EXPOSURE CONTROL PLAN

FOR

OCCUPATIONAL EXPOSURE TO BLOODBORNE PATHOGENS (BBP)

FOR THE

U.S. ENVIRONMENTAL PROTECTION AGENCY

NATIONAL ENFORCEMENT INVESTIGATIONS CENTER (NEIC)

PREPARED BY

U.S. PUBLIC HEALTH SERVICE

DIVISION OF FEDERAL EMPLOYEE OCCUPATIONAL HEALTH

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EXPOSURE CONTROL PLAN
FOR
NEIC OCCUPATIONAL EXPOSURE TO BLOODBORNE PATHOGENS

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SECTION I:
INTRODUCTION

This Exposure Control Plan for Occupational Bloodborne Pathogen (BBP) Exposure has been developed for the U.S. Environmental Protection Agency, National Enforcement Investigations Center (NEIC), by the U.S. Public Health Service (PHS), Division of Federal Occupational Health (FOH). The document has been developed in accordance with the CDC guidelines and the OSHA Bloodborne Pathogens Standard (1910.1030) to protect all NEIC employees from occupational exposure to blood or other potentially infectious materials. A copy of the Standard is included in Appendix A.

The document is presented in seven main sections:

I. Introduction

II. Exposure Determination

This section presents a method for determining bloodborne pathogen exposure risks for NEIC employees. A list of NEIC job classifications has been compiled in which employees may be potentially exposed to bloodborne pathogens. In some instances, specific tasks and procedures have also been identified in which occupational exposure may reasonably be expected to occur. In addition, there may be other potential occupational exposure settings not covered by these lists.

III. Methods of Compliance

This section discusses work practice controls which shall be used to minimize or eliminate employee exposure. Included in this section is the use, accessibility, cleaning, repair and replacement, and disposal of personal protective equipment (PPE).

IV. Handling Exposure Incidents

This section discusses NEIC procedures once an exposure occurs. Exposure incident means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials.

V. Training

This section discusses the required information needed for training.

SECTION II:
EXPOSURE DETERMINATION

Contents of this section:

A. NEED FOR IDENTIFYING INCREASED RISK GROUPS

This section presents a mechanism to determine which NEIC employees may be at increased risk for occupational exposure to bloodborne pathogens (BBP), as required by the OSHA Bloodborne Pathogens Standard. Such employees at increased risk need to be included in special programs designated by the Standard including special training, issuance of personal protective gear (i.e., gloves and airway masks for CPR) and the availability of immunization for Hepatitis B and gamma globulin for treatment after exposure.

Employees determined to not be at increased risk for exposure are not covered by the Standard. However, the PHS recommends that all employees receive limited information about certain aspects of the Standard, whether or not they are considered in the increased risk group. Such information should include availability of protective equipment at first aid stations and post-exposure treatment/monitoring procedures if a BBP exposure occurs.

B. DEFINITIONS

1. 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. The determination of potential exposure is made without regard to whether the employee uses personal protective equipment such as gloves.

2. Other potentially infectious materials means human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, 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.

C. WORK ACTIVITIES WITH INCREASED RISK

It is reasonable to assume that some NEIC workers will be at increased (i.e., moderate or high) risk for these exposures based on the nature of their jobs. There appear to be four general types of job tasks or exposure settings where NEIC employees MIGHT be at SOME risk for exposure to bloodborne pathogens. NEIC employees who should be considered at increased risk for such BBP exposures are identified below in each of the four categories.

1. First Aid Providers

a. First aid providers for co-workers (an increased risk group):

Some employees may be part of work groups which are at times remote from emergency medical services and/or may do tasks which pose a significantly increased risk for injury. In such work groups or settings these employees would be formally designated to serve as "first responders" in performing first aid on injured co-workers. In these instances, first aid training and the providing of such first aid to injured co-workers are a required or expected part of job duties. For the purposes of the Standard, such an expectation might be felt to exist unless it is explicitly and formally excluded in the written part of the job description or as an explicit policy clarification is issued to all employees. These employees would be in the increased risk group.

b. Voluntary or "Good Samaritan" first aid providers (a low risk group):

A distinction should be made between: (1) employees described in parts 2.a. above, who are required or expected to provide first aid as a part of their jobs and are in the increased risk group, versus (2) employees who receive first aid training primarily for their own benefit and are not designated or expected to perform first aid as part of their job, who are at low risk. Such employees may at times perform first aid on a voluntary basis as "Good Samaritans." Since they are not required to do this as part of their jobs, they would not be considered in the increased occupational risk group. However, if these employees should become exposed at work because of voluntary or "Good Samaritan" actions, they would still be covered by parts of the Standard dealing with exposure treatment and post-exposure monitoring. In addition, first aid training for all groups should cover the issue of BBP exposure and preventive measures.

2. Workers Engaged in Field Activities

Employees engaged in field activities (e.g., hazardous waste disposal sites or sanitary landfills) might have occasional exposure to potentially infectious materials. This would be particularly true with sites at which employees directly handle biohazard wastes or wastes from health care facilities. General landfills and illegal garbage dumps might also contain potentially infected materials. In general, since the contents of hazardous waste sites and landfills are usually not known with certainty, the most prudent policy may be to consider all employees who may work at such sites and who directly handle materials to be included in the increased risk group.

Alternately, workers assigned only to overview or supervisory tasks at these sites, who have no direct contact with waste material, would be at low risk. In addition, well-characterized and regulated hazardous waste land fills which only contain known chemical wastes are probably also low risk settings for BBP exposures.

Employees who may work at waste water treatment facilities or with waste water effluent are probably at low risk unless they directly handle raw sewage. (See Appendix I).

3. Laboratory Exposures

Employees in laboratory settings should be considered at increased risk for BBP exposures if they handle any human specimens (i.e., blood or other body fluids or tissues). Because of the possibility of glass sample container breakage, laboratory workers may also be at increased risk if they handle other materials which are potentially contaminated by BBP (e.g., solid samples of unknown materials from hazardous waste sites or any samples from crime labs, etc.)

4. Other Exposure Settings

There may other circumstances not noted above when a NEIC employee might be at increased risk for exposure to bloodborne pathogens. These may need to be determined on a case-by-case basis. Therefore some general educational information or brief training on the risks of bloodborne pathogens will probably need to be given to all NEIC employees.

D. ESTIMATING EXPOSURE RISKS FOR SPECIFIC JOBS/TASKS

After assessment of all NEIC activities, job titles, and potential for exposure, PHS has determined that only

employees engaged in field activities in the Criminal Enforcement Branch with the following titles constitute an increased risk group:

Supervisory Environmental Scientist,
Environmental Protection Specialist,
Environmental Investigation Specialist,
Environmental Scientist,
Environmental Engineer, and
Physical Science Technician.

However, supervisors and employees should review all job duties and tasks to assess whether any of the previously identified increased risk activities are part of the employee's job description. Those employees not included in the increased risk group above, but who feel they are at increased risk for occupational exposure to BBP, should be encouraged to discuss this with their supervisor or safety officer. In addition, managers and safety officers should be asked to identify increased risk worker groups or individuals not included in the categories above. These situations should be discussed with the appropriate public health personnel and individual decisions should be made on whether such employees should be considered in the increased risk group.

SECTION III:
METHODS OF COMPLIANCE

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 be used.

A. DEFINITIONS

1. Bloodborne Pathogens

Bloodborne pathogens are defined as pathogenic microorganisms present in human blood which can cause disease in humans. These bloodborne pathogens include, but are not limited to, Hepatitis B virus (HBV) and human immunodeficiency virus (HIV or AIDS virus).

2. Other Potentially Infectious Materials

Other potentially infectious materials are defined as the other types of body fluids and tissues besides blood which are potentially capable of causing disease. The OSHA Standard specifically defines other potentially infectious materials to include: semen, vaginal secretions, fluids from internal body spaces (such as spinal fluid or joint fluid), any body fluid visibly contaminated with blood, and all body fluids where it is difficult or impossible to differentiate between body fluids. Also included are any human tissues other than intact skin (unless the tissue has been fixed by histology procedures) and tissue culture and potentially infected experimental animals used in medical research.

The Standard does not specifically include tears, vomit, urine, or feces on this list unless visibly contaminated with blood. However, from a practical point of view, tears, vomit, urine, and feces should be regarded by employees as if they were potentially infectious, and the same precautions should be used as when dealing with blood and the other potentially infectious material specifically mentioned in the Standard. In disposing of tears, vomit, urine, and feces, these need not be treated as hazardous materials (see below) as long as they are not visibly contaminated with blood. It should be mentioned here that a number of serious human diseases can be transmitted by urine, feces, etc., even in the absence of blood. While such transmissions are not covered by the Standard unless contaminated with blood, they should still be regarded as potentially dangerous.

3. Engineering Controls

Engineering controls means control measures that isolate or remove the bloodborne pathogens from the workplace. These might include such things as special containers for disposal of contaminated needles or self-sheathing needles, or automated handling of contaminated materials.

4. Exposure Incident

Exposure incident is defined as a specific contact of blood or other potentially infectious materials with a person's eye, mouth, other mucous membrane, non-intact skin, or by parenteral contact (i.e., by a puncture wound or cut with a contaminated object such as a hypodermic needle).

5. Personal Protective Equipment

Personal protective equipment includes items an individual employee may use to prevent contamination by potentially infectious material. In the case of bloodborne pathogens, such personal protective equipment might include gloves, eye protection or face shields, masks covering the mouth, and protective clothing. (See specific information below.)

6. Sharps

Sharps are defined as all sharp items which may become contaminated with potentially infectious materials (this is primarily relevant to health care or lab settings). Sharps include all hypodermic needles, scalpel blades, glass lab pipettes or other sharp instruments considered as potentially infective and must be handled with extreme care to prevent accidental injuries.

7. Universal Precautions

Universal precautions are defined as the standard precautions all persons should use to prevent contact with blood or other potentially infectious materials whenever these situations occur or are anticipated. These may involve standard work practices and the use of personal protective equipment such as gloves, protective clothing, eye protection, and/or masks. (See more information in Section III.B.1., below).

B. APPROVED GENERAL WORK PRACTICES

1. UNIVERSAL PRECAUTIONS

Universal precautions should be used by all employees whenever the potential for exposure to bloodborne pathogens exists. Employees should adhere rigorously to the infection control precautions noted in this section in order to minimize the risk of exposure to blood and other body fluids. All body fluids shall be considered potentially infectious materials. All protective equipment needed to protect workers will be supplied, cleaned, disposed of, repaired, or replaced by NEIC.

Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in areas where there is a reasonable likelihood of occupational exposure to bloodborne pathogens.

Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets, or on counters where blood or other potentially infectious materials are present.

2. USE OF GLOVES

Gloves are to be worn when it can be reasonably anticipated that an employee's hands may be in contact with blood or other potentially infectious materials, including touching contaminated items or surfaces. Gloves should be located at appropriate sites for easy access. Hands shall be washed thoroughly and immediately after possible contact with blood and/or body fluids as well as before putting on and after taking off of the gloves.

Gloves must be of appropriate material, latex, vinyl, or rubber and of appropriate size for each worker. In a health care setting when doing procedures where gloves are needed, the gloves should be changed each time a new patient is being dealt with. Anytime the gloves are contaminated with blood and/or other body fluids, the gloves must be changed and disposed of as noted below. For field settings, thick non-disposable gloves of the materials identified above are acceptable so long as their surface is not cracked or abraded and the gloves are sterilized after each potential exposure. (See Section III.B.4. below on cleaning contaminated materials.)

3. USE OF RESPIRATORS, EYE PROTECTION, AND FACE SHIELDS

Respirators or eye protection and 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.

4. Use of Body Clothing

Coveralls, lab coats, aprons, and other protective body clothing shall be worn in occupational exposure situations. If contaminated, these clothing should be discarded (if disposable) or placed in a special receptacle to be cleaned (see Section III.B.7. below on handling contaminated linen). Plastic and rubberized aprons or gloves should be cleaned first by rinsing with soap and water, and then disinfected using a bleach solution (as noted below) or similar disinfectant recommended by the manufacturer.

5. Handling and Disposal of Sharps

a. All used or potentially contaminated sharps should be disposed of in puncture-resistant Approved Sharps Containers located as close as practical to the area of use. Needles or glass pipettes are not to be recapped, purposefully bent, broken, removed from disposable syringes, or otherwise manipulated by hand. The sharps containers shall be located in all areas where needles and sharps are commonly used. (See Appendix H for approved and suggested sharp containers).

b. When an Approved Sharps Container is full, it should be labelled as BIOHAZARD, sealed, disinfected using the bleach solution described below by pouring the solution into the container, label as BIOHAZARD, and sealed. The container should then be allowed to sit for 24 hours before being disposed of.

6. Use of Resuscitation (CPR) Equipment

Pocket masks and resuscitation bags will be provided in all First Aid Kit or emergency boxes intended for resuscitation. Resuscitation bags or pocket masks shall be used for all resuscitation where emergency mouth-to-mouth resuscitation is indicated.

Pocket cardiopulmonary resuscitation (CPR) masks and gloves should also be available in all non-CPR first aid kits, and should be used by any individual administering CPR or first aid. In addition, individuals who are required to be first aid certified as part of their jobs may wish to carry their own small packet containing gloves and a pocket mask for CPR.

7. Handling Contaminated Linen

Linen contaminated with blood and/or other body fluids shall be placed in a laundry bag and labelled. If the bag is

punctured or if outside contamination of the bag is likely, a second bag shall be used. Gloves shall be worn when working with linen contaminated with blood and/or other body fluids.

8. Cleaning Blood and/or Body Fluid Spill

The following procedures should be utilized for cleaning up blood or body fluid spills:

a. Area of the spill shall be cordoned off to prevent the accidental spread of body fluids.

b. Vinyl or latex gloves are donned if not already in place.

c. An appropriate germicide or bleach solution should be prepared. A germicide solution is the cleaning solution of choice. If a bleach solution is used it can be prepared with 800 ppm NaClO solution (i.e., standard household chlorine bleach) by mixing a quarter cup (60 ml) with one gallon of water. The bleach solution should only be used on hard floors. Do not use this solution on carpet. Bleach solution should be made fresh; never hold more than one day's worth at a time unless it is stored in an air-tight container in a cool dark place.

d. Remove any large pieces of glass or other particulate material. Do not pick up material with hands. Use a plastic scoop to remove this matter. A tongue depressor may be employed to maneuver items onto the scoop. Care should be taken not to flip material with the tongue depressor. Particulate material and tongue depressors are placed in a puncture-resistant and splatter-proof container. The scoop is placed in a clean place after being cleaned (see 8.h., below).

e. Carefully remove the body fluids from the spill surface with gauze sponges. When the sponge is saturated, replace it with a new one. Do not wring out fluids. All soiled sponges are placed in the puncture-resistant and splatter-proof container.

f. Once body fluids have been removed from the area, the bleach solution is used to decontaminate the area. This is done by starting two (2) inches outside the spill and moving into the center of the spill by making a series of overlapping concentric circles with a sponge. The area is allowed to air dry and the process is repeated. The soiled sponges are placed into the puncture-resistant splatter-proof container.

g. All material used in the cleanup are placed in a safe holding area until they can be disposed of in accordance with Section C.3., below.

h. All material in the container is disinfected in accordance with usual procedure for sharp containers. The germicide or bleach solution may be disposed of in a sanitary sewer; large quantities may be harmful to septic tank systems. The scoop may be allowed to air dry. NOTE: If it is desired to neutralize via the NaClO solution, there should be a minimum contact time of 10-minutes in the solution.

C. SPECIFIC PROCEDURES FOR HANDLING POTENTLY EXPOSURES

1. General Exposures:

a. **Cleaning Spills**
See specific instructions in Section III.B.8.

b. **Emesis**
Gloves must be worn when handling, cleaning, and/or disposing of emesis fluid.

c. **Injuries**
Gloves are to be worn whenever blood and/or other body fluids are present.

d. **CPR**
Follow instructions in Section III.B.6. regarding CPR and cleaning of resuscitation equipment.

e. **Disposal of Syringes/Needles/Lab Pipettes**
Please follow the instructions for sharps in Section III.B.5.

f. **Reusable Instruments**
Gloves must be worn in handling any contaminated instruments.

g. **Special Note on Exposures of Pregnant Women**
Pregnant women are not known to be at greater risk of contracting HBV or HIV infections than workers who are not pregnant. However, if a worker develops HIV infection during pregnancy, the infant is at increased risk of infection resulting from perinatal transmission. Because of this risk, pregnant women should be especially familiar with the above precautions.

SECTION IV:
EXPOSURE INCIDENT

A. DEFINITION OF EXPOSURE INCIDENT

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

B. WHAT TO DO IF AN EXPOSURE INCIDENT OCCURS

If an exposure incident occurs, the employee should be given the "Exposure Incident and Treatment Packet" (Appendix B). This packet contains all necessary instructions. It should be completed by the employee and taken with them to the designated medical clinic: federal employees to the FEOH Health Unit physician or insurance provider; for contractors, to their private health care provider (this is at the cost of the contractor). The health care provider seeing the employee at that clinic is to complete appropriate portions of the packet and use the information provided in the packet to determine appropriate treatment.

The completed packet is to be returned to the NEIC where it will be kept as a permanent part of the employee's occupational health record. This report only states that the employee was (1) evaluated and treated if appropriate for a bloodborne pathogen exposure incident and (2) was offered Hepatitis B vaccine if appropriate. All other information is considered medically confidential and is available only to the employee, their designees, health professionals, and others as designated in the OSHA Standard. These provisions are in accordance with OSHA standards with respect to exposure incident procedures and record keeping.

SECTION V: TRAINING

A. GENERAL TRAINING REQUIREMENTS

The OSHA Bloodborne Pathogen Standard requires initial training with annual updates for employees who are at increased risk for bloodborne pathogen exposure.

As described in Section II on exposure determination, employees can probably be classified in terms of their BBP exposure risk based on their specific job/task assignments. Therefore, two levels of training will occur as described below:

B. SPECIFIC LEVELS OF TRAINING

1. Training Level I: For NEIC Employees

a. Groups to be Included: NEIC Employees

All NEIC employees will receive some basic information about BBP exposure risks and should have an idea of what the agency's BBP Exposure Plan covers. This type of training is not required by the OSHA Standard for groups with no increased risk; however, it seems prudent since employees may hear about the program from others and this may raise concerns or questions. Also, all employees may occasionally come across blood or a body fluid spill, at work or at home, and they should know how to handle these situations.

b. Content of Training

This will include at minimum a memo sent to all federal employees stating that the NEIC is instituting a BBP Exposure Control Plan as per the OSHA Standard. It should be stated that employees felt to be at increased risk from occupational BBP exposure will be contacted by their supervisor or designee. The memo should also state gloves and CPR face masks should be in all first aid kits and should be used in performing any first aid. If an employee notes a blood or body fluid spill they should be told who to contact to assure proper cleaning. A small pamphlet on occupational BBP exposure could be included. If appropriate, a brief description of the BBP Exposure Control Plan might be presented at a regular staff or safety meeting. Alternately, all NEIC employees can be included in the initial training for employees in the increased risk group.

2. **Training Level II: NEIC Employees with Increased Work Exposure Risk**

a. Groups Included: All employees determined to be in the increased risk group should receive this level of training.

b. Content of the Training: This will be an overview of all the material in the BBP Exposure Control Plan.

The format of this training should be a classroom setting primarily focusing on Sections II, III (Sections A.1. through C.1.), IV, and VI of this document.

c. Anticipated training time: 1-2 hours.

Additional information such as record forms, brief training outlines, etc., are included in Appendix G.

SECTION VI:
RECORD KEEPING

A. MEDICAL RECORDS

1. General Requirements for Medical Record Maintenance

The U.S. Public Health Service, division of Federal Employee Occupational Health and NEIC are required to establish and maintain an accurate record for each federal employee at increased risk for occupational exposure in accordance with the Standard. All medical records are to be kept confidential and not disclosed or reported to any person within or outside the workplace without the employee's express written consent except as required by law. Each record is to be maintained for at least the duration of employment, plus 30 years, in accordance with the Standard.

2. Specific Components of Medical Records to be Kept by NEIC for Potentially Exposed Employees

These records shall include:

a. The name and social security number of the employee.

b. A copy of the employee's Hepatitis B vaccination status if accepted by the employee including the dates of all the Hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination. (See Appendix C on Hepatitis B Vaccination). If the employee declines vaccination, a copy of the signed declination statement will be included.

c. The employer's copy of the health care professional's written opinion if actually exposed.

d. A copy of the information provided to the health care professional during the evaluation of an exposure incident (such as the document included as Appendix C.)

B. TRAINING RECORDS

1. General Requirements of Training Record Maintenance

Training records shall be maintained by NEIC for three years from the date on which the training occurred.

SECTION VII:
BIOHAZARD WASTE

A. GENERAL REQUIREMENTS FOR HANDLING BIOHAZARD WASTE

All regulated waste shall be disposed of in accordance with applicable regulations of the United States, as well as the States and Territories and their political subdivisions. The OSHA Bloodborne Pathogens Standard does not appear to require any measures which are not already mandated by these regulations. However, general guidelines for handling biohazard waste are given below. The OSHA standard, in Appendix A, can be consulted for more information.

B. SPECIFIC GUIDELINES FOR HANDLING BIOHAZARD WASTES

1. The containers for storage, transport, or shipping shall be labelled or color-coded and closed prior to being stored, transported, or shipped.

2. If contamination of the outside 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.

3. 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. 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.

4. Regulated waste need not be handled as biohazard waste if it has been properly disinfected, except for "sharps" as described in Section III.

5. Communication of the hazards of potential exposure must be made to all individuals who deal with biohazard wastes.

APPENDIX A

APPENDIX A

OSHA BLOODBORNE PATHOGENS STANDARD (1920.1030)

XI. The Standard

General Industry

Part 1910 of title 29 of the Code of Federal Regulations is amended as follows:

PART 1910—[AMENDED]

Subpart Z—[Amended]

1. The general authority citation for subpart Z of 29 CFR part 1910 continues to read as follows and a new citation for § 1910.1030 is added:

Authority: Secs. 6 and 8, Occupational Safety and Health Act, 29 U.S.C. 655, 657, Secretary of Labor's Orders Nos. 12-71 (36 FR 8754), 8-76 (41 FR 25059), or 9-83 (48 FR 35736), as applicable; and 29 CFR part 1911.

* * * * *

Section 1910.1030 also issued under 29 U.S.C. 653.

* * * * *

2. Section 1910.1030 is added to read as follows:

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

HBV means hepatitis B virus.

HIV means human immunodeficiency virus.

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.

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

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

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

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

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

eliminate or minimize employee exposure.

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

(A) The exposure determination required by paragraph(c)(2).

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

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

(iii) Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.20(e).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) Puncture resistant;

(B) Labeled or color-coded in accordance with this standard;

(C) Leakproof on the sides and bottom; and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(*1*) Periodically reevaluate this policy:

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

(*3*) Not discourage the use of gloves for phlebotomy: and

(*4*) Require that gloves be used for phlebotomy in the following circumstances.

(*i*) When the employee has cuts. scratches. or other breaks in his or her skin:

(*ii*) When the employee judges that hand contamination with blood may occur. for example. when performing phlebotomy on an uncooperative source individual: and

(*iii*) When the employee is receiving training in phlebotomy.

(x) Masks. Eye Protection. and Face Shields. Masks in combination with eye protection devices. such as goggles or glasses with solid side shields. or 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.

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

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

(4) *Housekeeping* (i) General. Employers shall ensure that the worksite is maintained in a clean and sanitary condition. The employer shall determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility. type of surface to be cleaned. type of soil present. and tasks or procedures being performed in the area

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

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

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

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

(D) Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means.

such as a brush and dust pan, tongs, or forceps.

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

(iii) Regulated Waste.

(A) Contaminated Sharps Discarding and Containment. (*1*) Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:

(*i*) Closable;

(*ii*) Puncture resistant;

(*iii*) Leakproof on sides and bottom; and

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

(*2*) During use, containers for contaminated sharps shall be:

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

(*ii*) Maintained upright throughout use; and

(*iii*) Replaced routinely and not be allowed to overfill.

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

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

(*ii*) Placed in a secondary container if leakage is possible. The second container shall be:

(*A*) Closable;

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

(*C*) Labeled or color-coded according to paragraph (g)(1)(i) of this standard.

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

(B) Other Regulated Waste Containment.(*1*) Regulated waste shall be placed in containers which are:

(*i*) Closable;

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

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

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

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

(*i*) Closable;

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

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

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

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

(iv) Laundry.

(A) Contaminated laundry shall be handled as little as possible with a minimum of agitation. (1) Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.

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

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

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

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

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

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

(i) Standard microbiological practices. All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

(ii) Special practices.

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

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

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

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

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

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

(G) Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with other potentially infectious materials is unavoidable.

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

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

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

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

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

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

(ii) Containment equipment. (A) Certified biological safety cabinets (Class I. II. or III) or other appropriate combinations of personal protection or physical containment devices. such as special protective clothing. respirators. centrifuge safety cups. sealed centrifuge rotors. and containment caging for animals. shall be used for all activities with other potentially infectious materials that pose a threat of exposure to droplets. splashes. spills. or aerosols

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(A) Made available at no cost to the employee:

(B) Made available to the employee at a reasonable time and place.

(C) Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional: and

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

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

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

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

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

(iv) The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the statement in appendix A.

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

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

(i) Documentation of the route(s) of exposure. and the circumstances under which the exposure incident occurred:

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

(A) The source individual's blood shall be tested as soon as feasible and

after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.

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

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

(iii) Collection and testing of blood for HBV and HIV serological status:

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

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

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

(v) Counseling; and

(vi) Evaluation of reported illnesses.

(4) *Information Provided to the Healthcare Professional.* (i) The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

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

(A) A copy of this regulation.

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

(C) Documentation of the route(s) of exposure and circumstances under which exposure occurred.

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

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

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

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

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

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

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

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

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

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

BIOHAZARD

BIOHAZARD

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

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

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

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

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

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

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

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

BIOHAZARD

BIOHAZARD

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

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

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

(ii) Training shall be provided as follows:

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

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

(C) At least annually thereafter.

(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.

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

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

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

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

(A) Anaccessible copy of the regulatory text of this standard and an explanation of its contents:

(B) A general explanation of the epidemiology and symptoms of bloodborne diseases:

(C) An explanation of the modes of transmission of bloodborne pathogens:

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

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

(F) An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls. work practices. and personal protective equipment:

(G) Information on the types. proper use. location. removal. handling. decontamination and disposal of personal protective equipment:

(H) An explanation of the basis for selection of personal protective equipment:

(I) Information on the hepatitis B vaccine. including information on its efficacy. safety. method of administration. the benefits of being vaccinated. and that the vaccine and vaccination will be offered free of charge:

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

(K) An explanation of the procedure to follow if an exposure incident occurs. including the method of reporting the incident and the medical follow-up that will be made available:

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

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

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

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

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

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

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

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

(h) *Recordkeeping—(1) Medical Records.* (i) The employer shall establish and maintain an accurate record for each employee with occupational exposure. in accordance with 29 CFR 1910.20.

(ii) This record shall include:

(A) The name and social security number of the employee

(B) A copy of the employee s hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee s ability to receive vaccination as required by paragraph (f)(2):

(C) A copy of all results of examinations. medical testing. and follow-up procedures as required by paragraph (f)(3):

(D) The employer s copy of the healthcare professional's written opinion as required by paragraph (f)(5). and

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

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

(A) Kept confidential and

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

(iv) The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.20.

(2) *Training Records. (i) Training records shall include the following information:*

(A) The dates of the training sessions:

(B) The contents or a summary of the training sessions:

(C) The names and qualifications of persons conducting the training: and

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

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

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

(ii) Employee training records required by this paragraph shall be provided upon request for examination and copying to employees. to employee representatives. to the Director. and to the Assistant Secretary in accordance with 29 CFR 1910.20.

(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 1910.20

(4) *Transfer of Records* (i) The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.20(h)

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

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

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

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

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

Appendix A to Section 1910.1030—Hepatitis B Vaccine Declination (Mandatory)

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

[FR Doc. 91-28886 Filed 12-2-91; 8:45 am]

BILLING CODE 4510-26-M

APPENDIX B

APPENDIX B

EXPOSURE INCIDENT AND TREATMENT PACKET

EXPOSURE INCIDENT RECORD
FOR BLOODBORNE PATHOGEN EXPOSURE

EMPLOYEE INSTRUCTIONS

You are completing this form because you have experienced an actual or a potential exposure to blood or other potentially infectious material. An evaluation of this exposure is required by the Bloodborne Pathogen Standard of the Occupational Safety and Health Administration.

Please complete all the information below. Take this form with you when you go to a physician or other health care provider for the evaluation of the exposure. The information contained on this form is crucial to a proper evaluation of the exposure. Please take the time and care in completing the form to insure that the information is clear and accurate.

If you need information on where to have this medical evaluation performed, please contact your supervisor.

The medical evaluation for a suspected exposure to blood or other potentially infectious material should be done soon as possible after the exposure. The effectiveness of certain vaccines or other medication which might prevent any illness resulting from these exposures is greatest if given shortly after the exposure.

Complete the appropriate accident report for your supervisor.

EMPLOYEE'S STATEMENT: (PLEASE PRINT)

A. Employee Identification.

Name: _____

Social Security Number: _____

Job Title: _____

Work Location: _____

Work Phone: _____

Supervisor: _____

B. Description of Exposure Incident.

Date: _____ Time: _____ am/pm (circle one)

City/Town: _____ State: _____

Describe Incident (Please include the type of infectious material to which you were exposed and the circumstances of the exposure):

SUPERVISOR'S STATEMENT: (PLEASE PRINT)

Employee's Name:

A. Supervisor Identification.

Name: _____

Work Phone: _____

B. Description of Incident
Please describe the employee's duties as they relate to the exposure incident:

C. Hepatitis B Status

The employee named above O has /0 has not received a three dose series of Hepatitis B Vaccine. If yes, the series was completed on _____ (date).

D. Investigation of Source

Please describe what information is known about the source (person) of the exposure (especially name, address, telephone number, or other contact point), the result(s) of the blood testing of the source (if known), or why blood testing of the source is not feasible. Also, if the source is known to have or test positive for Hepatitis B or Human Immunodeficiency Virus (HIV), please indicate this fact. The OSHA standard requires that the source be tested for these agents unless such testing is not legally possible.

Exposure Incident Record for Bloodborne Pathogen Exposure

Health Care Provider Instructions

This employee is being referred for your evaluation of an exposure incident to blood or another potentially infectious material. This referral is to be performed under the provisions of the OSHA Bloodborne Pathogen Standard (29 CFR 1910.1030). A copy of this standard is attached. Several items included in the OSHA standard deserve your close attention.

- Under the OSHA standard, the following bodily fluids are considered potentially infectious: blood, semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva (in dental procedures), and any body fluid visibly contaminated with blood.

- The exposed employee's blood should be collected as soon as feasible after consent is obtained and tested for HBV and HIV status.

- If the employee gives consent for baseline blood collection, but does not give consent for HIV serological testing at the time of collection, the blood sample should be stored for 90 days. If within 90 days of the exposure incident, the employee elects that the baseline sample be tested, such testing should be performed.

- Post-exposure prophylaxis is to be given according to the guidelines of the U.S. Public Health Service, which are attached. Optimal use of these recommendations requires knowledge of the HBV status of the source and the exposed individual.

- OSHA requires that you submit a report of the post-exposure evaluation. A form for this purpose is attached.

EXPOSURE INCIDENT RECORD FOR BLOODBORNE PATHOGEN EXPOSURE

HEALTH CARE PROVIDER REPORT OF POST-EXPOSURE EVALUATION

Employee name: _____

Date of office visit: _____

Health Care Facility Address: _____

_____

_____

Health Care Facility Telephone: _____

As required under the OSHA Bloodborne Pathogen Standard:

- o The employee named above has been informed of the results of the post-exposure medical evaluation.

- o The employee named above has been told about any medical conditions resulting from exposure to blood or other potentially infections materials which require further evaluation or treatment.

_____
(Printed Or Typed Name of Health Care Provider)

_____
(Signature of Health Care Provider)

_____
(Date of Signature)

Treatment Protocol Table.

Recommendations for hepatitis B prophylaxis following exposure incident.[1]

	Treatment when source is found to be		
Exposed person	**HBsAG positive**	**HBsAG negative**	**Unknown or not tested**
Unvaccinated	Administer HBIG x 1* and initiate hepatitis B vaccine†	Initiate hepatitis B vaccine†	Initiate hepatitis B vaccine†
Previously vaccinated			
Known responder	Test exposed person for anti-HBs 1 If adequate, no treatment 2 If inadequate, hepatitis B vaccine booster dose	No treatment	No treatment
Known non-responder	HBIG x 2 or HBIG x 1, plus 1 dose of hepatitis B vaccine	No treatment	No treatment
Response unknown	Test exposed person for anti-HB§ 1 If inadequate HBIG x 1, plus hepatitis B vaccine booster dose 2 If adequate, no treatment	No treatment	Test exposed person for anti-HBs§ 1 If inadequate, hepatitis B vaccine booster dose 2 If adequate, no treatment

* Hepatitis B immune globulin (HBIG) dose 0.06 ml/kg intramuscularly
† Hepatitis B vaccine dose—see Table 1
§ Adequate anti-HBs is ≥ 10 milli-international units

[1] U.S. Public Health Service, Center for Disease Control, Morbidity and Mortality Weekly, November 22, 1991, 40:(RR-13) 22.

APPENDIX C

APPENDIX C

HEPATITIS B VACCINATION INFORMATION AND CONSENT/DECLINATION FORMS

APPENDIX C

HEPATITIS B VACCINATION INFORMATION AND CONSENT/DECLINATION FORMS

NEIC offers free vaccinations against Hepatitis B virus for all employees who are at increased risk for bloodborne pathogens (BBP) at work. Employees are at increased risk and should consider vaccination if they (1) have direct contact with human blood or other body tissues or (2) are at risk of trauma, needle sticks, cuts, or abrasions that may result in percutaneous exposure to materials infected with Hepatitis B virus.

The Disease

Hepatitis B, formerly called serum , hepatitis is a disease caused by the Hepatitis B virus (HBV). There is no specific treatment for Hepatitis B infection other than supportive measures. Most persons who become infected with Hepatitis B recover completely and are immune to subsequent exposures. However, of all those who develop Hepatitis B infection, about 0.1% die of fulminating hepatitis. The prognosis depends on age, dose, and severity of underlying disease. Five to 10% of cases become chronic lifetime carriers who are capable of transmitting the disease to others and are at risk of developing chronic active Hepatitis B, cirrhosis (2%) or liver cancer (0.4%).

Risks of Hepatitis B Infection for Health Care Workers

Health care workers who have contact with blood, infected tissue or secretions, and regular exposure to trauma, needle sticks, cuts, and abrasions are most at risk for acquiring Hepatitis B. In the United States, about 5% of the general population show evidence of past or present Hepatitis B infection, while up to 30% or more health care workers in high risk areas show evidence of past Hepatitis B infection.

The Vaccine

A genetically engineered Hepatitis B vaccine was first licensed by the Food and Drug Administration in July of 1986. Genetically engineered vaccine is the vaccine offered to NEIC employees. The

vaccine, referred to as recombinant HB vaccine, ("Recombivax HB", or "Engerix-B") is very comparable, immunologically, to the earlier "Heptovax B" vaccine which was introduced in 1981. The difference between the two vaccines relates to their methods of derivation. Recombinant HB vaccine is genetically engineered from common baker's yeast into which a plasmid containing the gene for the Hepatitis B surface antigen (HBsAg) and has been inserted. The first available plasma derived Hepatitis B vaccine ("Heptovax B") is derived from highly purified plasma of chronic HBV carriers and then inactivated so that it is not infectious. The plasma derived vaccine is no longer produced in the United States.

The full vaccination series for Hepatitis B includes an initial vaccination followed by repeat doses one month and six months later. Over 95 percent of susceptible healthy adults (20-39 years of age) who receive the full vaccination series achieve high levels (titers) of Hepatitis B surface antibody (anti-HBs) and are considered to be immune from Hepatitis B infection. The vaccine produces somewhat lower antibody responses in older adults than in younger adults.

The dose is 10Lg (1 ml) injected into the deltoid muscle. There is no evidence that the vaccine has ever caused Hepatitis B. Administration of the vaccine to persons already positive has no effect, good or bad. Administration of Hepatitis B hyper-immune globulin (HBIG) given prophylactically does not interfere with the development of antibodies to the vaccine. Persons already incubating Hepatitis B prior to receiving the vaccine may go on to develop clinical hepatitis in spite of the immunization although the vaccination may reduce the severity of the illness.

Vaccine Risks and Possible Side Effects

The incidence of side effects is very low, usually limited to soreness at the injection site, and mild systemic symptoms (fever, headache, fatigue, and nausea).

There is no danger of acquiring any blood borne disease from the Hepatitis B vaccine Itself. Early concerns about safety of plasma-derived HB vaccine (no longer in use here), especially the concern that infectious agents such as human immunodeficiency virus (HIV) present in donor plasma pools might contaminate the final product, have proven to be unfounded. The recombinant HB vaccine does not contain infectious materials.

Post vaccination antibody testing for immune response

It is currently recommended that titers of anti-HBs (Hepatitis B antibody) be tested 1-2 months after the completion of the full vaccination series for Hepatitis B. Those with a positive antibody titer* (i.e., a titer of ≥ 10 milli-international units per milliliter of blood) at that time are considered to be immune. It is not known how long this immunity will last but the current thinking is that immunity will last for at least five to seven years and may be lifelong. At this time, the CDC is not recommending any booster shots for these and it is hoped that this immunity will be permanent. Further data on the need for booster shots may be available in coming years.

Individuals who have a low antibody titer when tested (i.e., < 10 MIU/ml) 1-2 months after completion of the full vaccination series should receive further vaccinations and testing as noted below: They should receive a fourth injection (at the same dose as the original injection) just after the negative test results are received, and 1-2 months later should be tested again for anti-HBs titers. If the titers are positive, the person should be considered immune. If the titers are still low, a fifth vaccination should be given at that time and anti-HBs titers tested once more 1-2 months later. If these titers are positive, the individual is considered immune. If antibody titers remain low after five injections, it is presumed the individual will not be able to develop an immune response and no further injections are indicated. In these cases the individual is considered a non-responder to Hepatitis B vaccinations and a physician should be consulted regarding the need for medical work restrictions.

Appendix C: Hepatitis B Vaccination Information and Consent/Declination Forms

HEPATITIS B VACCINATION: CONSENT FORM

I have read the information about Hepatitis B and the Hepatitis B vaccine. I have had the opportunity to ask questions and understand the benefits and risks of Hepatitis B immunization. I agree to receive the three doses required for the optimum immune response. However, as with all medical treatment, I understand there is no guarantee that I will become immune or that I will not experience adverse side effects from the vaccine. Please print.

Name of person to receive vaccine	Social Security Number
Signature of person receiving vaccine	Witness
Date	Date

HEPATITIS B VACCINATION RECORD

	DATE	GIVEN BY	LOT #
Primary dose			
1 Month after Primary Dose			
6 Months after Primary Dose			

HEPATITIS B VACCINATION: DECLINATION FORM

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 cost to me. 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 cost to me.

Print Name	Signature
Social Security Number	Address
Date	City/State

APPENDIX D

APPENDIX D

REFERENCE INFORMATION ON HEPATITIS B INFECTIONS FROM MMWR

MMWR

The *Morbidity and Mortality Weekly Report* (*MMWR*) Series is prepared by the Centers for Disease Control and is available on a paid subscription basis from the Superintendent of Documents U S Government Printing Office, Washington DC 20402 telephone (202) 783 3238

The data in the weekly *MMWR* are provisional based on weekly reports to CDC by state health departments The reporting week concludes at close of business on Friday compiled data on a national basis are officially released to the public on the succeeding Friday Inquiries about the *MMWR* Series including material to be considered for publication, should be directed to Editor, *MMWR* Series, Mailstop C 08 Centers for Disease Control Atlanta GA 30333 telephone (404) 332 4555

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MMWR

Recommendations and Reports

MORBIDITY AND MORTALITY WEEKLY REPORT

Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination

Recommendations of the Immunization Practices Advisory Committee (ACIP)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control
National Center for Infectious Diseases
Atlanta, Georgia 30333

CDC

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Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination

Recommendations of the Immunization Practices Advisory Committee (ACIP)

*The following statement updates all previous recommendations on protection against hepatitis B virus infection, including use of hepatitis B vaccine and hepatitis B immune globulin for prophylaxis against hepatitis B virus infection (*MMWR *1985,34 313 24,329-35,* MMWR *1987,36 353 66, and* MMWR *1990,39 (No RR 2) 8 19) and universal screening of pregnant women to prevent perinatal hepatitis B virus transmission (*MMWR *1988,37 341 46,51, and* MMWR *1990,39(No RR-2) 8-19) Recommendations concerning the prevention of other types of viral hepatitis are found in* MMWR *1990,39(No RR 2) 1 8, 22-26*

This document provides the rationale for a comprehensive strategy to eliminate transmission of hepatitis B virus in the United States This prevention strategy includes making hepatitis B vaccine a part of routine vaccination schedules for all infants

INTRODUCTION

The acute and chronic consequences of hepatitis B virus (HBV) infection are major health problems in the United States The reported incidence of acute hepatitis B increased by 37% from 1979 to 1989, and an estimated 200,000 300,000 new infections occurred annually during the period 1980–1991 The estimated 1 million-1 25 million persons with chronic HBV infection in the United States are potentially infectious to others In addition, many chronically infected persons are at risk of long term sequelae, such as chronic liver disease and primary hepatocellular carcinoma, each year approximately 4,000-5,000 of these persons die from chronic liver disease (*1*)

Immunization with hepatitis B vaccine is the most effective means of preventing HBV infection and its consequences In the United States, most infections occur among adults and adolescents (*2,3*) The recommended strategy for preventing these infections has been the selective vaccination of persons with identified risk factors (*1,2*) However, this strategy has not lowered the incidence of hepatitis B primarily because vaccinating persons engaged in high-risk behaviors, life styles, or occupations before they become infected generally has not been feasible In addition, many infected persons have no identifiable source for their infections and thus cannot be targeted for vaccination (*2*)

Preventing HBV transmission during early childhood is important because of the high likelihood of chronic HBV infection and chronic liver disease that occurs when children less than 5 years of age become infected (*3*) Testing to identify pregnant

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Contents

women who are hepatitis B surface antigen(HBsAg) positive and providing their infants with immunoprophylaxis effectively prevents HBV transmission during the perinatal period (*4,5*) Integrating hepatitis B vaccine into childhood vaccination schedules in populations with high rates of childhood infection (e g , Alaskan Natives and Pacific Islanders) has been shown to interrupt HBV transmission (*6*)

This document provides the rationale for a comprehensive strategy to eliminate transmission of HBV and ultimately reduce the incidence of hepatitis B and hepatitis B-associated chronic liver disease in the United States The recommendations for implementing this strategy include making hepatitis B vaccine a part of routine vaccination schedules for infants

EPIDEMIOLOGY AND PREVENTION OF HEPATITIS B VIRUS INFECTION

Infections among Infants and Children

In the United States, children become infected with HBV through a variety of means The risk of perinatal HBV infection among infants born to HBV-infected mothers ranges from 10% to 85%, depending on each mother's hepatitis B e antigen (HBeAg) status (*3,7,8*) Infants who become infected by perinatal transmission have a 90% risk of chronic infection, and up to 25% will die of chronic liver disease as adults (*9*) Even when not infected during the perinatal period, children of HBV-infected mothers remain at high risk of acquiring chronic HBV infection by person to-person (horizontal) transmission during the first 5 years of life (*10*) More than 90% of these infections can be prevented if HBsAg positive mothers are identified so that their infants can receive hepatitis B vaccine and hepatitis B immune globulin (HBIG) soon after birth (*4,5*)

Because screening selected pregnant women for HBsAg has failed to identify a high proportion of HBV-infected mothers (*11,12*), prenatal HBsAg testing of all pregnant women is now recommended (*1,13,14*) Universal prenatal testing would identify an estimated 22,000 HBsAg positive women and could prevent at least 6,000 chronic HBV infections annually (*3*) Screening and vaccination programs for women and infants receiving care in the public sector have already been initiated through state immunization projects

Horizontal transmission of HBV during the first 5 years of life occurs frequently in populations in which HBV infection is endemic The risk of chronic infection is age dependent, ranging from 30% to 60% for children 1-5 years of age (*15*) Worldwide, it has been recommended that, in populations in which HBV infection is acquired during childhood, hepatitis B vaccine should be integrated into routine vaccination schedules for infants, usually as a part of the World Health Organization's Expanded Programme on Immunization (*16*) In the United States, racial/ethnic groups shown to have high rates of childhood HBV infection include Alaskan Natives (*6,17*), Pacific Islanders (*18*), and infants of first generation immigrant mothers from parts of the world where HBV infection is endemic, especially Asia (*19,20*) Vaccination programs to prevent perinatal, childhood, and adult HBV infections among Alaskan Natives were begun in late 1982, as a result, the incidence of acute hepatitis B in this population has declined by over 99% (*6*) Hepatitis B vaccine was integrated into

vaccination schedules for infants in American Samoa beginning in 1986 and by 1990 was incorporated into the schedules of the remaining Pacific Islands under U S jurisdiction

Each year, approximately 150,000 infants are born to women who have immigrated to the United States from areas of the world where HBV infection is highly endemic (*3*) Children born to HBsAg positive mothers can be identified through prenatal screening programs However, children born to HBsAg negative immigrant mothers are still at high risk of acquiring HBV infection, usually from other HBV carriers in their families or communities (*3,19,20*) Infections among these children can be prevented by making hepatitis B vaccine part of their routine infant vaccinations (*1*)

Infections among Adolescents and Adults

In the United States most persons with hepatitis B acquire the infection as adolescents or adults Several specific modes of transmission have been identified including sexual contact, especially among homosexual men and persons with multiple heterosexual partners, parenteral drug use, occupational exposures, household contact with a person who has an acute infection or with a chronic carrier, receipt of certain blood products, and hemodialysis However, over one third of patients with acute hepatitis B do not have readily identifiable risk factors (*1,2*)

The rates of HBV infection differ significantly among various racial and ethnic groups (*2,21*) For example, the prevalence of infection among adolescents and adults has been shown to be threefold to fourfold greater for blacks than for whites and to be associated with serologic evidence of previous infection with syphilis (*21,22*)

Efforts to vaccinate persons in the major risk groups have had limited success For example, programs directed at injecting drug users failed to motivate them to receive three doses of vaccine (CDC, unpublished data) Health care providers are often not aware of groups at high risk of HBV infection and frequently do not identify candidates for vaccination during routine health care visits (CDC, unpublished data) In addition, there has been limited vaccination of susceptible household and sexual contacts of HBsAg carriers identified in screening programs for blood donors (*23*) Hepatitis B vaccination of health-care workers appears to have resulted in a substantial decrease in the rate of disease in this group, but has had little effect on overall rates of hepatitis B (*2*) Moreover, to achieve widespread vaccination of persons at occupational risk, regulations have had to be developed to ensure implementation of vaccination programs (*24*)

Educational programs to reduce parenteral drug use and unprotected sexual activity are important components of the strategy to prevent infection with the human immunodeficiency virus (HIV), which causes acquired immunodeficiency syndrome These programs appear to have reduced the risk of HBV infections among homosexual men but have not had an impact on hepatitis B attributable to parenteral drug use or heterosexual transmission (*2*) Educational efforts alone are not likely to fully eliminate the high risk behaviors responsible for HBV transmission

EPIDEMIOLOGY AND PREVENTION OF HEPATITIS DELTA VIRUS INFECTION

Hepatitis delta virus (HDV) is a defective virus that causes infection only in the presence of active HBV infection (*25*) HDV infection occurs as either coinfection with HBV or superinfection of an HBV carrier Coinfection usually resolves, superinfection, however, frequently causes chronic HDV infection and chronic active hepatitis Both types of infection may cause fulminant hepatitis

Routes of transmission are similar to those of HBV In the United States, HDV infection most commonly affects persons at high risk of HBV infection, particularly injecting drug users and persons receiving clotting factor concentrates (*26*) Preventing acute and chronic HBV infection of susceptible persons will also prevent HDV infection

STRATEGY TO ELIMINATE HEPATITIS B VIRUS TRANSMISSION

A comprehensive strategy to prevent HBV infection, acute hepatitis B, and the sequelae of HBV infection in the United States must eliminate transmission that occurs during infancy and childhood, as well as during adolescence and adulthood In the United States it has become evident that HBV transmission cannot be prevented through vaccinating only the groups at high risk of infection No current medical treatment will reliably eliminate chronic HBV infection and thus eliminate the source of new infections in susceptible persons (*27*) Therefore, new infections can be prevented only by immunizing susceptible persons with hepatitis B vaccine Routine visits for prenatal and well-child care can be used to target hepatitis B prevention A comprehensive prevention strategy includes a) prenatal testing of pregnant women for HBsAg to identify newborns who require immunoprophylaxis for the prevention of perinatal infection and to identify household contacts who should be vaccinated, b) routine vaccination of children born to HBsAg negative mothers, c) vaccination of certain adolescents and d) vaccination of adults at high risk of infection

Infants and children can receive hepatitis B vaccine during routine health care visits, no additional visits would be required Costs include that of the vaccine and the incremental expense associated with delivering an additional vaccine during a scheduled health care visit Implementation of this immunization strategy would be greatly facilitated by the development and use of multiple antigen vaccines (e g , diphtheria-tetanus-pertussis[DTP]/hepatitis B, *Haemophilus influenzae* type b conjugate/hepatitis B) These vaccines would reduce the number of injections received by the infant, reduce the cost of administration, and greatly facilitate widespread vaccine delivery

Since most HBV infections occur among adults, disease control could be accelerated by vaccinating emerging at-risk populations, such as adolescents and susceptible contacts of chronic HBV carriers The recommendation for universal infant vaccination neither precludes vaccinating adults identified to be at high risk of infection nor alters previous recommendations for postexposure prophylaxis for hepatitis B (*1*)

The reduction in acute hepatitis B and hepatitis B associated chronic liver disease resulting from universal infant vaccination may not become apparent for a number of years However universal HBsAg screening of pregnant women to prevent perinatal

HBV infection has been shown to be cost saving (*28*, CDC, unpublished data), and the estimated cost of universal hepatitis B vaccination for infants is less than the direct medical and work loss costs associated with the estimated 5% lifetime risk of infection (CDC, unpublished data) Currently, the cost of an infant's dose of hepatitis B vaccine delivered in the public sector is about the same as each of the other childhood vaccinations Vaccinating adolescents and adults is substantially more expensive because of the higher vaccine cost and the higher implementation costs of delivering vaccine to target populations In the long term, universal infant vaccination would eliminate the need for vaccinating adolescents and high-risk adults

PROPHYLAXIS AGAINST HEPATITIS B VIRUS INFECTION

Two types of products are available for prophylaxis against HBV infection Hepatitis B vaccine, which provides long term protection against HBV infection, is recommended for both preexposure and postexposure prophylaxis HBIG provides temporary protection (i e , 3 6 months) and is indicated only in certain postexposure settings

Hepatitis B Immune Globulin

HBIG is prepared from plasma known to contain a high titer of antibody against HBsAg (anti HBs) In the United States, HBIG has an anti HBs titer of >100,000 by radioimmunoassay The human plasma from which HBIG is prepared is screened for antibodies to HIV, in addition, the process used to prepare HBIG inactivates and eliminates HIV from the final product There is no evidence that HIV can be transmitted by HBIG (*29,30*)

Hepatitis B Vaccine

Two types of hepatitis B vaccine have been licensed in the United States One, which was manufactured from the plasma of chronically infected persons, is no longer produced in the United States The currently available vaccines are produced by recombinant DNA technology

The recombinant vaccines are produced by using HBsAg synthesized by *Saccharomyces cerevisiae* (common bakers' yeast), into which a plasmid containing the gene for HBsAg has been inserted Purified HBsAg is obtained by lysing the yeast cells and separating HBsAg from the yeast components by biochemical and biophysical techniques Hepatitis B vaccines are packaged to contain 10 40 µg of HBsAg protein/mL after adsorption to aluminum hydroxide (0 5 mg/mL), thimerosal (1 20,000 concentration) is added as a preservative

Routes and sites of administration

The recommended series of three intramuscular doses of hepatitis B vaccine induces a protective antibody response (anti HBs ≥ 10 milli international units [mIU]/mL) in >90% of healthy adults and in >95% of infants, children and adolescents (*31-33*) Hepatitis B vaccine should be administered only in the deltoid muscle of adults and children or in the anterolateral thigh muscle of neonates and infants the immunogenicity of the vaccine for adults is substantially lower when injections are

administered in the buttock (*34*) When hepatitis B vaccine is administered to infants at the same time as other vaccines, separate sites in the anterolateral thigh may be used for the multiple injections This method is preferable to administering vaccine at sites such as the buttock or deltoid

Compared with three standard doses admistered intramuscularly, three low doses of plasma derived or recombinant vaccine administered intradermally to adults result in lower seroconversion rates (55%-81%) and lower final titers of anti-HBs (*35-38*), although four doses of plasma derived vaccine administered intradermally have produced responses comparable with vaccine administered intramuscularly (*39*) Plasma derived vaccine administered intradermally to infants and children does not induce an adequate antibody response (*40*) At this time, low dose intradermal vaccination of adults should be performed only under research protocol with written informed consent Persons who have been vaccinated intradermally should be tested for anti HBs Those with an inadequate response (anti HBs <10 mIU/mL) should be revaccinated with three full doses of vaccine administered intramuscularly Intradermal vaccination should not be used for infants or children

Vaccination during pregnancy.

On the basis of limited experience, there is no apparent risk of adverse effects to developing fetuses when hepatitis B vaccine is administered to pregnant women (CDC, unpublished data) The vaccine contains noninfectious HBsAg particles and should cause no risk to the fetus HBV infection affecting a pregnant woman may result in severe disease for the mother and chronic infection for the newborn Therefore, neither pregnancy nor lactation should be considered a contraindication to vaccination of women

Vaccine Usage

Preexposure prophylaxis

Vaccination schedule and dose The vaccination schedule most often used for adults and children has been three intramuscular injections, the second and third administered 1 and 6 months, respectively, after the first An alternate schedule of four doses has been approved for one vaccine that would allow more rapid induction of immunity However, for preexposure prophylaxis, there is no clear evidence that this regimen provides greater protection than that obtained with the standard three dose schedule

Each vaccine has been evaluated to determine the age specific dose at which an optimum antibody response is achieved The recommended dose varies by product and the recipient's age and, for infants, by the mother's HBsAg serologic status (Table 1) In general, the vaccine dose for children and adolescents is 50%-75% lower than that required for adults (Table 1)

Incorporating hepatitis B vaccine into childhood vaccination schedules may require modifications of previously recommended schedules However, a protective level of anti-HBs (~10 mIU/mL) was achieved when hepatitis B vaccine was administered in a variety of schedules, including those in which vaccination was begun soon after birth (*5,8,41*)

In a three dose schedule, increasing the interval between the first and second doses of hepatitis B vaccine has little effect on immunogenicity or final antibody titer

The third dose confers optimal protection, acting as a booster dose Longer intervals between the last two doses (4 12 months) result in higher final titers of anti HBs (*42,43*) Several studies have shown that the currently licensed vaccines produce high rates of seroconversion (>95%) and induce adequate levels of anti HBs when administered to infants at birth, 2 months, and 6 months of age or at 2 months, 4 months, and 6 months of age (CDC, Merck Sharpe & Dohme, SmithKline Beecham, unpublished data) When the vaccine is administered in four doses at 0, 1, 2, and 12 months, the last dose is necessary to ensure the highest final antibody titer

When hepatitis B vaccine has been administered at the same time as other vaccines, no interference with the antibody response of the other vaccines has been demonstrated (*44*)

If the vaccination 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 only the third dose is delayed, it should be administered when convenient

The immune response when one or two doses of a vaccine produced by one manufacturer are followed by subsequent doses from a different manufacturer has been shown to be comparable with that resulting from a full course of vaccination with a single vaccine

Larger vaccine doses or an increased number of doses are required to induce protective antibody in a high proportion of hemodialysis patients (*45,46*) and may also be necessary for other immunocompromised persons (e g , those who take immunosuppressive drugs or who are HIV positive), although few data are available concerning response to higher doses of vaccine by these patients (*47*)

Prevaccination testing for susceptibility Susceptibility testing is not indicated for immunization programs for children or for most adolescents because of the low rate of HBV infection and the relatively low cost of vaccine For adults, the decision to do

TABLE 1 Recommended doses of currently licensed hepatitis B vaccines

Group	Recombivax HB*		Engerix B*	
	Dose (µg)	(mL)	Dose (µg)	(mL)
Infants of HBsAg† negative mothers and children <11 years	2 5	(0 25)	10	(0 5)
Infants of HBsAg positive mothers, prevention of perinatal infection	5	(0 5)	10	(0 5)
Children and adolescents 11 19 years	5	(0 5)	20	(1 0)
Adults ≥20 years	10	(1 0)	20	(1 0)
Dialysis patients and other immunocompromised persons	40	(1 0)§	40	(2 0)¶

*Both vaccines are routinely administered in a three dose series Engerix B has also been licensed for a four dose series administered at 0, 1, 2, and 12 months
†HBsAg = Hepatitis B surface antigen
§Special formulation
¶Two 1 0 mL doses administered at one site, in a four dose schedule at 0 1 2 and 6 months

prevaccination testing should include an analysis of cost effectiveness because of the higher cost of the vaccine Testing for prior infection should be considered for adults in risk groups with high rates of HBV infection (e g , injecting drug users, homosexual men, and household contacts of HBV carriers) The decision for testing should be based on whether the costs of testing balance the costs of vaccine saved by not vaccinating already-infected persons Estimates of the cost effectiveness of testing depend on three variables the cost of vaccination, the cost of testing for susceptibility, and the expected prevalence of immune persons If susceptibility testing is being considered, careful attention should also be given to the likelihood of patient follow up and vaccine delivery

For routine testing, only one antibody test is necessary (antibody either to the core antigen [anti HBc] or anti-HBs) Anti HBc testing identifies all previously infected persons, including HBV carriers, but does not differentiate carriers and non-carriers The presence of anti HBs identifies previously infected persons, except for HBV carriers Neither test has a particular advantage for groups expected to have HBV carrier rates <2%, such as health care workers Anti-HBc may be preferable so that unnecessary vaccination of HBV carriers can be avoided in groups with high carrier rates

Postvaccination testing for serologic response Such testing is not necessary after routine vaccination of infants, children, or adolescents Testing for immunity is advised only for persons whose subsequent clinical management depends on knowledge of their immune status (e g , infants born to HBsAg positive mothers, dialysis patients and staff, and persons with HIV infection) Postvaccination testing should also be considered for persons at occupational risk who may have exposures from injuries with sharp instruments, because knowledge of their antibody response will aid in determining appropriate postexposure prophylaxis When necessary, postvaccination testing should be performed from 1 to 6 months after completion of the vaccine series Testing after immunoprophylaxis of infants born to HBsAg-positive mothers should be performed from 3 to 9 months after the completion of the vaccination series (see section on Postexposure prophylaxis)

Revaccination of nonresponders When persons who do not respond to the primary vaccine series are revaccinated, 15% 25% produce an adequate antibody response after one additional dose and 30%-50% after three additional doses (*48*) Therefore, revaccination with one or more additional doses should be considered for persons who do not respond to vaccination initially

Postexposure prophylaxis

After a person has been exposed to HBV, appropriate immunoprophylactic treatment can effectively prevent infection The mainstay of postexposure immunoprophylaxis is hepatitis B vaccine, but in some settings the addition of HBIG will provide some increase in protection Table 2 provides a guide to recommended treatment for various HBV exposures

Transmission of perinatal HBV infection can be effectively prevented if the HBsAg positive mother is identified and if her infant receives appropriate immunoprophylaxis Hepatitis B vaccination and one dose of HBIG, administered within 24 hours after birth, are 85% 95% effective in preventing both HBV infection and the chronic carrier state (*4,5,8*) Hepatitis B vaccine administered alone in either a three dose or four-dose schedule (Table 1), beginning within 24 hours after birth, is

70% 95% effective in preventing perinatal HBV infections (*8 41*) The infants of women admitted for delivery who have not had prenatal HBsAg testing pose problems in clinical management Initiating hepatitis B vaccination at birth for infants born to these women will provide adequate postexposure prophylaxis if the mothers are indeed HBsAg positive The few infections not prevented by either of these treatment regimens were most likely acquired *in utero* or may be due to very high levels of maternal HBV-DNA (*49*)

Serologic testing of infants who receive immunoprophylaxis to prevent perinatal infection should be considered as an aid in the long term medical management of the few infants who become HBV carriers Testing for anti HBs and HBsAg at 9 15 months of age will determine the success of the therapy and, in the case of failure, will identify HBV carriers or infants who may require revaccination

Recommendations for postexposure prophylaxis in circumstances other than the perinatal period (Table 2) have been addressed in a previous statement and are reprinted as Appendix A to this document

Vaccine Efficacy and Booster Doses

Clinical trials of the hepatitis B vaccines licensed in the United States have shown that they are 80% 95% effective in preventing HBV infection and clinical hepatitis among susceptible children and adults (*5,33,41,50*) If a protective antibody response develops after vaccination, vaccine recipients are virtually 100% protected against clinical illness

The duration of vaccine induced immunity has been evaluated in long term follow up studies of both adults and children (*48,51*) Only the plasma derived hepatitis B vaccine has been evaluated because it has had the longest clinical use, however, on the basis of comparable immunogenicity and short term efficacy, similar

TABLE 2 Guide to postexposure immunoprophylaxis for exposure to hepatitis B virus

Type of exposure	Immunoprophylaxis	Reference
Perinatal	Vaccination + HBIG*	p 11 12
Sexual–acute infection	HBIG ± Vaccination	Appendix
Sexual–chronic carrier	Vaccination	p 12 15
Household contact–chronic carrier	Vaccination	p 12 15
Household contact–acute case	None unless known exposure	Appendix
Household contact–acute case, known exposure	HBIG ± vaccination	Appendix
Infant (< 12 months)–acute case in primary care giver	HBIG + vaccination	Appendix
Inadvertent–percutaneous/permucosal	Vaccination + HBIG	Appendix

*HBIG = Hepatitis B immune globulin

results would be expected with recombinant vaccines The magnitude of the antibody response induced by the primary vaccination series is predictive of antibody persistence, and a logarithmic decline of antibody levels occurs over time Among young adults (homosexual men and Alaskan Eskimos) who initially responded to a three-dose vaccine series, loss of detectable antibody has ranged from 13% to 60% after 9 years of follow up For children vaccinated after the first year of life, the rate of antibody decline has been lower than for adults (*51*) The peak antibody titers for infants are lower than those for children immunized after 12 months of age, but the rate of antibody decline is comparable with that observed for adults in the same population

Long term studies of healthy adults and children indicate that immunologic memory remains intact for at least 9 years and confers protection against chronic HBV infection, even though anti-HBs levels may become low or decline below detectable levels (*48,51,52*) In these studies, the HBV infections were detected by the presence of anti HBc. No episodes of clinical hepatitis were reported and HBsAg was not detected, although brief episodes of viremia may not have been detected because of infrequent testing The mild, inapparent infections among persons who have been previously vaccinated should not produce the sequelae associated with chronic HBV infection and should provide lasting immunity In general, follow-up studies of children vaccinated at birth to prevent perinatal HBV infection have shown that a continued high level of protection from chronic HBV infections persists at least 5 years (*52,53*)

For children and adults whose immune status is normal, booster doses of vaccine are not recommended, nor is serologic testing to assess antibody levels necessary The possible need for booster doses will be assessed as additional information becomes available For hemodialysis patients, vaccine-induced protection may be less complete and may persist only as long as antibody levels are ≥ 10 mIU/mL For these patients, the need for booster doses should be assessed by annual antibody testing, and a booster dose should be administered when antibody levels decline to < 10 mIU/mL

Vaccine Side Effects and Adverse Reactions

Hepatitis B vaccines have been shown to be safe when administered to both adults and children Over 4 million adults have been vaccinated in the United States, and at least that many children have received hepatitis B vaccine worldwide

Vaccine-associated side effects

Pain at the injection site (3%-29%) and a temperature greater than 37 7 C (1%-6%) have been among the most frequently reported side effects among adults and children receiving vaccine (*5,31-33,50*). In placebo-controlled studies, these side effects were reported no more frequently among vaccinees than among persons receiving a placebo (*33,50*) Among children receiving both hepatitis B vaccine and DTP vaccine, these mild side effects have been observed no more frequently than among children receiving DTP vaccine alone.

Serious adverse events

In the United States, surveillance of adverse reactions has shown a possible association between Guillain-Barré syndrome (GBS) and receipt of the first dose of plasma derived hepatitis B vaccine (*54*, CDC unpublished data) GBS was reported at a very low rate (0 5/100,000 vaccinees), no deaths were reported, and all reported cases were among adults An estimated 2 5 million adults received one or more doses of recombinant hepatitis B vaccine during the period 1986 1990 Available data from reporting systems for adverse events do not indicate an association between receipt of recombinant vaccine and GBS (CDC, unpublished data)

Until recently, large-scale hepatitis B vaccination programs for infants (e g , Taiwan, Alaska, and New Zealand) have primarily used plasma-derived hepatitis B vaccine No association has been found between vaccination and the occurrence of severe adverse events, including seizures and GBS (*55*, B McMahon and A Milne, unpublished data) However, systematic surveillance for adverse reactions has been limited in these populations, and only a small number of children have received recombinant vaccine Any presumed risk of adverse events possibly associated with hepatitis B vaccination must be balanced against the expected risk of acute and chronic liver disease associated with the current 5% lifetime risk of HBV infection in the United States It is estimated that, for each U S birth cohort, 2,000 5,000 persons will die from HBV-related liver disease

As hepatitis B vaccine is introduced for routine vaccination of infants, surveillance for vaccine-associated adverse events will continue to be an important part of the program in spite of the current record of safety Any adverse event suspected to be associated with hepatitis B vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS) VAERS forms can be obtained by calling 1-800 822-7967

RECOMMENDATIONS

Prevention of Perinatal Hepatitis B Virus Infection

1 All pregnant women should be routinely tested for HBsAg during an early prenatal visit in each pregnancy, preferably at the same time other routine prenatal laboratory testing is done HBsAg testing should be repeated late in the pregnancy for women who are HBsAg negative but who are at high risk of HBV infection (e g , injecting drug users, those with intercurrent sexually transmitted diseases) or who have had clinically apparent hepatitis Tests for other HBV markers are not necessary for the purpose of maternal screening However, HBsAg positive women identified during screening may have HBV-related liver disease and should be evaluated (*56*)
2 Infants born to mothers who are HBsAg positive should receive the appropriate doses of hepatitis B vaccine (Table 1) and HBIG (0 5 mL) within 12 hours of birth Both should be administered by intramuscular injection Hepatitis B vaccine should be administered concurrently with HBIG but at a different site Subsequent doses of vaccine should be administered according to the recommended schedule (Table 3)
3 Women admitted for delivery who have not had prenatal HBsAg testing should have blood drawn for testing While test results are pending, the infant should receive hepatitis B vaccine within 12 hours of birth, in a dose appropriate for infants born to HBsAg *positive* mothers (Table 1)

a. If the mother is later found to be HBsAg positive, her infant should receive the additional protection of HBIG as soon as possible and within 7 days of birth, although the efficacy of HBIG administered after 48 hours of age is not known (57). If HBIG has not been administered, it is important that the infant receive the second dose of hepatitis B vaccine at 1 month and not later than 2 months of age because of the high risk of infection. The last dose should be administered at age 6 months (Table 3).*

b. If the mother is found to be HBsAg negative, her infant should continue to receive hepatitis B vaccine as part of his or her routine vaccinations (Tables 3 and 4), in the dose appropriate for infants born to HBsAg-*negative* mothers (Table 1).

4. In populations in which screening pregnant women for HBsAg is not feasible, *all* infants should receive their first dose of hepatitis B vaccine within 12 hours of birth, their second dose at 1-2 months of age, and their third dose at 6 months of age as a part of their childhood vaccinations and well-child care (Table 3).

5. Household contacts and sex partners of HBsAg positive women identified through prenatal screening should be vaccinated. The decision to do prevaccination testing of these contacts to determine susceptibility to HBV infection should be made according to the guidelines in the section "Prevaccination testing for

*If a four-dose schedule is used (Tables 1 and 3), the second and third doses should be administered at 1 and 2 months of age, respectively, and the fourth dose at 12-18 months of age.

TABLE 3. Recommended schedule of hepatitis B immunoprophylaxis to prevent perinatal transmission of hepatitis B virus infection

Infant born to mother known to be HBsAg* positive	
Vaccine dose†	***Age of infant***
First	Birth (within 12 hours)
HBIG§	Birth (within 12 hours)
Second	1 month
Third	6 months¶
Infant born to mother not screened for HBsAg	
Vaccine dose**	***Age of infant***
First	Birth (within 12 hours)
HBIG§	If mother is found to be HBsAg positive, administer dose to infant as soon as possible, not later than 1 week after birth
Second	1-2 months††
Third	6 months¶

*HBsAg = Hepatitis B surface antigen.
†See Table 1 for appropriate vaccine dose.
§Hepatitis B immune globulin (HBIG)–0.5 mL administered intramuscularly at a site different from that used for vaccine.
¶If four-dose schedule (Engerix-B) is used, the third dose is administered at 2 months of age and the fourth dose at 12-18 months.
**First dose = dose for infant of HBsAg positive mother (see Table 1). If mother is found to be HBsAg positive, continue that dose; if mother is found to be HBsAg negative, use appropriate dose from Table 1.
††Infants of women who are HBsAg negative can be vaccinated at 2 months of age.

susceptibility." Hepatitis B vaccine should be administered at the age-appropriate dose (Table 1) to those determined to be susceptible or judged likely to be susceptible to infection.

Universal Vaccination of Infants Born to HBsAg-Negative Mothers

1. Hepatitis B vaccination is recommended for all infants, regardless of the HBsAg status of the mother. Hepatitis B vaccine should be incorporated into vaccination schedules for children. The first dose can be administered during the newborn period, preferably before the infant is discharged from the hospital, but no later than when the infant is 2 months of age (Table 4). Because the highest titers of anti-HBs are achieved when the last two doses of vaccine are spaced at least 4 months apart, schedules that achieve this spacing may be preferable (Table 4). However, schedules with 2-month intervals between doses, which conform to schedules for other childhood vaccines, have been shown to produce a good antibody response (Table 4) and may be appropriate in populations in which it is difficult to ensure that infants will be brought back for all their vaccinations. The development of combination vaccines containing HBsAg may lead to other schedules that will allow optimal use of combined antigens.
2. Special efforts should be made to ensure that high levels of hepatitis B vaccination are achieved in populations in which HBV infection occurs at high rates among children (Alaskan Natives, Pacific Islanders, and infants of immigrants from countries in which HBV is endemic).

TABLE 4. Recommended schedules of hepatitis B vaccination for infants born to HBsAg*-negative mothers

Hepatitis B vaccine	Age of infant
Option 1	
Dose 1	Birth–before hospital discharge
Dose 2	1-2 months†
Dose 3	6-18 months†
Option 2	
Dose 1	1-2 months†
Dose 2	4 months†
Dose 3	6-18 months†

*HBsAg = Hepatitis B surface antigen.
†Hepatitis B vaccine can be administered simultaneously with diphtheria-tetanus-pertussis, *Haemophilus influenzae* type b conjugate, measles-mumps-rubella, and oral polio vaccines at the same visit.

Vaccination of Adolescents

All adolescents at high risk of infection because they are injecting drug users or have multiple sex partners (more than one partner/6 months) should receive hepatitis B vaccine. Widespread use of hepatitis B vaccine is encouraged. Because risk factors are often not identified directly among adolescents, universal hepatitis B vaccination of teenagers should be implemented in communities where injecting drug use, pregnancy among teenagers, and/or sexually transmitted diseases are common.

Adolescents can be vaccinated in school based clinics, community health centers, family planning clinics, clinics for the treatment of sexually transmitted diseases, and special adolescent clinics

The 0 , 1-, and 6 month schedule is preferred for vaccinating adolescents with the age appropriate dose of vaccine (Table 1) However, the choice of vaccination schedule should take into account the feasibility of delivering three doses of vaccine over a given period of time The use of alternate schedules (e g , 0, 2, and 4 months) may be advisable to achieve complete vaccination

Vaccination of Selected High-Risk Groups

Efforts to vaccinate persons at high risk of HBV infection should follow the vaccine doses shown in Table 1 High risk groups for whom vaccination is recommended include

1 ***Persons with occupational risk*** HBV infection is an occupational hazard for health care workers and for public safety workers who have exposure to blood in the workplace (*24,58*) The risk of acquiring HBV infections from occupational exposures depends on the frequency of percutaneous and permucosal exposure to blood or blood contaminated body fluids Any health-care or public safety worker may be at risk for HBV exposure, depending on the tasks he or she performs Workers who perform tasks involving contact with blood or blood contaminated body fluid should be vaccinated (*24,58,59*) For public-safety workers whose exposure to blood is infrequent, timely postexposure prophylaxis should be considered rather than routine preexposure vaccination

   For persons in health care fields, vaccination should be completed during training in schools of medicine, dentistry, nursing, laboratory technology, and other allied health professions, before trainees have their first contact with blood

2 ***Clients and staff of institutions for the developmentally disabled*** Susceptible clients in institutions for the developmentally disabled, as well as staff who work closely with clients, should be vaccinated Susceptible clients and staff who live or work in smaller residential settings with known HBV carriers should also receive hepatitis B vaccine Clients discharged from residential institutions into community programs should be screened for HBsAg so that appropriate measures can be taken to prevent HBV transmission These measures should include both environmental controls and appropriate use of vaccine

   Staff of nonresidential day-care programs for the developmentally disabled (e g , schools, sheltered workshops) attended by known HBV carriers have a risk of infection comparable with that of health care workers and therefore should be vaccinated (*60*) The risk of infection for other clients appears to be lower than the risk for staff Vaccination of clients in day care programs may be considered Vaccination of classroom contacts is strongly encouraged if a classmate who is an HBV carrier behaves aggressively or has special medical problems (e g , exudative dermatitis, open skin lesions) that increase the risk of exposure to his or her blood or serous secretions

3 ***Hemodialysis patients*** Hepatitis B vaccination is recommended for susceptible hemodialysis patients Vaccinating patients early in the course of their renal disease is encouraged because patients with uremia who are vaccinated before they require dialysis are more likely to respond to the vaccine (*61*) Although their seroconversion rates and anti HBs titers are lower than those of healthy persons, patients who respond to vaccination will be protected from infection, and the need for frequent serologic testing will be reduced (*62*)

4 ***Recipients of certain blood products*** Patients who receive clotting factor concentrates have an increased risk of HBV infection and should be vaccinated as soon as their specific clotting disorder is identified Prevaccination testing is recommended for patients who have already received multiple infusions of these products

5 ***Household contacts and sex partners of HBV carriers*** All household and sexual contacts of persons identified as HBsAg positive should be vaccinated The decision to do prevaccination testing to determine susceptibility to HBV infection should be made according to the guidelines described earlier in the section "Prevaccination testing for susceptibility " Hepatitis B vaccine should be administered at the age appropriate dose (Table 1) to those determined to be susceptible or judged likely to be susceptible to infection

6 ***Adoptees from countries where HBV infection is endemic*** Adopted or fostered orphans or unaccompanied minors from countries where HBV infection is endemic should be screened for HBsAg (*3*) If the children are HBsAg positive, other family members should be vaccinated (*63*)

7 ***International travelers*** Vaccination should be considered for persons who plan to spend more than 6 months in areas with high rates of HBV infection and who will have close contact with the local population Short term travelers who are likely to have contact with blood (e g , in a medical setting) or sexual contact with residents of areas with high or intermediate levels of endemic disease should be vaccinated Vaccination should begin at least 6 months before travel to allow for completion of the full vaccine series, although a partial series will offer some protection The alternate four dose schedule (see Table 1) should provide protection if the first three doses can be delivered before departure

8 ***Injecting drug users*** All injecting drug users who are susceptible to HBV should be vaccinated as soon as their drug use begins Because of the high rate of HBV infection in this population, prevaccination screening should be considered as outlined in the section "Prevaccination testing for susceptibility " Injecting drug users known to have HIV infection should be tested for anti HBs response after completion of the vaccine series Those who do not respond to vaccination should be counseled accordingly

9 ***Sexually active homosexual and bisexual men*** Susceptible sexually active homosexual and bisexual men should be vaccinated Because of the high rate of HBV infection in this population, prevaccination screening should be considered as described in the section "Prevaccination testing for susceptibility " Men known to have HIV infection should be tested for anti HBs response after completion of the vaccine series Those who do not respond to vaccination should be counseled accordingly

10 ***Sexually active heterosexual men and women*** Vaccination is recommended for men and women who are diagnosed as having recently acquired other sexually transmitted diseases for prostitutes and for persons who have a

history of sexual activity with more than one partner in the previous 6 months (*2*) Most patients seen in clinics for sexually transmitted diseases should be considered candidates for vaccination

11 ***Inmates of long-term correctional facilities*** Prison officials should consider undertaking screening and vaccination programs directed at inmates with histories of high risk behaviors

EVOLVING ISSUES IN HEPATITIS B IMMUNIZATION PROGRAMS

Hepatitis B vaccine has now been used extensively throughout the world and is currently being incorporated into the Expanded Programme on Immunization of the World Health Organization (*16*) New information, vaccines, and technology will have implications for this effort, and adjustments and changes are expected to occur over the years Some of the issues that can be expected to be addressed in clinical and operational studies include the following:

1 In most developing countries with hepatitis B immunization programs, the first dose of vaccine is administered to all infants soon after birth to prevent perinatal infections, pregnant women are not screened for HBsAg, and HBIG is not used (*8,16,45*) The feasibility and effectiveness of incorporating this approach into the hepatitis B prevention strategy for the United States must be evaluated

2 Booster doses of hepatitis B vaccine have not been recommended because of the persistence of protective efficacy 9 years after vaccination (*48,51*) The duration of protective efficacy for adolescents who were vaccinated during infancy or childhood must be evaluated, the results will determine future recommendations concerning booster doses

3 Flexible dosage schedules are required to effectively integrate hepatitis B vaccine into current and future immunization programs for infants Schedules may change as optimum dosage and timing are studied and new information becomes available

4 Multiple-antigen vaccines that incorporate HBsAg as one component are currently being evaluated The routine use of these vaccines may alter child hood vaccination schedules or may result in the administration of additional doses of certain antigens However, these vaccines should greatly facilitate vaccine delivery and minimize the number of injections

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APPENDIX A
Postexposure Prophylaxis for Hepatitis B

Adapted from CDC Protection against viral hepatitis recommendations of the Immunization Practices Advisory Committee (ACIP) *MMWR* 1990,39(No RR 2) 17 22

INTRODUCTION

Prophylactic treatment to prevent infection after exposure to HBV should be considered in the following situations perinatal exposure of an infant born to an HBsAg positive mother, inadvertent percutaneous or permucosal exposure to HBsAg positive blood, sexual exposure to an HBsAg positive person, and household exposure of an infant 12 months of age to a primary care giver who has acute hepatitis B

Various studies have established the relative efficacies of HBIG and/or hepatitis B vaccine in different exposure situations For an infant with perinatal exposure to an HBsAg positive and HBeAg positive mother, a regimen combining one dose of HBIG at birth with the hepatitis B vaccine series started soon after birth is 85% 95% effective in preventing development of the HBV carrier state (*A1 A3*) Regimens involving either multiple doses of HBIG alone or the vaccine series alone have 70% 90% efficacy (*A4,A5*)

For inadvertent perrcutaneous exposure, only regimens including HBIG and/or immune globulin (IG) have been studied A regimen of two doses of HBIG, one given after exposure and one a month later, is about 75% effective in preventing hepatitis B in this setting (*A6,A7*) For sexual exposure to a person with acute hepatitis B, a single dose of HBIG is 75% effective if administered within 2 weeks of last sexual exposure (*A8*) The efficacy of IG for postexposure prophylaxis is uncertain, IG no longer has a role in postexposure prophylaxis of hepatitis B because of the availability of HBIG and the wider use of hepatitis B vaccine

Recommendations on postexposure prophylaxis are based on available efficacy data and on the likelihood of future HBV exposure for the person requiring treatment In all exposures, a regimen combining HBIG with hepatitis B vaccine will provide both short- and long term protection, will be less costly than the two dose HBIG treatment alone, and is the treatment of choice

Acute Exposure to Blood that Contains (or Might Contain) HBsAg

For inadvertent percutaneous (needlestick, laceration, or bite) or permucosal (ocular or mucous membrane) exposure to blood, the decision to provide prophylaxis must include consideration of several factors a) whether the source of the blood is available, b) the HBsAg status of the source, and c) the hepatitis B vaccination and vaccine response status of the exposed person Such exposures usually affect persons for whom hepatitis B vaccine is recommended For any exposure of a person not previously vaccinated, hepatitis B vaccination is recommended

After any such exposure a blood sample should be obtained from the person who was the source of the exposure and should be tested for HBsAg The hepatitis B

vaccination status and anti HBs response status (if known) of the exposed person should be reviewed The outline below and Table A1 summarize prophylaxis for percutaneous or permucosal exposure to blood according to the HBsAg status of the source of exposure and the vaccination status and vaccine response of the exposed person For greatest effectiveness, passive prophylaxis with HBIG, when indicated, should be administered as soon as possible after exposure since its value beyond 7 days after exposure is unclear

1 Source of exposure known and HBsAg positive
  a Exposed person has not been vaccinated or has not completed vaccination Hepatitis B vaccination should be initiated A single dose of HBIG (0 06 mL/kg) should be administered as soon as possible after exposure and within 24 hours, if possible The first dose of hepatitis B vaccine should be administered intramuscularly at a separate site (deltoid for adults) and can be administered simultaneously with HBIG or within 7 days of exposure, subsequent doses should be administered as recommended for the specific vaccine If the exposed person has begun but has not completed vaccination, one dose of HBIG should be administered immediately and vaccination should be completed as sched uled
  b Exposed person has already been vaccinated against hepatitis B, and anti HBs response status is known

TABLE A1 Recommendations for hepatitis B prophylaxis following percutaneous exposure

	Treatment when source is found to be		
Exposed person	**HBsAg positive**	**HBsAg negative**	**Unknown or not tested**
Unvaccinated	Administer HBIG x 1* and initiate hepatitis B vaccine†	Initiate hepatitis B vaccine†	Initiate hepatitis B vaccine†
Previously vaccinated			
Known responder	Test exposed person for anti HBs 1 If adequate, no treatment 2 If inadequate, hepatitis B vaccine booster dose	No treatment	No treatment
Known non responder	HBIG x 2 or HBIG x 1, plus 1 dose of hepatitis B vaccine	No treatment	If known high risk source, may treat as if source were HBsAg positive
Response unknown	Test exposed person for anti HB§ 1 If inadequate HBIG x 1, plus hepatitis B vaccine booster dose 2 If adequate no treatment	No treatment	Test exposed person for anti HBs§ 1 If inadequate, hepatitis B vaccine booster dose 2 If adequate, no treatment

*Hepatitis B immune globulin (HBIG) dose 0 06 mL/kg intramuscularly
†Hepatitis B vaccine dose see Table 1
§Adequate anti HBs is ·10 milli international units

  (1) If the exposed person is known to have had adequate response in the past, the anti HBs level should be tested unless an adequate level has been demonstrated within the last 24 months Although current data show that vaccine induced protection does not decrease as antibody level wanes, most experts consider the following approach to be prudent
    (a) If the anti HBs level is adequate, no treatment is necessary
    (b) If the anti HBs level is inadequate,* a booster dose of hepatitis B vaccine should be administered
  (2) If the exposed person is known not to have responded to the primary vaccine series, he or she should receive either a single dose of HBIG and a dose of hepatitis B vaccine as soon as possible after exposure, or two doses of HBIG (0 06 mL/kg), one as soon as possible after exposure and the second 1 month later The latter treatment is preferred for those who have not responded to at least four doses of vaccine
  c Exposed person has already been vaccinated against hepatitis B, and the anti HBs response is unknown The exposed person should be tested for anti HBs
  (1) If the exposed person has adequate antibody, no additional treatment is necessary
  (2) If the exposed person has inadequate antibody on testing, one dose of HBIG (0 06 mL/kg) should be administered immediately and a standard booster dose of vaccine administered at a different site
2 Source of exposure known and HBsAg-negative
  a Exposed person has not been vaccinated or has not completed vaccination If unvaccinated, the exposed person should be administered the first dose of hepatitis B vaccine within 7 days of exposure, and vaccination should be completed as recommended If the exposed person has not completed vacci nation, vaccination series should be completed as scheduled
  b Exposed person has already been vaccinated against hepatitis B No treatment is necessary
3 Source of exposure unknown or not available for testing
  a Exposed person has not been vaccinated or has not completed vaccination If unvaccinated, the exposed person should be administered the first dose of hepatitis B vaccine within 7 days of exposure and vaccination should be completed as recommended If the exposed person has not completed vacci nation, vaccination should be completed as scheduled
  b Exposed person has already been vaccinated against hepatitis B, and anti HBs response status is known
  (1) If the exposed person is known to have had adequate response in the past, no treatment is necessary
  (2) If the exposed person is known not to have responded to the vaccine, prophylaxis as described earlier in section 1 b (2) under "Source of exposure known and HBsAg-positive" may be considered if the source of the exposure is known to be at high risk of HBV infection
  c Exposed person has already been vaccinated against hepatitis B, and the anti HBs response is unknown The exposed person should be tested for anti HBs

*An adequate antibody level is 10 mIU/mL

(1) If the exposed person has adequate anti HBs, no treatment is necessary
(2) If the exposed person has inadequate anti HBs, a standard booster dose of vaccine should be administered

Sex Partners of Persons with Acute Hepatitis B Virus Infection

Sex partners of HBsAg positive persons are at increased risk of acquiring HBV infection, and HBIG has been shown to be 75% effective in preventing such infections (*A8*) Because data are limited, the period after sexual exposure during which HBIG is effective is unknown, but extrapolation from other settings makes it unlikely that this period would exceed 14 days Before treatment, testing sex partners for susceptibility is recommended if it does not delay treatment beyond 14 days after last exposure Testing for anti-HBc is the most efficient prescreening procedure to use in this population

All susceptible persons whose sex partners have acute hepatitis B infection should receive a single dose of HBIG (0 06 mL/kg) and should begin the hepatitis B vaccine series if prophylaxis can be started within 14 days of the last sexual contact or if sexual contact with the infected person will continue Administering the vaccine with HBIG may improve the efficacy of postexposure treatment The vaccine has the added advantage of conferring long lasting protection

An alternate treatment for persons who are not from a high risk group for whom vaccine is routinely recommended and whose regular sex partners have acute HBV infection is to administer one dose of HBIG (without vaccine) and retest the sex partner for HBsAg 3 months later No further treatment is necessary if the sex partner becomes HBsAg negative If the sex partner remains HBsAg positive, a second dose of HBIG should be given and the hepatitis B vaccine series started

Household Contacts of Persons with Acute Hepatitis B Virus Infection

Since infants have close contact with primary care givers and they have a higher risk of becoming HBV carriers after acute HBV infection, prophylaxis of an infant less than 12 months of age with HBIG (0 5 mL) and hepatitis B vaccine is indicated if the mother or primary care giver has acute HBV infection Prophylaxis for other household contacts of persons with acute HBV infection is not indicated unless they have had identifiable blood exposure to the index patient, such as by sharing toothbrushes or razors Such exposures should be treated like sexual exposures If the index patient becomes an HBV carrier, all household contacts should receive hepatitis B vaccine

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APPENDIX E

APPENDIX E

OPTIONAL POST-EXPOSURE TESTING FOR HUMAN IMMUNODEFICIENCY VIRUS (HIV): INFORMATION AND CONSENT/DECLINATION FORMS

APPENDIX E

OPTIONAL POST-EXPOSURE TESTING FOR HUMAN IMMUNODEFICIENCY VIRUS (HIV): INFORMATION AND CONSENT/DECLINATION FORMS

A. BACKGROUND INFORMATION ON HIV (AIDS) INFECTIONS

Following job related exposure, the NEIC may be required to offer HIV antibody testing without cost to a federal employee. The blood test for antibodies against the HIV determines if someone has had exposure to this virus. A positive test (one that shows the presence of antibodies) does not necessarily mean that you now have or will develop Acquired Immunodeficiency Syndrome (AIDS). A positive test does mean that you should have further medical evaluation by your physician or usual source of medical care. A positive test also means that you may spread the virus by intimate sexual contact or by exposure to infected blood or other body fluids. Individuals who have a positive test must never be blood donors and should seek information from their usual source of medical care on ways to avoid spreading the virus. The virus can also be spread by an infected mother to her developing child.

There is presently no permanently effective treatment for AIDS and the disease has thus far been uniformly fatal.

The populations which have experienced the highest prevalence of AIDS in the United States include homosexual and bisexual men, people who use intravenous drugs, hemophiliacs, and people who received blood transfusions subsequent to 1977 and prior to the adoption of proper HIV antibody testing of donor blood in 1985. It is unsafe sex and abuse of illegal drugs which have been identified as the major risk factors which place individuals at greatest risk to AIDS through exposure to infected blood and/or other body fluids.

Appendix E: Optional Post-Exposure Testing for Human Immunodeficiency Virus (HIV): Information and Consent Declination Forms

B. PROCEDURES FOR VOLUNTARY HIV ANTIBODY SCREENING

If the source patient has AIDS, is positive for HIV antibody, or refuses the test, an employee or contractor will be counseled regarding the risk of infection and evaluated clinically and serologically for evidence of HIV infection as soon as possible after the exposure.

Testing will be done:
_____ immediately after exposure,
_____ 6 weeks after exposure,
_____ 12 weeks after exposure, and
_____ 6 months after exposure.
_____ Counselling must be done both before and after HIV testing.

All testing for HIV following blood exposure is strictly voluntary.

Results will be confidential and will be given only to the employee, in person. Due to the extremely sensitive nature of these test results, and to insure absolute confidentiality,these results will only be presented in person and will not be provided over the phone or by mail.

A copy of the results will be stored in a confidential medical file at the clinical facility.

It is important for you to be acquainted with the above information before you consider having your blood drawn for this test.

C. STATEMENT OF CONSENT FOR HIV ANTIBODY SCREENING

I have read and understand the information on voluntary post-exposure HIV anti-body screening. I have also had an opportunity to ask any questions I may have concerning this screening. I consent to have the blood test for antibodies to the HIV virus, which will be paid for by my employer. I understand that a screening test will be performed first. If this test result is positive, the screening test will be repeated on the same specimen. If the repeat test is positive, a more specific test will be performed on the same specimen. My results will be reported to me in person. Individual test results will be kept confidential in my medical record.

_____ _____

Signed Date

_____

Social Security Number

_____ _____

Witness Date

D. DECLINATION OF HIV ANTIBODY SCREENING

I have decided not to have the HIV blood screening at this time but understand that my blood will be stored for 90 days in the event that I change my mind and later consent to the test.

_____ _____

Signed Date

_____

Social Security Number

_____ _____

Witness Date

APPENDIX F

APPENDIX F

Reference Information on HIV Infections from MMWR

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MORBIDITY AND MORTALITY WEEKLY REPORT

Recommendations and Reports

Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers

U S Department of Health and Human Services
Public Health Service
Centers for Disease Control
National Institute for Occupational Safety and Health
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NOTICE

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Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers

A Response to P.L. 100-607
The Health Omnibus Programs Extension
Act of 1988

U.S. Department of Health and Human Services
Public Health Service
Centers for Disease Control
Atlanta, Georgia

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Guidelines for Prevention of Transmission of Human Immunodeficiency Virus and Hepatitis B Virus to Health-Care and Public-Safety Workers

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I. Introduction

A. Background

This document is a response to recently enacted legislation, Public Law 100 607, The Health Omnibus Programs Extension Act of 1988, Title II, Programs with Respect to Acquired Immune Deficiency Syndrome ("AIDS Amendments of 1988") Subtitle E, General Provisions, Section 253(a) of Title II specifies that "the Secretary of Health and Human Services, acting through the Director of the Centers for Disease Control, shall develop, issue, and disseminate guidelines to all health workers, public safety workers (including emergency response employees) in the United States concerning –

(1) methods to reduce the risk in the workplace of becoming infected with the etiologic agent for acquired immune deficiency syndrome; and

(2) circumstances under which exposure to such etiologic agent may occur."

It is further noted that "The Secretary [of Health and Human Services] shall transmit the guidelines issued under subsection (a) to the Secretary of Labor for use by the Secretary of Labor in the development of standards to be issued under the Occupational Safety and Health Act of 1970," and that "the Secretary, acting through the Director of the Centers for Disease Control, shall develop a model curriculum for emergency response employees with respect to the prevention of exposure to the etiologic agent for acquired immune deficiency syndrome during the process of responding to emergencies "

Following development of these guidelines and curriculum, "[t]he Secretary shall –

(A) transmit to State public health officers copies of the guidelines and the model curriculum developed under paragraph (1) with the request that such officers disseminate such copies as appropriate throughout the State; and

(B) make such copies available to the public."

B. Purpose and Organization of Document

The purpose of this document is to provide an overview of the modes of transmission of human immunodeficiency virus (HIV) in the workplace, an assessment of the risk of transmission under various assumptions, principles underlying the control of risk, and specific risk-control recommendations for employers and workers This document also includes information on medical management of persons who have sustained an exposure at the workplace to these viruses (e g , an emergency medical technicians who incur a needle stick injury while performing professional duties). These guidelines are intended

for use by a technically informed audience. As noted above, a separate model curriculum based on the principles and practices discussed in this document is being developed for use in training workers and will contain less technical wording

Information concerning the protection of workers against acquisition of the human immunodeficiency virus (HIV) while performing job duties, the virus that causes AIDS, is presented here. Information on hepatitis B virus (HBV) is also presented in this document on the basis of the following assumptions:

- the modes of transmission for hepatitis B virus (HBV) are similar to those of HIV,
- the potential for HBV transmission in the occupational setting is greater than for HIV,
- there is a larger body of experience relating to controlling transmission of HBV in the workplace, and
- general practices to prevent the transmission of HBV will also minimize the risk of transmission of HIV

Blood borne transmission of other pathogens not specifically addressed here will be interrupted by adherence to the precautions noted below It is important to note that the implementation of control measures for HIV and HBV does not obviate the need for continued adherence to general infection-control principles and general hygiene measures (e g , hand washing) for preventing transmission of other infectious diseases to both worker and client. General guidelines for control of these diseases have been published (*1,2,3*).

This document was developed primarily to provide guidelines for fire-service personnel, emergency medical technicians, paramedics (see section IV, page 19), and law enforcement and correctional facility personnel (see section V, page 22) Throughout the report, paramedics and emergency medical technicians are called "emergency medical workers" and fire-service, law enforcement, and correctional facility personnel, "public safety workers " Previously issued guidelines address the needs of hospital , laboratory , and clinic based health-care workers (*4,5*) A condensation of general guidelines for protection of workers from transmission of blood-borne pathogens, derived from the Joint Advisory Notice of the Departments of Labor and Health and Human Services (*6*), is provided in section III (see page 11).

C. Modes and Risk of Virus Transmission in the Workplace

Although the potential for HBV transmission in the workplace setting is greater than for HIV, the modes of transmission for these two viruses are similar. Both have been transmitted in occupational settings only by percutaneous inoculation or contact with an open

wound, nonintact (e g , chapped, abraded, weeping, or dermatitic) skin, or mucous membranes to blood, blood contaminated body fluids, or concentrated virus Blood is the single most important source of HIV and HBV in the workplace setting. Protection measures against HIV and HBV for workers should focus primarily on preventing these types of exposures to blood as well as on delivery of HBV vaccination.

The risk of hepatitis B infection following a parenteral (i e , needle stick or cut) exposure to blood is directly proportional to the probability that the blood contains hepatitis B surface antigen (HBsAg), the immunity status of the recipient, and on the efficiency of transmission (*7*). The probability of the source of the blood being HBsAg positive varies from 1 to 3 per thousand in the general population to 5%–15% in groups at high risk for HBV infection, such as immigrants from areas of high endemicity (China and Southeast Asia, sub Saharan Africa, most Pacific islands, and the Amazon Basin); clients in institutions for the mentally retarded; intravenous drug users, homosexually active males, and household (sexual and non sexual) contacts of HBV carriers Of persons who have not had prior hepatitis B vaccination or postexposure prophylaxis, 6%–30% of persons who receive a needle stick exposure from an HBsAg-positive individual will become infected (*7*)

The risk of infection with HIV following one needle stick exposure to blood from a patient known to be infected with HIV is approximately 0 5% (*4,5*) This rate of transmission is considerably lower than that for HBV, probably as a result of the significantly lower concentrations of virus in the blood of HIV infected persons Table 1 (see page 31) presents theoretical data concerning the likelihood of infection given repeated needlestick injuries involving patients whose HIV serostatus is unknown Though inadequately quantified, the risk from exposure of nonintact skin or mucous membranes is likely to be far less than that from percutaneous inoculation.

D. Transmission of Hepatitis B Virus to Workers

1. Health-care workers

In 1987, the CDC estimated the total number of HBV infections in the United States to be 300,000 per year, with approximately 75,000 (25%) of infected persons developing acute hepatitis Of these infected individuals, 18,000–30,000 (6%–10%) will become HBV carriers, at risk of developing chronic liver disease (chronic active hepatitis, cirrhosis, and primary liver cancer), and infectious to others

CDC has estimated that 12,000 health care workers whose jobs entail exposure to blood become infected with HBV each year, that 500–600 of them are hospitalized as a result of that infection, and that 700–1,200 of those infected become HBV carriers Of the infected workers, approximately 250 will die (12–15 from fulminant hepatitis, 170–200 from cirrhosis, and 40–50 from liver cancer) Studies indicate that

10%–30% of health care or dental workers show serologic evidence of past or present HBV infection.

2. Emergency medical and public-safety workers

Emergency medical workers have an increased risk for hepatitis B infection (*8,9,10*). The degree of risk correlates with the frequency and extent of blood exposure during the conduct of work activities. A few studies are available concerning risk of HBV infection for other groups of public-safety workers (law-enforcement personnel and correctional facility workers), but reports that have been published do not document any increased risk for HBV infection (*11,12,13*). Nevertheless, in occupational settings in which workers may be routinely exposed to blood or other body fluids as described below, an increased risk for occupational acquisition of HBV infection must be assumed to be present.

3. Vaccination for hepatitis B virus

A safe and effective vaccine to prevent hepatitis B has been available since 1982. Vaccination has been recommended for health care workers regularly exposed to blood and other body fluids potentially contaminated with HBV (*7,14,15*). In 1987, the Department of Health and Human Services and the Department of Labor stated that hepatitis B vaccine should be provided to all such workers at no charge to the worker (*6*).

Available vaccines stimulate active immunity against HBV infection and provide over 90% protection against hepatitis B for 7 or more years following vaccination (*7*). Hepatitis B vaccines also are 70–88% effective when given within 1 week after HBV exposure. Hepatitis B immune globulin (HBIG), a preparation of immunoglobulin with high levels of antibody to HBV (anti-HBs), provides temporary passive protection following exposure to HBV. Combination treatment with hepatitis B vaccine and HBIG is over 90% effective in preventing hepatitis B following a documented exposure (*7*).

E. Transmission of Human Immunodeficiency Virus to Workers

1. Health-care workers with AIDS

As of September 19, 1988, a total of 3,182 (5.1%) of 61,929 adults with AIDS, who had been reported to the CDC national surveillance system and for whom occupational information was available, reported being employed in a health care setting. Of the health-care workers with AIDS, 95% reported high-risk behavior; for the remaining 5% (169 workers), the means of HIV acquisition was undetermined.

Of these 169 health care workers with AIDS with undetermined risk, information is

incomplete for 28 (17%) because of death or refusal to be interviewed; 97 (57%) are still being investigated. The remaining 44 (26%) health care workers were interviewed directly or had other follow-up information available. The occupations of these 44 were nine nursing assistants (20%); eight physicians (18%), four of whom were surgeons; eight housekeeping or maintenance workers (18%); six nurses (14%); four clinical laboratory technicians (9%); two respiratory therapists (5%); one dentist (2%); one paramedic (2%); one embalmer (2%); and four others who did not have contact with patients (9%). Eighteen of these 44 health care workers reported parenteral and/or other non-needle-stick exposure to blood or other body fluids from patients in the 10 years preceding their diagnosis of AIDS. None of these exposures involved a patient with AIDS or known HIV infection, and HIV seroconversion of the health care worker was not documented following a specific exposure.

2. Human immunodeficiency virus transmission in the workplace

As of July 31, 1988, 1,201 health-care workers had been enrolled and tested for HIV antibody in ongoing CDC surveillance of health-care workers exposed via needlestick or splashes to skin or mucous membranes to blood from patients known to be HIV-infected (*16*). Of 860 workers who had received needle-stick injuries or cuts with sharp objects (i.e., parenteral exposures) and whose serum had been tested for HIV antibody at least 180 days after exposure, 4 were positive, yielding a seroprevalence rate of 0.47%. Three of these individuals experienced an acute retroviral syndrome associated with documented seroconversion. Investigation revealed no nonoccupational risk factors for these three workers. Serum collected within 30 days of exposure was not available from the fourth person. This worker had an HIV-seropositive sexual partner, and heterosexual acquisition of infection cannot be excluded. None of the 103 workers who had contamination of mucous membranes or nonintact skin and whose serum had been tested at least 180 days after exposure developed serologic evidence of HIV infection.

Two other ongoing prospective studies assess the risk of nosocomial acquisition of HIV infection among health-care workers in the United States. As of April 1988, the National Institutes of Health had tested 983 health care workers, 137 with documented needle-stick injuries and 345 health-care workers who had sustained mucous-membrane exposures to blood or other body fluids of HIV-infected patients; none had seroconverted (*17*) (one health care worker who subsequently experienced an occupational HIV seroconversion has since been reported from NIH [*18*]). As of March 15, 1988, a similar study at the University of California of 212 health care workers with 625 documented accidental parenteral exposures involving HIV-infected patients had identified one seroconversion following a needle stick (*19*). Prospective studies in the United Kingdom and Canada show no evidence of HIV

transmission among 220 health care workers with parenteral, mucous membrane, or cutaneous exposures (*20,21*).

In addition to the health-care workers enrolled in these longitudinal surveillance studies, case histories have been published in the scientific literature for 19 HIV-infected health-care workers (13 with documented seroconversion and 6 without documented seroconversion). None of these workers reported nonoccupational risk factors (see Table 2, pages 32, 33).

3. Emergency medical service and public safety workers

In addition to the one paramedic with undetermined risk discussed above, three public-safety workers (law-enforcement officers) are classified in the undetermined risk group. Follow-up investigations of these workers could not determine conclusively if HIV infection was acquired during the performance of job duties.

II. Principles of Infection Control and Their Application to Emergency and Public-Safety Workers

A. General Infection Control

Within the health care setting, general infection control procedures have been developed to minimize the risk of patient acquisition of infection from contact with contaminated devices, objects, or surfaces or of transmission of an infectious agent from health care workers to patients (*1,2,3*). Such procedures also protect workers from the risk of becoming infected. General infection-control procedures are designed to prevent transmission of a wide range of microbiological agents and to provide a wide margin of safety in the varied situations encountered in the health-care environment.

General infection-control principles are applicable to other work environments where workers contact other individuals and where transmission of infectious agents may occur. The modes of transmission noted in the hospital and medical office environment are observed in the work situations of emergency and public safety workers, as well. Therefore, the principles of infection control developed for hospital and other health-care settings are also applicable to these work situations. Use of general infection control measures, as adapted to the work environments of emergency and public safety workers, is important to protect both workers and individuals with whom they work from a variety of infectious agents, not just HIV and HBV.

Because emergency and public-safety workers work in environments that provide inherently unpredictable risks of exposures, general infection-control procedures should be adapted to these work situations. Exposures are unpredictable, and protective measures may often be used in situations that do not appear to present risk. Emergency and public safety workers perform their duties in the community under extremely variable conditions; thus, control measures that are simple and uniform across all situations have the greatest likelihood of worker compliance. Administrative procedures to ensure compliance also can be more readily developed than when procedures are complex and highly variable.

B. Universal Blood and Body Fluid Precautions to Prevent Occupational HIV and HBV Transmission

In 1985, CDC developed the strategy of "universal blood and body fluid precautions" to address concerns regarding transmission of HIV in the health care setting (*4*). The concept, now referred to simply as "universal precautions" stresses that all patients should be assumed to be infectious for HIV and other blood-borne pathogens. In the hospital and other health care setting, "universal precautions" should be followed when workers are exposed to blood, certain other body fluids (amniotic fluid, pericardial fluid, peritoneal fluid, pleural fluid, synovial fluid, cerebrospinal fluid, semen, and vaginal secretions), or any body fluid visibly contaminated with blood. Since HIV and HBV

transmission has not been documented from exposure to other body fluids (feces, nasal secretions, sputum, sweat, tears, urine, and vomitus), "universal precautions" do not apply to these fluids. Universal precautions also do not apply to saliva, except in the dental setting, where saliva is likely to be contaminated with blood (7).

For the purpose of this document, human "exposure" is defined as contact with blood or other body fluids to which universal precautions apply through percutaneous inoculation or contact with an open wound, nonintact skin, or mucous membrane during the performance of normal job duties. An "exposed worker" is defined, for the purposes of this document, as an individual exposed, as described above, while performing normal job duties.

The unpredictable and emergent nature of exposures encountered by emergency and public safety workers may make differentiation between hazardous body fluids and those which are not hazardous very difficult and often impossible. For example, poor lighting may limit the worker's ability to detect visible blood in vomitus or feces. Therefore, when emergency medical and public-safety workers encounter body fluids under uncontrolled, emergency circumstances in which differentiation between fluid types is difficult, if not impossible, they should treat all body fluids as potentially hazardous.

The application of the principles of universal precautions to the situations encountered by these workers results in the development of guidelines (listed below) for work practices, use of personal protective equipment, and other protective measures. To minimize the risks of acquiring HIV and HBV during performance of job duties, emergency and public-safety workers should be protected from exposure to blood and other body fluids as circumstances dictate. Protection can be achieved through adherence to work practices designed to minimize or eliminate exposure and through use of personal protective equipment (i.e., gloves, masks, and protective clothing), which provide a barrier between the worker and the exposure source. In some situations, redesign of selected aspects of the job through equipment modifications or environmental control can further reduce risk. These approaches to primary prevention should be used together to achieve maximal reduction of the risk of exposure.

If exposure of an individual worker occurs, medical management, consisting of collection of pertinent medical and occupational history, provision of treatment, and counseling regarding future work and personal behaviors, may reduce risk of developing disease as a result of the exposure episode (22). Following episodic (or continuous) exposure, decontamination and disinfection of the work environment, devices, equipment, and clothing or other forms of personal protective equipment can reduce subsequent risk of exposures. Proper disposal of contaminated waste has similar benefits.

III. Employer Responsibilities

A. General

Detailed recommendations for employer responsibilities in protecting workers from acquisition of blood borne diseases in the workplace have been published in the Department of Labor and Department of Health and Human Services Joint Advisory Notice and are summarized here (6). In developing programs to protect workers, employers should follow a series of steps: 1) classification of work activity, 2) development of standard operating procedures, 3) provision of training and education, 4) development of procedures to ensure and monitor compliance, and 5) workplace redesign. As a first step, every employer should classify work activities into one of three categories of potential exposure (see Table 3, page 34). Employers should make protective equipment available to all workers when they are engaged in Category I or II activities. Employers should ensure that the appropriate protective equipment is used by workers when they perform Category I activities.

As a second step, employers should establish a detailed work practices program that includes standard operating procedures (SOPs) for all activities having the potential for exposure. Once these SOPs are developed, an initial and periodic worker education program to assure familiarity with work practices should be provided to potentially exposed workers. No worker should engage in such tasks or activities before receiving training pertaining to the SOPs, work practices, and protective equipment required for that task. Examples of personal protective equipment for the prehospital setting (defined as a setting where delivery of emergency health care takes place away from a hospital or other health care setting) are provided in Table 4 (page 35). (A curriculum for such training programs is being developed in conjunction with these guidelines and should be consulted for further information concerning such training programs.)

To facilitate and monitor compliance with SOPs, administrative procedures should be developed and records kept as described in the Joint Advisory Notice (6). Employers should monitor the workplace to ensure that required work practices are observed and that protective clothing and equipment are provided and properly used. The employer should maintain records documenting the administrative procedures used to classify job activities and copies of all SOPs for tasks or activities involving predictable or unpredictable exposure to blood or other body fluids to which universal precautions apply. In addition, training records, indicating the dates of training sessions, the content of those training sessions along with the names of all persons conducting the training, and the names of all those receiving training should also be maintained.

Whenever possible, the employer should identify devices and other approaches to modifying the work environment which will reduce exposure risk. Such approaches are desirable, since they don't require individual worker action or management activity. For example, jails and correctional facilities should have classification procedures that require

the segregation of offenders who indicate through their actions or words that they intend to attack correctional facility staff with the intent of transmitting HIV or HBV

B Medical

In addition to the general responsibilities noted above, the employer has the specific responsibility to make available to the worker a program of medical management. This program is designed to provide for the reduction of risk of infection by HBV and for counseling workers concerning issues regarding HIV and HBV. These services should be provided by a licensed health professional. All phases of medical management and counseling should ensure that the confidentiality of the worker's and client's medical data is protected.

1. Hepatitis B vaccination

All workers whose jobs involve participation in tasks or activities with exposure to blood or other body fluids to which universal precautions apply (as defined above on page 9) should be vaccinated with hepatitis B vaccine.

2. Management of percutaneous exposure to blood and other infectious body fluids

Once an exposure has occurred (as defined above on page 10), a blood sample should be drawn after consent is obtained from the individual from whom exposure occurred and tested for hepatitis B surface antigen (HBsAg) and antibody to human immunodeficiency virus (HIV antibody). Local laws regarding consent for testing source individuals should be followed. Policies should be available for testing source individuals in situations where consent cannot be obtained (e.g., an unconscious patient). Testing of the source individual should be done at a location where appropriate pretest counseling is available; posttest counseling and referral for treatment should be provided. It is extremely important that all individuals who seek consultation for any HIV-related concerns receive counseling as outlined in the "Public Health Service Guidelines for Counseling and Antibody Testing to Prevent HIV Infection and AIDS" (*22*).

a. Hepatitis B virus posterposure management

For an exposure to a source individual found to be positive for HBsAg, the worker who has not previously been given hepatitis B vaccine should receive the vaccine series. A single dose of hepatitis B immune globulin (HBIG) is also recommended, if this can be given within 7 days of exposure. For exposures from an HBsAg positive source to workers who have previously received vaccine, the exposed worker should be tested for antibody to hepatitis B surface antigen (anti-HBs), and given one dose of vaccine and one dose of HBIG if the antibody level in the worker's blood sample is inadequate (i.e., < 10 SRU by RIA, negative by EIA) (*7*).

If the source individual is negative for HBsAg and the worker has not been vaccinated, this opportunity should be taken to provide hepatitis B vaccination.

If the source individual refuses testing or he/she cannot be identified, the unvaccinated worker should receive the hepatitis B vaccine series. HBIG administration should be considered on an individual basis when the source individual is known or suspected to be at high risk of HBV infection. Management and treatment, if any, of previously vaccinated workers who receive an exposure from a source who refuses testing or is not identifiable should be individualized (*7*).

b Human immunodeficiency virus posterposure management

For any exposure to a source individual who has AIDS, who is found to be positive for HIV infection (*4*), or who refuses testing, the worker should be counseled regarding the risk of infection and evaluated clinically and serologically for evidence of HIV infection as soon as possible after the exposure. In view of the evolving nature of HIV posterposure management, the health-care provider should be well informed of current PHS guidelines on this subject. The worker should be advised to report and seek medical evaluation for any acute febrile illness that occurs within 12 weeks after the exposure. Such an illness, particularly one characterized by fever, rash, or lymphadenopathy, may be indicative of recent HIV infection. Following the initial test at the time of exposure, seronegative workers should be retested 6 weeks, 12 weeks, and 6 months after exposure to determine whether transmission has occurred. During this follow-up period (especially the first 6-12 weeks after exposure, when most infected persons are expected to seroconvert), exposed workers should follow U.S. Public Health Service (PHS) recommendations for preventing transmission of HIV (*22*). These include refraining from blood donation and using appropriate protection during sexual intercourse (*23*). During all phases of follow-up, it is vital that worker confidentiality be protected.

If the source individual was tested and found to be seronegative, baseline testing of the exposed worker with follow-up testing 12 weeks later may be performed if desired by the worker or recommended by the health care provider.

If the source individual cannot be identified, decisions regarding appropriate follow up should be individualized Serologic testing should be made available by the employer to all workers who may be concerned they have been infected with HIV through an occupational exposure as defined above (see page 10)

3 Management of human bites

On occasion, police and correctional facility officers are intentionally bitten by suspects or prisoners When such bites occur, routine medical and surgical therapy (including an assessment of tetanus vaccination status) should be implemented as soon as possible, since such bites frequently result in infection with organisms other than HIV and HBV. Victims of bites should be evaluated as described above (see page 12) for exposure to blood or other infectious body fluids.

Saliva of some persons infected with HBV has been shown to contain HBV-DNA at concentrations 1/1,000 to 1/10,000 of that found in the infected person's serum (*5,24*) HbsAg positive saliva has been shown to be infectious when injected into experimental animals and in human bite exposures (*25–27*) However, HBsAg-positive saliva has not been shown to be infectious when applied to oral mucous membranes in experimental primate studies (*27*) or through contamination of musical instruments or cardiopulmonary resuscitation dummies used by HBV carriers (*28,29*). Epidemiologic studies of nonsexual household contacts of HIV-infected patients, including several small series in which HIV transmission failed to occur after bites or after percutaneous inoculation or contamination of cuts and open wounds with saliva from HIV-infected patients, suggest that the potential for salivary transmission of HIV is remote (*5,30–33*). One case report from Germany has suggested the possibility of transmission of HIV in a household setting from an infected child to a sibling through a human bite (*34*). The bite did not break the skin or result in bleeding. Since the date of seroconversion to HIV was not known for either child in this case, evidence for the role of saliva in the transmission of virus is unclear (*34*))

4 Documentation of exposure and reporting

As part of the confidential medical record, the circumstances of exposure should be recorded Relevant information includes the activity in which the worker was engaged at the time of exposure, the extent to which appropriate work practices and protective equipment were used, and a description of the source of exposure.

Employers have a responsibility under various federal and state laws and regulations to report occupational illnesses and injuries Existing programs in the National Institute for Occupational Safety and Health (NIOSH), Department of Health and Human Services, the Bureau of Labor Statistics, Department of Labor (DOL); and the Occupational Safety and Health Administration (DOL.) receive such information

for the purposes of surveillance and other objectives. Cases of infectious disease, including AIDS and HBV infection, are reported to the Centers for Disease Control through State health departments.

5 Management of HBV- or HIV-infected workers

Transmission of HBV from health-care workers to patients has been documented. Such transmission has occurred during certain types of invasive procedures (e.g , oral and gynecologic surgery) in which health-care workers, when tested, had very high concentrations of HBV in their blood (at least 100 million infectious virus particles per milliliter, a concentration much higher than occurs with HIV infection), and the health care workers sustained a puncture wound while performing invasive procedures or had exudative or weeping lesions or microlacerations that allowed virus to contaminate instruments or open wounds of patients (*35,36*) A worker who is HBsAg positive and who has transmitted hepatitis B virus to another individual during the performance of his or her job duties should be excluded from the performance of those job duties which place other individuals at risk for acquisition of hepatitis B infection.

Workers with impaired immune systems resulting from HIV infection or other causes are at increased risk of acquiring or experiencing serious complications of infectious disease. Of particular concern is the risk of severe infection following exposure to other persons with infectious diseases that are easily transmitted if appropriate precautions are not taken (e g , measles, varicella). Any worker with an impaired immune system should be counseled about the potential risk associated with providing health care to persons with any transmissible infection and should continue to follow existing recommendations for infection control to minimize risk of exposure to other infectious agents (*2,3*) Recommendations of the Immunization Practices Advisory Committee (ACIP) and institutional policies concerning requirements for vaccinating workers with live-virus vaccines (e.g., measles, rubella) should also be considered

The question of whether workers infected with HIV can adequately and safely be allowed to perform patient-care duties or whether their work assignments should be changed must be determined on an individual basis. These decisions should be made by the worker's personal physician(s) in conjunction with the employer's medical advisors.

C Disinfection, Decontamination, and Disposal

As described in Section I C. (see page 4), the only documented occupational risks of HIV and HBV infection are associated with parenteral (including open wound) and mucous membrane exposure to blood and other potentially infectious body fluids Nevertheless, the precautions described below should be routinely followed.

1. Needle and sharps disposal

All workers should take precautions to prevent injuries caused by needles, scalpel blades, and other sharp instruments or devices during procedures; when cleaning used instruments, during disposal of used needles; and when handling sharp instruments after procedures To prevent needle stick injuries, needles should not be recapped, purposely bent or broken by hand, removed from disposable syringes, or otherwise manipulated by hand. After they are used, disposable syringes and needles, scalpel blades, and other sharp items should be placed in puncture-resistant containers for disposal; the puncture-resistant containers should be located as close as practical to the use area (e g., in the ambulance or, if sharps are carried to the scene of victim assistance from the ambulance, a small puncture-resistant container should be carried to the scene, as well). Reusable needles should be left on the syringe body and should be placed in a puncture-resistant container for transport to the reprocessing area.

2. Hand washing

Hands and other skin surfaces should be washed immediately and thoroughly if contaminated with blood, other body fluids to which universal precautions apply, or potentially contaminated articles Hands should always be washed after gloves are removed, even if the gloves appear to be intact. Hand washing should be completed using the appropriate facilities, such as utility or restroom sinks Waterless antiseptic hand cleanser should be provided on responding units to use when hand washing facilities are not available. When hand washing facilities are available, wash hands with warm water and soap. When hand-washing facilities are not available, use a waterless antiseptic hand cleanser. The manufacturer's recommendations for the product should be followed.

3. Cleaning, disinfecting, and sterilizing

Table 5 (see pages 36, 37) presents the methods and applications for cleaning, disinfecting, and sterilizing equipment and surfaces in the prehospital setting These methods also apply to housekeeping and other cleaning tasks Previously issued guidelines for health-care workers contain more detailed descriptions (4).

4. Cleaning and decontaminating spills of blood

All spills of blood and blood-contaminated fluids should be promptly cleaned up using an EPA-approved germicide or a 1:100 solution of household bleach in the following manner while wearing gloves Visible material should first be removed with disposable towels or other appropriate means that will ensure against direct contact with blood. If splashing is anticipated, protective eyewear should be worn along with an impervious gown or apron which provides an effective barrier to splashes The

area should then be decontaminated with an appropriate germicide Hands should be washed following removal of gloves. Soiled cleaning equipment should be cleaned and decontaminated or placed in an appropriate container and disposed of according to agency policy Plastic bags should be available for removal of contaminated items from the site of the spill

Shoes and boots can become contaminated with blood in certain instances Where there is massive blood contamination on floors, the use of disposable impervious shoe coverings should be considered. Protective gloves should be worn to remove contaminated shoe coverings The coverings and gloves should be disposed of in plastic bags A plastic bag should be included in the crime scene kit or the car which is to be used for the disposal of contaminated items. Extra plastic bags should be stored in the police cruiser or emergency vehicle.

5. Laundry

Although soiled linen may be contaminated with pathogenic microorganisms, the risk of actual disease transmission is negligible. Rather than rigid procedures and specifications, hygienic storage and processing of clean and soiled linen are recommended. Laundry facilities and/or services should be made routinely available by the employer Soiled linen should be handled as little as possible and with minimum agitation to prevent gross microbial contamination of the air and of persons handling the linen All soiled linen should be bagged at the location where it was used Linen soiled with blood should be placed and transported in bags that prevent leakage Normal laundry cycles should be used according to the washer and detergent manufacturers' recommendations.

6. Decontamination and laundering of protective clothing

Protective work clothing contaminated with blood or other body fluids to which universal precautions apply should be placed and transported in bags or containers that prevent leakage Personnel involved in the bagging, transport, and laundering of contaminated clothing should wear gloves Protective clothing and station and work uniforms should be washed and dried according to the manufacturer's instructions Boots and leather goods may be brush scrubbed with soap and hot water to remove contamination

7. Infective waste

The selection of procedures for disposal of infective waste is determined by the relative risk of disease transmission and application of local regulations, which vary widely In all cases, local regulations should be consulted prior to disposal procedures and followed. Infective waste, in general, should either be incinerated or should be decontaminated before disposal in a sanitary landfill Bulk blood, suctioned

fluids, excretions, and secretions may be carefully poured down a drain connected to a sanitary sewer, where permitted. Sanitary sewers may also be used to dispose of other infectious wastes capable of being ground and flushed into the sewer, where permitted. Sharp items should be placed in puncture-proof containers and other blood-contaminated items should be placed in leak-proof plastic bags for transport to an appropriate disposal location.

Prior to the removal of protective equipment, personnel remaining on the scene after the patient has been cared for should carefully search for and remove contaminated materials. Debris should be disposed of as noted above.

IV. Fire and Emergency Medical Services

The guidelines that appear in this section apply to fire and emergency medical services. This includes structural fire fighters, paramedics, emergency medical technicians, and advanced life support personnel. Fire fighters often provide emergency medical services and therefore encounter the exposures common to paramedics and emergency medical technicians. Job duties are often performed in uncontrolled environments, which, due to a lack of time and other factors, do not allow for application of a complex decision-making process to the emergency at hand.

The general principles presented here have been developed from existing principles of occupational safety and health in conjunction with data from studies of health-care workers in hospital settings. The basic premise is that workers must be protected from exposure to blood and other potentially infectious body fluids in the course of their work activities. There is a paucity of data concerning the risks these worker groups face, however, which complicates development of control principles. Thus, the guidelines presented below are based on principles of prudent public health practice.

Fire and emergency medical service personnel are engaged in delivery of medical care in the prehospital setting. The following guidelines are intended to assist these personnel in making decisions concerning use of personal protective equipment and resuscitation equipment, as well as for decontamination, disinfection, and disposal procedures.

A. Personal Protective Equipment

Appropriate personal protective equipment should be made available routinely by the employer to reduce the risk of exposure as defined above. For many situations, the chance that the rescuer will be exposed to blood and other body fluids to which universal precautions apply can be determined in advance. Therefore, if the chances of being exposed to blood is high (e.g., CPR, IV insertion, trauma, delivering babies), the worker should put on protective attire before beginning patient care. Table 4 (see page 35) sets forth examples of recommendations for personal protective equipment in the prehospital setting; the list is not intended to be all-inclusive.

1. Gloves

Disposable gloves should be a standard component of emergency response equipment, and should be donned by all personnel prior to initiating any emergency patient care tasks involving exposure to blood or other body fluids to which universal precautions apply. Extra pairs should always be available. Considerations in the choice of disposable gloves should include dexterity, durability, fit, and the task being performed. Thus, there is no single type or thickness of glove appropriate for protection in all situations. For situations where large amounts of blood are likely to be encountered, it is important that gloves fit tightly at the wrist to prevent blood contamination

of hands around the cuff For multiple trauma victims, gloves should be changed between patient contacts, if the emergency situation allows

Greater personal protective equipment measures are indicated for situations where broken glass and sharp edges are likely to be encountered, such as extricating a person from an automobile wreck. Structural fire fighting gloves that meet the Federal OSHA requirements for fire fighters gloves (as contained in 29 CFR 1910 156 or National Fire Protection Association Standard 1973, Gloves for Structural Fire Fighters) should be worn in any situation where sharp or rough surfaces are likely to be encountered (*37*).

While wearing gloves, avoid handling personal items, such as combs and pens, that could become soiled or contaminated. Gloves that have become contaminated with blood or other body fluids to which universal precautions apply should be removed as soon as possible, taking care to avoid skin contact with the exterior surface Contaminated gloves should be placed and transported in bags that prevent leakage and should be disposed of or, in the case of reusable gloves, cleaned and disinfected properly.

2. Masks, eyewear, and gowns

Masks, eyewear, and gowns should be present on all emergency vehicles that respond or potentially respond to medical emergencies or victim rescues These protective barriers should be used in accordance with the level of exposure encountered. Minor lacerations or small amounts of blood do not merit the same extent of barrier use as required for exsanguinating victims or massive arterial bleeding Management of the patient who is not bleeding, and who has no bloody body fluids present, should not routinely require use of barrier precautions. Masks and eyewear (e g , safety glasses) should be worn together, or a faceshield should be used by all personnel prior to any situation where splashes of blood or other body fluids to which universal precautions apply are likely to occur. Gowns or aprons should be worn to protect clothing from splashes with blood. If large splashes or quantities of blood are present or anticipated, impervious gowns or aprons should be worn. An extra change of work clothing should be available at all times.

3 Resuscitation equipment

No transmission of HBV or HIV infection during mouth to mouth resuscitation has been documented. However, because of the risk of salivary transmission of other infectious diseases (e g , herpes simplex and *Neisseria meningitidis*) and the theoretical risk of HIV and HBV transmission during artificial ventilation of trauma victims, disposable airway equipment or resuscitation bags should be used. Disposable resuscitation equipment and devices should be used once and disposed of or, if reusable, thoroughly cleaned and disinfected after each use according to the manufacturer's recommendations

Mechanical respiratory assist devices (e g , bag-valve masks, oxygen demand valve resuscitators) should be available on all emergency vehicles and to all emergency response personnel that respond or potentially respond to medical emergencies or victim rescues.

Pocket mouth to mouth resuscitation masks designed to isolate emergency response personnel (i e , double lumen systems) from contact with victims' blood and blood-contaminated saliva, respiratory secretions, and vomitus should be provided to all personnel who provide or potentially provide emergency treatment

V. Law-Enforcement and Correctional-Facility Officers

Law enforcement and correctional facility officers may face the risk of exposure to blood during the conduct of their duties. For example, at the crime scene or during processing of suspects, law-enforcement officers may encounter blood-contaminated hypodermic needles or weapons, or be called upon to assist with body removal. Correctional-facility officers may similarly be required to search prisoners or their cells for hypodermic needles or weapons, or subdue violent and combative inmates.

The following section presents information for reducing the risk of acquiring HIV and HBV infection by law-enforcement and correctional facility officers as a consequence of carrying out their duties. However, there is an extremely diverse range of potential situations which may occur in the control of persons with unpredictable, violent, or psychotic behavior. Therefore, informed judgment of the individual officer is paramount when unusual circumstances or events arise. These recommendations should serve as an adjunct to rational decision making in those situations where specific guidelines do not exist, particularly where immediate action is required to preserve life or prevent significant injury.

The following guidelines are arranged into three sections: a section addressing concerns shared by both law enforcement and correctional facility officers, and two sections dealing separately with law-enforcement officers and correctional-facility officers, respectively. Table 4 (see page 35) contains selected examples of personal protective equipment that may be employed by law-enforcement and correctional facility officers

A. Law-Enforcement and Correctional Facilities Considerations

1. Fights and assaults

Law-enforcement and correctional-facility officers are exposed to a range of assaultive and disruptive behavior through which they may potentially become exposed to blood or other body fluids containing blood. Behaviors of particular concern are biting, attacks resulting in blood exposure, and attacks with sharp objects Such behaviors may occur in a range of law-enforcement situations including arrests, routine interrogations, domestic disputes, and lockup operations, as well as in correctional facility activities. Hand to hand combat may result in bleeding and may thus incur a greater chance for blood-to-blood exposure, which increases the chances for blood-borne disease transmission.

Whenever the possibility for exposure to blood or blood contaminated body fluids exists, the appropriate protections should be worn, if feasible under the circumstances. In all cases, extreme caution must be used in dealing with the suspect or prisoner if there is any indication of assaultive or combative behavior. When blood is present and a suspect or an inmate is combative or threatening to staff, gloves should always be put on as soon as conditions permit. In case of blood contamination of clothing, an extra change of clothing should be available at all times

2. Cardiopulmonary resuscitation

Law-enforcement and correctional personnel are also concerned about infection with HIV and HBV through administration of cardiopulmonary resuscitation (CPR). Although there have been no documented cases of HIV transmission through this mechanism, the possibility of transmission of other infectious diseases exists Therefore, agencies should make protective masks or airways available to officers and provide training in their proper use Devices with one-way valves to prevent the patients' saliva or vomitus from entering the caregiver's mouth are preferable

B. Law-Enforcement Considerations

1. Searches and evidence handling

Criminal justice personnel have potential risks of acquiring HBV or HIV infection through exposures which occur during searches and evidence handling Penetrating injuries are known to occur, and puncture wounds or needle sticks in particular pose a hazard during searches of persons, vehicles, or cells, and during evidence handling The following precautionary measures will help to reduce the risk of infection·

- An officer should use great caution in searching the clothing of suspects Individual discretion, based on the circumstances at hand, should determine if a suspect or prisoner should empty his own pockets or if the officer should use his own skills in determining the contents of a suspect's clothing
- A safe distance should always be maintained between the officer and the suspect.
- Wear protective gloves if exposure to blood is likely to be encountered
- Wear protective gloves for all body cavity searches
- If cotton gloves are to be worn when working with evidence of potential latent fingerprint value at the crime scene, they can be worn over protective disposable gloves when exposure to blood may occur.
- Always carry a flashlight, even during daylight shifts, to search hidden areas Whenever possible, use long-handled mirrors and flashlights to search such areas (e g , under car seats)

- If searching a purse, carefully empty contents directly from purse, by turning it upside down over a table.
- Use puncture proof containers to store sharp instruments and clearly marked plastic bags to store other possibly contaminated items.
- To avoid tearing gloves, use evidence tape instead of metal staples to seal evidence.
- Local procedures for evidence handling should be followed. In general, items should be air dried before sealing in plastic.

Not all types of gloves are suitable for conducting searches. Vinyl or latex rubber gloves provide little protection against sharp instruments, and they are not puncture-proof. There is a direct trade-off between level of protection and manipulability. In other words, the thicker the gloves, the more protection they provide, but the less effective they are in locating objects. Thus, there is no single type or thickness of glove appropriate for protection in all situations. Officers should select the type and thickness of glove which provides the best balance of protection and search efficiency.

Officers and crime scene technicians may confront unusual hazards, especially when the crime scene involves violent behavior, such as a homicide where large amounts of blood are present. Protective gloves should be available and worn in this setting. In addition, for very large spills, consideration should be given to other protective clothing, such as overalls, aprons, boots, or protective shoe covers. They should be changed if torn or soiled, and always removed prior to leaving the scene. While wearing gloves, avoid handling personal items, such as combs and pens, that could become soiled or contaminated.

Face masks and eye protection or a face shield are required for laboratory and evidence technicians whose jobs which entail potential exposures to blood via a splash to the face, mouth, nose, or eyes.

Airborne particles of dried blood may be generated when a stain is scraped. It is recommended that protective masks and eyewear or face shields be worn by laboratory or evidence technicians when removing the blood stain for laboratory analyses.

While processing the crime scene, personnel should be alert for the presence of sharp objects such as hypodermic needles, knives, razors, broken glass, nails, or other sharp objects.

2. Handling deceased persons and body removal

For detectives, investigators, evidence technicians, and others who may have to touch or remove a body, the response should be the same as for situations requiring CPR or first aid: wear gloves and cover all cuts and abrasions to create a barrier and carefully wash all exposed areas after any contact with blood. The precautions to be used with blood and deceased persons should also be used when handling amputated limbs, hands, or other body parts. Such procedures should be followed after contact with the blood of anyone, regardless of whether they are known or suspected to be infected with HIV or HBV.

3. Autopsies

Protective masks and eyewear (or face shields), laboratory coats, gloves, and waterproof aprons should be worn when performing or attending all autopsies. All autopsy material should be considered infectious for both HIV and HBV. Onlookers with an opportunity for exposure to blood splashes should be similarly protected. Instruments and surfaces contaminated during postmortem procedures should be decontaminated with an appropriate chemical germicide (4). Many laboratories have more detailed standard operating procedures for conducting autopsies; where available, these should be followed. More detailed recommendations for health-care workers in this setting have been published (4).

4. Forensic laboratories

Blood from all individuals should be considered infective. To supplement other worksite precautions, the following precautions are recommended for workers in forensic laboratories.

a. All specimens of blood should be put in a well constructed, appropriately labelled container with a secure lid to prevent leaking during transport. Care should be taken when collecting each specimen to avoid contaminating the outside of the container and of the laboratory form accompanying the specimen.

b. All persons processing blood specimens should wear gloves. Masks and protective eyewear or face shields should be worn if mucous membrane contact with blood is anticipated (e.g., removing tops from vacuum tubes). Hands should be washed after completion of specimen processing.

c. For routine procedures, such as histologic and pathologic studies or microbiological culturing, a biological safety cabinet is not necessary. However, biological safety cabinets (Class I or II) should be used whenever procedures are conducted that have a high potential for generating droplets. These include activities such as blending, sonicating, and vigorous mixing.

d. Mechanical pipetting devices should be used for manipulating all liquids in the laboratory. Mouth pipetting must not be done.

e. Use of needles and syringes should be limited to situations in which there is no alternative, and the recommendations for preventing injuries with needles outlined under universal precautions should be followed.

f. Laboratory work surfaces should be cleaned of visible materials and then decontaminated with an appropriate chemical germicide after a spill of blood, semen, or blood-contaminated body fluid and when work activities are completed.

g. Contaminated materials used in laboratory tests should be decontaminated before reprocessing or be placed in bags and disposed of in accordance with institutional and local regulatory policies for disposal of infective waste.

h. Scientific equipment that has been contaminated with blood should be cleaned and then decontaminated before being repaired in the laboratory or transported to the manufactures.

i. All persons should wash their hands after completing laboratory activities and should remove protective clothing before leaving the laboratory.

j. Area posting of warning signs should be considered to remind employees of continuing hazard of infectious disease transmission in the laboratory setting.

C. Correctional Facility Considerations

1. Searches

Penetrating injuries are known to occur in the correctional facility setting, and puncture wounds or needle sticks in particular pose a hazard during searches of prisoners or their cells. The following precautionary measures will help to reduce the risk of infection:

- A correctional-facility officer should use great caution in searching the clothing of prisoners. Individual discretion, based on the circumstances at hand, should determine if a prisoner should empty his own pockets or if the officer should use his own skills in determining the contents of a prisoner's clothing.

- A safe distance should always be maintained between the officer and the prisoner.

- Always carry a flashlight, even during daylight shifts, to search hidden areas. Whenever possible, use long handled mirrors and flashlights to search such areas (e.g., under commodes, bunks, and in vents in jail cells).

- Wear protective gloves if exposure to blood is likely to be encountered.

- Wear protective gloves for all body cavity searches.

Not all types of gloves are suitable for conducting searches. Vinyl or latex rubber gloves can provide little, if any, protection against sharp instruments, and they are not puncture-proof. There is a direct trade-off between level of protection and manipulability. In other words, the thicker the gloves, the more protection they provide, but the less effective they are in locating objects. Thus, there is no single type or thickness of glove appropriate for protection in all situations. Officers should select the type and thickness of glove which provides the best balance of protection and search efficiency.

2. Decontamination and disposal

Prisoners may spit at officers and throw feces; sometimes these substances have been purposefully contaminated with blood. Although there are no documented cases of HIV or HBV transmission in this manner and transmission by this route would not be expected to occur, other diseases could be transmitted. These materials should be removed with a paper towel after donning gloves, and the area then decontaminated with an appropriate germicide. Following clean-up, soiled towels and gloves should be disposed of properly.

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VII. Tables

Table 1. The Risk of HIV Infection Following Needlestick Injury: Hypothetical Model

Prevalence of HIV Infection (A)	Probability of Infection Given Needlestick Injury with Blood Containing HIV (B)	Probability of Infection Given Random Needlestick (Unknown Serostatus) A * B = (C)	Probability of Infection Given 10 Random Needlesticks 1-(1-C)[10]	Probability of Infection Given 100 Random Needlesticks 1-(1-C)[100]
0.0001	0.001	0.0000001	0.000001	0.00001
0.0001	0.005	0.0000005	0.000005	0.00005
0.001	0.001	0.000001	0.00001	0.0001
0.001	0.005	0.000005	0.00005	0.0005
0.01	0.001	0.00001	0.0001	0.001
0.01*	0.005	0.00005	0.0005	0.005
0.05	0.001	0.00005	0.0005	0.005
0.05	0.005	0.00025	0.0025	0.025

* For example, if the prevalence of infection in the population is 0.01 (i.e., 1 per 100) and the risk of a seroconversion following a needlestick with blood known to contain HIV is 0.005 (i.e., 1 in 200), then the probability of HIV infection given a random needlestick is 0.00005 (i.e., 5 in 100,000). If an individual sustains 10 needlestick injuries, the probability of acquiring HIV infection is 0.0005 (i.e., 1 in 2,000); if the individual sustains 100 needlestick injuries, the probability of acquiring HIV infection is 0.005 (i.e., 1 in 200).

Table 2
HIV-infected health care workers with no reported nonoccupational risk factors and for whom case histories have been published in the scientific literature

Cases with Documented Seroconversion

Case	Occupation	Country	Type of Exposure	Source
1*	NS†	United States	Needlestick	AIDS patient
2	NS	United States	Needlestick	AIDS patient
3	NS	United States	Needlestick	AIDS patient
4	NS	United States	2 Needlesticks	AIDS patient, HIV-infected patient
5	NS	United States	Needlestick	AIDS patient
6	Nurse	England	Needlestick	AIDS patient
7	Nurse	France	Needlestick	HIV-infected patient
8	Nurse	Martinique	Needlestick	AIDS patient
9	Research lab worker	United States	Cut with sharp object	Concentrated virus
10	Home health-care worker	United States	Cutaneous#	AIDS patient
11	NS	United States	Nonintact skin	AIDS patient
12	Phlebotomist	United States	Mucous-membrane	HIV-infected patient
13	Technologist	United States	Nonintact skin	HIV-infected patient
14	NS	United States	Needlestick	AIDS patient
15	Nurse	Italy	Mucous membrane	HIV infected patient
16	Nurse	France	Needlestick	AIDS patient
17	Navy medic	United States	Needlestick	AIDS patient
18	Clinical lab worker	United States	Cut with sharp object	AIDS patient

* AIDS case
† Not specified
# Mother who provided nursing care for her child with HIV infection; extensive contact with the child's blood and body secretions and excretions occurred; the mother did not wear gloves and often did not wash her hands immediately after exposure.

Table 2, continued.
HIV infected health care workers with no reported nonoccupational risk factors and for whom case histories have been published in the scientific literature

Cases without Documented Seroconversion

Case	Occupation	Country	Type of Exposure	Source
19	NS	United States	Puncture wound	AIDS patient
20	NS	United States	2 Needlesticks	2 AIDS patients
21	Research lab worker	United States	Nonintact skin	Concentrated virus
22	Home health-care provider	England	Nonintact skin	AIDS patient
23	Dentist	United States	Multiple needle-sticks	Unknown
24*	Technician	Mexico	Multiple needle-sticks and mucous membrane	Unknown
25	Lab worker	United States	Needlestick, puncture wound	Unknown

* AIDS case

Table 3. Summary of Task Categorization and Implications for Personal Protective Equipment

Joint Advisory Notice Category[1]	Nature of Task/Activity	Personal protective equipment should be: Available?	Worn?
I.	Direct contact with blood or other body fluids to which universal precautions apply	Yes	Yes
II.	Activity performed without blood exposure but exposure may occur in emergency	Yes	No
III.	Task/activity does not entail predictable or unpredictable exposure to blood	No	No

[1] U.S. Department of Labor, U.S. Department of Health and Human Services. Joint advisory notice: protection against occupational exposure to hepatitis B virus (HBV) and human immunodeficiency virus (HIV). Washington, DC: US Department of Labor, US Department of Health and Human Services, 1987.

Table 4. Examples of Recommended Personal Protective Equipment for Worker Protection Against HIV and HBV Transmission[1] in Prehospital[2] Settings

Task or Activity	Disposable Gloves	Gown	Mask[3]	Protective Eyewear
Bleeding control with spurting blood	Yes	Yes	Yes	Yes
Bleeding control with minimal bleeding	Yes	No	No	No
Emergency childbirth	Yes	Yes	Yes, if splashing is likely	Yes, if splashing is likely
Blood drawing	At certain times[4]	No	No	No
Starting an intravenous (IV) line	Yes	No	No	No
Endotracheal intubation, esophageal obturator use	Yes	No	No, unless splashing is likely	No, unless splashing is likely
Oral/nasal suctioning, manually cleaning airway	Yes[5]	No	No, unless splashing is likely	No, unless splashing is likely
Handling and cleaning instruments with microbial contamination	Yes	No, unless soiling is likely	No	No
Measuring blood pressure	No	No	No	No
Measuring temperature	No	No	No	No
Giving an injection	No	No	No	No

[1] The examples provided in this table are based on application of universal precautions. Universal precautions are intended to supplement rather than replace recommendations for routine infection control, such as handwashing and using gloves to prevent gross microbial contamination of hands (e.g., contact with urine or feces).

[2] Defined as setting where delivery of emergency health care takes place away from a hospital or other health care facility.

[3] Refers to protective masks to prevent exposure of mucous membranes to blood or other potentially contaminated body fluids. The use of resuscitation devices, some of which are also referred to as "masks," is discussed on page 23.

[4] For clarification see Appendix A, page [illegible] and Appendix B, page [illegible].

[5] While not clearly necessary to prevent HIV or HBV transmission unless blood is present, gloves are recommended to prevent transmission of other agents (e.g., Herpes simplex).

Table 5 Reprocessing Methods for Equipment Used in the Prehospital[1] Health Care Setting

Sterilization	Destroys	All forms of microbial life including high numbers of bacterial spores.
	Methods:	Steam under pressure (autoclave), gas (ethylene oxide), dry heat, or immersion in EPA approved chemical "sterilant" for prolonged period of time, e.g., 6–10 hours or according to manufacturers' instructions. Note: liquid chemical "sterilants" should be used only on those instruments that are impossible to sterilize or disinfect with heat.
	Use:	For those instruments or devices that penetrate skin or contact normally sterile areas of the body, e.g., scalpels, needles, etc. Disposable invasive equipment eliminates the need to reprocess these types of items. When indicated, however, arrangements should be made with a health-care facility for reprocessing of reusable invasive instruments.
High Level Disinfection:	Destroys	All forms of microbial life except high numbers of bacterial spores.
	Methods	Hot water pasteurization (80–100 C, 30 minutes) or exposure to an EPA registered "sterilant" chemical as above, except for a short exposure time (10–45 minutes or as directed by the manufacturer).
	Use	For reusable instruments or devices that come into contact with mucous membranes (e.g., laryngoscope blades, endotracheal tubes, etc.).
Intermediate Level Disinfection.	Destroys	*Mycobacterium tuberculosis*, vegetative bacteria, most viruses, and most fungi, but does not kill bacterial spores.
	Methods	EPA registered "hospital disinfectant" chemical germicides that have a label claim for tuberculocidal activity; commercially available hard surface germicides or solutions containing at least 500 ppm free available chlorine (a 1:100 dilution of common household bleach – approximately ⅓ cup bleach per gallon of tap water).
	Use:	For those surfaces that come into contact only with intact skin, e.g., stethoscopes, blood pressure cuffs, splints, etc., and have been visibly contaminated with blood or bloody body fluids. Surfaces must be precleaned of visible material before the germicidal chemical is applied for disinfection.

Table 5 Reprocessing Methods for Equipment Used in the Prehospital[1] Health Care Setting – Continued

Low Level Disinfection	Destroys	Most bacteria, some viruses, some fungi, but not *Mycobacterium tuberculosis* or bacterial spores.
	Methods	EPA registered "hospital disinfectants" (no label claim for tuberculocidal activity).
	Use:	These agents are excellent cleaners and can be used for routine housekeeping or removal of soiling in the absence of visible blood contamination.
Environmental Disinfection:		Environmental surfaces which have become soiled should be cleaned and disinfected using any cleaner or disinfectant agent which is intended for environmental use. Such surfaces include floors, woodwork, ambulance seats, countertops, etc.
IMPORTANT		To assure the effectiveness of any sterilization or disinfection process, equipment and instruments must first be thoroughly cleaned of all visible soil.

[1]Defined as setting where delivery of emergency health-care takes place prior to arrival at hospital or other health care facility.

APPENDIX G

APPENDIX G

TRAINING PACKET

APPENDIX G: TRAINING PACKET

(SAMPLE)
TRAINING RECORD
(Note: Fill out separate form for each training session)

Date of Training Session: _____
Number of Hours of Training: _____
Location of Training Session: _____

Level of Training Session:

Level I: Brief Overview for All Employees
Level II: All Employees at Increased Risk

Total Number in Training Session: _____

Trainer: _____

Printed Name: _____ Phone: _____

Signature: _____ Date: _____

Please attach content or summary of training session and names and qualifications of persons conducting the training. (See "Trainer Information Sheet.")

Complete one line below for each person attending the training session.

Work Location	NAME	Job Title	Number

QUALIFICATION VITAE FORM FOR TRAINERS

TRAINER NAME: _____

ADDRESS: _____

TELEPHONE NUMBER: _____

PRESENT POSITION: _____

PROFESSIONAL EDUCATION: _____

Institution	Major	Degree	Year

PROFESSIONAL LICENSURE AND/OR CERTIFICATION:

RELEVANT PROFESSIONAL EXPERIENCE OR SPECIAL PREPARATION WHICH QUALIFIES YOU FOR TEACHING THIS COURSE:

_____ _____

Signature: Date:

SAMPLE TRAINING OUTLINE FOR OCCUPATIONAL EXPOSURE TO BLOODBORNE PATHOGENS (BBP) 29 CFR 1910.1030

Level I Training (approximately 30 minutes, or via a memorandum and/or brochure)

This training is not required under the Standard but is highly recommended. It briefly highlights the general concepts in the Bloodborne Pathogen Standard for those people who will probably not be occupationally exposed to BBP and includes:

1. Where an employee can find a copy of the regulatory text of this Standard.

2. A brief explanation of the Standard:
   a. Who is covered under the Standard,
   b. Definitions of:

      1. Blood and body fluids.
      2. Bloodborne pathogen.
      3. Exposure incident.
      4. Occupational exposure.
      5. Potentially infectious material.
      6. Universal precautions.

3. A brief explanation of the employer's Exposure Control Plan and means by which the employee can obtain a copy of the written plan.

4. Information on the appropriate actions to take and person(s) to contact in an emergency involving blood or other potentially infectious materials.

5. Information about Hepatitis B and Human Immunodeficiency Virus (HIV).

6. Question and answer period.

SAMPLE TRAINING OUTLINE FOR OCCUPATIONAL EXPOSURE TO BLOODBORNE PATHOGENS (BBP) 29 CFR 1910.1030

Level II Training (approximately 2 hours)

This training highlights the general concepts in the Standard for those people who will probably be exposed to BBP, and includes:

1. Where an individual can find a copy of the regulatory text of this Standard.
2. A general explanation of the epidemiology (incidence, distribution, and control of disease in population) mode of transmission, and symptoms of bloodborne disease. Emphasis will be placed on Hepatitis B (HBV) and Human Immunodeficiency Virus (HIV).
3. A general explanation of:
   a. Who is covered under the Standard,
   b. Definitions of:
      1. Blood and body fluids.
      2. Bloodborne pathogen.
      3. Exposure incident.
      4. Occupational exposure.
      5. Potentially infectious material.
      6. Universal precautions.
   c. Engineering controls
   d. Work practices
   e. Personal protective equipment, including types, use, handling, and disposal.
4. A brief explanation of the employer's Exposure Control Plan and means by which the employee can obtain a copy of the written plan, including methods of recognizing work tasks and other activities that may result in exposure.
5. Information on Hepatitis B Vaccine (HBV), and that the vaccine and vaccination will be offered free of charge.
6. Information on Human Immunodeficiency Virus (HIV), and that the screening will be provided free of charge under certain conditions.
7. Information on the appropriate actions to take, procedures to follow, and person(s) to contact in an emergency or exposure incident involving blood or other potentially infectious materials.
8. Information on the post-exposure evaluation and follow-up.
9. Discussion of record keeping requirements for the agency.
10. An explanation of signs and labels and/or color coding required for biohazardous waste.
11. Question and answer period.

APPENDIX H

APPENDIX H

INFORMTION FOR ORDERING APPROVED SHARPS CONTAINERS

APPENDIX H

APPROVED SHARPS CONTAINERS

Approved sharps containers for disposal of syringes/needles are puncture-resistant and splatter-proof.

Perry Point:

Perry Point is the HRSA Supply Service Center located in Perry Pomt. Maryland 21902. (All federal agencies, including federally funded projects, can use Perry Point once an account is established.)

The following are approved sharps containers that can be ordered through Perry Point:

3.5 qt. (24/case) 6515011885345
7.5 qt. (12/case) 6530011832863

For more information on approved sharps containers. call an FEOH regional office which will also likely be able to provide advice on local disposal regulations.

APPENDIX I

APPENDIX I

STATE OF CALIFORNIA - HEALTH AND WELFARE AGENCY

CALIFORNIA MORBIDITY REPORT

DATED SEPTEMBER 4, 1992

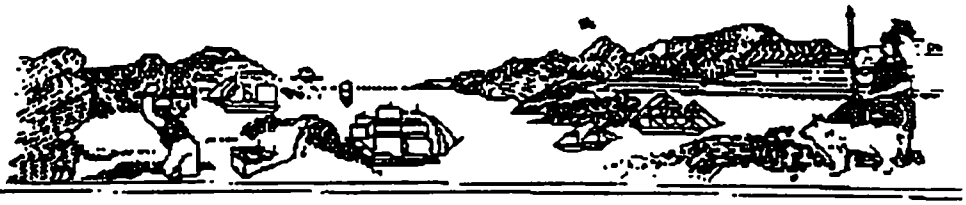
State of California - Health and Welfare Agency
PETE WILSON, Governor

September 4, 1992
#35/#36

Department of Health Services
Molly Joel Coye, M.D., M.P.H., Director

California Morbidity

Biweekly Report from the
Infectious Disease Branch
2151 Berkeley Way, Berkeley, CA 94704-1011
(510) 540-2308 After Hours (510) 540-2308
Contributions are Welcome



ILLNESS IN SEWAGE WORKERS/RECOMMENDATIONS FOR PREVENTION

The Division of Communicable Disease Control (formerly, the "Infectious Disease Branch") previously published recommendations for preventing illness in sewage workers (**California Morbidity**, #33, August 24, 1984). Questions continue to be received, not only for the diseases discussed last time but also because of newer concerns about cholera, HIV, and Hepatitis B.

It should be emphasized that there are NO state immunization requirements mandated for sewage workers. Any such requirements that exist are made at the local level, by employers or by local health agencies. According to Cal/OSHA officials, sewage workers are not covered by the "Cal/OSHA Bloodborne Pathogens Standard" unless those workers work directly on sewerage lines within health care facilities or before those lines join other (e.g., municipal) sewerage lines.

It should also be emphasized that there are no national guidelines or formal recommendations in this area (as enunciated by the Advisory Committee on Immunization Practices of the USPHS) nor is there universal agreement on what immunizing agents should be recommended. This is a difficult area, where the very small risk of disease (from pooled human sewage) must be balanced against the very small risk of adverse effects (and cost) of immunization. Though published data do not exist for all of the disease-specific recommendations outlined below, there is Department of Health Services concensus on the following recommendations:

1. Frequent, routine handwashing is the most important safeguard in preventing infection by agents present in sewage.
2. Protective clothing (i.e., work clothes, coveralls, boots, gloves—where appropriate, and plastic face shields—where appropriate) is recommended, and such work clothes should not be worn home or outside the immediate work environment.
3. Immunization recommendations can be categorized as follows:
   a. Strongly Recommended
      1. Tetanus-diphtheria (Td)....All adults, and especially sewage workers, should be up-to-date on Td immunization. For those who have completed the basic series of three immunizations, a booster should be given every ten years.
      2. No other immunizations are strongly recommended at the present time, but Hepatitis A vaccine, recently licensed in Europe (by SmithKline Beecham), may become licensed and available in the United States within the next several years. The need for sewage workers to receive this vaccine will be reviewed at that time.
   b. Optional
      1. Poliomyelitis - This is a complex issue. Sewage workers are probably at some risk of exposure to vaccine polio virus but very rarely to wild polio virus. In communities with substantial numbers of recent immigrants from Southeast Asia, the risk of wild virus exposure from pooled sewage may be somewhat greater. However, no cases of occupationally acquired poliomyelitis have been reported in United States sewage workers in the vaccine era. Further, immunization with oral (Sabin) polio vaccine is not routinely recommended for United States adults (age 18 and over) because of the small risk (perhaps one in a million) of developing paralytic polio after receiving oral polio vaccine. This risk is greatest for those who have received no prior doses of polio vaccine of any type; the risk extends to unimmunized household contacts of these vaccinees, as well.

         Polio immunization is not routinely recommended for sewage workers. If it is to be considered, we suggest that:

         a) Persons who have received three doses of oral polio vaccine or inactivated polio vaccine should receive one dose of inactivated polio vaccine (IPV) for lifetime protection.
         b) Persons who have received one or two doses of oral polio vaccine or inactivated polio vaccine should receive IPV to complete the three doses.
         c) Persons who have never received any oral polio vaccine or inactivated polio vaccine should receive inactivated polio vaccine (IPV), exclusively. The primary series consists of two doses 4-8 weeks apart and a third dose 6-12 months after the second. The need and interval for booster doses of IPV in adults have not been established. Probably, at least one booster dose should be taken five years after completion of the primary series.
      2. Typhoid Fever - The risk of this disease for sewage workers in California is exceedingly small. Only one case has ever been reported in a California sewage worker and this was in an individual who had received at least one dose of typhoid vaccine nine months previously. Typhoid immunization is **not generally recommended**. If immunization is considered, either of two vaccines can be used:
         a) **Injectable vaccine:** The inactivated vaccine is only 70-80 percent effective. The primary series is two doses, given four weeks apart. Pain at the injection site, fever, and malaise are common. One fatal reaction has been recorded in California. A booster dose is needed at least every three years for continued protection. The intradermal 0.1 cc dosage can be used for boosters (but not for the primary series) and is associated with fewer side effects. The intradermal injection is best given at the triceps or deltoid area, not the volar aspect of the forearm.
         b) **Oral vaccine:** This live bacterial vaccine, given in four capsules on alternate days, is at least as effective as the inactivated vaccine and has fewer side effects. The four-capsule series must be repeated every five years for continued protection.
   c. Not Recommended
      1. Immune globulin (IG), also called Gamma Globulin (GG) for Hepatitis A prophylaxis is not recommended because:
         a) It is relatively expensive, painful, and in rare instances is associated with allergic reactions.
         b) IG injections must be repeated every 4-6 months for continued protection.
      2. Hepatitis B Vaccine - While blood and other body fluids (e.g., menstrual discharges, etc.) enter the sewage stream, Hepatitis B virus is present in very dilute concentrations. No cases of Hepatitis B have ever been linked to sewage exposure. Moreover, since Hepatitis B is not transmitted by the fecal-oral route, there is no risk from sewage by this route. Hepatitis B vaccine is now universally recommended for all infants born in the United States and for certain high-risk persons, for example, to protect against sexual transmission, exposures in health care settings, and transmission by injected drugs, etc.
      3. Cholera - The risk of cholera for sewage workers is extremely remote. Only a few cases of imported cholera are reported each year in California and there has been no secondary transmission. *Vibrio cholerae* concentration in California sewage is so dilute as to probably be non-infectious. (Whereas 10^2 Shigella are needed to cause disease, as many as 10^6 to 10^8 *V. cholerae* are needed.) Even if cholera did result, specific treatment is readily available. Cholera vaccine is not recommended: it is only about 50 percent effective, requires booster doses every six months, and frequently produces pain and redness at the injection site, fever, and malaise.

Finally, a word about HIV and the risk of AIDS from sewage. The remarks made above about Hepatitis B, and its extreme dilution in sewage, apply to

vaccine of any type; the risk extends to unimmunized household contacts of these vaccinees, as well.

Polio immunization is not routinely recommended for sewage workers. If it is to be considered, we suggest that:

a) Persons with a history of three or more doses of oral (Sabin) polio vaccine at any prior time do not need additional doses.
b) Persons with a history of 1-2 doses of oral polio vaccine at any prior time can take additional doses of either oral polio vaccine or inactivated (Salk) polio vaccine to bring their lifetime total to

produces pain and redness at the injection site, fever, and malaise.

Finally, a word about HIV and the risk of AIDS from sewage. The remarks made above about Hepatitis B, and its extreme dilution in sewage, apply to HIV as well...except that the level of HIV in sewage would be even several orders of magnitude less than that of Hepatitis B. Moreover, like Hepatitis B, HIV is not transmitted by the fecal-oral route. In summary, the risk of Hepatitis B from sewage is virtually non-existent and the risk of HIV transmission from sewage is even less.