority shall fully consider the clinical status of each individual, based on his or her specific situation and scope of practice. It is Department of Defense policy that Credentials Committees shall recommend curtailment of the privileges of providers who are at high risk for transmitting hepatitis B, as shown by positive serum hepatitis B E antigen or positive serum hepatitis B DNA, in such invasive procedures as cardiac surgery. In situations where a question of defining a provider's scope of privileges arises, Credentials Committees shall seek expert assistance from the facility's parent Service Consultant in Preventive Medicine. Limitation of clinical privileges under this policy is medical rather than administrative, and shall not be considered as an adverse action against the individual.

(2) A past history of recovery from hepatitis B, with known positive serum antibody to hepatitis B surface antigen. There is no requirement for Credentials Committee evaluation of this status.

(3) A disease or medical condition that would make hepatitis B immunization inadvisable in the judgement of the Service member's physician. Such a condition shall be adequately documented in the individual's medical record.

The same requirement, with the same provisions and exemptions, shall apply to all Department of Defense civilian personnel, including trainees, volunteers, and other temporary staff, with duties involving direct patient contact who are hired or begin activity on or after January 1, 1997. Currently employed civilian personnel involved in direct patient contact are strongly encouraged to have hepatitis B immunization. The same requirement, with the same provisions and exemptions, shall be incorporated into contracts for civilian medical personnel who provide care within Department of Defense medical and dental treatment facilities.

This policy is effective immediately. Forward two copies of implementing documents to the Assistant Secretary of Defense (Health Affairs) within 120 days.

Stephen C. Joseph, M.D., M.P.H.

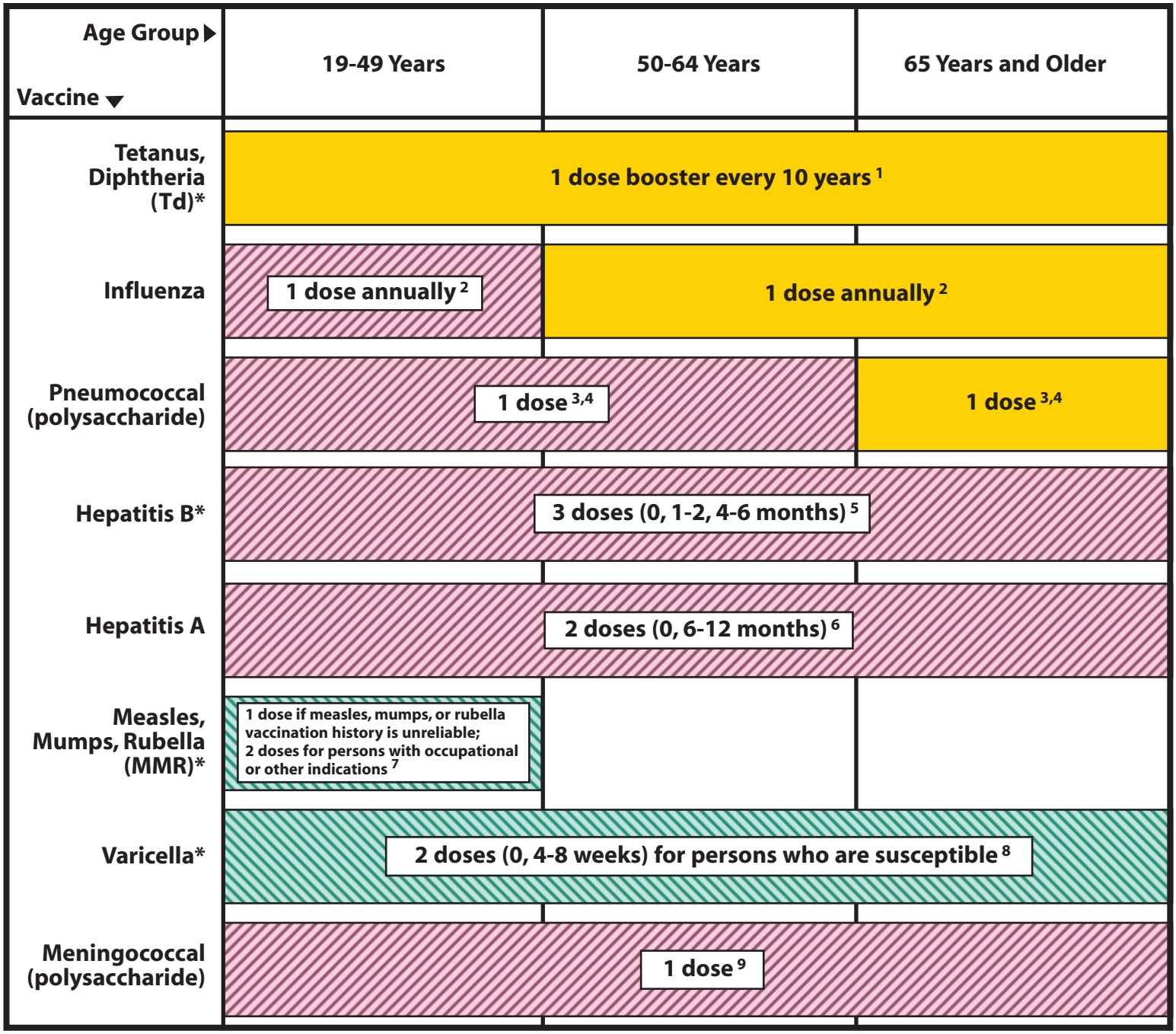
Recommended Adult Immunization Schedule by Age Group and Medical Conditions United States, 2003-2004

Summary of Recommendations Published by

The Advisory Committee on Immunization Practices

Department of Health and Human Services
Centers for Disease Control and Prevention

Recommended Adult Immunization Schedule, United States, 2003-2004
by Age Group



See Footnotes for Recommended Adult Immunization Schedule, by Age Group and Medical Conditions, United States, 2003-2004 on back cover

For all persons in this group

Catch-up on childhood vaccinations

For persons with medical / exposure indications

*Covered by the Vaccine Injury Compensation Program. For information on how to file a claim call 800-338-2382. Please also visit www.hrsa.gov/osp/vicp To file a claim for vaccine injury contact: U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington D.C. 20005, 202-219-9657.

This schedule indicates the recommended age groups for routine administration of currently licensed vaccines for persons 19 years of age and older. Licensed combination vaccines may be used whenever any components of the combination are indicated and the vaccine's other components are not contraindicated. Providers should consult the manufacturers' package inserts for detailed recommendations.

Report all clinically significant post-vaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available by calling 800-822-7967 or from the VAERS website at www.vaers.org.

For additional information about the vaccines listed above and contraindications for immunization, visit the National Immunization Program Website at www.cdc.gov/nip/ or call the National Immunization Hotline at 800-232-2522 (English) or 800-232-0233 (Spanish).

Approved by the Advisory Committee on Immunization Practices (ACIP), and accepted by the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Family Physicians (AAFP)

Recommended Adult Immunization Schedule, United States, 2003-2004

by Medical Conditions

Medical Conditions ▼ / Vaccine ▶	Tetanus-Diphtheria (Td)*,[1]	Influenza [2]	Pneumo-coccal (polysacch-aride) [3,4]	Hepatitis B*,[5]	Hepatitis A[6]	Measles, Mumps, Rubella (MMR)*,[7]	Varicella*,[8]
Pregnancy		A					
Diabetes, heart disease, chronic pulmonary disease, chronic liver disease, including chronic alcoholism		B	C		D		
Congenital Immunodeficiency, leukemia, lymphoma, generalized malignancy, therapy with alkylating agents, antimetabolites, radiation or large amounts of corticosteroids			E				F
Renal failure / end stage renal disease, recipients of hemodialysis or clotting factor concentrates			E	G			
Asplenia including elective splenectomy and terminal complement component deficiencies		H	E, I, J				
HIV infection			E, K			L	

See Special Notes for Medical Conditions below—also see Footnotes for Recommended Adult Immunization Schedule, by Age Group and Medical Conditions, United States, 2003-2004 on back cover

For all persons in this group

Catch-up on childhood vaccinations

For persons with medical / exposure indications

Contraindicated

Special Notes for Medical Conditions

A. For women without chronic diseases/conditions, vaccinate if pregnancy will be at 2nd or 3rd trimester during influenza season. For women with chronic deseases/conditions, vaccinate at any time during the pregnancy.

B. Although chronic liver disease and alcoholism are not indicator conditions for influenza vaccination, give 1 dose annually if the patient is ≥ 50 years, has other indications for influenza vaccine, or if the patient requests vaccination.

C. Asthma is an indicator condition for influenza but not for pneumococcal vaccination.

D. For all persons with chronic liver disease.

E. For persons < 65 years, revaccinate once after 5 years or more have elapsed since initial vaccination.

F. Persons with impaired humoral immunity but intact cellular immunity may be vaccinated. *MMWR* 1999; 48 (RR-06): 1-5.

G. Hemodialysis patients: Use special formulation of vaccine (40 ug/mL) or two 1.0 mL 20 ug doses given at one site. Vaccinate early in the course of renal disease. Assess antibody titers to hep B surface antigen (anti-HBs) levels annually. Administer additional doses if anti-HBs levels decline to <10 milliinternational units (mIU)/ mL.

H. There are no data specifically on risk of severe or complicated influenza infections among persons with asplenia. However, influenza is a risk factor for secondary bacterial infections that may cause severe disease in asplenics.

I. Administer meningococcal vaccine and consider Hib vaccine.

J. Elective splenectomy: vaccinate at least 2 weeks before surgery.

K. Vaccinate as close to diagnosis as possible when CD4 cell counts are highest.

L. Withhold MMR or other measles containing vaccines from HIV-infected persons with evidence of severe immunosuppression. *MMWR* 1998; 47 (RR-8):21-22; *MMWR* 2002; 51 (RR-02): 22-24.

Footnotes for
Recommended Adult Immunization Schedule by Age Group and Medical Conditions, United States, 2003-2004

1. **Tetanus and diphtheria (Td)**—Adults including pregnant women with uncertain histories of a complete primary vaccination series should receive a primary series of Td. A primary series for adults is 3 doses: the first 2 doses given at least 4 weeks apart and the 3rd dose, 6-12 months after the second. Administer 1 dose if the person had received the primary series and the last vaccination was 10 years ago or longer. Consult *MMWR* 1991; 40 (RR-10): 1-21 for administering Td as prophylaxis in wound management. The ACP Task Force on Adult Immunization supports a second option for Td use in adults: a single Td booster at age 50 years for persons who have completed the full pediatric series, including the teenage/young adult booster.
Guide for Adult Immunization. 3rd ed. ACP 1994: 20.

2. **Influenza vaccination**—Medical indications: chronic disorders of the cardiovascular or pulmonary systems including asthma; chronic metabolic diseases including diabetes mellitus, renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus [HIV]), requiring regular medical follow-up or hospitalization during the preceding year; women who will be in the second or third trimester of pregnancy during the influenza season. Occupational indications: health-care workers. Other indications: residents of nursing homes and other long-term care facilities; persons likely to transmit influenza to persons at high-risk (in-home care givers to persons with medical indications, household contacts and out-of-home caregivers of children birth to 23 months of age, or children with asthma or other indicator conditions for influenza vaccination, household members and care givers of elderly and adults with high-risk conditions); and anyone who wishes to be vaccinated. For healthy persons aged 5-49 years without high risk conditions, either the inactivated vaccine or the intranasally administered influenza vaccine (Flumist) may be given.
MMWR 2003; 52 (RR-8): 1-36; *MMWR* 2003;53 (RR-13): 1-8.

3. **Pneumococcal polysaccharide vaccination**—Medical indications: chronic disorders of the pulmonary system (excluding asthma), cardiovascular diseases, diabetes mellitus, chronic liver diseases including liver disease as a result of alcohol abuse (e.g., cirrhosis), chronic renal failure or nephrotic syndrome, functional or anatomic asplenia (e.g., sickle cell disease or splenectomy), immunosuppressive conditions (e.g., congenital immunodeficiency, HIV infection, leukemia, lymphoma, multiple myeloma, Hodgkins disease, generalized malignancy, organ or bone marrow transplantation), chemotherapy with alkylating agents, anti-metabolites, or long-term systemic corticosteroids. Geographic/other indications: Alaskan Natives and certain American Indian populations. Other indications: residents of nursing homes and other long-term care facilities.
MMWR 1997; 46 (RR-8): 1-24.

4. **Revaccination with pneumococcal polysaccharide vaccine**—One time revaccination after 5 years for persons with chronic renal failure or nephrotic syndrome, functional or anatomic asplenia (e.g., sickle cell disease or splenectomy), immunosuppressive conditions (e.g., congenital immunodeficiency, HIV infection, leukemia, lymphoma, multiple myeloma, Hodgkins disease, generalized malignancy, organ or bone marrow transplantation), chemotherapy with alkylating agents, anti-metabolites, or long-term systemic corticosteroids. For persons 65 and older, one-time revaccination if they were vaccinated 5 or more years previously and were aged less than 65 years at the time of primary vaccination. *MMWR* 1997; 46 (RR-8): 1-24.

5. **Hepatitis B vaccination**—Medical indications: hemodialysis patients, patients who receive clotting-factor concentrates. Occupational indications: health-care workers and public-safety workers who have exposure to blood in the workplace, persons in training in schools of medicine, dentistry, nursing, laboratory technology, and other allied health professions. Behavioral indications: injecting drug users, persons with more than one sex partner in the previous 6 months, persons with a recently acquired sexually-transmitted disease (STD), all clients in STD clinics, men who have sex with men. Other indications: household contacts and sex partners of persons with chronic HBV infection, clients and staff of institutions for the developmentally disabled, international travelers who will be in countries with high or intermediate prevalence of chronic HBV infection for more than 6 months, inmates of correctional facilities. *MMWR* 1991; 40 (RR-13): 1-19. (www.cdc.gov/travel/diseases/hbv.htm)

6. **Hepatitis A vaccination**—For the combined HepA-HepB vaccine use 3 doses at 0, 1, 6 months). Medical indications: persons with clotting-factor disorders or chronic liver disease. Behavioral indications: men who have sex with men, users of injecting and noninjecting illegal drugs. Occupational indications: persons working with HAV-infected primates or with HAV in a research laboratory setting. Other indications: persons traveling to or working in countries that have high or intermediate endemicity of hepatitis A. *MMWR* 1999; 48 (RR-12): 1-37. (www.cdc.gov/travel/diseases/hav.htm)

7. **Measles, Mumps, Rubella vaccination (MMR)**—Measles component: Adults born before 1957 may be considered immune to measles. Adults born in or after 1957 should receive at least one dose of MMR unless they have a medical contraindication, documentation of at least one dose or other acceptable evidence of immunity. A second dose of MMR is recommended for adults who:
   - are recently exposed to measles or in an outbreak setting
   - were previously vaccinated with killed measles vaccine
   - were vaccinated with an unknown vaccine between 1963 and 1967
   - are students in post-secondary educational institutions
   - work in health care facilities
   - plan to travel internationally

   Mumps component: 1 dose of MMR should be adequate for protection. Rubella component: Give 1 dose of MMR to women whose rubella vaccination history is unreliable and counsel women to avoid becoming pregnant for 4 weeks after vaccination. For women of child-bearing age, regardless of birth year, routinely determine rubella immunity and counsel women regarding congenital rubella syndrome. Do not vaccinate pregnant women or those planning to become pregnant in the next 4 weeks. If pregnant and susceptible, vaccinate as early in postpartum period as possible.
   MMWR 1998; 47 (RR-8): 1-57; *MMWR* 2001;50: 1117.

8. **Varicella vaccination**—Recommended for all persons who do not have reliable clinical history of varicella infection, or serological evidence of varicella zoster virus (VZV) infection who may be at high risk for exposure or transmission. This includes, health-care workers and family contacts of immunocompromised persons, those who live or work in environments where transmission is likely (e.g., teachers of young children, day care employees, and residents and staff members in institutional settings), persons who live or work in environments where VZV transmission can occur (e.g., college students, inmates and staff members of correctional institutions, and military personnel), adolescents and adults living in households with children, women who are not pregnant but who may become pregnant in the future, international travelers who are not immune to infection. Note: Greater than 95% of U.S. born adults are immune to VZV. Do not vaccinate pregnant women or those planning to become pregnant in the next 4 weeks. If pregnant and susceptible, vaccinate as early in postpartum period as possible.
MMWR 1996; 45 (RR-11): 1-36; *MMWR* 1999; 48 (RR-6): 1-5.

9. **Meningococcal vaccine (quadrivalent polysaccharide for serogroups A, C, Y, and W-135)**—Consider vaccination for persons with medical indications: adults with terminal complement component deficiencies, with anatomic or functional asplenia. Other indications: travelers to countries in which disease is hyperendemic or epidemic ("meningitis belt" of sub-Saharan Africa, Mecca, Saudi Arabia for Hajj). Revaccination at 3-5 years may be indicated for persons at high risk for infection (e.g., persons residing in areas in which disease is epidemic). Counsel college freshmen, especially those who live in dormitories, regarding meningococcal disease and the vaccine so that they can make an educated decision about receiving the vaccination. *MMWR* 2000; 49 (RR-7): 1-20. Note: The AAFP recommends that colleges should take the lead on providing education on meningococcal infection and vaccination and offer it to those who are interested. Physicians need not initiate discussion of the meningococcal quadravalent polysaccharide vaccine as part of routine medical care.

DASG-ZA (OASD/5 Nov 96) (40a) 1st End COL Oliverson/jf/
DSN 471-6612
SUBJECT: Hepatitis B Immunization Policy for Department of Defense Medical and Dental Personnel

HQDA (DASG-ZA), 5109 Leesburg Pike, Falls Church, VA 22041-3258

FOR 26 MAR 1997

Commander, U.S. Army Medical Command, 2050 Worth Road, Suite 10, Fort Sam Houston, TX 78234-6010
Commander, 18th Medical Command, APO AP 96205-0054

1. References:

a. Department of Defense Instruction 6205.2, 9 October 1986, Immunization Requirements.

b. Memorandum, HQDA, SGPS-PSP, 17 April 1989, subject: Mandatory Hepatitis B Immunization Policy.

2. The attached memorandum is forwarded for immediate implementation. This interim policy is effective pending issuance of a revision of reference 1a, above.

3. The 1989 Hepatitis B policy (reference 1b, above) currently being followed directs that the three-dose series be administered to all active duty Army Medical Department personnel or that personnel provide proof of prior immunity. This same policy offers the vaccine to reservists working in military hospitals and to civilian employee health care providers and strongly encourages them to receive the vaccine.

4. Interim policy directs that the same provisions and exemptions outlined for Department of Defense (DOD) medical and dental personnel shall apply to all DOD civilian personnel, including trainees, volunteers, and other temporary staff, with duties involving direct patient contact who are hired or began activity on or after 1 January 1997. This is a change to reference 1b, above.

DASG-ZA
SUBJECT: Hepatitis B Immunization Policy for Department of Defense Medical and Dental Personnel

5. Our point of contact is COL Forrest Oliverson, Headquarters, U.S. Army Medical Command, DSN 471-6612 or Commercial (210) 221-6612.

FOR THE SURGEON GENERAL:

Atch
nc

JOHN J. CUDDY
Major General, DC
Deputy Surgeon General

CF (w/atch):
Assistant Secretary of the Army (Manpower and Reserve Affairs), 111 Army Pentagon, Washington, DC 20310-0111
Assistant Secretary of Defense (Health Affairs), Room 3E346, Washington, DC 20301-1200
Commander, U.S. Army Training and Doctrine Command, Fort Monroe, VA 23651-5000
Commander, U.S. Army Forces Command, Fort McPherson, GA 30330-6000
Commander, U.S. Army Materiel Command, 5001 Eisenhower Avenue, Alexandria, VA 22333-0001

HSCL-P (SGPS-PSP/17 Apr 89) (40) 1st End Mrs. Wickham/tw/
AV 471-3167
SUBJECT: Mandatory Hepatitis B Immunization Policy

HQ, U.S. Army Health Services Command, Fort Sam Houston, TX
78234-6000 26 MAY 1989

FOR Commanders, HSC MEDCEN/MEDDAC

1. The Surgeon General and his staff have provided comprehensive guidance for initiation of a mandatory Hepatitis B Immunization Program for our active duty Army Medical Department (AMEDD) personnel. I ask for your personal involvement to ensure full implementation of the mandate by The Surgeon General to have all susceptible active duty AMEDD personnel receive at least two doses of the Hepatitis B vaccine (HBV) by 31 December 1989, and 100 percent to be fully immunized by 1 July 1990. An implementation date of 1 June 1989 has been suggested; however, it may be more feasible at your location to delay initiation of this program until after the summer permanent change of station moves have taken place.

2. This program to be fully successful requires a concerted effort on the part of all medical treatment facility personnel, particularly the preventive medicine physicians, and immunization clinic personnel. Public Affairs offices should be encouraged to include information on this program in post publications.

3. To ensure maximum participation in a minimum amount of time, consideration should be given to immunizing AMEDD personnel in conjunction with other programs; e.g., the first immunization could be administered in September at the fall Army Physical Fitness Test (APFT) and the second in October at the same time that the influenza immunization is given. These two killed vaccines can be administered simultaneously at different sites on the body. The third immunization can be administered at the spring APFT. Immunizations could also be scheduled during HIV blood screens or HIV education training sessions. Consideration should be given to adding a 10-15 minute segment on Hepatitis B for AMEDD personnel during the HIV education training sessions.

4. The Office of The Surgeon General will centrally fund plasma-derived HBV vaccine initial immunizations. The immunization of civilian health care workers at risk must continue to be encouraged. The vaccine administered to these individuals, however, must be funded locally.

HSCL-P
SUBJECT: Mandatory Hepatitis B Immunization Policy

5. The implementation and progress of your program will be closely monitored. Specifics on reporting requirements will be forwarded under separate cover. In the interim, suggest status reports of your program be included in your monthly Command Health Report.

6. Paragraph 1--Scope of Program on Enclosure should be corrected to read: "This mandatory program applies to active duty AMEDD personnel."

7. Points of contact from the Office of the Deputy Chief of Staff for Clinical Services are COL James H. Nelson, Chief, Preventive Medicine Division, AUTOVON 471-6612/3167 and Mrs. Teresa Wickham, Health Systems Specialist, AUTOVON 471-6337.

John E. Major

JOHN E. MAJOR
Major General, MC
Commanding

Encl
nc

CF:
HQDA (SGPS-PSP), 5109 Leesburg Pike, Falls Church, VA 22041-3258 (wo/encl)

DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF

SGPS-PSP (40)

17 APR 1989

MEMORANDUM FOR

COMMANDER, U.S. ARMY HEALTH SERVICES COMMAND, ATTN: HSCL, FORT SAM HOUSTON, TX 78234-6000
COMMANDER, 7TH MEDICAL COMMAND, ATTN: AEMCL-PM, APO NEW YORK 09102-3304
COMMANDER, 18TH MEDICAL COMMAND, ATTN: EAMC-PM, APO SAN FRANCISCO 96301
COMMANDER, U.S. ARMY JAPAN, ATTN: SURG, CAMP ZAMA (SAGAMIHARA), APO SAN FRANCISCO 96343

SUBJECT: Mandatory Hepatitis B Immunization Policy

1. Hepatitis B virus (HBV) causes a vaccine-preventable disease that accounts for approximately 200,000 cases of infection in the United States annually. About 6-10% of cases become chronic carriers, and about 25% of carriers develop chronic active hepatitis. As much as 80% of all cases of primary liver cancer are due to HBV infection. The U.S. Public Health Service estimates that at least 250 health care workers die annually from HBV infection.

2. The Occupational Safety and Health Administration (OSHA) identified HBV vaccination as an issue of concern in OSHA inspections of health care facilities. In a 19 April 1988 memorandum, this office strongly recommended vaccination of all military and civilian health-care workers at occupational risk of acquiring HBV. In response, several Army hospitals began highly commendable and aggressive immunization programs, and have already immunized the majority of their workers at greatest risk. Others have immunized selected personnel, but have been hampered by high-vaccine costs.

3. All active duty members of the Army Medical Department (AMEDD) will be immunized against HBV. It is my goal to have all susceptible active duty AMEDD personnel receive at least two doses of the HBV vaccine by 31 December 1989, and 100% to be fully immunized by 1 July 1990. It is essential that all uniformed AMEDD personnel be immunized because every one of us may be called upon to administer to the injured during peacetime or on the battlefield.

4. Civilian health-care workers at risk will be approached individually and encouraged to be immunized, unless immunization

is specifically mandated in their work agreement or job description. Army reservists serving in Army hospitals will be offered the vaccine also. Volunteer workers will be provided the immunization only if it has been determined that they are at risk of contracting HBV as part of their services.

5. AMEDD personnel who provide evidence of having had HBV infection previously, having serologic evidence of immunity, or having received at least three intramuscular doses of HBV vaccine will be exempted from the program. Personnel who have received HBV vaccine intradermally in the past cannot be assured of long-term protection, and are, therefore, recommended to receive one additional booster dose intramuscularly. As an alternative, these people can be tested for serologic evidence of immunity and should receive an intramuscular booster dose if titers are low (below 10 IU/l). Additional information about this program is in the enclosure.

6. Either plasma-derived or recombinant HBV vaccine produces immunity. However, use of the plasma-derived vaccine is encouraged since the Army is procuring this vaccine at considerable cost reduction. My office will centrally fund plasma-derived HBV vaccine requirements for initiation of the AMEDD program this fiscal year.

7. HBV infection is a serious threat to health-care workers. This expanded mandatory policy is clearly indicated. I greatly appreciate your assistance in reaching the very important goals I have outlined above.

Encl

FRANK F. LEDFORD, JR.
Lieutenant General
The Surgeon General

CF:
CDR, FORCES COMMAND, ATTN: FCMD
CDR, U.S. ARMY TRAINING AND DOCTRINE COMMAND, ATTN: ATMD
COMDT, ACADEMY OF HEALTH SCIENCES, U.S. ARMY
CDR, U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
CDR, U.S. ARMY MEDICAL MATERIEL DEVELOPMENT AGENCY
CDR, U.S. ARMY MEDICAL MATERIEL AGENCY, ATTN: SGMMA
CDR, U.S. ARMY MATERIEL COMMAND, ATTN: AMCSG
CDR, NAVAL MEDICAL COMMAND, ATTN: NMC 241
SURGEON GENERAL, U.S. AIR FORCE, ATTN: SGPA
COMDT, MARINE CORPS, ATTN: MED
CHIEF, COAST GUARD HEALTH SERVICES, ATTN: GKOM

HEPATITIS B (HBV) IMMUNIZATION OF THE ARMY MEDICAL DEPARTMENT

1. Scope of Program. This mandatory program applies to active duty Army personnel. It is estimated that as much as 90% of active duty AMEDD personnel may need HBV immunization. The program is strongly encouraged for civilian health-care workers and reservists serving in Army hospitals.

2. Dates. The AMEDD program will begin on or about 1 June 1989. Target date for completion of all active duty personnel in the AMEDD is 1 July 1990.

3. Dosage Schedule. The immunization schedule for active duty AMEDD personnel will consist of a three-dose 1.0 ml intramuscular (IM) series of either the plasma-derived or recombinant HBV vaccine. However, the plasma-derived vaccine is strongly encouraged and will be centrally procured for this program. Vaccine will be administered at 0, 30, and at least 180 days following initial vaccination. The decision to initiate this mandatory program now and use a 1.0 ml dosage regimen for AMEDD personnel is based on the need to maintain a high level of readiness to respond to crises, the need to provide the best possible long-term protection to health-care workers, and the need to ensure the most optimal antibody response in all individuals, regardless of age.

4. Intradermal Admininstration. The intradermal (ID) HBV immunization program with the plasma-derived vaccine in Korea has been highly successful, but no data are yet available on long-term protection over several years. Therefore, AMEDD personnel who have completed a 3-dose (0.1 ml) ID series should receive an additional 1.0 ml IM dose. Prior screening for HBV antibody is not required, but can be performed if laboratory resources permit. Individuals with titers less than 10 IU/l should receive a 1.0 ml IM booster dose. Individuals need not be vaccinated if they have serological confirmation (presence of HBV antibody) in their medical records as a result of past HBV infection or previous immunization. AMEDD personnel who have recently begun receiving the vaccine ID should be changed to an IM schedule of vaccine administration to ensure the best possible long-term protection. Titers should be drawn at least one month following the third dose.

5. Prior Screening. Prior testing for HBV antibody (or HBV antigen) is not required. However, health-care workers with a past history of HBV are encouraged to be tested for HBV antigen. Should they be identified as being a carrier of HBV virus, they should be medically evaluated and counseled as to risks of transmission and chronicity of infection.

6. New Personnel. Army MTFs should have well defined procedures for records screening and counseling of all AMEDD personnel reporting to supported TOE and TDA units and organizations. This counseling must provide information concerning the occupational risks of blood-borne infections such as HBV and HIV infections. This should be an integral part of the occupational health program for all medical personnel. HBV vaccine will be provided at this time to all appropriate AMEDD personnel who have not begun immunization or have no evidence of antibody to HBV.

7. Program Guidelines. USAMMA will publish logistical guidance, which will include instructions for requisition submission. Activities should immediately compute their requirements in order to comply with a short-notice call for unfunded requisitions. Success of this program depends upon expeditious and accurate submission of unfunded requisitions to USAMMA during rigidly defined submission windows, which will be identified by USAMMA in forthcoming logistical implementation instructions. (Logistics POC: CPT LoSardo at AV 343-7161)

8. Funding. OTSG will centrally fund MTF requirements for plasma-derived HBV vaccine for the AMEDD. OTSG will not centrally fund recombinant vaccine requests. Army medical commands are requested to fund the expendable costs; i.e., syringes, gauzes, and alcohol.

9. Program Inquiries. Questions on the program should be directed to COL Takafuji or MAJ(P) Driggers at AV 289-0125.

Federal Register

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

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. H370A]

RIN 1218–AB85

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

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

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

SUMMARY: The Occupational Safety and Health Administration is revising the Bloodborne Pathogens standard in conformance with the requirements of the Needlestick Safety and Prevention Act. This Act directs OSHA to revise the Bloodborne Pathogens standard to include new examples in the definition of engineering controls along with two new definitions; to require that Exposure Control Plans reflect how employers implement new developments in control technology; to require employers to solicit input from employees responsible for direct patient care in the identification, evaluation, and selection of engineering and work practice controls; and to require certain employers to establish and maintain a log of percutaneous injuries from contaminated sharps.

DATES: Effective Date: The effective date is April 18, 2001. Written comments: Written comments on the Information Collection Requirements must be submitted on or before March 19, 2001.

ADDRESSES: Copies of materials in the docket may be obtained from the OSHA Docket Office, Room N–2625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, Telephone (202) 693–2350. Referenced documents are included in Docket H370A and are identified by the exhibit number indicated.

Submit written comments on the Information Collection Requirements to the Docket Office, Docket No. ICR–0180 (2001), OSHA, U.S. Department of Labor, Room N–2625, 200 Constitution Avenue, NW., Washington, DC 20210; telephone: (202) 693–2350. Commenters may transmit written comments of 10 pages or less in length by facsimile to (202) 693–1648.

In compliance with 28 U.S.C. 2112(a), the Agency designates the Associate Solicitor for Occupational Safety and Health, Office of the Solicitor, Room S–4004, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, as the recipient of petitions for review of the standard.

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

SUPPLEMENTARY INFORMATION:

I. Events Leading to the Amended Final Rule

Blood and other potentially infectious materials have long been recognized as a potential threat to the health of employees who are exposed to these materials by percutaneous contact (penetration of the skin). Injuries from contaminated needles and other sharps have been associated with an increased risk of disease from more than 20 infectious agents (Exs. 3–172GG, 3–274C). The primary agents of concern in current occupational settings are the human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV).

To reduce the health risk to workers whose duties involve exposure to blood or other potentially infectious materials, OSHA promulgated the Bloodborne Pathogens (BBP) standard (29 CFR 1910.1030) on December 6, 1991 (56 FR 64004). The provisions of the standard were based on the Agency's determination that a combination of engineering and work practice controls, personal protective equipment, training, medical surveillance, hepatitis B vaccination, signs and labels, and other requirements would minimize the risk of disease transmission.

Needlesticks and other percutaneous injuries resulting in exposure to blood or other potentially infectious materials continue to be of concern due to the high frequency of their occurrence and the severity of the health effects associated with exposure. The Centers for Disease Control and Prevention has estimated that healthcare workers in hospital settings sustain 384,325 percutaneous injuries involving contaminated sharps annually (Ex. 5–4). When non-hospital healthcare workers are included, the best estimate of the number of percutaneous injuries involving contaminated sharps is 590,164 per year (Ex. 3–172V). When these injuries involve exposure to infectious agents, the affected workers are at risk of contracting disease. Workers may also suffer from adverse side effects of drugs used for post-exposure prophylaxis and from psychological stress due to the threat of infection following an exposure incident.

Since publication of the BBP standard, a wide variety of medical devices have been developed to reduce the risk of needlesticks and other sharps injuries. These ''safer medical devices'' replace sharps with non-needle devices or incorporate safety features designed to reduce the likelihood of injury. In a September 9, 1998, Request for Information (RFI), OSHA solicited information on occupational exposure to bloodborne pathogens due to percutaneous injury (63 FR 48250). Based in part on the responses to the RFI, the Agency has pursued an approach to minimize the risk of occupational exposure to bloodborne pathogens that involves three components. First, the Agency proposed that the revised Recordkeeping standard (29 CFR 1904) include a requirement that all percutaneous injuries from contaminated needles and other sharps be recorded on OSHA logs (61 FR 4030). Second, OSHA issued a revised compliance directive for the BBP standard on November 5, 1999, to reflect advances made in medical technology and treatment. The directive guides OSHA's compliance officers in enforcing the standard and ensures that consistent inspection procedures are followed. Third, the Agency placed amendment of the bloodborne pathogens standard on its regulatory agenda to more effectively address sharps injuries.

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

II. Statutory Authority

On November 6, 2000, President Clinton signed the Needlestick Safety and Prevention Act, Pub. L. 106–430. The Act requires OSHA to revise the BBP standard within six months of the Act's enactment. To facilitate expeditious completion of this directive, Congress explicitly exempted OSHA from procedural requirements generally attending rulemaking under OSH Act 6(b) and from the procedural requirements of the Administrative Procedure Act (5 U.S.C. 500 *et seq.*).

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

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.,*

the procedure being performed, the body part affected, objects or substances involved and how they were involved) so that the intended evaluation of risk and device effectiveness can be accomplished.

Information in the sharps injury log must be recorded and maintained in a manner that protects the privacy of the injured employee. If data from the log are made available to other parties, any information that directly identifies an employee (e.g., name, address, social security number, payroll number) or information that could reasonably be used to identify indirectly a specific employee (*e.g.,* exact age, date of initial employment) must be withheld.

The format of the sharps injury log is not specified. The employer is permitted to determine the format in which the log is maintained (*e.g.,* paper or electronic), and may include information in addition to that required by the standard, so long as the privacy of injured workers is protected. The Agency recognizes that many employers already compile reports of percutaneous exposure incidents in a variety of ways. Existing mechanisms for collecting these reports will be considered sufficient to meet the requirements of the standard for maintaining a sharps injury log, provided that the information gathered meets the minimum requirements specified in the standard, and the confidentiality of the injured employee is protected.

Under newly published revisions to OSHA's Recordkeeping rule (29 CFR 1904), employers are required to record sharps injuries involving contaminated objects on the OSHA 300 Log of Work-Related Injuries and Illnesses and the OSHA 301 Injury and Illness Incident Report (the new forms replace the current 200 and 101 forms). When the revisions become effective, employers may elect to use the OSHA 300 and 301 forms to meet the sharps injury log requirements, provided two conditions are met. First, the employer must enter the type and brand of the device on either the 300 or 301 form. Second, the employer must maintain the records in a way that segregates sharps injuries from other types of work-related injuries and illnesses, or allows sharps injuries to be easily separated. For example, if OSHA 300 and 301 records are maintained on a computer, the employer must ensure that the computer is able to produce a record of sharps injuries that does not include other types of work-related injuries and illnesses (*i.e.,* through using a program that allows for sorting of entries by injury type). If records are kept on paper forms, the employer would need to use a separate page of the 300 Log for sharps injuries.

The revisions to the Recordkeeping rule will not become effective until January 1, 2002, at the earliest, and until then many sharps injuries involving contaminated objects will not be recordable on the OSHA log. Therefore, employers must keep a separate sharps log from the effective date of this rule until the revised Recordkeeping rule becomes effective.

These revisions to the BBP standard become effective April 18, 2001. Exposure Control Plans that are reviewed and updated on or after this effective date must reflect the requirements of the revised standard. Percutaneous exposure incidents that occur on or after this effective date must be recorded on the sharps injury log.

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

IV. Economic Analysis

Incremental Costs of the Mandated Revisions to the Standard

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

Cost of Establishing and Maintaining a Sharps Injury Log

The rule requires employers to maintain a log for all needlestick and sharps injuries. At a minimum, the sharps injury log must contain: ''(A) The type and brand of device involved in the incident, (B) the department or work area where the exposure incident occurred, and (C) an explanation of how the incident occurred.'' The costs attributable to the log correspond directly to the number of needlestick and sharps injuries. The International Health Care Worker Safety Center (IHCWSC) provides the best available estimate of the number of needlestick injuries (Ex. 3–172V). IHCWSC has computed that 590,164 needlestick and sharps injuries occur annually.

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

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

In summary, OSHA estimates that the total annual cost of maintaining a sharps injury log will be $1,294,352. This estimate is likely to overstate true costs for at least three reasons. First, for already recordable incidents, the data needed to maintain a separate sharps injury log are already collected and entered into a log format for other purposes, namely for the requirements set forth by 29 CFR Part 1904. It is unlikely that the data will need to be ''re-entered.'' Instead, businesses are likely to develop procedures for automating the process or for organizing log information, thereby significantly reducing the incremental costs associated with this incremental action. For nonrecordable cases, the data collection required by the Needlestick Safety and Prevention Act and this revision to the BBP standard will be required under 29 CFR Part 1904 (once revisions to Part 1904 become effective), so that the incremental costs associated with the separate sharps injury log are short-term in nature. Finally, and perhaps most importantly, the above cost estimate significantly overstates costs because it includes costs for all establishments in SIC 80. Under revisions to 29 CFR Part 1904, SICs 801, 802, 803, 804, 807, and 809 are exempted from recordkeeping requirements under Part 1904 and will thus not be required by this amendment to the BBP standard to keep a needlestick and sharps injury log. This is potentially significant because SICs 801, 802, 803, 804, 807, and 809 constitute 31 percent of employment for SIC 80, though not necessarily 31 percent of sharps injuries.

Cost of Solicitation of Employee Input

The cost associated with solicitation of employee input is comprised of three components: (1) The initial solicitation, conducted by a manager; (2) the employee response; and (3) documentation of the solicitation in the Exposure Control Plan.

The cost of the initial solicitation is likely to vary with establishment size, number of incidents, and employee interest. The establishments that will be affected are those that are: (1) Required to develop an Exposure Control Plan, and (2) have employees who are involved in direct patient care and who are potentially exposed to needlestick injuries. The overwhelming majority of such establishments are in SIC 80, Health Services. County Business Patterns reports that in 1997 (1997 data are used as the most recent year for which data are available using the SIC reporting system), there were 502,724 establishments in SIC 80. OSHA estimates that the initial solicitation or call for employee input will require an average of 15 minutes (0.25 hours) of managerial time. The wage rate of a Medicine and Health Care Manager is $33.22 per hour, including fringe benefits. (The hourly wage for a Medicine and Health Care Manager reported in the Bureau of Labor Statistics Occupational Employment Statistics Survey is $24.02; benefits are computed at 38.3 percent of the hourly wage.) The estimated cost of the initial solicitation is:

(502,724 establishments) × (0.25 hours/establishment) × ($33.22/hour) = $4,175,080.

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

(11,348,141 employees) × (33% response rate) × (0.25 hours/employee) × ($25.90/hour) = $24,248,140.

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

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

(502,724 establishments) × (0.25 hours/establishment) × ($33.22/hour) = $4,175,080.

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

Total Cost and Cost Per Establishment

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

V. Unfunded Mandates

OSHA has determined that, for the purposes of section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532), this rule does not include any

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

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.

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.

* * * * *

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