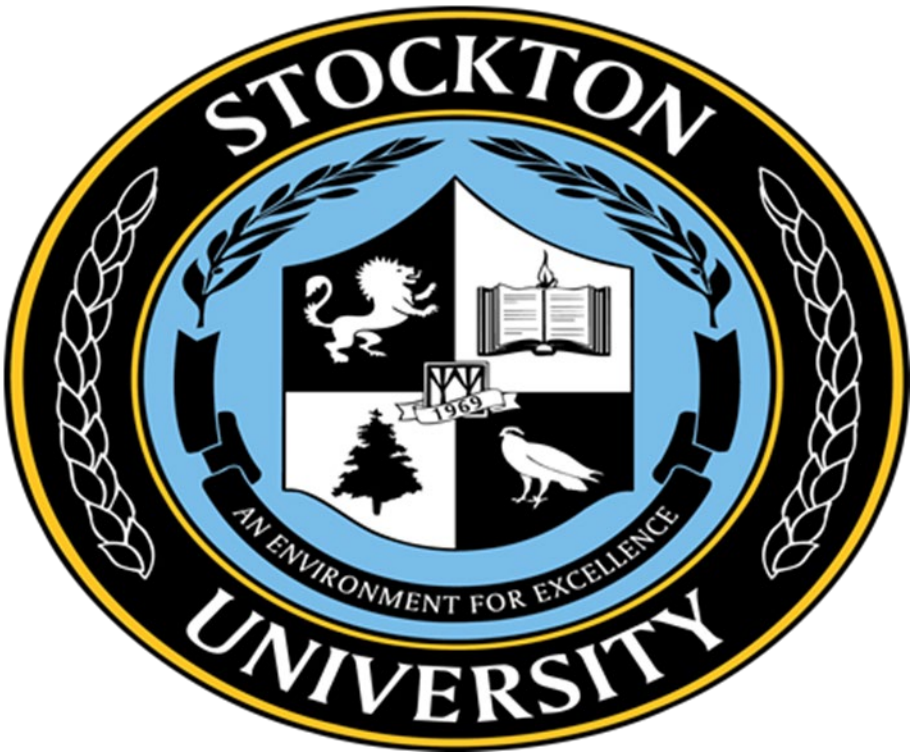

Stockton University
Bloodborne Pathogens Exposure Control Plan

October 24, 2024

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APPENDIX SECTION

INTRODUCTION

Acquired Immune Deficiency Syndrome (AIDS), hepatitis B, and hepatitis C warrant serious concern for workers occupationally exposed to blood and certain other body fluids that contain bloodborne pathogens. It is estimated nationally that more than 5.6 million workers in health care and public safety occupations could be potentially exposed. In recognition of these potential hazards, the New Jersey Public Employees Occupational Safety and Health Program has adopted the Occupational Safety and Health Administration (OSHA) regulation [Bloodborne Pathogens 29 Code of Federal Regulations (CFR) 1910.1030] to help protect New Jersey public workers from these health hazards.

The major intent of this regulation is to prevent the transmission of bloodborne diseases within potentially exposed workplace occupations. The standard is expected to reduce and prevent employee exposure to the human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV) and other bloodborne diseases. The Occupational Safety and Health Administration (OSHA) estimates the standard could prevent more than 200 deaths and about 9,000 infections per year from HBV alone. The standard requires that employers follow universal precautions, which means that all blood or other potentially infectious materials must be treated as being infectious for HIV, HBV, and other bloodborne pathogens. (This includes hepatitis C.) Each employer must determine the application of universal precautions by performing an employee exposure evaluation. If employee exposure is recognized, as defined by the standard, then the standard mandates a number of requirements. One of the major requirements is the development of an Exposure Control Plan, which mandates engineering controls, work practices, personal protective equipment, HBV vaccinations and training. The standard also mandates practices and procedures for housekeeping, medical evaluations, hazard communication, and recordkeeping.

POLICY

Stockton University and the Office of Environmental Health and Safety (EHS) is committed to provide a safe and healthful work environment for our entire staff. In pursuit of this endeavor, the following Exposure Control Plan (ECP) is provided to eliminate or minimize occupational exposure to bloodborne pathogens in accordance with the PEOSH Bloodborne Pathogens Standard, Title 29 Code of Federal Regulations 1910.1030.

The ECP is a key document to assist our facility in implementing and ensuring compliance with the standard, thereby protecting our employees. This ECP includes:

I. Employee exposure determination

II. The procedures for evaluating the circumstances surrounding an exposure incident, and

III. The schedule and method for implementing the specific sections of the standard, including:

- < Methods of compliance
- < Hepatitis B vaccination and post-exposure follow-up
- < Training and communication of hazards to employees
- < Recordkeeping

PROGRAM ADMINISTRATION

- Stockton University EHS is responsible for the implementation of the ECP. The Office of EHS will maintain and update the written ECP at least annually and whenever necessary to include new or modified tasks and procedures.

- Those employees who are reasonably anticipated to have contact with or exposure to blood or other potentially infectious materials are required to comply with the procedures and work practices outlined in this ECP.

- Stockton University Facilities and Operations (F&OP) will have the responsibility for written housekeeping protocols and will ensure that effective disinfectants are purchased.

- Stockton University will be responsible for ensuring that all medical actions required are performed and that appropriate medical records are maintained.

- The Office of EHS will be responsible for training, documentation of training, and making the written ECP available to employees, PEOSH and NIOSH representatives.

- The Office of EHS will maintain and provide all necessary personal protective equipment (PPE), engineering controls (i.e., sharp containers, self-sheathing needles, etc.), labels and red bags as required by the standard. EHS will ensure that adequate supplies of the aforementioned equipment are available.

EMPLOYEE EXPOSURE DETERMINATION

I. Employee Exposure Determination

A. The following is a list of job classifications in which **some** employees at our establishment have occupational exposure. Included are a list of tasks and procedures in which occupational exposure may occur for these individuals.

a. Custodians
   i. Cleaning up blood spills
   ii. Handling infectious waste
   iii. Handling discarded sanitary items
   iv. Taking out trash that may contain needles or sharps
   v. Picking up or disposing of used needles

b. Plumbers
   i. Responding to clean up possible infectious materials from spills or accidents
   ii. Repairs- working on pipes, drains, toilets, etc

c. Grounds Workers
   i. Taking out trash that may contain needles or sharps
   ii. Cleaning general areas
   iii. Handling disposed syringe needles
   iv. Contact with feminine sanitary items
   v. Handling infectious waste

B. Employees in Laboratories
   a. Handling contaminated sharps, such as needles, scalpels, or broken glass
   b. Handling laundry that may be soiled with blood or potentially infectious materials

All exposure determinations for A and B were made without regard to the use of Personal Protective Equipment (PPE).

Note to Employer: "Good Samaritan" acts which result in exposure to blood or other potentially infectious materials from assisting a fellow employee (i.e., assisting a coworker with nosebleed, giving CPR or first aid) are not included in the Bloodborne Pathogens Standard. PEOSH, however, encourages employers to offer Post-Exposure Evaluation and Follow-up in such cases.

II. Effective Dates:

The Bloodborne Pathogens Standard was published in the New Jersey Register on July 6, 1993. The standard became operative on October 4, 1993. The dates for completing the different parts of the Standard were:

Exposure Control Plan	December 3, 1993
Recordkeeping	January 6, 1994
Information and Training	January 6, 1994
Methods of Compliance (Except Universal Precautions)	February 6, 1994
Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-Up	February 6, 1994
Labels and Signs	February 6, 1994
PEOSH Revised Bloodborne Pathogens Standard Published in New Jersey Register	**September 4, 2001 (Effective Date)**

The methods of implementation of these elements of the standard are discussed in the subsequent pages of this Exposure Control Plan.

III. Methods of Implementation and Control

1.0 Universal Precautions

1.1 All employees will utilize Universal Precautions. Universal Precautions is an infection control method which requires employees to assume that all human blood and specified human body fluids are infectious for HIV, HBV and other bloodborne pathogens and must be treated accordingly. (This includes hepatitis C.)

2.0 Exposure Control Plan (ECP)

2.1 Employees covered by the Bloodborne Pathogens Standard will receive an explanation of this ECP during their initial training session. It will also be reviewed in their annual refresher training. All employees will have an opportunity to review this Plan at any time during their work shifts by contacting The Office of EHS. Employees seeking copies of the Plan may contact The Office of EHS. A copy of the Plan will be made available free of charge and within 15 days of the request.

2.2 The Office of EHS will be responsible for reviewing and updating the ECP annually or sooner if necessary to reflect any new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure.

3.0 Engineering Controls and Work Practices

3.1 Engineering controls and work practice controls will be used to prevent or minimize exposure to bloodborne pathogens. The specific engineering controls and work practices used are listed below:

- Using brooms and dustpans, and grabbers to pick up contaminated items, or using mops and spill kits for wet clean up.
- Safer medical Devices
- Biohazard symbols on rooms, refrigerators, freezers, and incubators, along with emergency contact information
- Sharps disposal containers are inspected and maintained or replaced by Facilities & Operations every month, or whenever necessary to prevent overfilling
- _____
- _____

Sharps disposal containers are inspected and maintained or replaced by *(Name of responsible person or department)* every *(list frequency)* or whenever necessary to prevent overfilling.

This facility identifies the need for changes in engineering controls and work practices through Review of PEOSH records, employee interviews, committee activities, etc._____

_____

We evaluate new procedures or new products regularly by Researching relevant scientific literature, contacting suppliers for detailed product information, comparing specifications of potential products against our current standards, and soliciting feedback from frontline staff.

_____

_____

Both front-line workers and management officials are involved in this process by conducting monthly safety meetings, weekly supervisor meetings, and employee interviews.

_____

_____

The Office of EHS **will ensure effective implementation of these recommendations.**

ENGINEERING CONTROLS

Examples of engineering controls include, but are not limited to:

- ❑ self-sheathing needles
- ❑ puncture-resistant disposal containers for contaminated sharps
- ❑ sharps with engineered sharps injury protections (SESIPs)
- ❑ needleless systems

Examples of work practice controls include, but are not limited to:

- ❑ providing readily accessible hand washing facilities
- ❑ washing hands immediately or as soon as feasible after removal of gloves
- ❑ at non-fixed sites (i.e., emergency scenes, mobile blood collection sites) which lack hand washing facilities, providing interim hand washing measures, such as antiseptic towelettes and paper towels. Employees can later wash their hands with soap and water as soon as feasible
- ❑ washing body parts as soon as possible after skin contact with blood or other potentially infectious materials occurs
- ❑ prohibiting the recapping or bending of needles
- ❑ shearing or breaking contaminated needles is prohibited
- ❑ labeling
- ❑ equipment decontamination

- ❑ prohibiting eating, drinking, smoking, applying cosmetics or lip balm and handling contact lenses in work area where there is a likelihood of occupational exposure
- ❑ prohibiting food and drink from being kept in refrigerators, freezers, shelves, cabinets or on counter tops or bench tops where blood or other potentially infectious materials are present
- ❑ requiring that all procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, splattering, and generation of droplets of these substances
- ❑ placing specimens of blood or other potentially infectious materials in a container which prevents leakage during collection, handling, processing, storage, transport or shipping
- ❑ examining equipment which may become contaminated with blood or other potentially infectious materials prior to servicing or shipping and decontaminating such equipment as necessary. Items will be labeled per the standard if not completely decontaminated

4.0 Personal Protective Equipment (PPE)

Personal protective equipment must be used if occupational exposure remains after instituting engineering and work practice controls, or if the controls are not feasible. Training will be provided by The Office of EHS in the use of the appropriate personal protective equipment for employees' specific job classifications and tasks/procedures they will perform.

Additional training will be provided, whenever necessary , such as if an employee takes a new position or if new duties are added to their current position.

Appropriate personal protective equipment is required for the following tasks; the specific equipment to be used is listed after the task:

Task	**Equipment**
_Picking up syringes_____	puncture resistant gloves, broom and dustpan, grabber, forceps
_____	
_____	_____
_____	_____
_____	_____

Note to Employer: The employer should decide how to make PPE "readily accessible" for employees' use. Specify in writing what will be issued, how, when and who will provide the PPE. For large facilities which might have numerous tasks present, a summary of the tasks and required PPE can be used. The important part to remember is that it is imperative that employees wear appropriate protective body coverings such as gowns, aprons, caps, and boots when occupational exposure is anticipated. The type and characteristics will depend upon the task and degree of exposure anticipated.

PPE items include:

- < gloves
- < gowns
- < laboratory coats
- < face shields
- < masks
- < eye protection (splash-proof goggles, safety glasses with side shields)
- < resuscitation bags and mouthpieces

Note to Employer: Employers with first aid responders are reminded to have quick access to kits having impervious gloves, resuscitation bags or mouthpieces, eye protection, aprons, disinfectant towelettes for hand washing, and red bags or biohazard-labeled bags.

4.2 As a general rule, all employees using PPE must observe the following precautions:

- ❑ Wash hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.
- ❑ Remove protective equipment before leaving the work area and after a garment becomes contaminated.
- ❑ Place used protective equipment in appropriately designated areas or containers being stored, washed, decontaminated, or discarded.

PERSONAL PROTECTIVE EQUIPMENT

Note to Employer: Designate areas or containers which are to be used and their location.

{ _____

_____

_____

_____

_____

- ❑ Wear appropriate gloves when it can be reasonably anticipated that you may have contact with blood or other potentially infectious materials and when handling or touching contaminated items or surfaces. Replace gloves if torn, punctured, contaminated, or if their ability to function as a barrier is compromised.

- ❑ Following any contact of body areas with blood or any other infectious materials, you must wash your hands and any other exposed skin with soap and water as soon as possible. Employees must also flush exposed mucous membranes (eyes, mouth, etc) with water.

- ❑ Utility gloves may be decontaminated for reuse if their integrity is not compromised. The decontamination procedure will consist of __New gloves will be provided. _____.

- ❑ Discard utility gloves when they show signs of cracking, peeling, tearing, puncturing, or deterioration.

- ❑ Never wash or decontaminate *disposable* gloves for reuse or before disposal.

- ❑ Wear appropriate face and eye protection such as a mask with glasses with solid side shields or a chin-length face shield when splashes, sprays, splatters, or droplets of blood or other potentially infectious materials pose a hazard to the eye, nose, or mouth.

- ❑ If a garment is penetrated by blood and other potentially infectious materials, the garment(s) must be removed immediately or as soon as feasible. If a pullover scrub (as opposed to scrubs with snap closures) becomes minimally contaminated, employees should be trained to remove the pullover scrub in such a way as to avoid contact with the outer surface; e.g., rolling up the garment as it is pulled toward the head for removal.

However, if the amount of blood exposure is such that the blood penetrates the scrub and contaminates the inner surface, not only is it impossible to remove the scrub without exposure to blood, but the penetration itself would constitute exposure. It may be prudent to train employees to cut such a contaminated scrub to aid removal and prevent exposure to the face.

- Repair and/or replacement of PPE will be at no cost to employees.

Refer to Appendix I for additional information on PPE.

5.0 **Training**

5.1 All employees who have or are reasonably anticipated to have occupational exposure to bloodborne pathogens will receive training conducted by The Office of EHS. The Office of EHS will provide training on the epidemiology of bloodborne pathogen diseases. OSHA pamphlet "Occupational Exposure to Bloodborne Pathogens" and Fact Sheets located in the Appendix Section and _____ will be used to inform employees of the epidemiology, symptoms, and transmission of bloodborne diseases. In addition, the training program will cover, at a minimum, the following elements:

- A copy and explanation of the revised standard
- Epidemiology and symptoms of bloodborne pathogens
- Modes of transmission
- Our Exposure Control Plan and how to obtain a copy
- Methods to recognize exposure tasks and other activities that may involve exposure to blood
- Use and limitations of Engineering Controls, Work Practices, and PPE
- PPE - types, use, location, removal, handling, decontamination, and disposal
- PPE - the basis for selection

- < Hepatitis B Vaccine - offered free of charge. Training will be given prior to vaccination on its safety, effectiveness, benefits, and method of administration (See Appendix P)

- ❑ Emergency procedures - for blood and other potentially infectious materials
- ❑ Exposure incident procedures
- ❑ Post-exposure evaluation and follow-up
- ❑ Signs and labels - and/or color coding
- ❑ Questions and answer session

An Employee Education and Training Record (see Appendix B) will be completed for each employee upon completion of training. This document will be kept with the employee's records at _The Office of EHS.

Highlights of Training Program Elements

- Contents of revised standard
- Epidemiology of bloodborne diseases
- Exposure Control Plan
- Job duties with exposure
- Types of controls
- Protective equipment
- Hepatitis B vaccination program
- Emergency procedures
- Post-exposure procedures
- Signs/labels/(color coding)
- Question and answer session

6.0 Hepatitis B Vaccination

6.1 The Office of EHS will provide information on hepatitis B vaccinations addressing its safety, benefits, efficacy, methods of administration and availability. A general overview of these considerations is given in Appendix L for review. The hepatitis B vaccination series will be made available at no cost within 10 days of initial assignment of employees who have occupational exposure to blood or other potentially infectious materials unless:

- ❑ the employee has previously received the series
- ❑ antibody testing reveals that the employee is immune
- ❑ medical reasons prevent taking the vaccination; or
- ❑ the employee chooses not to participate

Hepatitis B vaccination will be provided by *Atlanticare Occupational Health, Egg Harbor Township, NJ*

All employees are strongly encouraged to receive the hepatitis B vaccination series. However, if an employee chooses to decline HB vaccination, then the employee must sign a statement to this effect.

Employees who decline may request and obtain the vaccination at a later date at no cost. Documentation of refusal of the HB vaccination (see Appendix C2) will be kept in The Office of EHS with the employee's other medical records.

Appendix C1 is an optional form that may be used to record the employee vaccination series information.

Highlights of Hepatitis B Vaccination Other Requirements

- γ Participation in pre-screening is not a prerequisite for receiving the hepatitis B vaccination
- γ Hepatitis B vaccination provided even if employee declines but later accepts vaccine
- γ Employee must sign statement when declining HB vaccination
- γ Vaccination administered in accordance with United States Public Health Service (USPHS) recommended protocol*
- γ HB vaccination booster doses must be available to employees if recommended by USPHS

Antibody Testing after the Hepatitis B Vaccination

The CDC stated in their latest report* that health-care personnel (HCP) (e.g., employees, students attending clinicians, public safety workers or volunteers) who have contact with patients or blood and are at ongoing risk for percutaneous injuries should be tested 1-2 months after completion of the 3-dose vaccination series for antibodies for hepatitis B surface antigen (anti-HBs).

The PEOSH Bloodborne Pathogens Standard (29 CFR 1910.1030) requires that the most recent CDC guidelines be followed regarding the hepatitis B vaccine and post-exposure follow-up. *Therefore, employers of New Jersey public safety workers (e.g., EMT's, police, firefighters, corrections officers) and other public employees covered under the PEOSH Bloodborne Pathogens Standard must determine if their employees are at ongoing risk for percutaneous injuries.* If so, then the employer is required to offer blood testing to those employees 1-2 months after completion of the 3-dose vaccination series for antibodies for hepatitis B surface antigen (anti-HBs). (If the employee does not respond to the primary vaccine, consult the CDC report* for additional recommendations.) The employer does not have to offer antibody testing to those employees who have been previously vaccinated.

* See the "Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HBV, HCV, and HIV and Recommendations for Post Exposure Prophlylaxis (June 29, 2001/50 (RR11); 1-42 at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5o11a1.htm

7.0 Post Exposure Evaluation and Follow-up and Procedures for Reporting, Documenting and Evaluating the Exposure

7.1 Should an exposure incident occur contact your supervisor and The Office of EHS immediately. Each exposure must be documented by the employee on an "Exposure Report Form" (see Appendix D). The Office of EHS and dept. supervisor will add any additional information as needed.

An immediately available confidential medical evaluation and follow-up will be conducted by Atlanticare medical facilities. The following elements will be performed:

- ❑ Document the routes of exposure and how exposure occurred.
- ❑ Identify and document the source individual (see Appendix E), unless the employer can establish that identification is infeasible or prohibited by State or local law (See Note #1).
- ❑ Obtain consent (See Note #2) and test source individual's blood as soon as possible to determine HIV and HBV infectivity (See footnote) and document the source's blood test results.
- ❑ If the source individual is known to be infected with either HIV or HBV (See footnote), testing need not be repeated to determine the known infectivity.
- ❑ Provide the exposed employee with the source individual's test results and information about applicable disclosure laws and regulations concerning the source identity and infectious status.
- ❑ After obtaining consent, collect exposed employee's blood as soon as feasible after the exposure incident and test blood for HBV and HIV serological status. (See footnote)
- ❑ If the employee does not give consent for HIV serological testing during the collection of blood for baseline testing, preserve the baseline blood sample for at least 90 days. (See Note #3)

Appendix D "Exposure Incident Report" and Appendix E "Request for Source Individual Evaluation" and Appendix F "Employee Exposure Follow-Up Record" (see Note #4) will be provided to the employee so they may bring them along with any additional relevant medical information to the medical evaluation. Original copies of these appendixes will be maintained with the employee's medical records.

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* Update: The U .S. Public Health Service, Centers for Disease Control and Prevention (CDC) recommend including blood-testing of the source and the exposed individual for the presence of hepatitis C antibody (anti-HCV). See footnote, page 16 and Appendix M.

POST EXPOSURE EVALUATION

The Office of EHS will review the circumstances of the exposure incident to determine if procedures, protocols and/or training need to be revised.

Note to Employer:

Note #1 New Jersey Law (N.J.S.A. 26-5C et. seq.) and Regulation (N.J.A.C. 8:57-2) requires information about AIDS and HIV to be kept confidential. While the law requires reporting of positive HIV results to the State Health Department, the law strictly limits disclosure of HIV-related information. When disclosure of HIV-related information is authorized by a signed release, the person who has been given the information MUST keep it confidential. Redisclosure may occur ONLY with another authorized signed release.

Note #2 If, during this time, the exposed employee elects to have the baseline sample tested, testing shall be done as soon as feasible.

Note #3 Appendixes D, E, and F are optional forms which have been provided to assist employers with gathering information that is required by the standard. If an employer chooses not to use these forms, this information must still be provided and recorded in accordance with the Standard: Also note that HIV Confidential Case Report form and/or the AIDS Adult Confidential Case Report form, as well as, the HIV Testing Policy information applicable to New Jersey public sector employers can be obtained by contacting:

The New Jersey State Department of Health
and Senior Services
Data Analysis Unit
PO Box 363
Trenton, New Jersey 08625-0363
(609) 984-6204

Note #4 Following an exposure incident, prompt medical evaluation and prophylaxis is imperative. Timeliness is, therefore, an important factor in effective medical treatment

Highlights of Post Exposure Evaluation and Follow-Up Requirements

- γ Documentation of exposure routes and how exposure incident occurred
- γ Identification and documentation of source individual's infectivity, if possible
- γ Collection and testing of employee's blood for HBV and HIV serological status (employee's consent required) (See footnote)
- γ Post-exposure prophylaxis when medically indicated
- γ Counseling
- γ Evaluation of reported illnesses

For Health Care Providers and Health Care Professionals there is a 24-hour Hotline where clinicians can obtain post-exposure prophylaxis treatment guidelines.

For staff that has been exposed, the Hotline also provides counseling on treatment issues.

The Toll-free number is: 1-888-448-4911, 24 hours a day, 7 days a week, on call staff can always be reached.

The internet address is: www.ucsf.edu/hivcntr

Once you access the Internet go onto the PEPline (Post-exposure prophylaxis)

* Update: The U.S. Public Health Service, Centers for Disease Control and Prevention (CDC) recommend including blood-testing of the source and the exposed individual for the presence of hepatitis C antibody (anti-HCV). See footnote, p. 16 and Appendix M.

8.0 Health Care Professionals

8.1 The Office of EHS will ensure that health care professionals responsible for employee's HB vaccination and post-exposure evaluation and follow-up be given a copy of the PEOSH Bloodborne Pathogens Standard. The Office of EHS will also ensure that the health care professional evaluating an employee after an exposure incident receives the following:

- ❑ a description of the employee's job duties relevant to the exposure incident
- ❑ route(s) of exposure
- ❑ circumstances of exposure
- ❑ if possible, results of the source individual's blood test; and
- ❑ relevant employee medical records, including vaccination status

8.2 Healthcare Professional's Written Opinion

Facilities & Operations will provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days after completion of the evaluation.

For HB vaccinations, the healthcare professional's written opinion will be limited to whether the employee requires or has received the HB vaccination.

The written opinion for post-exposure evaluation and follow-up will be limited to whether or not the employee has been informed of the results of the medical evaluation and any medical conditions which may require further eva1uation and treatment.

All other diagnoses must remain **confidential** and not be included in the written report to our facility.

> **Note to Employer:** If the employer is also the health care professional, the employer must ensure that the results of the employee's post-exposure evaluation remain confidential from his/her co-workers.

8.3 Procedures for Evaluating the Circumstances Surrounding an Exposure Incident

<u>The Office of EHS</u> will review the circumstances of all exposure incidents to determine.

- **engineering controls in use at the time**
- **work practices followed**
- **a description of the device being used (including type and brand)**
- **protective equipment or clothing that was used at the time of the exposure incident (gloves, eye shields, etc.)**
- **location of the incident**
- **procedure being performed when the incident occurred**
- **employee's training**

The Office of EHS **will record all percutaneous injuries from contaminated sharps in the Sharps Injury Log.**

If it is determined that revisions need to be made, *The Office of EHS* will ensure that appropriate changes are made to this ECP. (Changes may include an evaluation of safer devices, adding employees to the exposure determination list, etc.)

9.0 **Housekeeping**

9.1 Facilities & Operations has developed and implemented a written schedule for cleaning and decontaminating work surfaces as indicated by the standard.

Cleaning Schedule

Area	Scheduled Cleaning (Day/Time)	Cleaners and Disinfectants Used	Specific Instructions

Note to Employer: Include a housekeeping schedule and method of decontamination above. Include location of cleanup and decontamination supplies. A list of approved sterilants can be obtained from the Environmental Protection Agency (EPA), Antimicrobial Division at: http://www.epa.gov/oppad001/chemregindex.htm or e-mail: liem.david@epa.gov. A preformatted schedule sheet (Appendix O) is provided in the Appendix Section of this kit if additional space is required.

Note to Employer: To further assist employers in developing a written housekeeping schedule, the following procedures are provided as examples. To ensure a complete working document, it is recommended that the written task be as specific as possible.

- ❑ Decontaminate work surfaces with an appropriate disinfectant after completion of procedures, immediately when overtly contaminated, after any spill of blood or other potentially infectious materials, and at the end of the work shift when surfaces have become contaminated since the last cleaning.

- ❑ Remove and replace protective coverings such as plastic wrap and aluminum foil when contaminated.

- ❑ Inspect and decontaminate, on a regular basis, reusable receptacles such as bins, pails, and cans that have a likelihood for becoming contaminated. When contamination is visible, clean and decontaminate receptacles immediately, or as soon as feasible.

- ❑ Always use mechanical means such as tongs, forceps, or a brush and a dust pan to pick up contaminated broken glassware; never pick up with hands even if gloves are worn.

- ❑ Store or process reusable sharps in a way that ensures safe handling.

- ❑ Place regulated waste in closable and labeled or color-coded containers. When storing, handling, transporting or shipping, place other regulated waste in containers that are constructed to prevent leakage.

- ❑ When discarding contaminated sharps (including safer medical devices), place them in containers that are closable, puncture-resistant, appropriately labeled or color-coded, and leak-proof on the sides and bottom.

- ❑ Ensure that the sharps containers are easily accessible to personnel and located as close as feasible to the immediate area where sharps are used or can be reasonably anticipated to be found. Sharps containers also must be kept upright throughout use, replaced routinely, closed when moved, and not allowed to overfill.

    < Never manually open, empty, or clean reusable contaminated sharps disposal containers.

    < Discard all regulated waste according to federal, state, and local regulations, i.e., liquid or semi-liquid blood or other potentially infectious material; items contaminated with blood or other potentially infectious materials that would release these substances in a liquid or semi-liquid state if compressed; items caked with dried blood or other potentially infectious materials and capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

9.2 **Laundry**

The following contaminated articles will be laundered:

- _N/A_____
  _____
  _____
  _____

Laundry will be performed by __N/A_____
at _____N/A_____.

The following requirements must be met, with respect to contaminated laundry:

- Handle contaminated laundry as little as possible and with a minimum of agitation.
- Use appropriate personal protective equipment when handling contaminated laundry.
- Place wet contaminated laundry in leak-proof, labeled or color-coded containers before transporting.
- Bag contaminated laundry at its location of use.
- Never sort or rinse contaminated laundry in areas of its use.

- ❑ *Use red laundry bags or those marked with the biohazard symbol unless universal precautions are in use at the facility and all employees recognize the bags as contaminated and have been trained in handling the bags.

- ❑ *All generators of laundry must have determined if the receiving facility uses universal precautions. If universal precautions are not used, then clearly mark laundry sent off-site with orange biohazard labels or use red bags. Leak proof bags must be used when necessary to prevent soak-through or leakage.

- ❑ When handling and/or sorting contaminated laundry, utility gloves and other appropriate personal protective equipment (i.e., aprons, mask, eye protection) shall be worn.

- ❑ Laundries must have sharps containers readily accessible due to the incidence of needles and sharps being unintentionally mixed with laundry.

- ❑ Linen soiled with blood or body fluids should be placed and transported in bags that prevent leakage. If hot water is used, linen should be washed with detergent in water at least 140°F - 160°F for 25 minutes. If low-temperature (<140°F) laundry cycles are used, chemicals suitable for low-temperature washing at proper use concentration should be used.

* **NOTE:** For these items specify below which labeling system, red bags or biohazard labeling, will be used for laundering.

Note to Employer: Disposable protective clothing can be used to eliminate or greatly reduce the need for laundering.

10.0 **Laundry**

10.1 The following labeling method(s) will be used at our facility:

{ _____N/A_____

_____

_____ will ensure warning labels are affixed or red bags are used as required. Employees are to notify _____ if they discover unlabeled regulated waste containers.

Note to Employer: The employer must specify which warning methods are used and communicate this information to all employees. The standard requires that fluorescent orange or orange-red warning labels be attached to: (1) containers of regulated waste; (2) refrigerators and freezers containing blood and other potentially infectious materials; (3) sharps disposal containers; (4) laundry bags and containers; (5} contaminated equipment for repair (portion contaminated); and (6) other containers used to store, transport, or ship blood or other potentially infectious materials. These labels are not required when: (1) red bags or red containers are used; (2) containers of blood, blood components, or blood products are labeled as to their contents and have been released for transfusion or other clinical use; and (3) individual containers of blood or other potentially infectious materials are placed in a labeled container during storage, transport, shipment or disposal. The warning label must be fluorescent orange or orange-red, contain the biohazard symbol and the word "BIOHAZARD" (See Appendix H) in a contrasting color, and be attached to each object by string, wire, adhesive, or other method to prevent loss or unintentional removal of the label.

11.0 Recordkeeping

11.1 Medical Records

Medical records are maintained for each employee with occupational exposure in accordance with 29 CFR 1910.1020, "Access to Employee Exposure and Medical Records".

_The Office of Human Resources (OHR)is responsible for maintenance of the required medical records and they are kept at _____OHR_____.

NOTE: Refer to the Appendix Section for copies of applicable medical record forms.

In addition to the requirements of 29 CFR 1910.1020, the medical record will include:

- ❑ The name and social security number of employee;
- ❑ A copy of the employee's hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination;
- ❑ A copy of all results of examinations, medical testing, and follow-up procedures as required by the standard;
- ❑ A copy of all healthcare professional's written opinion(s) as required by the standard.

All employee medical records will be kept **confidential** and will not be disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by the standard or as may be required by law.

Employee medical records shall be confidential and maintained for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020.

Employee medical record shall be provided upon request of the employee or to anyone having written consent of the employee within 15 working days.

11.2 Training Records

Bloodborne pathogen training records will be maintained by _The Office of EHS at _Facilities & Operations- Bldg 70_____ (see Appendix B).

The training record shall include:

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

Training records will be maintained for a minimum of three (3) years from the date on which the training occurred.

Employee training records will be provided upon request to the employee or the employee's authorized representative within 15 working days.

11.3 Transfer of Records

If Stockton University ceases to do business and there is no successive employer to receive and retain the records for the prescribed period, the employer shall notify the Director of the National Institute for Occupational Safety and Health (NIOSH) at least three (3) months prior to scheduled record disposal and prepare to transmit them to the Director.

Highlights of Medical Records

- γ Employee name and social security number
- γ Employee hepatitis B vaccination status
- γ Medical testing and post-exposure follow-up results
- γ Healthcare Professional's written opinion
- γ Information provided to the health care professional

Highlights of Training Records

- γ Training dates
- γ Training session content or summary
- γ Names and qualifications of trainers
- γ Names and job titles of all trainees

PEOSH Recordkeeping

An exposure incident is evaluated to determine if the case meets PEOSH's Recordkeeping Requirements (29 CFR 1904). This determination and the recording activities are done by *The Office of EHS*.

Sharps Injury Log

In addition to the 29 CFR 1904 Recordkeeping Requirements, all percutaneous injuries from contaminated sharps are also recorded in the Sharps Injury Log. All incidences must include at least:

- $ **the date of the injury**
- $ **the type and brand of the device involved**
- $ **the department or work area where the incident occurred**
- $ **an explanation of how the incident occurred**

This log is reviewed at least annually as part of the annual evaluation of the program and is maintained for at least five years following the end of the calendar year that they cover. If a copy is requested by anyone, it must have any personal identifiers removed from the report.

FIRST AID PROVIDERS

This section only applies to employees who are designated to render first aid assistance, but this assistance is not their primary work assignment. First aid providers who are in this collateral duty category at this facility are listed below for easy reference and also in Section B of the Employer Exposure Determination on page five.

Designated First Aid Providers

- _____N/A_____
  _____
  _____
  _____

Our facility has decided to: (check box for facility's specific policy)

- ❑ offer hepatitis B vaccination to the first aid provider after a first aid incident
- ❑ offer pre-exposure vaccination.

In the event of a first aid incident where blood or other potentially infectious materials (OPIM) are present, the employee(s) providing the first aid assistance is (are) instructed to report to _____ before the end of their workshift.

_____ will maintain a report (Appendix D can be used) which describes name of the first aider, date, time and description of incident.

_____ will ensure that any first aider that desires the vaccine series after an incident involving blood or OPIM will receive it as soon as possible, but no later than twenty four hours after the incident.

_____ will train first aid providers on the specifics of the reporting procedures, in addition to all the training required in Section 5.0 Training.

Note to Employer: Examples of employees who may meet the above criteria include:

- Security Guards, Coaches, Bus Drivers, DPW/DOT, Office Workers, Industrial Plant Personnel, who are designated and trained to perform first aid.

Examples of employees who do not meet the criteria and must be offered the hepatitis B vaccination series include:

- Personnel who provide first aid at a first aid station, clinic, emergency response or public safety personnel, who are expected to render first aid in the normal course of their work (i.e., EMS personnel, police, firefighters).

This is not an all-inclusive list, nor does it imply that every employee in these job titles are covered.

Also, as a reminder, good samaritan acts are still not covered by the Standard

APPENDIX SECTION

APPENDIX A

OCCUPATIONS AT RISK

Occupations that may involve risk from occupational exposure to blood or other potentially infectious material:

- < Physician
- < Physicians Assistant
- < Nurse
- < Phlebotomist
- < Medical Examiner
- < Emergency Medical Technician (EM)
- < Supervisor (performing first-aid)
- < Dentist
- < Dental Hygienist
- < Medical Technologist
- < Regulated Waste Handler
- < Some laundry and housekeeping employees
- < Industrial Medical Center Personnel
- < Lab Workers
- < Life Guards
- < Firefighters
- < Corrections Officers
- < Police

DEFINITIONS

Before beginning a discussion of the standard there are several definitions that should be explained which specifically apply to this regulation. These definitions are also included in paragraph (b) of the standard.

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

B. **Bloodborne Pathogens** - pathogenic microorganisms that are present in human blood and can infect and cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV). (This includes hepatitis C virus.)

C. **Contaminated** - the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

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

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

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

G. **Other Potentially Infectious Materials (OPIM)**

1. The following human body fluids:

   a. semen
   b. vaginal secretions
   c. cerebrospinal fluid
   d. synovial fluid
   e. pleural fluid
   f. pericardial fluid
   g. peritoneal fluid
   h. amniotic fluid
   i. Saliva in dental procedures
   j. any body fluid visibly contaminated with blood
   k. 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);

3. HIV-containing cells or tissue cultures, organ cultures, and HIV or HBV-containing cultures medium or other solutions; and

4. Blood, organs, or other tissue from experimental animals infected with HIV or HBV.

H. **Regulated Waste -**

1. Liquid or semi-liquid blood or OPIM;

2. Contaminated items that would release blood or OPIM in a liquid or semi-liquid state if compressed;

3. Items that are caked with dried blood or OPIM and are capable of releasing these materials during handling;

4. Contaminated sharps; and

5. Pathological and microbiological wastes containing blood or OPIM.

I. **Universal Precautions** - an approach to infection control whereby all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

APPENDIX A

JOB CLASSIFICATIONS IN WHICH ALL EMPLOYEES HAVE OCCUPATIONAL EXPOSURE TO BLOODBORNE PATHOGENS

Below are listed the job classifications in our facility where **all** employees will have reasonably anticipated exposure to human blood and other potentially infectious materials:

Job Title	*Department/Location*

APPENDIX A

JOB CLASSIFICATIONS AND WORK ACTIVITIES IN WHICH SOME EMPLOYEES HAVE OCCUPATIONAL EXPOSURE TO BLOODBORNE PATHOGENS

Below are listed the job classifications and work activities in our facility where **some** employees will have reasonably anticipated exposure to human blood and other potentially infectious materials:

Job Title	*Department/Location*	*Task Procedure*

APPENDIX B

EMPLOYEE EDUCATION & TRAINING RECORD

Employee _____ Date of Hire _____

Job Title _____ Date Assigned _____

INITIAL TRAINING:				
SUBJECT	**DATE**	**LOCATION**	**TRAINER**	**EMPLOYEE SIGNATURE**
a. The Standard				
b. Epidemiology & Symptoms of Bloodborne Diseases				
c. Modes of Transmission				
d. Exposure Control Plan				
e. Recognizing Potential Exposure				
f. Use & Limitations of Exposure Control Methods				
g. Personal Protective Equipment (PPE)				
h. Selection of PPE				
i. HBV Immunization Program				
j. Emergencies involving Blood or Potentially Infectious Materials				
k. Exposure Follow-up Procedures				
l. Post Exposure Evaluation and Follow-up				
m. Signs & Labels				
n. Opportunity to Ask Questions				

ADDITIONAL EDUCATION:				
SUBJECT	**DATE**	**LOCATION**	**TRAINER**	**EMPLOYEE SIGNATURE**

ANNUAL RETRAINING:				
SUBJECT	**DATE**	**LOCATION**	**TRAINER**	**EMPLOYEE SIGNATURE**

APPENDIX C

CONFIDENTIAL

HEPATITIS B VACCINE IMMUNICATION RECORD

Vaccine is to be administered on: _____

Elected dates:

First: _____

One month from elected date: _____

Six months from elected date: _____

Employee Name: _____

Date of first dose: _____

Date of second dose: _____

Date of third dose: _____

Antibody test results - pre-vaccine (optional): _____

Antibody test results - post-vaccine: _____

Time interval since last injection: _____

Employee Signature: _____

DECLINATION STATEMENT

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.

_____ _____

Employee Signature Date

Side 1 of 2-sided form

EXPOSURE INCIDENT REPORT

(Routes and Circumstances of Exposure Incident)

Please Print

Date Completed _____

Employee's Name _____ SS# _____-_____-_____

Home Phone _____ Business Phone _____

DOB _____ Job Title _____

Employee Vaccination Status _____

Date of Exposure _____ Time of Exposure _____ am ❑ pm ❑

Location of Incident (Home, Street, Clinic, etc) Be Specific: _____
_____

Nature of Incident (Auto Accident, Trauma, Medical Emergency) Be Specific:
_____
_____
_____

Describe what task(s) you were performing when the exposure occurred. Be Specific:
_____
_____
_____

Were you wearing personal protective equipment (PPE)? Yes ❑ No ❑

If yes, list _____

Did the PPE fail? Yes ❑ No ❑

If yes, explain how: _____
_____
_____

What body fluid(s) were you exposed to (blood or other potentially infectious material)? Be Specific:
_____
_____
_____

Continued on back

Side 2 of 2-sided form

Continued from front

What parts of your body became exposed? Be specific: _____
_____

Estimate the size of the area of your body that was exposed: _____
_____

For how long? _____

Did a foreign body (needle, nail, auto part, dental wires, etc.) penetrate your body?
Yes ❑ No ❑

If yes, what was the object? _____

Where did it penetrate your body? _____

Was any fluid injected into your body? Yes ❑ No ❑

If yes, what fluid?: _____ How much? _____

Did you receive medical attention? Yes ❑ No ❑

If yes, where? _____

When _____

By whom _____

Identification of source individual(s) _____

Name(s) _____

Did you treat the patient directly? Yes ❑ No ❑

If yes, what treatment did you provide. Be specific: _____
_____

Other pertinent information: _____
_____
_____
_____

APPENDIX E LETTER

REQUEST FOR SOURCE INDIVIDUAL EVALUATION

Dear (Emergency Room Medical Director, Infection Control Practitioner):

During a recent transport of a patient to your facility, one of our prehospital care providers was involved in an event which may have resulted in exposure to a Bloodborne Pathogen.

I am asking you to perform an evaluation of the source individual who was transported to your facility. Given the circumstances surrounding this event, please determine whether our prehospital care worker is at risk for infection and/or requires medical follow-up.

Attached is a "Documentation and Identification of Source Individual" form which was initiated by the exposed worker. Please complete the source individual section and communicate the findings to the designated medical provider.

The evaluation form has been developed to provide confidentially assurances for the patient and the exposed worker concerning the nature of the exposure. Any communication regarding the findings is to be handled at the medical provider level.

We understand that information relative to human immunodeficiency virus (HIV) and AIDS has specific protections under the law and cannot be disclosed or released without the written consent of the patient. It is further understood that disclosure obligates persons who receive such information to hold it confidential.

Thank you for your assistance in this very important matter.

Sincerely,

_____

APPENDIX E FORM

CONFIDENTIAL

DOCUMENTATION AND IDENTIFICATION OF SOURCE INDIVIDUAL

Name of Exposed Employee _____

Name and Phone Number of Medical Provider Who Should be Contacted:

_____

Incident Information

Date: _____

Name or Medical Record Number of the Individual Who is the Source of the Exposure:

_____

Nature of the Incident

- ❑ Contaminated Needlestick Injury
- ❑ Blood or Bodyfluid Splash Onto Mucous Membrane or Non-Intact Skin

Other: _____

Report of Source Individual Evaluation

Chart Review By _____ Date: _____

Source Individual Unknown - Researched by _____
Date: _____

Testing of Source Individual's Blood **Consent** Obtained ❑ Refused ❑

Check One:

- ❑ Identification of source individual infeasible or prohibited by state or local law. State why is infeasible.
- ❑ Evaluation of the source individual reflected to known exposure to Bloodborne Pathogen.
- ❑ Evaluation of the source individual reflected possible exposure to Bloodborne Pathogen and medical follow-up is recommended.

Person Completing Report: _____ Date: _____

Note: Report the results of the source individual's blood test to the medical provider named above who will inform the exposed employee. Do not report blood test findings to the employer.

HIV-related information cannot be released without the written consent of the source individual.

APPENDIX F

CONFIDENTIAL

EMPLOYEE EXPOSURE FOLLOW-UP RECORD

Employee's Name _____ Job Title _____

Occurrence Date _____ Reported Date _____

Occurrence Time _____ am ❑ pm ❑

SOURCE INDIVIDUAL FOLLOW-UP

Request Made to _____
Date _____ Time _____ am ❑ pm ❑

EMPLOYEE FOLLOW-UP

Employee's Health File Reviewed by _____ Date: _____

Information given on source individual's blood test results Yes ❑ Not Obtained ❑

Referred to healthcare professional with required information

Name of healthcare professional _____

By Whom _____ Date _____

Blood Sampling/Testing Offered

By Whom _____ Date _____

Vaccination Offered/Recommended

By Whom _____ Date _____

Counseling Offered

By Whom _____ Date _____

Employee Advised of need for further evaluation of medical condition

By Whom _____ Date _____

APPENDIX G

INFORMATION ON REGULATED MEDICAL WASTE

The following information is included to assist you in evaluating and contracting for a transport, handling, and disposal company, should you not be equipped to handle your regulated medical waste.

Every Prospective Client is Urged to:

1. Request and check references and solicit information on reliability from colleagues who are known clients of vendor(s);

2. Obtain a specific detailed contract for services rendered;

3. Require accurate documentation on transportation practices and date, method and location of ultimate disposal;

4. If at all possible, make a site visit to the vendor's base of operation and disposal facilities; and

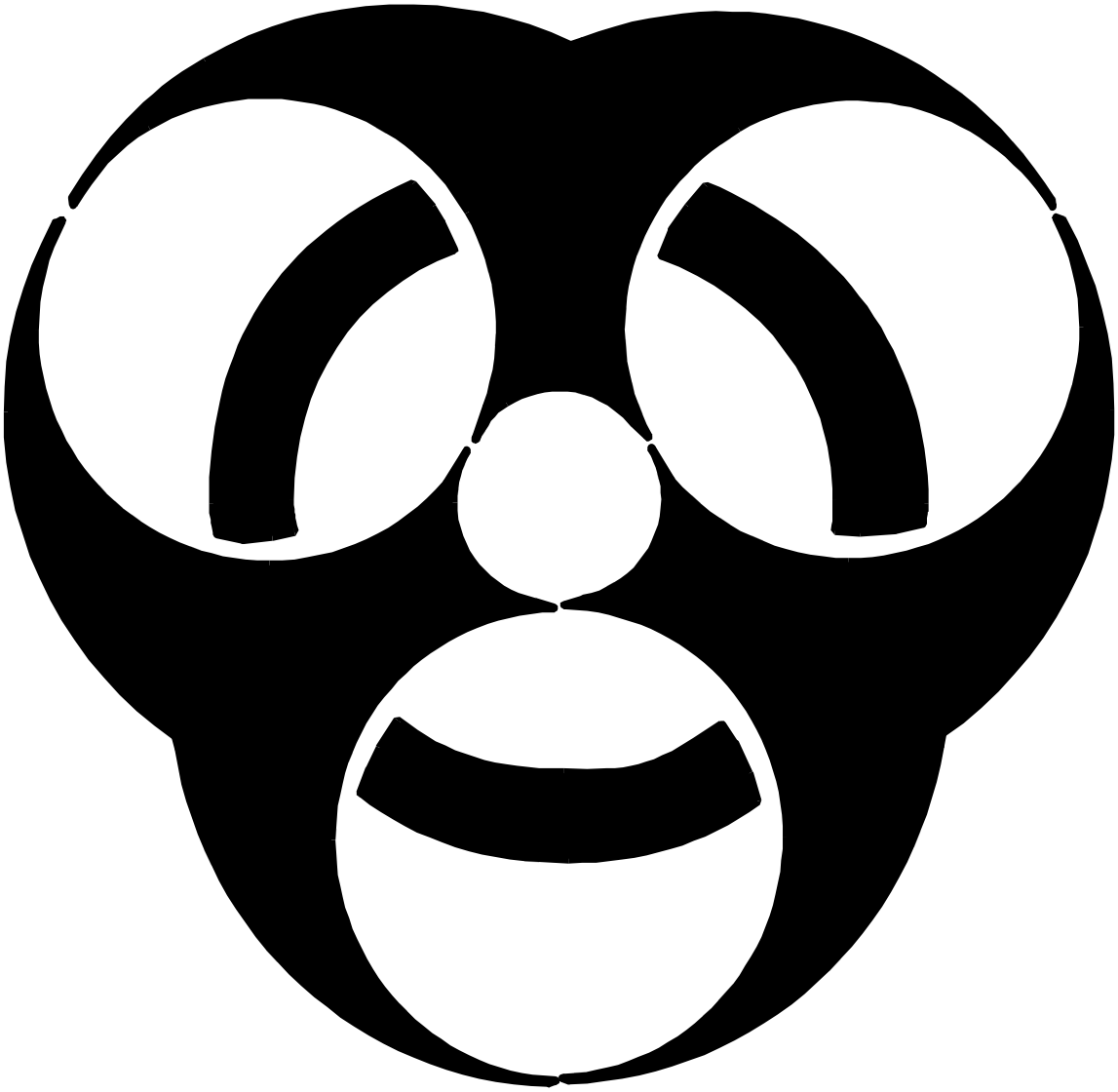
5. Strictly monitor all aspects of the services provided to you on an ongoing basis.

For Additional Information on Regulated Medical Waste, contact:

New Jersey Department of Environmental Protection
Division of Solid Waste Management
Bureau of Resource Recovery and Technical Programs
PO Box 414
401 East State Street
Trenton, NJ 08625-0414
(609) 984-6620

And/Or

New Jersey Department of Health and Senior Services
Division of Environmental and Occupational Health Services
Public Health Sanitation and Safety Program
PO Box 369
3635 Quakerbridge Road
Trenton, NJ 08625-0369
(609) 588-3124



BIOHAZARD

Bloodborne FACTS

Personal Protective Equipment Cuts Risk

U.S. Department of Labor
Occupational Safety and Health Administration

Wearing gloves, gowns, masks, and eye protection can significantly reduce health risks for workers exposed to blood and other potentially infectious materials. The new OSHA standard covering bloodborne disease requires employers to provide appropriate personal protective equipment (PPE) and clothing free of charge to employees.

Workers who have direct exposure to blood and other potentially infectious materials on their jobs run the risk of contracting bloodborne infections from hepatitis B virus (HBV), human immuno-deficiency virus (HIV) which causes AIDS, and other pathogens. About 8,700 health care workers each year are infected with HBV, and 200 die from the infection. Although the risk of contracting AIDS through occupational exposure is much lower, wearing proper personal protective equipment can greatly reduce potential exposure to all bloodborne infections.

SELECTING PPE

Person protective clothing and equipment must be suitable. This means the level of protection must fit the expected exposure. For example, gloves would be sufficient for a laboratory technician who is drawing blood, whereas a pathologist conducting an autopsy would need considerably more protective clothing.

PPE may include gloves, gowns, laboratory coats, face shields or masks, eye protection, pocket masks, and other protective gear. The gear must be readily accessible to employees and available in appropriate sizes.

If an employee is expected to have hand contact with blood or other potentially infectious materials or contaminated surfaces, he or she must wear gloves. Single use gloves cannot be washed or decontaminated for reuse. Utility gloves may be decontaminated if they are not compromised. They should be replaced when they show signs of cracking, peeling, tearing, puncturing, or deteriorating. If employees are allergic to standard gloves, the employer must provide hypoallergenic gloves or similar alternatives.

Routine gloving is not required for phlebotomy in voluntary blood donation centers, though it is necessary for all other phlebotomies. In any case, gloves must be available in voluntary blood donation centers for employees who want to use them. Workers in voluntary blood donation centers must use gloves (1) when they have cuts, scratches or other breaks in their skin, (2) while they are in training; and (3) when they believe contamination might occur.

Employees should wear eye and mouth protection such as goggles and masks, glasses with solid side shields, and masks or chin-length face shields when splashes, sprays, splatters, or droplets of potentially infectious materials pose a hazard through the eyes, nose or moth. More extensive coverings such as gowns, aprons, surgical caps and hoods, and shoe covers or boots are needed when gross contamination is expected. This often occurs, for example, during orthopedic surgery or autopsies.

AVOIDING CONTAMINATION

The key is that blood or other infectious materials must not reach an employee's work clothes, street cloths, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions for the duration of exposure.

Employers must provide the PPE and ensure that their workers wear it. This means that if a lab coat is considered PPE, it must be supplied by the

employer rather than the employee. The employer also must clean or launder clothing and equipment and repair or replace it as necessary.

Additional protective measures such as using PPE in animal rooms and decontaminating PPE before laundering are essential in facilities that conduct research on HIV or HBV.

EXCEPTION

There is one exception to the requirement for protective gear. An employee may choose, temporarily and briefly, **under rare and extraordinary circumstances**, to forego the equipment. It must be the employee's professional judgment that using the protective equipment would prevent the delivery of health case or public safety services or would pose an increased hazard to the safety of the worker or coworker. When one of those excepted situations occurs, employers are to investigate and document the circumstances to determine if there are ways to avoid it in the future. For example, if a firefighter's resuscitation device is damaged, perhaps another type of device should be used or the device should be carried in a different manner. Exceptions must be limited- -this is not a blanket exemption.

DECONTAMINATING AND DISPOSING OF PPE

Employees must remove personal protective clothing and equipment before leaving the work area or when the PPE becomes contaminated. If a garment is penetrated, workers must remove it immediately or as soon as feasible. Used protective clothing and equipment must be placed in designated containers for storage, decontamination, or disposal.

OTHER PROTECTIVE PRACTICES

If an employee's skin or mucous membranes come into contact with blood, he or she is to wash with soap and water and flush eyes with water as soon as feasible. In addition, workers must wash their hands immediately or as soon as feasible after removing protective equipment. If soap and water are not immediately available, employers may provide other handwashing measures such as moist towelettes. Employees still must wash with soap and water as soon as possible.

Employees must refrain from eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses in areas where they may be exposed to blood or other potentially infectious materials.

This is one of a series of fact sheets that discuss various requirements of the Occupational Safety and Health Administration's standard covering exposure to bloodborne pathogens. Single copies of fact sheets are available from OSHA Publications, Room N-3103, 200 Constitution Avenue, N.W., Washington, D.C. 20210 and from OSHA regional offices.

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Bloodborne FACTS

Reporting Exposure Incidents

U.S. Department of Labor
Occupational Safety and Health Administration

OSHA's new bloodborne pathogens standard includes provisions for medical follow-up for workers who have an exposure incident. The most obvious exposure incident is a needlestick. But any specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials is considered an exposure incident and should be reported to the employer.

Exposure incidents can lead to infection from hepatitis B virus (HBV) or human immuno-deficiency virus (HIV) which causes AIDS. Although few cases of AIDS are directly traceable to workplace exposure, every year about 8,700 health care workers contract hepatitis B from occupational exposures. Approximately 200 will die from this bloodborne infection. Some will become carriers, passing the infection on to others.

WHY REPORT?

Reporting an exposure incident right away permits immediate medical follow-up. Early action is crucial. Immediate intervention can forestall the development of hepatitis B or enable the affected worker to track potential HIV infection. Prompt reporting also can help the worker avoid spreading bloodborne infection to others. Further, it enables the employer to evaluate the circumstances surrounding the exposure incident to tray to find ways to prevent such a situation from occurring again.

Reporting is also important because part of the follow-up includes testing the blood of the source individual to determine HBV and HIV infectivity if this is unknown and if permission for testing can be obtained. The exposed employee must be informed of the results of these tests.

Employers must tell the employee what to do if an exposure incident occurs.

MEDICAL EVALUATION AND FOLLOW-UP

Employers must provide free medical evaluation and treatment to employees who experience an exposure incident. They are to refer exposed employees to a licensed health care provider who will counsel the individual about what happened and how to prevent further spread of any potential infection. He or she will prescribe appropriate treatment in line with current U.S. Public Health Service recommendations. The licensed health care provider also will evaluate any reported illness to determine if the symptoms may be related to HIV or HBV development.

The first step is to test the blood of the exposed employee. Any employee who wants to participate in the medical evaluation program must agree to have blood drawn. However, the employee has the option to give the blood sample but refuse permission for HIV testing at that time. The employer must maintain the employee's blood sample for 90 days in case the employee changes his or her mind about testing- -should symptoms develop that might relate to HIV or HBV infection.

The health care provider will counsel the employee based on the test results. If the source individual was HBV positive or in a high risk category, the exposed employee may be given hepatitis B immune globulin and vaccination, as necessary. If there is no information on the source individual or the test is negative, and the employee has not been vaccinated or does not have immunity based on his or her test, he or she may receive the vaccine. Further, the health care provider will discuss any other findings from the tests.

The standard requires that the employer make the hepatitis B vaccine available, at no cost to the employee, to all employees who have occupational exposure to blood and other potentially infectious materials. This requirement is in addition to post-exposure testing and treatment responsibilities.

WRITTEN OPINION

In addition to counseling the employee, the health care provider will provide a written report to the employer. This report simply identifies whether hepatitis B vaccination was recommended for the exposed employee and whether or not the employee received vaccination. The health care provider also must note that the employee has been informed of the results of the evaluation and told of any medical conditions resulting from exposure to blood which require further evaluation or treatment. Any added findings must be kept confidential.

CONFIDENTIALITY

Medical records must remain confidential. They are not available to the employer. The employee must give specific written consent for anyone to see the records. Records must be maintained for the duration of employment plus 30 years in accordance with OSHA's standard on access to employee exposure and medical records.

This is one of a series of fact sheets that discuss various requirements of the Occupational Safety and Health Administration's standard covering exposure to bloodborne pathogens. Single copies of fact sheets are available from OSHA Publications, Room N-3103, 200 Constitution Avenue, N.W., Washington, D.C. 20210 and from OSHA regional offices.

Bloodborne FACTS

Protecting Yourself When Handling Sharps

U.S. Department of Labor
Occupational Safety and Health Administration

A needlestick or a cut from a contaminated scalpel can lead to infection from hepatitis B virus (HBV) or human immunodeficiency virus which causes AIDS. Although few cases of AIDS have been documented from occupational exposure, approximately 8,700 health care workers each year contract hepatitis B. About 200 will die as a result. The new OSHA standard covering bloodborne pathogens specifies measures to reduce these risks of infection.

PROMPT DISPOSAL

The best way to prevent cuts and sticks is to minimize contact with sharps. That means disposing of them immediately after use. Puncture-resistant containers must be available nearby to hold contaminated sharps--either for disposal or, for reusable sharps, later decontaminated for re-use. When reprocessing contaminated reusable sharps, employees must not reach by hand into the holding container. Contaminated sharps must never be sheared or broken.

Recapping, bending, or removing needles is permissible **only** if there is no feasible alternative or if required for a specific medical procedure such as blood gas analysis. If recapping, bending, or removal is necessary, workers must use either a mechanical device or a none-handed technique. If recapping is essential--for example, between multiple injections for the same patient- - the employee must avoid using both hands to recap. Employees must recap with a one-handed "scoop" technique, using the needle itself to pick up the cap, pushing cap and sharp together against a hard surface to ensure a tight fit. Or they might hold the cap with tongs or forceps to place it on the needle.

SHARPS CONTAINERS

Containers for used sharps must be puncture resistant. The sides and the bottom must be leakproof. They must be labeled or color coded red to ensure that everyone knows the contents are hazardous. Containers for disposable sharps must have a lid, and they must be maintained upright to keep liquids and the sharps inside.

Employees must never reach by hand into containers of contaminated sharps. Containers for reusable sharps could be equipped with wire basket liners for easy removal during reprocessing, or employees could use tongs or forceps to withdraw the contents. Reusable sharps disposal containers may not be opened, emptied, or cleaned manually.

Containers need to be located as near to as feasible the area of use. In some cases, they may be placed on carts to prevent access to mentally disturbed or pediatric patients. Containers also should be available wherever sharps may be found, such as in laundries. The containers must be replaced routinely and not be overfilled, which can increase the risk of needlestick or cuts.

HANDLING CONTAINERS

When employees are ready to discard containers, they should first close the lids. If there is a chance of leakage from the primary container, the employees should use a secondary container that is closable, labeled, or color coded and leak resistant.

Careful handing of sharps can prevent injury and reduce the risk of infection. By following these work practices, employees can decrease their chances of contracting bloodborne illness.

This is one of a series of fact sheets that discuss various requirements of the Occupational Safety and Health Administration's standard covering exposure to bloodborne pathogens. Single copies of fact sheets are available from OSHA Publications, Room N-3103, 200 Constitution Avenue, N.W., Washington, D.C. 20210 and from OSHA regional offices.

Bloodborne FACTS

Hepatitis B Vaccination -- Protection For You

U.S. Department of Labor
Occupational Safety and Health Administration

WHAT IS HBV?

Hepatitis B virus (HBV) is a potentially life-threatening bloodborne pathogen. Centers for Disease Control estimates there are approximately 280,000 HBV infections each year in the U.S.

Approximately 8,700 health care workers each year contract hepatitis B, and about 200 will die as a result. In addition, some who contract HBV will become carriers, passing the disease on to others. Carriers also face a significantly higher risk for other liver ailments which can be fatal including cirrhosis of the liver and primary liver cancer.

HBV infection is transmitted through exposure to blood and other infectious body fluids and tissues. Anyone with occupational exposure to blood is at risk of contracting the infection.

Employers must provide engineering controls; workers must use work practices and protective clothing and equipment to prevent exposure to potentially infectious materials. However, the best defense against hepatitis B is vaccination.

WHO NEEDS VACCINATION?

The new OSHA standard covering bloodborne pathogens requires employers to offer the three injection vaccination series free to all employees who are exposed to blood or other potentially infectious materials as part of their job duties. This includes health care workers, emergency responders, morticians, first aid personnel, law enforcement officers, correctional facilities staff, launders, as well as others.

The vaccination must be offered within 10 days of initial assignment to a job where exposure to blood or other potentially infectious materials can be "reasonably anticipated." The requirements for vaccinations of those already on the job take effect July 6, 1992.

WHAT DOES VACCINATION INVOLVE?

The hepatitis B vaccination is a noninfectious, yeast-based vaccine given in three injections in the arm. It is prepared from recombinant yeast cultures, rather than human blood or plasma. Thus, there is no risk of contamination from other bloodborne pathogens nor is there any chance of developing HBV from the vaccine.

The second injection should be given one month after the first, and the third injection six months after the initial dose. More than 90 percent of those vaccinated will develop immunity to the hepatitis B virus. To ensure immunity, it is important for individuals to receive all three injections. At this point it is unclear how long the immunity lasts, so booster shots may be required at some point in the future.

The vaccine causes no harm to those who are already immune or to those who may be HBV carriers. Although employees may opt to have their blood tested for antibodies to determine need for the vaccine, employers may not make such screening a condition of receiving vaccination nor are employers required to provide prescreening.

Each employee should receive counseling from a health care professional when vaccination is offered. This discussion will help an employee determine whether inoculation is necessary.

WHAT IF I DECLINE VACCINATION?

Workers who decide to decline vaccination must complete a declination form. Employers must keep these forms on file so that they know the vaccination status of everyone who is exposed to blood. At any time after a worker initially declines to receive the vaccine, he or she may opt to take it.

WHAT IF I AM EXPOSED BUT HAVE NOT YET BEEN VACCINATED?

If a worker experiences an exposure incident, such as a needlestick or a blood splash in the eye, he or she must receive confidential medical evaluation from a licensed health care professional with appropriate follow-up. To the extent possible by law, the employer is to determine the source individual for HBV as well as human immunodeficiency virus (HIV) infectivity. The worker's blood will also be screened if he or she agrees.

The health care professional is to follow the guidelines of the U.S. Public Health Service in providing treatment. This would include hepatitis B vaccination. The health care professional must give a written opinion on whether or not vaccination is recommended and whether the employee received it. Only this information is reported to the employer. Employee medical records must remain confidential. HIV or HBV status must NOT be reported to the employer.

This is one of a series of fact sheets that discuss various requirements of the Occupational Safety and Health Administration's standard covering exposure to bloodborne pathogens. Single copies of fact sheets are available from OSHA Publications, Room N-3103, 200 Constitution Avenue, N.W., Washington, D.C. 20210 and from OSHA regional offices.

Bloodborne FACTS

Hepatitis C

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV) which is found in the blood of persons who have this disease. The infection is spread by contact with the blood of an infected person. Hepatitis C is serious for some persons, but not for others. A small number of persons die of liver failure shortly after getting hepatitis C. Most persons who get hepatitis C carry the virus for the rest of their lives. Most of these persons have some liver damage but many do not feel sick from the disease. Some persons with liver damage due to hepatitis C may develop cirrhosis (scarring) of the liver and liver failure which may take many years to develop.

The hepatitis C virus is involved in most cases of parenterally transmitted non-A, non-B hepatitis in the United States. An estimated 2% to 4% of the HCV infections in the United States occurred among healthcare personnel who were occupationally exposed to blood (needlestick, punctures). There is no vaccine or post-exposure prophylaxis available for HCV, and immune globulin is not recommended after an exposure incident. Blood-testing is now available to test for detection of antibody to HCV (anti-HCV), although screening assays do not distinguish acute, chronic, or resolved infection.

The Bloodborne Pathogens Standard requires that post-exposure evaluations, follow-up, and prophylaxis be provided according to the current recommendations of the U.S. Public Health Service (USPHS). The USPHS, Centers for Disease Control and Prevention (CDC) now recommend testing of the source and exposed individual for the presence of anti-HCV antibody after an exposure incident "Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HBV, HCV and HIV and Recommendations for Post Prophylaxis" (June 29, 20001/50 (RRII); 1-42). The CDC stated that healthcare institutions should consider implementing recommended policies and procedures for follow-up for HCV infection after percutaneous or mucosal exposures to blood. At a minimum, such policies can include:

(1) baseline testing of the source for anti-HCV;

(2) baseline and follow-up testing (e.g., 6 months) for anti-HCV and alanine aminotransferase activity of the person exposed to an anti-HCV sero-positive source;

(3) confirmation by supplemental anti-HCV testing of all anti-HCV results reported as repeatedly active by enzyme immunoassay;

(4) recommendation against post-exposure prophylaxis with immune globulin or antiviral agents (e.g., interferon); and

(5) education of healthcare personnel about the risk for the prevention of bloodborne infections, including HCV, in occupational settings, with information routinely updated to ensure accuracy.

Hepatitis C
Fact Sheet

www.cdc.gov/hepatitis
1-888-4HEP-CDC

SIGNS & SYMPTOMS

- jaundice
- fatigue
- dark urine
- abdominal pain
- loss of appetite
- nausea

80% of persons have no sign or symptoms.

CAUSE

Hepatitis C Virus (HCV)

LONG-TERM EFFECTS

- Chronic infection: 75-85% of infected persons
- Chronic liver disease: 70% of chronically infected persons
- Deaths from chronic liver disease: <3
- Leading indication for liver transplant

TRANSMISSION

- Occurs when blood or body fluids from an infected person enters the body of a person who is not infected.
- HCV is spread through sharing needles or "works" when "shooting" drugs, through needlesticks or sharps exposure on the job, or from an infected mother to her baby during birth.

RECOMMENDATIONS FOR TESTING BASED ON RISK FOR HCV INFECTION

Persons at risk for HCV infection might also be at risk for infection with hepatitis B virus (HBV) or HIV.

Recommendations for Testing Based on Risk for HCV infection

*Anyone who wants to get tested should ask their doctor.

PERSONS	RISK OF INFECTION	TESTING RECOMMENDED?
Injecting drug users	High	Yes
Recipients of clotting factors made before 1987	High	Yes
Hemodialysis patients	Intermediate	Yes
Recipients of blood and/or solid organs before 1998	Intermediate	Yes
People with undiagnosed liver problems	Intermediate	Yes
Infants born to infected mothers	Intermediate	After 12-18 months old
Healthcare/Public safety workers	Low	Only after known exposure
People having sex with multiple partners	Low	No*
People having sex with an infected steady partner	Low	No*

Hepatitis C
Fact Sheet

Page 2

www.cdc.gov/hepatitis
1-888-4HEP-CDC

PREVENTION	• There is no vaccine to prevent hepatitis C. • Do not shoot drugs. If you shoot drugs, stop and get into a treatment program. If you can't stop, never share needles, syringes, water, or "works", and get vaccinated against hepatitis A and B. • Do not share personal care items that might have blood on them (razors, toothbrushes). • If you are a healthcare or public safety worker, always follow routine barrier precautions and safely handle needles and sharps; get vaccinated against hepatitis B. • Consider the risks if you are thinking about getting a tattoo or body piercing. You might get infected if the tools have someone else's blood on them or if the artist or piercer does not follow good health practices. • HCV can be spread by sex, but this is very rare. If you are having sex with more than one steady sex partner, use condoms* correctly and every time to prevent the spread of sexually transmitted diseases. You should also get vaccinated against hepatitis B. • If you are HCV positive, do not donate blood, organs, or tissue.
TREATMENT & MEDICAL MANAGEMENT	• HCV positive persons should be evaluated by their doctor for liver disease. • Interferon and ribavirin are two drugs licensed for the treatment of persons with chronic hepatitis C. • Interferon can be taken alone or in combination with ribavirin. Combination therapy is currently the treatment of choice. • Combination therapy can get rid of the virus in up to 4 out of 10 persons. • Drinking alcohol can make your liver disease worse.
STATISTICS & TRENDS	• Number of new infections per year has declined from an average of 240,000 in the 1980s to about 40,000 in 1998. • Most infections are due to illegal injection drug use. • Transfusion-associated cases occurred prior to blood donor screening; now occurs in less than one per million transfused unit of blood. • Estimated 3.9 million (1.8%) Americans have been infected with HCV, of whom 2.7 million are chronically infected.

*The efficacy of latex condoms in preventing infection with HCV is unknown, but their proper use may reduce transmission.

Bloodborne FACTS

Holding the Line on Contamination

U.S. Department of Labor
Occupational Safety and Health Administration

Keeping work areas in a clean and sanitary condition reduces employees' risk of exposure to bloodborne pathogens. Each year about 8,700 health care workers are infected with hepatitis B virus, and 200 die from contracting hepatitis B through their work. The chance of contracting human immunodeficiency virus (HIV), the bloodborne pathogen which causes AIDS, from occupational exposure is small, yet a good housekeeping program can minimize this risk as well.

DECONTAMINATION

Every employer whose employees are exposed to blood or other potentially infectious materials must develop a written schedule for cleaning each area where exposures occur. The methods of decontaminating different surfaces must be specified, determined by the type of surface to be cleaned, the soil present and the tasks or procedures that occur in that area.

For example, different cleaning and decontamination measures would be used for a surgical operatory and a patient room. Similarly, hard surfaced flooring and carpeting require separate cleaning methods. More extensive efforts will be necessary for gross contamination than for minor spattering. Likewise, such varied tasks as laboratory analyses and normal patient care would require different techniques for clean-up.

Employees must decontaminate working surfaces and equipment with an appropriate disinfectant after completing procedures involving exposure to blood. Many laboratory procedures are performed on a continual basis throughout a shift. Except as discussed below, it is not necessary to clean and decontaminate between procedures. However, if the employee leaves the area for a period of time, for a break or lunch, then contaminated work surfaces must be cleaned.

Employees also must clean (1) when surfaces become obviously contaminated; (2) after any spill of blood or other potentially infectious materials; and (3) at the end of the work shift if contamination might have occurred. Thus, employees need not decontaminate the work area after each patient care procedure, but only after those that actually result in contamination.

If surfaces or equipment are draped with protective coverings such as plastic wrap or aluminum foil, these coverings should be removed or replaced if they become obviously contaminated. Reusable receptacles such as bins, pails and cans that are likely to become contaminated must be inspected and decontaminated on a regular basis. If contamination is visible, workers must clean and decontaminate the item immediately, or as soon as feasible.

Should glassware that may be potentially contaminated break, workers need to use mechanical means such as a brush and dustpan or tongs or forceps to pick up the broken glass - never by hand, even when wearing gloves.

Before any equipment is serviced or shipped for repairing or cleaning, it must be decontaminated to the extent possible. The equipment must be labeled, indicating which portions are still contaminated. This enables employees and those who service the equipment to take appropriate precautions to prevent exposure.

REGULATED WASTE

In addition to effective decontamination of work areas, proper handling of regulated waste is essential to prevent unnecessary exposure to blood and other potentially infectious materials. Regulated waste must be handled with great care -- i.e., liquid or semi-liquid blood and other potentially infectious materials, items caked with these materials if compressed, pathological or microbiological wastes containing them and contaminated sharps.

Containers used to store regulated waste must be closable and suitable to contain the contents and prevent leakage of fluids. Containers designed for sharps also must be puncture resistant. They must be labeled or color-coded to ensure that employees are aware of the potential hazards. Such containers must be closed before removal to prevent the contents from spilling. If the outside of a container becomes contaminated, it must be placed within a second suitable container.

Regulated waste must be disposed of in accordance with applicable state and local laws.

LAUNDRY

Laundry workers must wear gloves and handle contaminated laundry as little as possible, with a minimum of agitation. Contaminated laundry should be bagged or placed in containers at the location where it is used, but not sorted or rinsed there.

Laundry must be transported within the establishment or to outside laundries in labeled or red color-coded bags. If the facility uses Universal Precautions for handling all soiled laundry, then alternate labeling or color-coding that can be recognized by the employees may be used. If laundry is wet and it might soak through laundry bags, then workers must use bags that prevent leakage to transport it.

RESEARCH FACILITIES?

More stringent decontamination requirements apply to research laboratories and production facilities that work with concentrated strains of HIV and HBV.

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APPENDIX O

CLEANING SCHEDULE

AREA	SCHEDULED CLEANING (DAY/TIME)	CLEANERS & DISINFECTANTS USED	SPECIFIC INSTRUCTIONS

MERCK & CO., INC.
Whitehouse Station, NJ 08889, USA 7994325

RECOMBIVAX HB®
HEPATITIS B VACCINE (RECOMBINANT)

DESCRIPTION

RECOMBIVAX HB® Hepatitis B Vaccine (Recombinant) is a non-infectious subunit viral vaccine derived from hepatitis B surface antigen (HBsAg) produced in yeast cells. A portion of the hepatitis B virus gene, coding for HBsAg, is cloned into yeast, and the vaccine for hepatitis B is produced from cultures of this recombinant yeast strain according to methods developed in the Merck Research Laboratories.

The antigen is harvested and purified from fermentation cultures of a recombinant strain of the yeast *Saccharomyces cerevisiae* containing the gene for the adw subtype of HBsAg. The fermentation process involves growth of *Saccharomyces cerevisiae* on a complex fermentation medium which consists of an extract of yeast, soy peptone, dextrose, amino acids and mineral salts. The HBsAg protein is released from the yeast cells by cell disruption and purified by a series of physical and chemical methods. The purified protein is treated in phosphate buffer with formaldehyde and then coprecipitated with alum (potassium aluminum sulfate) to form bulk vaccine adjuvanted with amorphous aluminum hydroxyphosphate sulfate. The vaccine contains no detectable yeast DNA but may contain not more than 1% yeast protein. The vaccine produced by the Merck method has been shown to be comparable to the plasma-derived vaccine in terms of animal potency (mouse, monkey, and chimpanzee) and protective efficacy (chimpanzee and human).

The vaccine against hepatitis B, prepared from recombinant yeast cultures, is free of association with human blood or blood products.

Each lot of hepatitis B vaccine is tested for safety, in mice and guinea pigs, and for sterility.

RECOMBIVAX HB is a sterile suspension for intramuscular injection. However, for persons at risk of hemorrhage following intramuscular injection, the vaccine may be administered subcutaneously. (See DOSAGE AND ADMINISTRATION.)

RECOMBIVAX HB Hepatitis B Vaccine (Recombinant) is supplied in three formulations. (See HOW SUPPLIED.)

Pediatric/Adolescent Formulation (With and Without Preservative), 10 mcg/mL: each 0.5 mL dose contains 5 mcg of hepatitis B surface antigen.

Adult Formulation (With and Without Preservative), 10 mcg/mL: each 1 mL dose contains 10 mcg of hepatitis B surface antigen.

Dialysis Formulation, (With and Without Preservative), 40 mcg/mL: each 1 mL dose contains 40 mcg of hepatitis B surface antigen.

Formulations that contain a preservative include thimersoal, a mercury derivative, at 1:20,000 or 50 mcg/mL. All formulations contain approximately 0.5 mg of aluminum (provided as amorphous aluminum hydroxyphosphate sulfate, previously referred to as aluminum hydroxide) per mL of vaccine. In each formulation, hepatitis B surface antigen is absorbed onto approximately 0.5 mg of aluminum (provided as amorphous aluminum hydroxyphosphate sulfate) per mL of vaccine. The vaccine is of the *adw* subtype. RECOMBIVAX HB is indicated for vaccination of persons at risk of infection from hepatitis B virus including all known subtypes. RECOMBIVAX HB Dialysis Formulation is indicated for vaccination of adult predialysis and dialysis patients against infection caused by all known subtypes of hepatitis B virus.

CLINICAL PHARMACOLOGY

Hepatitis B virus is one of several hepatitis viruses that cause a systemic infection, with a major pathology in the liver. These include hepatitis A virus, hepatitis D virus, and hepatitis C and E viruses, previously referred to as non-A, non-B hepatitis viruses.

Hepatitis B virus is an important cause of viral hepatitis. There is no specific treatment for this disease. The incubation period for hepatitis B is relatively long; six weeks to six months may elapse between exposure and the onset of clinical symptoms. The prognosis following infection with hepatitis B virus is variable and dependent on at least three factors: (1) Age – Infants and younger children usually experience milder initial disease than older persons;[1] (2) Dose of Virus – The higher the dose, the more likely acute icteric hepatitis B will result;[1] and, (3) Severity of associated underlying disease – Underlying malignancy or pre-existing hepatic disease predisposes to increased morbidity and mortality.[1]

Persistence of viral infection (the chronic hepatitis B virus carrier state) occurs in 5-10% of persons following acute hepatitis B, and occurs more frequently after initial anicteric hepatitis B than after initial icteric disease. Consequently, carriers of hepatitis B surface antigen (HBsAg) frequently give no history of having had recognized acute hepatitis. The Centers for Disease Control and Prevention (CDC) estimates that there are more than 300 million chronic carriers worldwide and 1.25 million chronic carriers of hepatitis B virus in the USA.[29,30] Chronic carriers represent the largest human reservoir of hepatitis B virus.

Serious complications and sequelae of hepatitis B virus infection include massive hepatic necrosis, cirrhosis of the liver, and chronic active hepatitis. More than one million people worldwide die each year of hepatitis B associated acute and chronic liver disease.[34] In the United States, hepatitis B-virus-related acute and chronic liver disease causes approximately 4-5000 deaths annually.[29,30]

Reduced Risk of Hepatocellular Carcinoma

Hepatocellular carcinoma is another serious complication of hepatitis B virus infection. Studies have demonstrated the link between chronic hepatitis B infection and hepatocellular carcinoma; 80% of primary liver cancers are caused by hepatitis B virus infection. The CDC has recognized hepatitis B vaccine as the first anti-cancer vaccine because it can prevent primary liver cancer.[35]

There is also evidence that several diseases other than hepatitis have been associated with hepatitis B virus infection through an immunologic mechanism involving antigen-antibody complexes. Such diseases include a syndrome with rash, urticaria, and arthralgia resembling serum sickness; periarteritis nodosa; membranous glomerulonephritis; and infantile papular acrodermatilis.[3,4]

Although the vehicles for transmission of the virus are often blood and blood products, viral antigen has also been found in tears, saliva, breast milk, urine, semen and vaginal secretions. Hepatitis B virus is capable of surviving at least a month[29] on environmental surfaces exposed to infected body fluids containing hepatitis B virus. Infection may occur when hepatitis B virus, transmitted by infected body fluids, is implanted via mucous surfaces or percutaneously introduced through accidental or deliberate breaks in the skin.

Transmission of hepatitis B virus infection is often associated with close interpersonal contact with an infected individual and with crowded living conditions. In such circumstances, transmission by inoculation via routes other than overt percutaneous ones may be quite common.[1] Perinatal transmission of hepatitis B infection from infected mother to child, at or shortly after birth, can occur if the mother is a hepatitis B surface antigen (HBsAg) carrier or if the mother has an acute hepatitis B infection in the third trimester. Infection in infancy by the hepatitis B virus usually leads to the chronic carrier state. Without prophylaxis, infants born to women whose sera are positive for both the hepatitis B surface antigen and the e antigen have an 85-90% likelihood of being infected and becoming a chronic carrier.[5,6] Well-controlled studies have shown that administration of three 0.5 mL doses of Hepatitis B Immune Globulin (Human) – HBIG starting at birth is 75% effective in preventing establishment of the chronic carrier state in these infants during the first year of life.[6] However, the protective effect of HBIG is transient.

Hepatitis B is endemic throughout the world and is a serious medical problem in population groups at increased risk. Because vaccination limited to high-risk individuals has failed to substantially lower the overall incidence of hepatitis B infection, both the Advisory Committee on Immunization Practices (ACIP) and the Committee on Infectious Diseases of the American Academy of Pediatrics (AAP) have also endorsed universal infant immunization as part of a comprehensive strategy for the control of hepatitis B infection.[7,8] In addition, the ACIP also recommends hepatitis B vaccination for all infants and children born after November 21, 1991 and catch-up vaccination of children at high risk of infection (children <11 years of age in households of Pacific Islander ethnicity or of first generation immigrants/refugees from countries with an intermediate or high endemicity of infection).[30] These advisory groups further recommend broad-based vaccination of adolescents. The ACIP recommends that all individuals not previously vaccinated with hepatitis B vaccine be vaccinated at 11-12 years of age with the age-appropriate dose of vaccine and that the vaccination schedule take into account the feasibility of delivering three doses of vaccine to this age group. In addition, older unvaccinated adolescents with identified risk factors for hepatitis B virus infection should also be vaccinated.[30] Similarly, the AAP recommends that universal immunization of all adolescents should be implemented when resources permit with emphasis on those individuals in high-risk settings.[8] A National Institutes of Health Consensus Development Conference Panel on the management of hepatitis C recommends the immunization of all hepatitis C virus (HCV) positive individuals with hepatitis B vaccine.[36] (Refer to INDICATIONS AND USAGE).

Numerous epidemiological studies have shown that persons who develop anti-HBs following active infection with the hepatitis B virus are protected against the disease on re-exposure to the virus.[9]

Clinical studies have shown that RECOMBIVAX HB when injected into the deltoid muscle induced protective levels of antibody in 96% of 1,213 health adults who received the recommended 3-dose regimen. Antibody responses varied with age; a protective level of antibody was induced in 98% of 787 young adults 20-29 years of

age, 94% of 249 adults 30-39 years of age and in 89% of 177 adults ≥40 years of age.[10] Studies with hepatitis B vaccine derived from plasma have shown that a lower response rate (81%) to vaccine may be obtained if the vaccine is administered as a buttock injection.[11] Seroconversion rates and geometric mean antibody titers were measured 1 to 2 months after the third dose. Multiple clinical studies have defined a protective antibody (anti-HBs) level as 1) 10 or more sample ratio units (SRU) as determined by radioimmunoassay or 2) a positive result as determined by enzyme immunoassay.[2] Note: 10 SRU is comparable to 10 mIU/mL of antibody.[12,13,14,15]

RECOMBIVAX HB was shown to be highly immunogenic in clinical studies involving infants, children and adolescents. Three 5 mcg doses of vaccine induced a protective level of antibody in 100% of 92 infants, 99% of 129 children, and in 99% of 112 adolescents[10] (see DOSAGE AND ADMINISTRATION).

The protective efficacy of three 5 mcg doses of RECOMBIVAX HB has been demonstrated in neonates born of mothers positive for both HBsAg and HBeAg (a core-associated antigenic complex which correlates with high infectivity). In a clinical study of infants who received one dose of HBIG at birth followed by the recommended three-dose regimen of RECOMBIVAX HB, chronic infection had not occurred in 96% of 130 infants after nine months of follow-up.[16] The estimated efficacy in prevention of chronic hepatitis B infection was 95% as compared to the infection rate in untreated historical controls.[17] Significantly fewer neonates became chronically infected when given one dose of HBIG at birth followed by the recommended three-dose regimen of RECOMBIVAX HB when compared to historical controls who received only a single dose of HBIG.[8] Testing for HBsAg and anti-HBs is recommended at 12-15 months of age. If HBsAg is not detectable, and anti-HBs is present, the child has been protected.

As demonstrated in the above study, HBIG, when administered simultaneously with RECOMBIVAX HB at separate body sites, did not interfere with the induction of protective antibodies against hepatitis B virus elicited by the vaccine.

For adolescents (11 through 15 years of age), the immunogenicity of a two-dose regimen (10 mcg at 0 and 4-6 months) was compared with that of the standard three-dose regimen (5 mcg at 0.1, and 6 months) in an open, randomized, multicenter study. The proportion of adolescents receiving the two-dose regimen who developed a protective level of antibody one month after the last dose (99% of 255 subjects) appears similar to that among adolescents who received the three-dose regimen (98% of 121 subjects). After adolescents (11 through 15 years of age) received the first 10-mcg dose of the two-dose regimen, the proportion who developed a protective level of antibody was approximately 72%.[10]

In one published study, the seroprotection rates in individuals with chronic HCV infection given the standard regimen of RECOMBIVAC HB was approximately 70%.[37] In a second published study of intravenous drug users given an accelerated schedule of RECOMBIVAX HB, infection with HCV did not affect the response to RECOMBIVAX HB.[35]

As with other hepatitis B vaccines, the duration of the protective effect of RECOMBIVAX HB in healthy vaccines is unknown at present, and the need for booster doses is not yet defined. However, long-term follow-up (5 to 9 years) of approximately 3,000 high-risk vaccines (infants of carrier mothers, male homosexuals, Alaskan Natives) who developed an anti-HBs titer of ≥10 mIU/mL when given a similar plasma-derived vaccine at intervals of 0, 1, and 6 months showed that no subjects developed clinically apparent hepatitis B infection and that 5 subjects developed antigenemia, even though up to half of the subjects failed to maintain a titer at this level.[18-21] Persistence of vaccine-induced immunologic memory among healthy vaccines who responded to a primary course of plasma-derived or recombinant hepatitis B vaccine has been demonstrated by an anamnestic antibody response to a booster dose of RECOMBIVAX HB given 5-12 years later.[22]

Predialysis and Dialysis Patients

Predialysis and dialysis adult patients respond less well to hepatitis B vaccines than do healthy individuals; however, vaccination of adult patients early in the course of their renal disease produces higher seroconversion rates than vaccination after dialysis has been initiated.[30] In addition, the responses to these vaccines may be lower if the vaccine is administered as a buttock injection. When 40 mcg of Hepatitis B Vaccine (Recombinant), was administered in the deltoid muscle, 89% of 28 participants developed anti-HBs with 86% achieving levels ≥10 mIU/mL. However, when the same dosage of this vaccine was administered inappropriately either in the buttock or a combination of buttock and deltoid, 62% of 47 participants developed anti-HBs with 55% achieving levels of ≥10 mIU/mL.[10]

A booster dose of revaccination with RECOMBIVAX HB Dialysis Formulation may be considered in predialysis/dialysis patients if the anti-HBs level is less than 10 mIU/mL.[23]

Reports in the literature describe a more virulent form of hepatitis B associated with superinfections or coinfections by delta virus, an incomplete RNA virus. Delta virus can only infect and cause illness in persons infected with hepatitis B virus since the delta agent requires a coat of HBsAg in order to become infectious. Therefore, persons immune to hepatitis B virus infection should also be immune to delta virus infection.[2]

Interchangeability of Plasma-Derived and Recombinant Hepatitis B Vaccines

Although there have been no clinical studies in which a three-dose vaccine series was initiated with HEPTAVAX-B (Hepatitis B Vaccine) and completed with RECOMBIVAX HB, or vice versa, extensive *in vitro* and *in vivo* studies have demonstrated that these two vaccines are immunologically comparable.[22,24-28]

INDICATIONS AND USAGE

RECOMBIVAX HB is indicated for vaccination against infection caused by all known subtypes of hepatitis B virus. **RECOMBIVAX HB Dialysis Formulation** is indicated for vaccination of adult predialysis and dialysis patients against infection caused by all known subtypes of hepatitis B virus.

Vaccination with RECOMBIVAX HB is recommended for:

1) Infants including those born to HBsAg positive mothers (high-risk infants).
2) Children born after November 21, 1991.[30]
3) Adolescents (see CLINICAL PHARMACOLOGY).
4) Other persons of all ages in areas of high prevalence or those who are or may be at increased risk of infection with hepatitis B virus, such as:[30]

- *Health Care Personnel*
  - Dentists and oral surgeons.
  - Physicians and surgeons.
  - Nurses.
  - Paramedical personnel and custodial staff who may be exposed to the virus via blood or other patient specimens.
  - Dental hygienists and dental nurses.
  - Laboratory personnel handling blood, blood products, and other patient specimens.
  - Dental, medical and nursing students.
- *Selected Patients and patient Contacts*
  - Staff in hemodialysis units and hematology/oncology units.
  - Hemodialysis patients and patients with early renal failure before they require hemodialysis.
  - Patients requiring frequent and/or large volume blood transfusions or clotting factor concentrates (e.g., persons with hemophilia, thalassemia).
  - Clients (residents) and staff of institutions for the mentally handicapped.
  - Classroom contacts of deinstitutionalized mentally handicapped persons who have persistent hepatitis B surface antigenemia and who show aggressive behavior.
  - Household and other intimate contacts of persons with persistent hepatitis B surface antigenemia.
- *Sub-populations with a known high incidence of the disease, such as:*
  - Alaskan Natives.
  - Pacific Islanders.
  - Refugees from areas where hepatitis B virus infection is endemic.
  - Adoptees from countries where hepatitis B virus infection is endemic.
- *International Travelers*
- *Military Personnel Identified as being at increased risk*
- *Morticians and Embalmers*
- *Blood bank and plasma fractionation workers*
- *Persons at Increased Risk of the Disease Due to Their Sexual Practices, such as:*
  - Persons who have heterosexual activity with multiple partners.
  - Persons who repeatedly contract sexually transmitted diseases.
  - Homosexual and bisexual adolescent and adult men.
  - Female Prostitutes.
- *Prisoners*
- *Injection drug users*

Neither dosage strength will prevent hepatitis caused by other agents, such as hepatitis A virus, hepatitis C virus, hepatitis E virus or other viruses known to infect the liver.

Revaccination

See CLINICAL PHARMACOLOGY.

Use with Other Vaccines

Results from clinical studies indicate that RECOMBIVAX HB can be administered concomitantly with DTP (Diphtheria, Tetanus and whole cell Pertussis), OPV (oral Poliomyelitis vaccine), M-M-R* II (Measles, Mumps, and Rubella Virus Vaccine Live), Liquid PedvaxHIB* [Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)] or a booster dose of DTaP [Diphtheria, Tetanus, acellular Pertussis], using separate sites and syringes for injectable vaccines. No impairment of immune response to individually tested vaccine antigens was demonstrated.

The type, frequency and severity of adverse experiences observed in these studies with RECOMBIVAX HB were similar to those seen when the other vaccines were given alone.

In addition, and HBsAg-containing product, COMVAX [Haemophilus b Conjugate (Meningococcal Protein Conjugate) and Hepatitis B (Recombinant) Vaccine] was given concomitantly with eIPV (enhanced inactivated Poliovirus vaccine) or VARIVAX [Varicella Virus Vaccine Live (Oka/Merck)], using separate sites and syringes for injectable vaccines. No impairment of immune response to these individually tested vaccine antigens was demonstrated. No serious vaccine-related adverse events were reported.

COMVAX has also been administered concomitantly with the primary series of DTaP to a limited number of infants. No serious vaccine-related adverse events were reported.[10]

Separate sites and syringes should be used for simultaneous administration of injectable viruses.

CONTRAINDICATIONS

Hypersensitivity to yeast or any component of the vaccine.

WARNINGS

Patients who develop symptoms suggestive of hypersensitivity after an injection should not receive further injections of the vaccine (see CONTRAINDICATIONS).

Because of the long incubation period for hepatitis B, it is possible for unrecognized infection to be present at the time the vaccine is given. The vaccine may not prevent hepatitis B in such patients.

PRECAUTIONS

General

As with any percutaneous vaccine, epinephrine (1:1000) should be available for immediate use should an anaphyslactoid reaction occur.

Any serious active infection including febrile illness is reason for delaying use of the vaccine except when in the opinion of the physician, withholding the vaccine entails a greater risk.

Caution and appropriate care should be exercised in administering the vaccine to individuals with severely compromised cardiopulmonary status or to others in whom a febrile or systemic reaction could pose a significant risk.

Instructions to Healthcare Provider

The healthcare provider should determine the current health status and previous vaccination history of the vaccinee.

The healthcare provider should question the patient, parent or guardian about reactions to a previous dose of RECOMBIVAX HB or other hepatitis B vaccines.

The healthcare provider must record in the patient's permanent record: the manufacturer, lot number, date of administration, and the name and address of the person administering the vaccine.

Injection of a blood vessel should be avoided.

Information for Vaccine Recipients and Parents/Guardians

The healthcare provider should provide the vaccine information required to be given with each vaccination to the patient, parent or guardian.

The healthcare provider should inform the patient, parent or guardian of the benefits and risks associated with vaccination, as well as the importance of completing the immunization series. For risks associated with vaccination, see WARNINGS, PRECAUTIONS, and ADVERSE REACTIONS.

Patients, parents and guardians should be instructed to report any serious adverse reactions to their healthcare provider, who in turn should report such events to the U.S. Department of Health and Human Services through the Vaccine Adverse Event Reporting System (VAERS), 1-800-822-7967.[32] The healthcare provider should inform the parent or guardian of the National Vaccine Injury Compensation Program (NVICP), 1-888-338-2382 or http://www.hrsa.dhhs.gov/bhpr/vicp.

Drug Interactions

There are no known drug interactions. (See INDICATIONS AND USAGE, *Use with Other Vaccines*.)

Carcinogenesis, Mutagenesis, Impairment of Fertility

RECOMBIVAX HB has not been evaluated for its carcinogenic or mutagenic potential, or its potential to impair fertility.

Pregnancy

Pregnancy Category C: Animal reproduction studies have not been conducted with the vaccine. It is also not known whether the vaccine can cause fetal harm with administered to a pregnant woman or can affect reproduction capacity. The vaccine should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether the vaccine is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when the vaccine is administered to a nursing woman.

Pediatric use

RECOMBIVAX HB has been shown to be usually well-tolerated and highly immunogenic in infants and children of all ages. Newborns also respond well; maternally transferred antibodies do not interfere with the active immune response to the vaccine. See DOSAGE AND ADMINISTRATION for recommended pediatric dosage and for recommended dosage for infants born to HBsAg positive mothers.

The safety and effectiveness of RECOMBIVAX HB Dialysis Formulation in children have not been established.

Geriatric Use

Clinical studies of RECOMBIVAX HB did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reports from the clinical literature indicate that hepatitis B vaccines are less immunogenic in adults aged 65 years or older than in younger individuals.[33] No overall differences in safety were observed between these subjects and younger subjects.

ADVERSE REACTIONS

RECOMBIVAX HB and RECOMBIVAX HB Dialysis Formulation are generally well-tolerated. No serious adverse reactions attributable to the vaccine have been reported during the course of clinical trials. No adverse experiences were reported during clinical trials which could be related to changes in the titers of antibodies to yeast. As with any vaccine, there is the possibility that broad use of the vaccine could reveal adverse reactions not observed in clinical trials.

In three clinical studies, 434 doses of REOMBIVAX HB, 5 mcg, were administered to 147 healthy infants and children (up to 10 years of age) who were monitored for 5 days after each dose. Injection site reactions and systemic complaints were reported following 0.2% and 10.4% of the injections, respectively. The most frequently reported systemic adverse reaction (>1% injections), in decreasing order of frequency, were irritability, fever ($\geq$101°F oral equivalent), diarrhea, fatigue/weakness, diminished appetite, and rhinitis.[10]

In a study that compared the three-dose regimen (5 mcg) with the two-dose regimen (10 mcg) of RECOMBIVAX HB in adolescents, the overall frequency of adverse reactions was generally similar.

In a group of studies, 3,258 doses of RECOMBIVAX HB, 10 mcg, were administered to 1,252 healthy adults who were monitored for 5 days after each dose. Injection site reactions and systemic complaints were reported following 17% and 15% of the injections, respectively. The following adverse reactions were reported:

Incidence Equal To or Greater Than 1% of Injections

LOCAL REACTION (INJECTION SITE)

Injection site reactions consisting principally of soreness, and including pain, tenderness, pruritus, erythema, ecchymosis, swelling, warmth, and nodule formation.

BODY AS A WHOLE

The most frequent systemic complaints include fatigue/weakness; headache; fever ($\geq$100°F); and malaise.

DIGESTIVE SYSTEM

Nausea and diarrhea

RESPIRATORY SYSTEM

Pharyngitis and upper respiratory infection

Incidence Less Than 1% of Injections

BODY AS A WHOLE
Sweating; achiness; sensation of warmth; lightheadedness; chills; and flushing
DIGESTIVE SYSTEM
Vomiting; abnormal pains/cramps; dyspepsia; and diminished appetite
RESPIRATORY SYSTEM
Rhinitis; influenza; and cough
NERVOUS SYSTEM
Vertigo/dizziness; and paresthesia
INTEGUMENTARY SYSTEM
Pruritus; rash (non-specified); angioedema; and urticaria
MUSCULOSKELETAL SYSTEM
Arthralgia including monoarticular; myalgia; back pain; neck pain; shoulder pain; and neck stiffness
HEMICILYMPHATIC SYSTEM
Lymphadenopathy
PSYCHIATRIC/BEHAVIORAL
Insomnia/disturbed sleep
SPECIAL SENSES
Earache
UROGENITAL SYSTEM
Dysuria
CARDIOVASCULAR SYSTEM
Hypotension

Marketed Experience

The following additional adverse reactions have been reported with use of the marketed vaccine. In many instances, the relationship to the vaccine was unclear.

Hypersensitivity

Anaphylaxis and symptoms of immediate hypersensitivity reactions including rash, pruritus, urticaria, edema, angioedema, dyspnea, chest discomfort, bronchial spasm, palpitation or symptoms consistent with a hypotensive episode have been reported within the first few hours after vaccination. An apparent hypersensitivity syndrome (serum-sickness-like) of delayed onset have been reported days to weeks after vaccination, including: arthralgia/arthritis (usually transient), fever, and dermatologic reactions such as urticaria, erythema multiforme, ecchymoses and erythema nodosum (see WARNINGS and PRECAUTIONS).

Digestive System

Elevation of liver enzymes; constipation

Nervous System

Guillain-Barre Syndrome; multiple sclerosis; exacerbation of multiple sclerosis; myelitis including transverse myelitis; seizure; febrile seizure; peripheral neuropathy including Bell's Palsy; radiculopathy; herpes zoster; migraine; muscle weakness; hypesthesia; encephalitis

Integumentary System

Stevens-Johnson Syndrome; alopecia; petechiae

Musculoskeletal System

Arthritis

Hematologic

Increased erythrocytes sedimentation rate; thrombocytopenia

Immune System

Systemic lupus erythematosus (SLE); lupus-like syndrome; vasculitis

Psychiatric/Behavioral

Irritability; agitation; somnolence

Special Senses

Optic neuritis; tinnitus; conjunctivitis; visual disturbances

Cardiovascular System

Syncope; tachycardia

The following adverse reaction has been reported with another Hepatitis B Vaccine (Recombinant) but not with RECOMBIVAX HB; keratitis.

Patients, parents and guardians should be instructed to report any serious adverse reactions to their healthcare provider, who in turn should report such events to the U.S. Department of Health and Human Services through the Vaccine Adverse Event Reporting System (VAERS), 1-800-822-7967.[32]

DOSAGE AND ADMINISTRATION

Do not inject intravenously or intradermally.

RECOMBIVAX HB Hepatitis B Vaccine (Recombinant) DIALYSIS FORMULATION [(40 mcg/mL) (WITH AND WITHOUT PRESERVATIVE)] IS INTENDED ONLY FOR ADULT PREDIALYSIS/DIALYSIS PATIENTS.

RECOMBIVAX HB Hepatitis B Vaccine (Recombinant) PEDIATRIC/ADOLESCENT (WITH AND WITHOUT PRESERVATIVE) and ADULT FORMULATIONS (WITH AND WITHOUT PRESERVATIVE) ARE NOT INTENDED FOR USE IN PREDIALYSIS/DIALSYSIS PATIENTS.

RECOMBIVAX HB Hepatitis B Vaccine (Recombinant) PEDIATRIC/ADOLESCENT FORMULATION (WITHOUT PRESERVATIVE) IS AVAILABLE FOR USE IN INDIVIDUALS FOR WHOM A THIMEROSAL-FREE VACCINE MAY BE DESIRED.[31]

Three-Dose Regimen

The vaccination regimen for each population consists of 3 doses of vaccine given according to the following schedule:

First dose: at elected date

Second dose: 1 month later

Third dose: 6 months after the first dose

For infants born of mothers who are HBsAg positive or mothers of unknown HBsAg status, treatment recommendations are described in the subsection titled: *Guidelines For Treatment of Infants Born of HBsAG Positive Mothers or Mothers of Unknown HBsAG Status.*

Two-Dose Regimen – Adolescents (11 through 15 years of age)

An alternate two-dose regimen is available for routine vaccination of adolescents (11 through 15 years of age). The regimen consists of two doses of vaccine (10 mcg) given according to the following schedule:

First injection: at elected date

Second injection: 4-6 months later

Table 1 summarizes the dose and formulation of RECOMBIVAX HB for specific populations, regardless of the risk of infection with hepatitis B virus.

Table 1

Group	Dose/Regimen**	Formulation	Color Code
Infants, Children and Adolescents 0-18 years of age	5 mcg (0.5 mL) 3 x 5 mcg	Pediatric/ Adolescent	Yellow
Adolescents* 11 through 15 years of age	10 mcg (1.0 mL) 2 x 10 mcg	Adult	Green
Adults ≥20 years of age	10 mcg (1.0 mL) 3 x 10 mcg	Adult	Green
Predialysis and Dialysis Patients†	40 mcg (1.0 mL) 3 x 40 mcg	Dialysis	Blue

** If the suggested formulation is not available, the appropriate dosage can be achieved from another formulation provided that the total volume of vaccine administered does not exceed 1 mL (see text above regarding use of the formulation without preservative). However, the Dialysis Formulation may be used only for adult predialysis/dialysis patients.

* Adolescents (11 through 15 years of age) may receive either regimen, the 3 x 5 mcg (Pediatric/Adolescent Formulation) or the 2 x 10 mcg (Adult Formulation).

℞ See also recommendations for revaccination of predialysis and dialysis patients in DOSAGE AND ADMINISTRATION, Revaccination.

RECOMBIVAX HB is for intramuscular injection. The *deltoid muscle* is the preferred site for intramuscular injection in adults. Data suggest that injections given in the buttocks frequently are given into fatty tissue instead of into muscle. Such injections have resulted in a lower seroconversion rate than was expected. The *anterolateral thigh* is the recommended site for intramuscular injection in infants and young children.

For persons at risk of hemorrhage following intramuscular injection, RECOMBIVAX HB may be administered subcutaneously. However, when other aluminum-absorbed vaccines have been administered subcutaneously, an increased incidence of local reactions including subcutaneous nodules has been observed. Therefore, subcutaneous administration should be used only in persons (e.g. hemophiliacs) who are at risk of hemorrhage following intramuscular injections.

The vaccine should be used as supplied; no dilution or reconstitution is necessary. The full recommended dose of the vaccine should be used.

For All Formulations Without Preservative: Once the single-dose vial has been penetrated, the withdrawn vaccine should be used promptly, and the vial must be discarded.

For All Formulations With and Without Preservative: Shake well before use. Thorough agitation at the time of administration is necessary to maintain suspension of the vaccine.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. After thorough agitation, the vaccine is a slightly opaque, white suspension.

For Vials With and Without Preservative: Withdraw the recommended dose from the vial using a sterile needle and syringe free of preservatives, antiseptics, and detergents.

It is important to use a separate sterile syringe and needle for each individual patient to prevent transmission of hepatitis and other infectious agents from one person to another. Needles should be disposed of properly and should not be recapped.

Injection must be accomplished with a needle long enough to ensure intramuscular deposition of the vaccine.

Guidelines For Treatment of Infants Born of HBsAg Positive Mothers or Mothers of Unknown HBsAg Status

Each infant should receive three 5 mcg doses of RECOMBIVAX HB irrespective of the mother's HBsAg status (see Table 1). The ACIP recommends that if the mother is determined to be HBsAg positive within 7 days of delivery, the infant also should be given a dose of HBIG (0.5 mL) immediately. The first dose of RECOMBIVAX HB may be given at the same time as HBIG, but it should be administered in the opposite anterolateral thigh.[7]

Revaccination

The duration of the protective effect of RECOMBIVAX HB in healthy vaccines is unknown at present and the need for booster doses is not yet defined (see CLINICAL PHARMACOLOGY).

A booster dose or revaccination with RECOMBIVAX HB Dialysis Formulation (blue color code) may be considered in predialysis/dialysis patients if the anti-HBs level is less than 10 mIU/mL 1 to 2 months after the third dose.[23] The ACIP recommends that the need for booster doses of vaccine should be assessed by annual antibody testing and a booster dose given when antibody levels decline to <10 mIU/mL.[30]

Known or Presumed Exposure to HBsAg

There are no prospective studies directly testing the efficacy of a combination of HBIG and RECOMBIVAX HB in preventing clinical hepatitis B following percutaneous, ocular or mucous membrane exposure to hepatitis B virus. However, since most persons with such exposures (e.g., health-care workers) are candidates for RECOMBIVAX HB and since combined HBIG plus vaccine is more efficacious than HBIG alone in perinatal exposures, the following guidelines are recommended for persons who have been exposed to hepatitis B virus such as through (1) percutaneous (needlestick), ocular, mucous membrane exposure to blood known or presumed to contain HBsAg, (2) human bites by known presumed HBsAg carriers, that penetrate the skin, or (3) following intimate sexual contact with known or presumed HBsAg carriers.

HBIG (0.06 mL/kg) should be given intramuscularly as soon as possible after exposure and within 24 hours if possible. RECOMBIVAX HB (see dosage recommendation) should be given intramuscularly at a separate site within 7 days of exposure and second and third doses given one and six months, respectively, after the first dose.

HOW SUPPLIED

PEDIATRIC/ADOLESCENT FORMULATION (PRESERVATIVE-FREE)

No. 4980 – RECOMBIVAX HB for use in infants, children, and adolescents is supplied as 5 mcg/0.5 mL of HBsAg in a 0.5 mL single-dose vial, color coded with a yellow cap and stripe on the vial labels and cartons and an orange banner on the vial labels and cartons stating "Preservative Free", NDC 0006-4980-00.

No. 4981 – RECOMBIVAX HB for use in infants, children and adolescents is supplied as 5 mcg/0.5 mL of HBsAg in a 0.5 mL single-dose vial, in a box of 10 single-dose vials, color coded with a yellow cap and stripe on the vials labels and cartons and an orange banner on the vial labels and cartons stating "Preservative Free". NDC 0006-4981-00.

No. 4994 – RECOMBIVAX HB for use in infants, children, and adolescents is supplied as 5 mcg/0.5 mL of HBsAg in a 0.5 mL pre-filled single-dose Luer-Lok** syringe in a box of 10 pre-filled single-dose syringes, color coded with a yellow plunger rod and stripe on the syringe labels and cartons and an orange banner on the syringe labels and cartons stating "Preservative Free", NDC 0006-4994-41.

PEDIATRIC/ADOLESCENT FORMULATION

No. 4769 – RECOMBIVAX HB for use in infants, children, and adolescents is supplied as 5 mcg/0.5 mL of HBsAg in a 0.5 mL single-dose vial, color coded with a yellow cap and stripe on the vial labels and cartons, NDC 0006-4769-00.

No. 4876 – RECOMBIVAX HB for use in infants, children, and adolescents is supplied as 5 mcg/0.5 mL of HBsAg in a 0.5 mL single-dose vial, in a box of 10 single-dose vials, color coded with a yellow cap and stripe on the vial labels and cartons, NDC 0006-4876-00.

ADULT FORMULATION (PRESERVATIVE FREE)

No. 4995 – RECOMBIVAX HB for use in adults and adolescents (11 through 15 years of age) is supplied as 10 mcg/mL of HBsAg in a 1 mL single-dose vial, color coded with a green cap and stripe on the vial labels and cartons and an orange banner on the vial labels and cartons stating "Preservative Free", NDC 0006-4995-00.

No. 4995 – RECOMBIVAX HB for use in adults and adolescents (11 through 15 years of age) is supplied as 10 mcg/mL of HBsAg in a 1 mL single-dose vial, in a box of 10 single-dose vials, color coded with a green cap and stripe on the vial labels and cartons and an orange banner on the vial labels and cartons stating "Preservative Free", NCD 0006-4995-41.

ADULT FORMULATION

No. 4775 – RECOMBIVAX HB for use in adults and adolescents (11 through 15 years of age) is supplied as 10 mcg/mL of HBsAg in a 1 mL single-dose vial, color coded with a green cap and stripe on the vial labels and cartons, NDC 0006-4775-00.

No. 4773 – RECOMBIVAX HB for use in adults and adolescents (11 through 15 years of age) is supplied as 10 mcg/mL of HBsAg in a 3 mL multiple-dose vial, color coded with a green cap and stripe on the vial labels and cartons, NDC 0006-4773-00.

No. 4872 – RECOMBIVAX HB for use in adults and adolescents (11 through 15 years of age) is supplied as 10 mcg/mL of HBsAg in a 1 mL single-dose vial, in a box of 10 single-dose vials, color coded with a green cap and stripe on the vial labels and cartons, NDC 0006-4872-00.

No. 4873 – RECOMBIVAX HB for use in adults and adolescents (11 through 15 years of age) is supplied as 10 mcg/mL of HBsAg in a 3 mL multiple-dose vial, in a box of 10 multi-dose vials, color coded with a green cap and stripe on the vial labels and cartons, NDC 0006-4873-00.

DIALYSIS FORMULATION (PRESERVATIVE FREE)

No. 4992 – RECOMBIVAX HB Dialysis Formulation is supplied as 40 mcg/mL of HBsAg in a 1 mL single-dose vial, color coded with a blue cap and stripe on the vial labels and cartons and an orange banner on the vial labels and cartons stating "Preservative Free", NDC 0006-4992-00.

DIALYSIS FORMULATION

No. 4776 – RECOMBIVAX HB Dialysis Formulation is supplied as 40 mcg/mL of HBsAg in a 1 mL single-dose vial, color coded with a blue cap and stripe on the vial labels and cartons, NDC 0006-4776-00.

Storage

Store vials and syringes at 2-8°C (36-46°F). Storage above or below the recommended temperature may reduce potency.

Do not freeze since freezing destroys potency.

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** Luer-Lok is a trademark of Becton Dickinson & Company

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Manuf. and Dist. by:
MERCK & CO., INC., Whitehouse Station, NJ 08889, USA

Syringes of RECOMBIVAX HB are also manufactured by:
Evans Vaccines Ltd.
Gaskill Road, Speke, Liverpool L24 9GR, England

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APPENDIX P

PRESCRIBING INFORMATION

Engerix-B®
Hepatitis B Vaccine (Recombinant)

DESCRIPTION
Engerix-B [Hepatitis B Vaccine (Recombinant)] is a noninfectious recombinant DNA hepatitis B vaccine developed and manufactured by SmithKline Beecham Biologicals. It contains purified surface antigen of the virus obtained by culturing genetically engineered *Saccharomyces cerevisiae* cells, which carry the surface antigen gene of the hepatitis B virus. The surface antigen expressed in *Saccharomyces cerevisiae* cells is purified by several physicochemical steps and formulated as a suspension of the antigen adsorbed on aluminum hydroxide. The procedures used to manufacture *Engerix-B* result in a product that contains no more than 5% yeast protein. No substances of human origin are used in its manufacture.

Engerix-B is supplied as a sterile suspension for intramuscular administration. The vaccine is ready for use without reconstitution; it must be shaken before administration since a fine white deposit with a clear colorless supernatant may form on storage.

Pediatric/Adolescent
Each 0.5 mL of vaccine consists of 10 mcg of hepatitis B surface antigen adsorbed on 0.25 mg aluminum as aluminum hydroxide. The pediatric/adolescent vaccine is formulated without preservatives. The pediatric formulation contains a trace amount of thimerosal (<0.5 mcg mercury) from the manufacturing process, sodium chloride (9 mg/mL) and phosphate buffers (disodium phosphate dihydrate, 0.98 mg/mL; sodium dihydrogen phosphate dihydrate, 0.71 mg/mL).

Adult
Each 1 mL adult dose consists of 20 mcg of hepatitis B surface antigen adsorbed on 0.5 mg aluminum as aluminum hydroxide. The adult vaccine is formulated without preservatives. The adult formulation contains a trace amount of thimerosal (<1.0 mcg mercury) from the manufacturing process, sodium chloride (9 mg/mL) and phosphate buffers (disodium phosphate dihydrate, 0.98 mg/mL; sodium dihydrogen phosphate dihydrate, 0.71 mg/mL).

CLINICAL PHARMACOLOGY
Several hepatitis viruses are known to cause a systemic infection resulting in major pathologic changes in the liver (e.g., A,B,C,D,E,G). The estimated lifetime risk of HBV infection in the United States varies from almost.100% for the highest-risk groups to less than 20% for the population as a whole.[1] Hepatitis B Infection Can have serious consequences including acute massive hepatic necrosis, chronic active hepatitis and cirrhosis of the liver. Up to 90% of neonates and 6 to 10% of adults who are infected in the United States will become hepatitis B virus carriers.[1] It has been estimated that 200 to 300 million people in the world today are persistently infected with hepatitis B virus.[1] The Centers for Disease Control (CDC) estimates that there are approximately 1 to 1.25 million chronic carriers of hepatitis B virus in the United States.[1] Those patients who become chronic carriers can infect others and are at increased risk of developing primary hepatocellular carcinoma. Among other factors, infection with hepatitis B may be the single most important factor for development of this carcinoma.[1,2]

Reduced Risk of Hepatocellular Carcinoma: According to the CDC, the hepatitis B vaccine is recognized as the first anti-cancer vaccine because it can prevent primary liver cancer.[3]

A clear link has been demonstrated between chronic hepatitis B infection and the occurrence of hepatocellular carcinoma. In a Taiwanese study, the institution of universal childhood immunization against hepatitis B virus has been shown to decrease the incidence of hepatocellular carcinoma among children.[4] In a Korean study in adult males, vaccination against hepatitis B virus has been shown to decrease the incidence of, and risk of, developing hepatocellular carcinoma in adults.[5]

Considering the serious consequences of infection, immunization should be considered for all persons at potential risk of exposure to the hepatitis B virus. Mothers infected with hepatitis B virus can infect their infants at, or shortly after, birth if they are carriers of the HBsAg antigen or develop an active infection during the third trimester of pregnancy. Infected infants usually become chronic carriers. Therefore, screening of pregnant women for hepatitis B is recommended.[1] Because a vaccination strategy limited to high-risk individuals has failed to substantially lower the overall incidence of hepatitis B infection, the Advisory Committee on Immunization Practices (ACIP) recommends vaccination of all persons from birth to age 18.[6] The Committee on Infectious Diseases of the American Academy of Pediatrics (AAP) has also endorsed universal infant immunization as part of a comprehensive strategy for the control of hepatitis B infection.[7] The AAP, American Academy of Family Physicians (AAFP) and American Medical Association (AMA) also recommend routine vaccination of adolescents 11 to 12 years of age who have not been vaccinated previously.[8] The AAP further recommends that providers administer hepatitis B vaccine to all previously unvaccinated adolescents.[9] (See INDICATIONS AND USAGE.) There is no specific treatment for acute hepatitis B infection. However, those who develop anti-HBs antibodies after active infection are usually protected against subsequent infection. Antibody titers ≥10 mIU/mL against HBsAg are recognized as conferring protection against hepatitis B.[1] Seroconversion is defined as antibody titers ≥1 mIU/mL.

Protective Efficacy: Protective efficacy with Engerix-B [Hepatitis B Vaccine (Recombinant)] has been demonstrated in a clinical trial in neonates at high risk of hepatitis B infection.[10,11] Fifty-eight neonates born of mothers who were both HBsAg and HBeAg positive were given *Engerix-B* (10 mcg at 0, 1 and 2 months) without concomitant hepatitis B immune globulin. Two infants became chronic carriers in the 12-month follow-up period after initial inoculation. Assuming an expected carrier rate of 70%, the protective efficacy rate against the chronic carrier state, during the first 12 months of life was 95%.

Immunogenicity in Neonates: Immunization with 10 mcg at 0, 1 and 6 months of age produced seroconversion in 100% of infants by month 7 with a GMT of 713 mIU/mL (N=52), and the seroprotection rate was 97%.

Clinical trials indicate that administration of hepatitis B immune globulin at birth does not alter the response to Engenx-B [Hepatitis B Vaccine (Reconmbinant)].

Immunization with 10 mcg at 0, 1 and 2 months of age produced a seroprotection rate of 96% in infants by month 4, with a GMT among seroconverters of 210 mIU/mL (N=311); an additional dose at month 12 produced a GMT among seroconverters of 2,941 mIU/mL at month 13 (N=126).

Immunogenicity in Pediatric Patients: In clinical trials with 242 children ages 6 months to, and including, 10 years given 10 mcg at months 0, 1 and 6, the seroprotection rate was 98% 1 to 2 months after the third dose; the GMT of seroconverters was 4,023 mIU/mL.

In a separate clinical trial including both children and adolescent aged 5 to 16 years, 10 mcg of *Engerix-B* was administered at 0, 1, and 6 months (N=181) or 0, 12, and 24 months (N=161). Immediately before the third dose of vaccine, seroprotection was achieved in 92.3% of subjects vaccinated on the 0, 1, 6-month schedule and 88.8% of subjects on the 0, 12, 24-month schedule (117.9 mIU/mL vs. 162.1 mIU/mL, respectively, p=0.18). One month following the third dose, seroprotection was achieved in 99.5% of children vaccinated on the 0, 1, 6-month schedule compared to 98.1% of those on the 0, 12, 24-month schedule. GMTs were higher (p=0.02) for children receiving vaccine on the 0, 1, 6-month schedule compared to those on the 0, 12, 24-month schedule (5,687.4 mIU/mL vs. 3,158.7 mIU/mL, respectively). The clinical relevance of this finding is unknown.

Immunogenicity in Adolescents: In clinical trials with healthy adolescent subjects 11 through 19 years of age, immunization with 10 mcg using a 0, 1, 6-month schedule produced a seroprotection rate of 97% at month 8 (N=119) with a GMT of 1,989 mIU/mL (N=118, 95% confidence intervals=1,318-3,020). Immunization with 20 mcg using a 0, 1, 6-month schedule produced a seroprotection rate of 99% at month 8 (N=122) with a GMT of 7,672 mIU/mL (N=122, 95% confidence intervals=5,248-10,965).

Immunogenicity in Healthy Adults and Adolescents: Clinical trials in healthy adult and adolescent subjects have shown that following a course of three doses of 20 mcg Engerix-B [Hepatitis B Vaccine (Recombinant)] given according to the ACIP recommended schedule of injections at months 0, 1 and 6, the seroprotection (antibody titers $\geq$10 mIU/mL) rate for all individuals was 79% at month 6 and 96% at month 7; the geometric mean antibody titer (GMT) for seroconverters at month 7 was 2,204 mIU/mL. On an alternate schedule (injections at months 0, 1 and 2) designed for certain populations (e.g., neonates born of hepatitis B infected mothers, individuals who have or might have been recently exposed to the virus, and certain travelers to high-risk areas. See INDICATIONS AND USAGE.), 99% of all individuals were seroprotected at month 3 and remained protected through month 12. On the alternate schedule, an additional dose at 12 months produced a GMT for seroconverters at month 13 of 9,163 mIU/mL.

Immunogenicity in Older Subjects: Among older subjects given 20 mcg at months 0, 1 and 6, the seroprotection rate 1 month after the third dose was 88%. However, as with other hepatitis B. vaccines, in adults over 40 years of age, *Engerix-B* vaccine produced anti-HBs titers that were lower than those in younger adults (GMT among seroconverters 1 month after the third 20 mcg dose with a 0, 1, 6-month schedule: 610 mIU/mL for individuals over 40 years of age, N=50).

Immunogenicity in Subjects with Chronic Hepatitis C: In a clinical trial of subjects with chronic hepatitis C, 31 subjects received *Engerix-B* on the usual 0, 1, 6-month schedule. All subjects responded with seroprotective titers. The GMT of anti-HBs was 1,260 mIU/mL (95% CI:709-2237).

Hemodialysis Patients: Hemodialysis patients given hepatitis B vaccines respond with lower titers,[12] which remain at protective levels for shorter durations than in normal subjects. In a study in which patients on chronic hemodialysis (mean time on dialysis was 24 months; N=562) received 40 mcg of the plasma-derived vaccine at months 0, 1 and 6, approximately 50% of patients achieved antibody titers $\geq$10 mIU/mL.[12] Since a fourth dose of Engerix-B [Hepatitis B Vaccine (Recombinant)] given to healthy adults at month 12 following the 0, 1, 2-month schedule resulted in a substantial increase in the GMT (see above), a four-dose regimen was studied in hemodialysis patients. In a clinical trial of adults who had been on hemodialysis for a mean of 56 month (N=43), 67% of patients were seroprotected 2 months after the last dose of 40 mcg of *Engerix-B* (two x 20 mcg) given on a 0, 1, 2, 6-month schedule; the GMT among seroconverters was 93 mIU/mL.

Interchangeability with Other Hepatitis B Vaccines: Recombinant DNA vaccines are produced in yeast by expression of a hepatitis B virus gene sequence that codes for the hepatitis B surface antigen. Like plasma-derived vaccine, the yeast-derived vaccines are protein particles visible by electron microscopy and have hepatitis B surface antigen epitopes as determined by monoclonal antibody analyses. Yeast-derived vaccines have been shown by *in vitro* analyses to induce antibodies (anti-HBs) which are immunologically comparable by epitope specificity and binding affinity to antibodies induced by plasma-derived vaccine.[13] In cross absorption studies, no differences were detected in the spectra of antibodies induced in man to plasma-derived or to yeast-derived hepatitis B vaccines.[13]

Additionally, patients immunized approximately 3 years previously with plasma-derived vaccine and whose antibody titers were <100 mIU/mL (GMT: 35 mIU/mL; range: 9-94) were given a 20 mcg dose of Engerix-B [Hepatitis B Vaccine (Recombinant)]. All patients, including two who had not responded to the plasma-derived vaccine, showed a response to *Engerix-B* (GMT: 5,069 mIU/mL; range: 624-15,019). There have been no clinical studies in which a three-dose vaccine series was initiated with a plasma-derived hepatitis B vaccine and completed with *Engerix-B*, or vice versa. However, because *the in vitro* and *in vivo* studies described above indicate the comparability of the antibody produced in response to plasma-derived vaccine and *Engerix-B*, it should be possible to interchange the use of *Engerix-B* and plasma-derived vaccines (but see CONTRAINDICATIONS).

A controlled study (N=48) demonstrated that completion of a course of immunization with one dose of *Engerix-B* (20 mcg, month 6) following two doses of Recombivax HB®* (10 mcg, months 0 and 1) produced a similar GMT (4,077 mIU/mL) to immunization with three doses of Re*combivax HB* (10 mcg, months 0, 1 and 6; 2,654 mIU/mL). Thus, *Engerix-B* can be used to complete a vaccination course initiated with *Recombivax HB*.[14]

Other Clinical Studies: In one study,[15] four of 244 (1.6%) adults (homosexual men) at high risk of contracting hepatitis B virus became infected during the period prior to completion of three doses of *Engerix-B* (20 mcg at 0, 1, 6 months). No additional patients became infected during the 18-month follow-up period after completion of the immunization course.

INDICATIONS AND USAGE

Engerix-B is indicated for immunization against infection caused by all known subtypes of hepatitis B virus. As hepatitis D (caused by the delta virus) do s not occur in the absence of hepatitis B infection, it can be expected that hepatitis D will also be prevented by *Engerix-B* vaccination.

Engerix-B will not prevent hepatitis caused by other agents, such as hepatitis A, C and E viruses, or other pathogens known to infect the liver.

Immunization is recommended in persons of all ages, especially those who are, or will be, at increased risk of exposure to hepatitis B virus,[1] for example:

Infants, Including Those Born of HBsAg-Positive Mothers (See DOSAGE AND ADMINISTRATION.)

Adolescents (See CLINICAL PHARMACOLOGY.)

Health Care Personnel: Dentists and oral surgeons. Dental, medical and nursing students. Physicians, surgeons and podiatrists. Nurses. Paramedical and ambulance personnel and custodial staff who may be exposed to the virus via blood or other patient specimens. Dental hygienists and dental nurses. Laboratory and blood-bank personnel handling blood, blood products, and other patient specimens. Hospital cleaning staff who handle waste.

Selected Patients and Patient Contacts: Patients and staff in hemodialysis units and hematology/oncology units. Patients requiring frequent and/or large volume blood transfusions or clotting factor concentrates (e.g., persons with hemophilia, thalassemia, sickle-cell anemia, cirrhosis). Clients (residents) and staff of institutions for the mentally handicapped. Classroom contacts of deinstitutionalized mentally handicapped persons who have persistent hepatitis B surface antigenemia and who show aggressive behavior. Household and other intimate contacts of persons with persistent hepatitis B surface antigenemia.

Subpopulations with a Known High Incidence of the Disease, such as: Alaskan Eskimos. Pacific Islanders. Indochinese immigrants. Haitian immigrants. Refugees from other HBV endemic areas. All infants of women born in areas where the infection is highly endemic.

Individuals with Chronic Hepatitis C: Risk factors for hepatitis C are similar to those for hepatitis B. Consequently, immunization with hepatitis B vaccine is recommended for individuals with chronic hepatitis C.

Persons Who May Be Exposed to the Hepatitis B Virus by Travel to High-Risk Areas (See ACIP Guidelines, 1990.)

Military Personnel Identified as Being at Increased Risk

Morticians and Embalmers

Persons at Increased Risk of the Disease Due to Their Sexual Practices,[1,16] such as: Persons with more than one sexual partner in a 6-month period. Persons who have contracted a sexually transmitted disease. Homosexually active males. Female prostitutes.

Prisoners

Users of Illicit Injectable Drugs

Others: Police and fire department personnel who render first aid or medical assistance, and any others who, through their work or personal life-style, may be exposed to the hepatitis B virus. Adoptees from countries of high HBV endemicity.

Use with Other Vaccines: The Immunization Practices Advisory Committee states that, in general, simultaneous administration of certain live and inactivated pediatric vaccines has not resulted in impaired antibody responses or increased rates of adverse reactions.[17] Separate sites and syringes should be used for simultaneous administration of injectable vaccines.

CONTRAINDICATIONS
Hypersensitivity to yeast or any other component of the vaccine .is a contraindication for use of the vaccine. Patients experiencing hypersensitivity after Engerix-B [Hepatitis B Vaccine (Recombinant)] injection should not receive further injections of *Engerix-B*.

WARNINGS
Hepatitis B has a long incubation period. Hepatitis B vaccination may not prevent hepatitis B infection in individuals who had an unrecognized hepatitis B infection at the time of vaccine administration. Additionally, it may not prevent infection in individuals who do not achieve protective antibody titers.

PRECAUTIONS
General As with other vaccines, although a moderate or severe febrile illness is sufficient reason to postpone vaccination, minor illnesses such as mild upper respiratory infections with or without low-grade fever are not contraindications.[17]

Prior to immunization, the patient's medical history should be reviewed. The physician should review the patient's immunization history for possible vaccine sensitivity, previous vaccination-related adverse reactions and occurrence of any adverse-event-related symptoms and/or signs, in order to determine the existence of any contraindication to immunization with *Engerix-B* and to allow at assessment of benefits and risks. Epinephrine injection (1:1000) and other appropriate agents used for the control of immediate allergic reactions must be immediately available should an acute anaphylactic reaction occur.

A separate sterile syringe and needle or a sterile disposable unit should be used for each individual patient to prevent transmission of hepatitis or other infectious agents from one person to another. Needles should be disposed of properly and should not be recapped.

Special care should be taken to prevent injection into a blood vessel.

As with any vaccine administered to immunosuppressed persons or persons receiving immunosuppressive therapy, the expected immune response may not be obtained. For individuals receiving immunosuppressive therapy, deferral of vaccination for at least 3 months after therapy may be considered.[1]

Multiple Sclerosis: Although no causal relationship has been established, rare instances of exacerbation of multiple sclerosis have been reported following administration of hepatitis B vaccines and other vaccines. In persons with multiple sclerosis, the benefit of immunization for prevention of hepatitis B infection and sequelae must be weighed against the risk of exacerbation of the disease.

Information for the Patient
Patients, parents or guardians should be informed of the potential benefits and risks of the vaccine, and of the importance of completing the immunization series. As with any vaccine, it is important when a subject returns for the next dose in a series that he/she be questioned concerning occurrence of any symptoms and/or signs of an adverse reaction after a previous dose of the same vaccine. Patients, parents or guardians should be told to report severe or unusual adverse reactions to their healthcare provider.

The parent or guardian should be given the Vaccine Information Materials, which are required by the National Childhood Vaccine Injury Act of 1986 to be given prior to immunization.

Drug Interactions
For information regarding simultaneous administration with, other vaccines, refer to INDICATIONS AND USAGE.

Carcinogenesis, Mutagenesis, Impairment of Fertility
Engerix-B [Hepatitis B Vaccine (Recombinant)] has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility.

Pregnancy Pregnancy Category C: Animal reproduction studies have not been conducted with *Engerix-B*. It is also not known whether *Engerix-B* can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. *Engerix-B* should be given to a pregnant woman only if clearly needed.

Nursing Mothers It is not known whether *Engerix-B* is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when *Engerix-B* is administered to a nursing woman.

Pediatric Use *Engerix-B* has been shown to be well tolerated and highly immunogenic in infants and children of all ages. Newborns also respond well; maternally

transferred antibodies do not interfere with the active immune response to the vaccine. (See CLINICAL PHARMACOLOGY for seroconversion rates and titers in neonates and children. See DOSAGE AND ADMINISTRATION for recommended pediatric dosage and for recommended dosage for infants born of HBsAg-positive mothers.)

ADVERSE REACTIONS

Engerix-B [Hepatitis B Vaccine (Recombinant)] is generally well tolerated. As with any vaccine, however, it is possible that expanded commercial use of the vaccine could reveal rare adverse reactions.

Ten double-blind studies involving 2,252 subjects showed no significant difference in the frequency or severity of adverse experiences between *Engerix-B* and plasma-derived vaccines. In 36 clinical studies a total of 13,495 doses of *Engerix-B* were administered to 5,071 healthy adults and children who were initially seronegative for hepatitis B markers, and healthy neonates. All subjects were monitored for 4 days post-administration. Frequency of adverse experiences tended to decrease with successive doses of *Engerix-B*. Using a symptom checklist,† the most frequently reported adverse reactions were injection site soreness (22%) and fatigue† (14%). Other reactions are listed below.

Incidence 1% to 10% of Injections

Local reactions at injection site: Induration; erythema; swelling.
Body as a whole: Fever (>37.5°C).
Nervous system: Headache†; dizziness.†

† Parent or guardian completed forms for children and neonate. Neonatal checklist did not include headache, fatigue or dizziness.

Incidence <1 % of Injections

Local reactions at injection site: Pain; pruritus; ecchymosis.
Body as a whole: Sweating; malaise; chills; weakness; flushing; tingling.
Cardiovascular system: Hypotension.
Respiratory system: Influenza-like symptoms; upper respiratory tract illnesses.
Gastrointestinal system: Nausea; anorexia; abdominal pain/cramps; vomiting; constipation; diarrhea.
Lymphatic system: Lymphadenopathy.
Musculoskeletal system: Pain/stiffness in arm, shoulder or neck; arthralgia; myalgia; back pain.
Skin and appendages: Rash; urticaria; petechiae; pruritus; erythema.
Nervous system: Somnolence; insomnia; irritability; agitation.

Additional adverse experiences have been reported with the commercial use of *Engerix-B*. Those listed below are to serve as alerting information to physicians.

Hypersensitivity: Anaphylaxis; erythema multiforme including Stevens-Johnson syndrome; angioedema; arthritis. An apparent hypersensitivity syndrome (serum-sickness-like) of delayed onset has been reported days to weeks after vaccination, including: arthralgia/arthritis (usually transient), fever and dermatologic reactions such as urticaria, erythema multiforme, ecchymoses and erythema nodosum (see CONTRAINDICATIONS).

Cardiovascular system: Tachycardia/palpitations.
Respiratory system: Bronchospasm including asthma-like symptoms.
Gastrointestinal system: Abnormal liver function tests; dyspepsia.
Nervous system: Migraine; syncope; paresis; neuropathy including hypoesthesia, paresthesia, Guillain-Barré syndrome and Bell's palsy, transverse myelitis; optic neuritis; multiple sclerosis; seizures.
Hematologic: Thrombocytopenia.
Skin and appendages: Eczema; purpura; herpes zoster; erythema nodosum; alopecia.
Special senses: Conjunctivitis; keratitis; visual disturbances; vertigo; tinnitus; earache.

Reporting Adverse Events

The National Childhood Vaccine Injury Act requires that the manufacturer and lot number of the vaccine administered be recorded by the healthcare provider in the vaccine recipient's permanent medical record, along with the date of administration of the vaccine and the name, address and title of the person administering the vaccine.[18] The Act further requires the healthcare provider to report to the U.S. Department of Health and Human Services via VAERS the occurrence following immunization of any event set forth in the Vaccine Injury Table including: anaphylaxis or anaphylactic shock within 4 hours, encephalopathy or encephalitis within 72 hours, or any sequelae thereof (including death).[18,19] In addition, any event considered a contraindication to further doses should be reported. The VAERS toll-free number is 1-800-822-7967.

DOSAGE AND ADMINISTRATION

Injection: Engerix-B [Hepatitis B Vaccine (Recombinant)] should be administered by intramuscular injection. *Do not inject intravenously or intradermally*. In adults, the injection should be given in the deltoid region but it may be preferable to inject in the anterolateral thigh in neonates and infants, who have smaller deltoid muscles. *Engerix-B* should not be administered in the gluteal region; such injections may result in suboptimal response. The attending physician should determine final selection of the injection

site and needle size, depending upon the patient's age and the size of the target muscle. A 1-inch 23-gauge needle is sufficient to penetrate the anterolateral thigh in infants younger than 12 months of age. A 5/8-inch 25-gauge needle may be used to administer the vaccine in the deltoid region of toddlers and children up to, and including, 10 years of age. The 1-inch 23-gauge needle is appropriate for use in older children and adults.[17]

Engerix-B may be administered subcutaneously to persons at risk of hemorrhage (e.g., hemophiliacs). However, hepatitis B vaccines administered subcutaneously are known to result in lower GMTs. Additionally, when other aluminum-adsorbed vaccines have been administered subcutaneously, an increased incidence of local reactions including subcutaneous nodules has been observed. Therefore, subcutaneous administration should be used only in persons who are at risk of hemorrhage with intramuscular injections.

Preparation for Administration: Shake well before withdrawal and use. Parenteral drug products should be inspected visually for particulate matter or discoloration prior to administration. With thorough agitation, Engerix-B [Hepatitis B Vaccine (Recombinant)] is a slightly turbid white suspension. Discard if it appears otherwise. The vaccine should be used as supplied; no dilution is necessary. The full recommended dose of the vaccine should be used. Any vaccine remaining in a single-dose vial should be discarded.

Dosage Schedules: The usual immunization regimen (see Table 1) consists of three doses of vaccine given according to the following schedule: 1st dose: at elected date; 2nd dose: 1 month later; 3rd dose: 6 months after first dose.

Table 1. Recommended dosage and administration schedule

Group	Dose	Schedule
Infants born of:		
HBsAg-negative mothers	10 mcg/0.5 mL	0, 1, 6 months
HBsAg-positive mothers	10 mcg/0.5 mL	0, 1, 6 months
Children:		
Birth through 10 years of age	10 mcg/0.5 mL	0, 1, 6 months
Adolescents:		
11 through 19 years of age	10 mcg/0.5 mL	0, 1, 6 months
Adults (>19 years)	20 mcg/1.0 mL	0, 1, 6 months
Adult hemodialysis	40 mcg/2.0 mL[a]	0, 1, 2, 6 months

[a] Two x 20 mcg in one or two injections.

For hemodialysis patients, in whom vaccine-induced protection is less complete and may persist only as long as antibody levels remain above 10 mIU/mL, the need for booster doses should be assessed by annual antibody testing. 40 mcg (tw x 20 mcg) booster doses with *Engerix-B* should be given when antibody levels decline below 10 mIU/mL.[1] Data show individuals given a booster with *Engerix-B* achieve high antibody titers. (See CLINICAL PHARMACOLOGY.)

There are alternate dosing and administration schedules which may be used for specific populations (see Table 2 and accompanying explanations).

Table 2. Alternate dosage and administration schedules

Group	Dose	Schedule
Infants born of:		
HBsAg-positive mothers	10 mcg/0.5 mL	0, 1, 2, 12 months[b]
Children:		
Birth through 10 years of age	10 mcg/0.5 mL	0, 1, 2, 12 months[b]
5 through 10 years of age	10 mcg/0.5 mL	0, 12, 24 months[c]
Adolescents:		
11 through 16 years of age	10 mcg/0.5 mL	0, 12, 24 months[c]
11 through 19 years of age	20 mcg/1.0 mL	0, 1, 6 months
11 through 16 years of age	20 mcg/1.0 mL	0, 1, 2, 12 months[b]
Adults (>19 years)	20 mcg/1.0 mL	0, 1, 2, 12 months[b]

[b] This schedule is designed for certain populations (e.g., neonates born of hepatitis B infected mothers, others who have or might have been recently exposed to the virus, certain travelers to high-risk areas. See INDICATIONS AN USAGE.). On this alternate schedule, an additional dose at 12 months is recommended for prolonged maintenance of protective titers.

[c] For children and adolescents for whom an extended administration schedule is acceptable based on risk of exposure.

booster vaccinations: Whenever administration of a booster dose is appropriate, the dose of *Engerix-B* is 10 mcg for children 10 years of age and under; 20 mcg for adolescents 11 through 19 years of age and 20 mcg for adults. Studies have demonstrated a substantial increase in antibody titers after Engerix-B [Hepatitis B Vaccine (Recombinant)] booster vaccination following an initial course with both plasma- and yeast-derived vaccines. (See CLINICAL PHARMACOLOGY.)

See previous section for discussion on booster vaccination for adult hemodialysis patients.

Known or presumed exposure to hepatitis B virus: Unprotected individuals with known or presumed exposure to the hepatitis B virus (e.g., neonates born of infected mothers, others experiencing percutaneous or permucosal exposure) should be given hepatitis B immune globulin (HBIG) in addition to Engerix-B [Hepatitis B Vaccine (Recombinant)] in accordance with ACIP recommendations[1] and with the package insert for HBIG. Engerix.-B [Hepatitis B Vaccine (Recombinant)] can be given on either dosing schedule (see above).

STORAGE
Store refrigerated 2° and 8°C (36° and 46°P). *Do not freeze*; discard if product has been frozen. Do not dilute to administer.

HOW SUPPLIED
Engerix-B [Hepatitis B Vaccine (Recombinant)] is supplied as a slightly turbid white suspension in vials and prefilled Tip-Lok® syringes.

Adult Dose
20 mcg/mL in Single-Dose Vials in packages of 1 and 25 vials.
NDC 58160-857-01 (package of 1)
NDC 58160-857-16 (package of 25)

20 mcg/mL in Single-Dose Prefilled Disposable Tip-Lok® Syringes with 1-inch 23-gauge needles.
NDC 58160-857-35 (package of 5)
NDC 58160-857-26 (package of 25)

Pediatric/Adolescent Doses
10 mcg/0.5 mL in Single-Dose Vials in packages of 1 and 10 vials.
NDC 58160-856-01 (package of 1)
NDC 58160-856-11 (package of 10)

10 mcg/0.5 mL in Single-Dose Prefilled Disposable Tip-Lok® Syringes (packaged without needles)
NDC 58160-856-46 (package of 5)
NDC 58160 856-50 (package of 25)

10 mcg/0.5 mL in Single-Dose Prefilled Disposable Tip-Lok® Syringes with 1-inch 25-gauge SafetyGlide™ needles.
NDC 58160-856-56 (package of 25)

10 mcg/0.5 mL in Single-Dose Prefilled Disposable Tip-Lok® Syringes with 1-inch 23-gauge SafetyGlide™ needles.
NDC 58160-856-58 (package of 25)

10 mcg/0.5 mL in Single-Dose Prefilled Disposable Tip-Lok® Syringes with 5/8-inch 25-gauge SafetyGlide™ needles.
NDC 58160-856-57 (package of 25)

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* yeast-derived, Hepatitis B Vaccine, MSD.

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REGULATED MEDICAL WASTE
GENERATOR FACT SHEET

THE NEW JERSEY REGULATED MEDICAL WASTE PROGRAM IS A COMPREHENSIVE MANAGEMENT SYSTEM THAT PROVIDES FOR THE PROPER AND SAFE TRACKING, ON-SITE CONTROL, COLLECTION AND DISPOSAL OF MEDICAL WASTES BY USING A SPECIAL TRACKING FORM TOGETHER WITH SPECIFIC PACKAGING, MARKING, LABELING, REPORTING AND OTHER REQUIREMENTS.

BACKGROUND

A comprehensive, cradle-to-grave, regulated medical waste (RMW) management program was developed by the New Jersey Department of Environmental Protection (NJDEP) under New Jersey's Comprehensive Regulated Medical Waste Management Act (N.J.S.A. 13:1 E-48 et seq.), with the assistance of the Department of Health and Senior Services (DOHSS). Procedures for the proper processing, transportation and ultimate disposal of RMW are listed in the New Jersey Administrative Code, Title 7, Chapter 26, Subchapter 3A, (N.J.A.C. 7:26-3A). Guidelines for general procedures in other medical situations may be found in the DOHSS Hospital Licensure Manual, Section 306 and in the Occupational Safety and Health Administration Instruction (CPL 2-2.44).

The Regulated Medical Waste Fact sheets are a publication of the Division of Solid and Hazardous Waste (DSHW), Bureau of Resource Recovery and Technical Programs. These fact sheets are designed only as an information guide, to be read in conjunction with the New Jersey RMW regulations. All persons are responsible for compliance with the RMW Regulations at N.J.A.C. 7:26-3A et seq.

COPIES OF REGULATIONS & FORMS

Copies of the New Jersey Comprehensive Regulated Medical Waste Management Act E-48.1 et seq.), the New Jersey medical waste regulations (N.J.A.C. 7:26-3A) are available from the publishing firm West Group, 610 Opperman Drive, PO Box 64526, St. Paul, MN 55164-0526, telephone - 1-800-808-9378, Fax -1-800-562-2329. The RMW regulations are found at pages 26-121 through 26-152. As an alternative to purchasing the regulations from the publishing firm, access to an unofficial version of the regulations is made available from the Department's web site at http://www.state.nj.us/dep/dshw/resource/index.htm#Rules. New Jersey RMW tracking forms, reporting forms and technical assistance with regulatory interpretations may be obtained from the NJDEP, DSHW, Bureau of Resource Recovery and Technical Programs, PO Box 414, Trenton, NJ 08625-0414 or by calling (609) 984-6620 during normal business hours.

WHAT IS REGULATED MEDICAL WASTE? (N.J.A.C.7:26-3A.6)

RMW is defined as any solid waste, generated in the diagnosis, treatment (e.g., provision of medical services), or immunization of human beings or animals, in research pertaining thereto or in the production or testing of biologicals, that is not excluded or exempted under N.J.A.C. 7:26-3A.6(b) and that is listed or meets any waste characterization criteria described in the table at N.J.A.C. 7:26-3A.6(a). Refer to the rule for excluded wastes (N.J.A.C. 7:26-3A.6(b)).

"Treated RMW" means RMW that has been treated to substantially reduce or eliminate its potential for causing disease, but has not yet been destroyed (N.J.A.C. 7:26-3A.5).

"Destroyed RMW" means RMW that is no longer generally recognizable as RMW because all components of the waste have been ruined, torn apart, or mutilated to produce unrecognizable and unusable pieces smaller than three-quarters of an inch, except that all sharps must be smaller than one-half inch. It does not mean compaction or encapsulation except through:

1. Processes such as thermal treatment or melting, during which treatment and destruction occur;
2. Processes such as shredding, grinding, tearing, or breaking, during which only destruction takes place; or
3. Processes that melt plastics and fully encapsulate metallic or other sharps and seals waste completely in a container that will not be penetrated by undestroyed sharps.

REGULATED MEDICAL WASTE TABLE -WASTE CLASS & DESCRIPTION

1.	Cultures & Stocks	Cultures and stocks of infectious agents and associated biologicals, including: cultures from medical and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; wastes from the production of biologicals; discarded live and attenuated vaccines; and culture dishes and devices used to transfer, inoculate, and mix cultures.
2.	Pathological Wastes	Human pathological wastes, including tissues, organs and body parts and body fluids that are removed during surgery or autopsy, or other medical procedures, and specimens of body fluids and their containers. * (* *Regulated body fluids means liquids emanating or derived from humans and limited to blood; dialysate; amniotic; cerebrospinal, synovial, pleural, peritoneal and pericardial fluids; and semen and vaginal secretions (N.J.A.C. 7:26-3-A.5))*
3.	Human Blood & Blood Products	Liquid waste human blood; blood; items saturated and/or dripping with human blood; or items that were saturated and/or dripping with human blood that are now caked with (dried human blood; including serum, plasma, and other blood components, and their containers, which were used or intended for use in either patient care, testing and laboratory analysis or the development of pharmaceuticals. Intravenous bags, soft plastic pipettes and plastic blood vials are also included in this category.
4.	Sharps	Sharps that were used in animal or human patient care or treatment or in medical research, or industrial laboratories, including sharp or potentially sharp if broken items such as, but not limited to hypodermic needles, all syringes to which a needle can be attached (with or without the attached needle) and their components, including those from manufacturing research, manufacturing and marketing, pasteur pipettes, scalpel blades, blood vials, carpules, needles with attached tubing, and culture dishes (regardless of presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides and cover slips.
5.	Animal Waste	Contaminated animal carcasses, body parts, and bedding of animals that were known to have been exposed to infectious agents during research (including research in veterinary hospitals), production of biologicals, or testing of pharmaceuticals.
6.	Isolation Wastes	Biological waste and discarded materials contaminated with blood, excretion, exudates, or secretions from humans who are isolated to protect others from certain highly communicable diseases, or isolated animals known to be infected with highly communicable diseases.
7.	Unused Sharps	The following unused, discarded, sharps that were intended to be used: hypodermic needles, suture needles, syringes, and scalpel blades.

N.J.A.C. 7:26-3A.6(b)4 excludes residues from treatment and destruction processes once RMW has been both treated and destroyed. RMW that is treated but not destroyed, or destroyed but not treated, is still considered RMW.

WHO IS A MEDICAL WASTE GENERATOR? (N.J.A.C. 7:26-3A.5)

"Generator" means any person, by site, whose act or process produces RMW as defined in N.J.A.C. 7:26-3A.6) or whose act first causes a RMW to become subject to regulation. Noncontiguous properties owned or operated by the same person are separate sites and in the case where more than one person (for example, doctors with separate medial practices) are located in the same building and office, each individual business entity is a separate generator for the purposes of this subchapter. However, households utilizing home self-care exclusively are not generators.

USE OF THE NJDEP RMW TRACKING FORM

The New Jersey medical waste regulations require all medical waste generators, transporters, intermediate handlers and destination facilities to track RMW, no matter how small the amount generated. Each generator shipping RMW off-site is responsible for initiating the New Jersey RMW Tracking Form. Each person in the chain of custody (handling process) of RMW assumes the responsibility for getting the waste to the proper destination facility for treatment, destruction or disposal.

CLASSIFICATION OF WASTE

Portions of the New Jersey RMW Tracking Form must be completed by the RMW generators, transporters, intermediate handlers and by destination or disposal facilities (N.J.A.C. 7:26-3A.19,3A.31 and 3A.39).

REGISTRATION AND FEES

In addition, RMW generated in New Jersey but transported for disposal to another state, which prints and requires use of its own tracking form, must also be reported on that state's tracking form (N.J.A.C. 7:26-3A.19(a)).

GENERATOR REQUIREMENTS

SEGREGATION OF WASTE (N.J.A.C. 7:26-3A.10)

Assistance with waste classification can be obtained from NJDEP's Bureau of Resource Recovery and Technical Programs at (609) 984-6620 or the DOHSS, Division of Environmental and Occupational Health Services at (609) 588-3124.

All medical waste generators, no matter how small the amount produced, with the exception of home self-care medical waste, must register with the NJDEP and pay the appropriate fees (N.J.A.C. 7:26- 3A.8(a)). For information on medical waste generator registration call (609) 984-3448.

Generators must segregate RMW intended for transport off-site, to the extent practicable, prior to placement in containers. * Generators must segregate RMW into:

1. Sharps (Classes 4 and 7 as defined at N.J.A.C. 7:26-3A.6(a)) including sharps containing residual fluids;
2. Fluids (quantities greater than 20 cubic centimeters); and
3. 0ther RMW.

* *If waste other than RMW is placed in the same container(s) as RMW then the generator must package, label and mark the container and its entire contents according to the RMW rule requirements at N.J.A.C. 7:26-3A.11, 3A.14 and 3A.15.*

STORAGE (N.J.A.C. 7:26-3A.12

Any person who stores RMW prior to treatment or disposal on-site or for transport off-site must:

1. Store the RMW in a manner and location that maintains the integrity of the packaging and provides protection from the elements;
2. Maintain the RMW in a nonputrescent state using refrigeration if necessary;
3. Lock any outdoor storage areas containing RMW to prevent unauthorized access;
4. Limit access to on-site storage areas only to authorized employees;
5. Store the RMW in a manner that provides protection from animals and does not provide a breeding place or a food source for insects and rodents;
6. Dispose of RMW immediately if it becomes putrescent; and
7. Store RMW for no longer than one year.

PACKAGING (N.J.A.C. 7:26-3A.11)

Generators must ensure that all RMW is placed in containers * that are:

1. Rigid;
2. Leak-resistant;
3. Impervious to moisture;
4. Sufficiently strong to prevent tearing or bursting under normal conditions of use and handling;
5. Sealed to prevent leakage during transport;
6. Puncture resistant for packaging sharps and sharps with residual fluids; and
7. Break-resistant and tightly lidded or stoppered for packaging fluids (quantities greater than 20 cubic centimeters).
8. Solid waste that is not managed as RMW shall not be packaged for shipment inside a RMW container or in containers attached to, or part of an RMW container.

* *Oversized RMW need not be placed in containers (N.J.A.C. 7:26-3A.11(d)).*

TRANSPORTATION OF RMW

Generators must use only medical waste transporters that are registered with the Division of Solid and Hazardous Waste, NJDEP and who possess a Certificate of Public Convenience and Necessity (N.J.A.C. 7:26-3A.27) from the NJDEP (609) 292-7081 (N.J.A.C. 7:26-3A.16(d)). *

* *Exemptions: N.J.A.C. 7:26-3A.17(a): Generators of less than* 3 *cubic feet (50 pounds) of RMW per month that transport only their own RMW to another generator for storage or disposal are exempt from transporter registration requirements provided:* (1) *the RMW is transported by the generator or authorized employee in* a *vehicle with* a *gross weight of less than 8,000 pounds, owned by the generator or an authorized employee;* (2) *the original generation point and the storage point or disposal facility are located in* New Jersey*; and* (3) *the generator completes* a *New Jersey Tracking Form in accordance with (N.J.A.C. 7:26-3A.19(e)).*

LABELING AND MARKING

Transporters may not accept any shipment of RMW from a generator unless the outer surface of the container is properly labeled and marked in accordance with N.J.A.C. 7:26-3A.14 and 3A.15 (N.J.A.C. 7:26-3A.28(a)).

Labeling refers to the designation of the contents as "medical waste" or "infectious waste". Labeling means each generator must, prior to offering for transport off-site, label each container of untreated RMW with a water-resistant label affixed to or printed on the outside of the container. The label shall include the words "Medical Waste", or "Infectious Waste", or display the universal biohazard symbol. Containers of treated medical waste or red plastic bags used as inner packaging are not required to be labeled (N.J.A.C. 7:26-3A.14(a)1).

Marking refers to the use of a name and address. Treated RMW is required to be marked (N.J.A.C. 3A.14(a)2). Marking means the generator, including an intermediate handler must mark the outermost surface of the outer container of RMW prepared for shipment with a water-resistant identification tag containing the generator's or intermediate handler's name and address, the transporter's name and NJDEP solid waste registration number, date of shipment, and identification of the contents as RMW (N.J.A.C. 7:26-3A.15(a)1).

TRACKING FORM

Each New Jersey RMW Tracking Form contains 6 copies to be distributed as follows: (N.J.A.C. 7:26-3A.19)

Copy 6	Generator Copy	-	retained by generator
Copy 3,4 & 5	Transporter Copy	-	retained by transporter
Copy 2	Destination Facility Copy	-	retained by destination facility owner/operator
Copy 1	Generator Copy	-	mailed by destination facility back to generator

a. The Generator completes items 1 through 15, including signing the certification at Item 15;
b. The Transporter verifies the quantity, notes any discrepancies in Item 23, and completes and signs item 16:
c. The Generator removes copy 6 and keeps it; and
d. The Transporter retains copies 3, 4 and 5 and delivers the waste to the approved destination facility.

RESPONSIBILITIES

Generators must complete the generator portion of the tracking form and sign the certification. A licensed medical waste transporter may complete the generator section of the tracking form but it is the generator who is ultimately responsible for ensuring the information is accurate. All RMW that is shipped off the site of generation must be accompanied by a properly completed tracking form. Certification should be completed at the time that the RMW is picked up by the licensed transporter (N.J.A.C. 7:26-3A.19).

RECORDKEEPING

Retain a copy of each tracking form for at least three years from the date the waste was accepted by the initial transporter unless the Department specifically requires an additional retention period (N.J.A.C. 7:26-3A.21 (a)1).

RECEIPT OF DESTINATION

If a copy of the completed tracking form is not received from the destination facility within 35 days of acceptance of waste by the initial transporter, contact the transporter or facility to determine the status of the tracked waste (N.J.A.C. 7:26-3A.22(a)).

EXCEPTION REPORT

If a signed copy of the tracking form is not received from the destination facility within 45 days of acceptance of the waste by the transporter, the generator must submit a Generator Exception Report (N.J.A.C. 7:26-3A.22(b)) *to:*

NJDEP
Division of Enforcement Field Operations
Bureau of Inspections and Investigations
PO Box 407
Trenton, New Jersey 08625-0407

The Exception Report must be postmarked on or before the 46th day and include:

1. A legible copy of the original tracking form for which the generator does not have confirmation;
2. A cover letter signed by the generator explaining the efforts taken and the results to locate the RMW.

A copy of the Exception Report must be kept for at least 3 years from the date of the report.

ANNUAL REPORTS

All generators of RMW must complete and submit an Annual Generator Report (forms are provided by the NJDEP) to the Department for the period of June 22 through June 21 of each calendar year by July 21 of each calendar year (N.J.A.C. 7:26-3A.21 (d)) unless the Department specifically changes the reporting or filing date.

GENERATOR WITH ON-SITE INCINERATORS OPERATING LOG

Generators of RMW with on-site incinerators must keep a Generator On-Site Incinerator Operating Log at their facility that includes: date, duration and quantity (in pounds) of the incineration cycle, the quantity of ash generated and transported off site, including dates of transport and identification of the transporter and disposal facility (N.J.A.C. 7:26-3A.25(a)).

OPERATORS WITH ON-SITE INCINERATORS THAT ACCEPT RMW FROM OTHER GENERATORS

Generators of RMW with on-site incinerators that accept RMW from other generators must maintain information on: the date of waste acceptance and the origin and quantity of the RMW. Generators must also register with the NJDEP and declare intent to operate on a commercial or non-commercial basis. Additional information on registration as a disposal facility may be obtained by calling (609) 984-6620 (N.J.A.C. 7:26-3A.25(b)).

GENERATORS ON-SITE REPORTS (N.J.A.C. 7:26-3A.26)

Generators of RMW with on-site incinerators must submit annual on-site incinerator reports on or before July 30 of each calendar year covering the period of July 1 through June 30.

The report shall be submitted to the NJDEP at the following address:

New Jersey Department of Environmental Protection
Division of Solid and Hazardous Waste
Bureau of Resource Recovery and Technical Programs
PO Box 414
Trenton, NJ 08625-0414
Phone (609) 984-6620

REGULATED MEDICAL WASTE
Q & A
GENERATOR FACT SHEET

THE NEW JERSEY REGULATED MEDICAL WASTE PROGRAM IS A COMPREHENSIVE MANAGEMENT SYSTEM THAT PROVIDES FOR THE PROPER AND SAFE TRACKING, ON-SITE CONTROL, COLLECTION AND DISPOSAL OF MEDICAL WASTES BY USING A SPECIAL TRACKING FORM TOGETHER WITH SPECIFIC PACKAGING, MARKING, LABELING, REPORTING AND OTHER REQUIREMENTS. THE REGULATED MEDICAL WASTE FACT SHEETS ARE A PUBLICATION OF THE DIVISION OF SOLID AND HAZARDOUS WASTE (DSHW), BUREAU OF RESOURCE RECOVERY AND TECHNICAL PROGRAMS. THESE FACT SHEETS ARE DESIGNED ONLY AS AN INFORMATION GUIDE, TO BE READ IN CONJUNCTION WITH THE NEW JERSEY RMW REGULATIONS. ALL PERSONS ARE RESPONSIBLE FOR COMPLIANCE WITH THE RMW REGULATIONS AT N.J.A.C. 7:26-2a ET SEQ.

COMMON QUESTIONS AND ANSWERS ABOUT NEW JERSEY'S MEDICAL WASTE REGULATIONS

Q1. Are regulated medical waste (RMW) generators required to dispose of (have a registered transporter pick up) their waste monthly or at definite time periods?

A. No, the medical waste regulations do not require generators to dispose of their waste monthly or provide specific time frames for the disposal of RMW. However, all RMW must be disposed of at least once per year. (N.J.A.C. 7:26-3A.12.(b))

Q2. Are carpules generated at a dentist's office considered RMW?

A. Yes, carpules are RMW (N.J.A.C. 7:26-3A.6(a)). They are classified as Class 4 - Sharps. They must be handled with the other sharps such as syringes (with or without the attached needle), needles, endo files, burrs, etc. generated at a dentist's office.

Q3. What are the regulated body fluids?

A. Regulated body fluids are liquids emanating or derived from humans and are limited to blood, cerebro-spinal, synovial, pleural, peritoneal, pericardial fluids, semen, vaginal secretions, dialysate solution and amniotic fluid. Saliva and urine are not regulated body fluids.

Q4. What is isolation waste Class 6? Is waste generated while treating a patient with AIDS (Acquired Immune Deficiency Syndrome) considered to be isolation waste?

A. Isolation waste is defined as "Any biological waste and discarded materials contaminated with blood, excretion, exudates or secretions from humans who are isolated to protect others from certain highly communicable diseases (such as lassa fever or smallpox, etc.) or animals known to be infected with highly communicable diseases" (N.J.A.C. 7:26-3A.6(a)). The infectious agents causing these diseases are listed in Level 4 of the Centers for Disease Control's (CDC's) Document "Classification of Etiologic Agents on the Basis of Hazard". The CDC guidelines do not list the AIDS virus, therefore waste generated while treating a patient with AIDS is not an isolation waste Class 6. A list of infectious agents included in Class 6 is available from the Bureau of Resource Recovery and Technical Programs (Bureau).

Q5. Are intravenous (IV) bags, tubes and needles that had only saline or nutrient medium in them considered regulated medical waste (RMW)?

A. The IV bags and needles are always considered RMW pursuant to N.J.A.C. 3A.6(a). however, if the tubing that had only saline or nutrient medium in it is separated from the IV bag and the needle, then the tubing alone is not considered RMW.

Q6. Are paper towels or latex gloves containing a drop (or a few drops) of blood or other regulated body fluid considered RMW?

A. No, paper towels or gloves that are not saturated with blood or a regulated body fluid and are not either dripping and soaked in or have dried or caked after having been saturated with such fluids are not RMW.

Q7. Are orthodontic wires, brackets and bonding material considered RMW?

A. Orthodontic wires, brackets and bonding material are generally not considered RMW as they do not meet the definition of RMW. These items would only meet the definition for Class 4 RMW and have to be managed as RMW, if they became saturated and/or dripping with blood or regulated body fluids, or were saturated and/or dripping and are now dried and caked with blood or regulated body fluids (N.J.A.C. 7:26-3A.6(a)). Additionally, in certain very rare circumstances, orthodontic wires or other oral appliances would be regulated as Class 6 - Isolation Wastes, if they were removed for some reason from a patient with any of the serious diseases listed at CDC Level 4.

Q8. Are strep test cards, discs and slides considered RMW?

A. If strep test cards, discs and slides are medical diagnostic test systems that contain and biologicals, such as animal antibodies or products of their metabolism, they would be considered RMW Class 1 - Cultures and Stocks and would be subject to all RMW regulations (N.J.A.C. 7:26-3A.6(a)). However, if they are medical diagnostic test systems that consist of non-biological reagents, they would not be considered RMW. Swabs that are used to inoculate a culture are considered RMW Class 1 - Cultures and Stocks.

Q9. Are animal blood and vaccine vials considered RMW?

A. Blood vials that have been used in animal care are considered RMW Class 4 - Sharps and must be handled as such. Animal vaccine vials that have contained agents that have the potential to cause disease in humans are considered RMW Class 4 - Sharps (N.J.A.C. 7:26-3A.6(a)). Vaccine vials that have contained agents infectious only to non-humans are not considered RMW.

Q10. Are barium enema bags considered RMW?

A. No barium enema bags are generally not considered RMW, as they do not meet the definition of RMW found at N.J.A.C. 7:26-3A.6. These items would only be considered RMW if they are saturated and/or dripping with blood or are now caked with dried human blood or regulated body fluids. Additionally, in certain very rare circumstances these items would be regulated as Class 6 - Isolation Wastes, if they were generated from a patient with any of the serious diseases listed at CDC Level 4.

Q11. When is my annual generator report (AGR) due? Must I request it be mailed to me?

A. Generators are responsible for submitting a completed annual report to NJDEP by July 21 of each calendar year (N.J.A.C. 7:26-3A.21.d). The AGR form is mailed to all registered generators. However, if you fail to receive a form you may request one by calling (609) 984-6620.

Q12. If for some reason the NJDEP did not receive an AGR from a generator by the due date and requests the AGR from the generator; however, the generator did submit the report and has documentation to prove that, what should the generator do to respond to such request?

A. The generator should submit a copy of the completed AGR from its records.

Q13. If I have more than one office, must I register each location with the Department?

A. Yes, each location that generates RMW must be registered with the NJDEP (N.J.A.C. 7:26-3A.5) unless a location is a temporary location operating less than 15 days per year (N.J.A.C. 7:26-3A.17(e)). Call (609) 984-3448 for a registration packet.

Q14. If generators treat and destroy their own RMW by methods such as treating with chlorine bleach and grinding, are they considered to be a destination facility? Do they have to be registered as a destination facility?

A. Yes, generators that both treat and destroy their own RMW on site are considered destination facilities and they must be registered as such with the NJDEP. This includes all facilities that accept RMW from other registered generators for treatment and destruction. Registration forms are available by calling (609) 984-6620.

Q15. Where can a generator obtain medical waste tracking forms? Is there a fee for them? How many forms can be ordered at one time?

A. A generator/transporter can obtain the medical waste tracking forms, free of charge from the NJDEP, Bureau of Resource Recovery and Technical Programs, PO Box 414, Trenton, NJ 08625-0414 or by calling (609) 984-6620 during normal business hours.

Q16. Is a generator required to submit copies of tracking forms to the NJDEP?

A. No, generators are not required to submit copies of tracking forms to the NJDEP. The copies of these forms must be retained at the generator's office for at least three years from the date the waste was generated/ accepted by the initial medical waste transporter unless the NJDEP specifically requires an additional retention period. The New Jersey Department of Health and Senior Services (DOHSS) inspectors during their compliance inspections check these records.

A. No, generators, such as hospitals cannot transport another generator's RMW without possessing the permits listed at N.J.A.C. 7:26-3A.27. These requirements include:

a. Registering as an RMW transporter in accordance with N.J.A.C. 7:26-3A.8;

b. Registering as a solid waste transporter, and

c. Obtaining a certificate of public convenience and necessity issued by the Division of Solid and Hazardous Waste.

Q18. What should I do if I do not receive Copy 1 of the Medical Waste Tracking Form from the destination facility?

A. If you do not receive a completed Copy 1 of the tracking form with a handwritten signature of the owner/ operator within 35 days of initial transport off site, you should contact the destination facility and attempt to determine the status of the tracked waste. If, within 45 days of initial transport off site you still do not receive Copy 1 of the tracking form you must submit an exception report to: NJDEP, Bureau of Solid Waste Compliance and Enforcement, PO Box 407, Trenton, NJ 08525-0407 (N.J.A.C. 7:26-3A.22(b)).

Q19. If I have more than one office, may I take the RMW to one site for storage, consolidation or disposal?

A. Yes, if a generator generates less than 50 lbs. per month and transports its waste in a vehicle weighing less than 8,000 lbs. (N.J.A.C. 7:26-3A.17) but a RMW tracking form must still be used to transport the RMW from one site to another. Please note that generators which accept RMW for storage or consolidation must be registered as a collection facility and generators which accept RMW for disposal must be registered as RMW destination facility.

Q20. May mail services be used to transport RMW?

A. Yes, the U.S. Postal Service can be used to transport RMW Class 4 - Sharps and Class 7 - Unused Sharps for disposal. The RMW must be sent registered for certified mail, return receipt requested. The generator must retain the original receipt and the returned registered or certified mail receipt and attach them to the generator copy of the tracking form.

The generator must sign the certification section of the tracking form by hand; sign the transporter section indicating the transporter is the U.S. Postal Service and note the date the shipment was mailed; and ensure that the tracking form accompanies the RMW while in transit (N.J.A.C. 7:26-3A.17(b)).

Q21. How do I dispose of RMW that is derived from radioactive medical materials?

A. Such waste may be returned to the supplier of the original radioactive medical materials using a registered RMW transporter and completing a RMW form as described in N.J.A.C. 7:26-3A.19(h).

Q22. May I recycle RMW?

A. Yes, certain materials that are reused or recycled in accordance with all applicable Federal, State and local laws and regulations for the handling and managing of such materials, are not considered RMW if the generator first treats the materials and, for sharps, destroys them prior to shipping off site (N.J.A.C. 7;26-3A.6(b)).

Q23. What is the proper way to mark and label packages of RMW?

A. See Figure 1 on page 4 (N.J.A.C. 7:26.3A.14 and 15).

Q24. If I am in compliance with the NJDEP's medical waste regulations, can I assume that I am in compliance with OSHA's regulations?

A. No, the Federal Occupational Safety and Health Administration (OSHA) has separate regulations with which you must comply for a broader range of patient contact issues; materials and wastes produced at your business other than RMW. You may contact OSHA at (609) 757-5181.

APPENDIX Q

Telephone Numbers for Regulatory and Technical Assistance:

NJDEP
Medical Waste Technical Assistance
(609) 984-6620

Medical Waste Registration:
! Generators
(609) 984-3448

! Transporter Registration
(609) 292-7081

! Facilities
(609) 984-6620

Bureau of Solid Waste Compliance
And Enforcement
(Transporters & Facilities)
(609) 584-4180

U.S. Department of Labor

Occupational Safety and Health
Administration (OSHA)
(609) 757-5181

New Jersey Department of Health And Senior Services

Division of Environmental and
Occupational Health
(Consumer and Environmental
Health Services)
(Generator Inspections)
(609) 588-3124

Figure 1

REPORT ALL INCIDENTS CONCERNING RELEASES OF RMW BY CALLING
THE NJDEP 24-HOUR EMERGENCY HOTLINE AT
(609) 292-7172

OSHA Occupational Safety & Health Administration
U.S. Department of Labor

Regulations (Standards - 29 CFR)

Bloodborne pathogens. - 1910.1030

◄ OSHA Regulations (Standards - 29 CFR) - Table of Contents

- **Standard Number:** 1910.1030-
- **Standard Title:** Bloodborne pathogens.
- **SubPart Number:** Z
- **SubPart Title:** Toxic and Hazardous Substances

Interpretation(s)

(a)

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

(b)

Definitions. For purposes of this section, the following shall apply:

Assistant Secretary means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

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

Bloodborne Pathogens means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

Clinical Laboratory means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

Contaminated means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

Contaminated Laundry means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.

Contaminated Sharps means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

Decontamination means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

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

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

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

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

Licensed 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.

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

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

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

Other Potentially Infectious Materials means (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

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

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

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

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

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

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

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

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

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

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

(c)

Exposure Control --

(c)(1)

Exposure Control Plan.

(c)(1)(i)

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

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

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

..1910.1030(c)(1)(ii)(B)

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

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

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

(c)(1)(iv)
The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure. The review and update of such plans shall also:

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

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

(c)(1)(v)
An employer, who is required to establish an Exposure Control Plan shall solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan.

(c)(2)
Exposure Determination.

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

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

..1910.1030(c)(2)(i)(B)

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

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

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

(d)
***Methods* of *Compliance* --**

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

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

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

..1910.1030(d) (2)(ii)

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

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

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

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

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

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

..1910.1030(d) (2)(vii)(A)

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

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

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

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

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

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

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

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

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

..1910.1030(d)(2)(xi)

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

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

(d)(2)(xiii)

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

(d)(2)(xiii)(A)

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

(d)(2)(xiii)(B)

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

..1910.1030(d)(2)(xiii)(C)

(d)(2)(xiii)(C)

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

(d)(2)(xiv)

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

(d)(2)(xiv)(A)

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

(d)(2)(xiv)(B)

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

(d)(3)

Personal Protective Equipment -.-

{d){3)(i)

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

(d)(3)(ii)

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

(d)(3)(iii)

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

(d)(3)(iv)

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

..1910.1030(d)(3)(v)

(d)(3)(v)

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

(d)(3)(vi)

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

(d)(3)(vii)

All personal protective equipment shall be removed prior to leaving the work area.

(d)(3)(viii)

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

(d)(3)(ix)

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

(d)(3)(ix)(A)

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

..1910.1030(d)(3)(ix)(B)

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

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

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

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

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

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

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

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

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

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

..1910.1030(d)(3)(x)

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

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

(d)(3)(xii)

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

(d)(4)

Housekeeping --

(d)(4)(i)

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

(d)(4)(ii)

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

..1910.1030(d)(4)(ii)(A)

(d)(4)(ii)(A)

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

(d)(4)(ii)(B)

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

(d)(4)(ii)(C)

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

(d)(4)(ii)(D)

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

(d)(4)(ii)(E)

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

(d)(4)(iii)

Regulated Waste --

..1910.1030(d)(4)(iii)(A)

(d)(4)(iii)(A)
Contaminated Sharp's Discarding and Containment.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

..1910.1030(d)(4)(iv)

(d)(4)(iv)
Laundry.

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

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

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

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

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

..1910.1030(d)(4)(iv)(C)

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

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

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

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

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

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

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

..1910.1030(e)(2)(ii)(B)

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

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

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

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

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

..1910.1030(e)(2)(ii)(G)

(e)(2)(ii)(G)
Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with other potentially infectious materials is unavoidable.

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

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

(e)(2)(ii)(J)

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

(e)(2)(ii)(K)

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

..1910.1030(e)(2)(ii)(L)

(e)(2)(ii)(L)

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

(e)(2)(ii)(M)

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

(e)(2)(iii)

Containment Equipment.

(e)(2)(iii)(A)

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

(e)(2)(iii)(B)

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

(e)(3)

HIV and HBV research laboratories shall meet the following criteria:

..1910.1030(e)(3)(i)

(e)(3)(i)

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

(e)(3)(ii)

An autoclave for decontamination of regulated waste shall be available.

(e)(4)

HIV and HBV production facilities shall meet the following criteria:

(e)(4)(i)

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

(e)(4)(ii)

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

..1910.1030(e)(4)(iii)

(e)(4)(iii)

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

(e)(4)(iv)

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

(e)(4)(v)

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

(e)(4)(vi)

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

(e)(5)

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

(f)

Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up --

..1910..1030(f)(1)

(f)(1)(i)

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

(f)(1)(ii)

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

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

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

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

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

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

..1910.1030(f)(2)

(f)(2)
Hepatitis B Vaccination.

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

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

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

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

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

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

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

..1910.1030(f)(3)(ii)

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

(f)(3)(ii)(A)
The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.

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

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

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

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

..1910.1030(f)(3)(iii)(B)

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

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

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

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

(f)(4)

Information Provided to the Healthcare Professional.

(f)(4)(i)

The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

(f)(4)(ii)

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

(f)(4)(ii)(A)

A copy of this regulation;

(f)(4)(ii)(B)

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

(f)(4)(ii)(C)

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

..1910.1030(f)(4)(ii)(D)

(f)(4)(ii)(D)

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

(f)(4)(ii)(E)

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

(f)(5)

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.

(f)(5)(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.

(f)(5)(ii)

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

(f)(5)(ii)(A)

That the employee has been informed of the results of the evaluation; and

(f)(5)(ii)(B)

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

..1910.1030(f)(5)(iii)

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

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

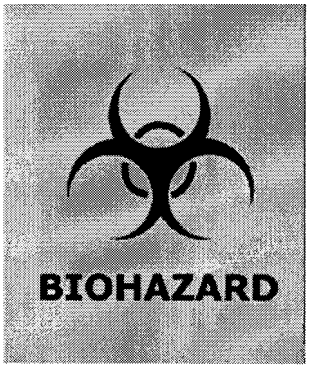
(g)
***Communication* of *Hazards to Employees* --**

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

(g)(1)(i)
Labels.

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

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



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

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

..1910.1030(g)(1)(i)(E)

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

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

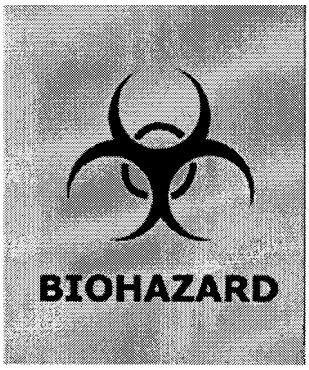
(g)(1)(i)(G)
Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.

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

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

(g)(1)(ii)
Signs.

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



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

..1910.1030(g)(1)(ii)(B)

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

(g)(2)
Information and Trarining.

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

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

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

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

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

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

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

..1910.1030(g)(2)(v)

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

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

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

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

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

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

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

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

..1910.1030(g)(2)(vii)(F)

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

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

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

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

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

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

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

..1910.1030(g)(2)(vii)(M)

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

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

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

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

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

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

..1910.1030(g)(2)(ix)(C)

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

(h)
Recordkeeping **--**

(h)(1)
Medical Records.

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

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

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

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

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

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

.,1910.1030(h)(1)(ii)(E)

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

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

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

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

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

(h)(2)
Training Records.

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

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

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

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

..1910.1030(h)(2)(i)(D)

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

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

(h)(3)
Availability.

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

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

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

..1910.1030(h)(4)

(h)(4)
Transfer of Records.

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

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

(h)(5)
Sharps injury log.

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

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

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

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

(h)(5)(ii)
The requirement to establish and maintain a sharps injury log shall apply to any employer who is required to maintain a log of occupational injuries and illnesses under 29 CFR 1904.

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

(i)

Dates --

(i)(1)

Effective Date. The standard shall become effective on March 6, 1992.

(i)(2)

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

(i)(3)

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

(i)(4)

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

[56 FR 64004, Dec. 06, 1991, as amended at 57 FR 12717, April 13, 1992; 57 FR 29206, July 1, 1992; 61 FR 5507, Feb. 13, 1996; 66 FR 5325 Jan., 18, 2001]

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APPENDIX S

WEB SITE RESOURCE LIST

New Jersey Department of Health and Senior Services
Public Employees Occupational Safety And Health Program
PO Box 360, 7th Floor
Trenton, NJ 08625-0360
(609) 984-1863
http://www.state.nj.us/health/eoh/peoshweb

New Jersey Department of Labor
Public Employees Occupational Safety and Health Program
PO Box 386
Trenton, NJ 08625-0386
(609) 292-0767
(800) 624-1644
http://www.state.nj.us/labor/lsse/lspeosh.html

Effective Engineering Controls
CDC Guidelines and Recommendations
Vaccine Safety

NOTE: This appendix contains web sites that can be used for the purposes of information and research. The examples of effective engineering controls in this appendix do not include all those on the market, but are simply representative of the devices available. **PEOSH does not approve, endorse, register, or certify medical devices**. Inclusion in this list does not indicate PEOSH approval, endorsement, registration, or certification. The final determination of compliance with PEOSH's standards takes into account all factors pertaining to the use of such devices at a particular worksite.

Effective Engineering Controls

ECRI
Available: http://healthcare.ecri.org
ECRI, designated as an Evidence-based Practice Center by the Agency for Health Care Policy and Research, is a nonprofit international health services research organization.

Food and Drug Administration (FDA) Safety Alerts
Available: http://www.fda.gov/cdrh/safety.html
Link page for Safety Alerts and Advisories that warn of the risk of injuries from medical devices.

International Health Care Worker Safety Center, University of Virginia
Available: http://www.people.virginia.edu/~epinet/products.html
Features a list of safety devices with manufacturers and specific project names.

National Institute for Occupational Safety and Health (NIOSH) Sharps Disposal Containers
Available: http://www.cdc.gov/niosh/sharps1.html
Features information on selecting, evaluating, and using sharps disposal containers.

Occupational Safety and Health Administration (OSHA) Glass Capillary Tubes: Joint Safety Advisory About Potential Risks
Available: http://www.osha-sic.gov/OshDoc/Interp_data/I19990222.html
Describes safer alternatives to conventional glass capillary tubes.

Occupational Safety and Health Administration (OSHA) Needlestick Injuries
Available: http://www.osha-slc.gov/SLTC/needlestick/index.html
Features recent news, recognition, evaluation, controls, compliance, and links to information on effective engineering controls.

Safety Sharp Device Contracts
Available: http://www.va.gov/vasafety/osh-issues/needlesafety/safetysharpcontracts.htm
Features safety sharp devices on contract with the US Department of Veterans Affairs (VA).

SHARPS Injury Control Program
Available: http://www.dhs.ca.gov/ohb/sharps/default.htm
Established by Senate Bill 2005 to study sharps injuries in hospitals, skilled nursing facilities, and home health agencies in California. Features a Beta version of Safety Enhanced Device Database Listing by Manufacturer.

Training for Development of Innovative Control Technologies (TDICT) Project
Available: http://www.tdict.org/criteria.html
Features "Safety Feature Evaluation Forms" for specific devices.

US DEPARTMENT OF HEALTH & HUMAN SERVICES (HHS): CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) GUIDELINES AND RECOMMENDATIONS

CDC Prevention Guidelines Database
Available: http://aepo-xdv-www.epo.cdc.gov/wonder/PrevGuid/PrevGuid.shtml
Provides access to the CDC Prevention Guidelines Database, which is a compilation of all of the official guidelines and recommendations published by the CDC for the prevention of diseases, disabilities, and injuries. Information on how to find a specific CDC Prevention Guideline.

Morbidity and Mortality Weekly Report (MMWR)
Available: http://www2.cdc.gov/mmwr/mmwr.html
Provides access to the MMWR, a series which is prepared by the CDC. Contains comprehensive information on policy statements for prevention and treatment that are within the CDC's scope of responsibility, for example, recommendations from the Advisory Committee on Immunization Practice (ACIP).

The following are CDC guidelines and recommendations on HIV, Hepatitis B, and Hepatitis C:

Guideline for Infection Control in Health Care Personnel, 1998.
Available: http://www.cdc.gov/ncidod/hip/GUIDE/InfectControl98.pdf

Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease. Publication date 10/16/1998.
Available: http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00055154.htm

Public Health Service Guidelines for the Management of Health-Care Worker Exposures to HIV and Recommendations for Postexposure Prophylaxis. Publication date 5/15/1998.
Available: http://www.cdc.gov/eop/mmwr/preview/mmwrhtml/00052722.htm

Appendix - First-Line Drugs for HIV Postexposure Prophylaxis (PEP). Publication date 5/15/1998.
Available: http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00052801.htm

Immunization of Health-Care Workers: Recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). Publication date 12/26/1997.
(Provides recommendations for Hepatitis B).
Available: http://www.cdc.gov/epo/mmwr/preview/mmwrhtml/00050577.htm

APPENDIX S

Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis.
Publication date June 29, 2001.
Available: http://www.cdc.gov/mmwr/PDF/rr/rr5011.pdf

VACCINE SAFETY

Centers for Disease Control and Prevention (CDC)
Available: http://www.cdc.gov/nip/vacsafe/
The National Immunization Program (NIP) of the CDC features information on vaccine safety.

Food and Drug Administration (FDA)
Available: http://www.fda.gov/fdac/features/095_vacc.html and
http://www.fda.gov/cber/vaers/vaers.htm
The first site features information on how the FDA ensures vaccine safety. The second site features information on the Vaccine Adverse Event Reporting System (VAERS), a cooperative program for vaccine safety of the FDA and CDC.

Immunization Action Coalition (IAC)
Available: http://www.immunize.org/
The IAC is a nonprofit organization working to increase immunization rates and prevent disease. Features Vaccine Information Statements, free print materials, and other hepatitis and immunization sites.

Infectious Diseases Society of America (IDSA)
Available: http://www.idosociety.org/vaccine/index.html
The Vaccine Initiative is a project of the IDSA and the Pediatric Infectious Diseases Society. Features information on vaccination and vaccination-related issues.

Institute for Vaccine Safety, Johns Hopkins School of Public Health
Available: http://www.vaccinesafety.edu/
The purpose of the Institute is to obtain and distribute information on the safety of recommended immunizations.

National Institutes of Health (NIH)
Available: http://www.niaid.nih.gov/publications/vaccine/undvacc.htm
Features a 40 page brochure "Understanding Vaccines".

World Health Organization (WHO)
Available: http://www.who.int/gpv-safety/
Features a vaccine safety home page which offers links to vaccine safety-related information.

Centers for Disease Control ***Morbidity and Mortality Weekly Report:*** "Updated U.S. Public Health Services Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis." June 29, 2001, Vol.50, No. RR-11
http://www.cdc.gov/mmwr/PDF/rr/rr5011.pdf

Establishment/Facility Name: _____

Sample Sharps Injury Log Year 2____

Date	Case/ Report No.	Type of Device (e.g., syringe, suture needle)	Brand Name of Device	Work Area were injury occurred (e.g., Geriatrics, Lab)	Brief description of how the incident occurred (i.e., procedure being done, action being performed (disposal, injection, etc.), body part injured)

29 CFR 1910.1030, OSHA's Bloodborne Pathogens Standard, in paragraph (h)(5), requires an employer to establish and maintain a Sharps Injury Log for recording all percutaneous injuries in a facility occurring from *contaminated* sharps. The purpose of the Log is to aid in the evaluation of devices being used in healthcare and other facilities and to identify problem devices or procedures requiring additional attention or review. This log must be kept in addition to the injury and illness log required by 29 CFR 1904. The Sharps Injury Log should Include all sharps injuries occurring in a calendar year. The log must be retained for five years following the end of the year to which it relates. The Log must be kept in a manner that preserves the confidentiality of the affected employee.

APPENDIX U

QUESTIONNAIRE FOR EVALUATING SHARPS DISPOSAL CONTAINER PERFORMANCE

INSTRUCTIONS: Product evaluators should inspect and operate containers to be evaluated in side-by-side comparisons. Representative sharps (syringes, IV sets, blades, biopsy needles, pipettes, etc.) should be used to test candidate products. Actual use conditions should be simulated, if possible. Prior to inserting test sharps, attempt to reopen sealed containers and attempt to spill or remove contents from unsealed containers if this is a functional requirement. Evaluation facilitators should provide product manufacturer literature and visual instructions and should demonstrate proper operation of each of the containers. Use of this guideline requires knowledge that the ideal product may not exist and that this evaluation tool was based on common product designs available at the time.

PLEASE CIRCLE YOUR RESPONSE

FUNCTIONALITY

	agree ..... disagree				
Container is stable when placed on horizontal surface and when used as described in the product labeling for use in trays, holders, or enclosures	1	2	3	4	5
Container provides for puncture, leak, and impact resistance	1	2	3	4	5
Container, labels, warming devices, and brackets are durable	1	2	3	4	5
Container is autoclavable, if necessary	1	2	3	4	5
Container is available in various sizes and capacities	1	2	3	4	5
Container is available with auxiliary safety features (e.g., restricted access to sharps in the container), if required	1	2	3	4	5
Closure mechanism will not allow needlestick injury	1	2	3	4	5
Closure mechanism provides secure seal	1	2	3	4	5
Design minimizes needle-tip flipback	1	2	3	4	5
Design promotes clinical performance (e.g., will not compromise sterile field or increase injury or infection control hazards)	1	2	3	4	5
Design resists easy reopening after sealing for final disposal or autoclaving	1	2	3	4	5
Inlet design defeats waste removal when open	1	2	3	4	5
Inlet design prevents spillage of contents (physical or liquid) while sharps disposal container is in use in the intended upright position	1	2	3	4	5
Containers designed to be reopenable have removable lids design with tight closure that facilities ease of removal with grip safety and conduct	1	2	3	4	5
Mounting brackets are rugged and designed for ease of service and documentation	1	2	3	4	5

ACCESSIBILITY

	agree ..... disagree				
Container available in various opening sizes and shapes	1	2	3	4	5
Containers are supplied in sufficient quantity	1	2	3	4	5
Container has an entanglement-free opening/access way	1	2	3	4	5
Container opening/access way and current fill status visible to user prior to placing sharps into container	1	2	3	4	5
Internal design/molding of container does not impede ease of use	1	2	3	4	5
Handles, if present, located above full-fill level	1	2	3	4	5
Handles, if present, facilitate safe vertical transport and are located away from opening/access way and potentially soiled surfaces	1	2	3	4	5
Fixed locations place container within arm's reach of point of waste generation	1	2	3	4	5
Fixed locations allow for installation of the container below horizontal vision level	1	2	3	4	5
If necessary, in high patient or visitor traffic areas, container should provide for security against tampering	1	2	3	4	5

VISIBILITY

	agree				disagree
Color or warming label implies danger	1	2	3	4	5
A warning indicator (i.e., color or warming label) is readily visible to the user prior to user placing sharps into container	1	2	3	4	5
Overfill level provided and current fill status is readily visible to the user prior to use placing sharps into container	1	2	3	4	5
Sharps disposal container complies with OSHA requirements	1	2	3	4	5
Disposal opening/access way is visible prior to user placing sharps into container	1	2	3	4	5
Security, mounting, aesthetic, and safety features do not distort visibility of the opening/access way or fill status indicator	1	2	3	4	5

ACCOMMODATION

	agree				disagree
No sharp edges in construction or materials	1	2	3	4	5
Safety features do not impede free access	1	2	3	4	5
Promotes patient and user satisfaction (i.e., aesthetic to extent possible)	1	2	3	4	5
Is simple to operate	1	2	3	4	5
Any emissions from final disposal comply with pollution regulations	1	2	3	4	5
Easy to assemble, if required	1	2	3	4	5
Components of containers that require assembly are easy to store prior to use	1	2	3	4	5
Use allows one handed disposal	1	2	3	4	5
Product available in special designs for environments with specific needs (e.g., laboratories, emergency rooms, emergency medical services, pediatrics, correctional facilities)	1	2	3	4	5
Mounting system durable, secure, safe, cleanable, and, where appropriate, lockable	1	2	3	4	5
Mounting systems allow height adjustments	1	2	3	4	5
Design promotes task confidence	1	2	3	4	5
Cost effectiveness	1	2	3	4	5

OTHER COMMENTS

What design or performance requirements are missing from the product you evaluated that are really needed to safely or more comfortably conduct your job or sharps related task?

Additional Evaluator Concerns and Comments:

This product selection questionnaire was developed by the Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health in conjunction with NIOSH Educational Resource Centers; The John Hopkins University, Baltimore; the University of Texas, Houston; the University of California, Berkeley; and the Mount Sinai School of Medicine, New York City.

APPENDIX U

ECRI's Needlestick-Prevention Device Evaluation Form

Device: _____

Supplies/Trade Name: _____

Applications: _____

Reviewer: _____ **Date:** _____

For each question circle the appropriate response for the needlestick-prevention (NPD) device being evaluated.

Healthcare Worker Safety

1. A. Does the NPD prevent needlesticks during use (i.e., before disposal)? ..... Yes No
   B. Does it do so after use (i.e., does the safety mechanism remain activated through disposal of the NPD)? ..... Yes No
2. A. Does NPD provide protection one of the following ways: Either intrinsically or automatically? (Answer "No" if a specific action by the user is required to activate the safety mechanism.) ..... Yes No
   B. If "No," is the mechanism activated in one of the following ways: either by one-handled technique or by a two-handed technique accomplished as part of the usual procedure? ..... Yes No
3. During the use of NPD do user's hands remain behind the needle until activation of the safety mechanism is complete? ..... Yes No
4. Is the safety mechanism reliable when activated properly? ..... Yes No
5. Does the NPD minimize the risk of user exposure to the patient's blood? ..... Yes No

Patient Safety and Comfort

6. Does the NPD minimize the risk of infection to the patient (e.g., through cross-contamination)? ..... Yes No
7. Can the NPD be used without causing more patient discomfort than a conventional device? ..... Yes No
8. *For IV NPDs:* Does the NPD attach comfortably (i.e., without causing patient discomfort at the catheter port or IV tubing? ..... Yes No

Ease of use and Training

9. Is NPD Operation obvious? That is can the device be used properly without extensive training? ..... Yes No
10. Can the NPD be used by a left-handed person as easily as by a right-handed person? ..... Yes No
11. Is the technique required for using the NPD the same as that for using a conventional device? ..... Yes No
12. Is it easy to identify the type and size of the product from the packaging? ..... Yes No
13. *For Intravenous (IV) catheters and blood collection needle sets*: Does the NPD provide a visible blood flashback during initial insertion? ..... Yes No
14. Please rate the ease of using this NPD ..... Exc. Good Fair Poor
15. Please rate the quality of the in-service training ..... Exc. Good Fair Poor

Compatibility

16. Is the NPD compatible with devices (e.g., blood collection tubes) from a variety of suppliers? ..... Yes No
17. *For IV NPDs:*
    A. Is the NPD compatible with intralipid solutions? ..... Yes No
    B. Does the NPD attach securely at the catheter port? ..... Yes No
    C. Does the NPD attach securely or lock at a Y-site (e.g., for piggybacking)? ..... Yes No
18. Is the NPD easy to dispose of in sharps containers of all sizes (if required)? ..... Yes No
19. Does using the NPD instead of a conventional device result in only a modest (if any) increase in sharps container waste volume? (Answer "No" if the NPD will increase waste volume significantly) ..... Yes No

Overall

20. Would you recommend using this device? ..... Yes No

Comments (e.g., describe problems, list incompatibilities)

_____

_____

NPD Cost Calculation Worksheet*

WORKSHEET				SAMPLE DATA	
PROTECTIVE SYSTEM				**Protective blood collection tube holder**	
NPD (supplier/trade name)				XYZ Medical Pro Hold	
A.	Price per device	A=	$	A=	$4.00
B.	Uses per year	B=		B=	130,000
C.	Uses per device	C=		C=	300
D.	Quantity used per year (B) C)	D=		D=	433
E.	NPD cost per year (A x D)	E=	$	E=	$1,732
Additional component				XYZ Medical ProHold Companion 1 Qt Sharps Container	
F.	Price per device	F=	$	F=	$3.50
G.	Uses per year	G=		G=	Dispose of 130,000 needles
H.	Uses per device	H=		H=	NA (see next entry)
I.	Quantity used per year (G) H)	I=		I=	32**
J.	NPD cost per year (F x I)	J=	$	J=	$112
K. Annual protective system cost (E) J)		K=	$	K=	$1,844
CONVENTIONAL SYSTEM				**Blood collection tube holder**	
Conventional device				XYZ Medical Tube Holder	
L.	Price per device	L=	$	L=	$0.15
M.	Uses per year	M=		M=	130,000
N.	Uses per device	N=		N=	300
O.	Quantity used per year (M) N)	O=		O=	433
P.	NPD cost per year (L x O)	P=	$	P=	$65
Additional component				**Conventional 1 qt sharps container**	
Q.	Price per device	Q=	$	Q=	$2.13
R.	Uses per year	R=		R=	Dispose of 130,000 needles
S.	Uses per device	S=		S=	NA (see next entry)
T.	Quantity used per year (R) S)	T=		T=	32**
U.	NPD cost per year (Q x T)	U=	$	U=	$68.16
V. Annual conventional system cost (P) U)		V=	$	V=	$133.16
RELATED DISPOSAL COSTS					
Additional sharps containers					
W.	Disposal volume of each NPD	W=		W=	14 cm^3 (tube holder only)
X.	Disposal volume of each conventional device	X=		X=	12 cm^3 (tube holder only)
Y.	Sharps container volume	Y=		Y=	1 qt (=943cm^3)
Z.	Number of additional sharps containers per year (W x	Z=		Z=	1 (assumes 100% packing efficiency)
AA.	Price per sharps container	AA=	$	AA+	$3.50
AB.	Annual additional sharps containers cost (Z x AA)	AB=	$	AB=	$3.50
AC. Other additional disposal costs		AC=	$	AC=	None
AD. Total annual increase in disposal costs (AB + AC)		AD=	$	AD=	$3.50
NSI Cost					
AE.	Number of NSIs per year with conventional device	AE=	$	AE=	6
AF.	Projected NSIs per year with NPD (50% x AE)	AF=	$	AF=	3
AG.	Cost of each NSI	AG=	$	AG=	$540
AH.	Annual NSI cost savings (AG x [AE - AF])	AH=	$	AH=	$1,620
AI. MISCELLANEOUS COSTS		AI=	$	AI=	None
AJ. NET PROTECTIVE SYSTEM COSTS (K+AD+AI-AH)		AH=	$	AJ=	$227.50
AK. ANNUAL INCREASE IN EXPENDITURES (AJ-V)		AK=	$	**Annual increase in expenditures = $94.34**	

*The figures obtained by completing this worksheet should be used for comparison purposes only. These figures will not reflect the actual costs and cost savings associated with implementing the alternative under consideration, and they cannot reflect the true value of using an NPD in terms of staff safety and the economic impact on NSIs that result in seroconversion.

**Calculated by multiplying the estimated volume of one needle (0.23 cm^3) by the number of needles per year (130,000) and then dividing by the volume of one sharps container (1 qt = 943 cm^3). Note that this analysis assume 100% packing efficiency.

GUIDELINES FOR THE USE OF SAFETY FEATURE EVALUATION SHEETS

Coordinator:

Determine which products are to be evaluated and provide at least four or more test samples for each individual evaluating the product. (Each evaluator should have enough samples to disassemble and examine the design thoroughly.)

Set up a testing station for each type of device which allows testers to evaluate products in a simulated patient procedure. Provide training dummies (injection pads, oranges, etc.) as necessary.

Provide visual instructions and demonstrate proper use of each device.

Review the instructions and rating system with each evaluator.

Encourage each evaluator to comment on the sheets and prioritize the questions at the end of the evaluation. This will provide a useful decision making tool and will help alert you to specific areas of concern which may not have been covered by the questionnaire.

Evaluators:

Re-enact all steps of intended or possible procedures performed with the device being tested.

Attempt to misuse the device and circumvent or disable the safety feature.

Answer each question, including the short answer section at the end. If you do not understand a question, please write comments directly on the sheets.

NOTE: The utility of these criteria is for initial screening of devices and **NOT** for clinical assessment/pilot testing. Certain assumptions have been made in the development of these forms based on information about currently available products. We recognize the likelihood that the ideal product may not exist. TDICT welcomes your comments on the use of these tools.

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San Francisco, CA 94110

SAFETY FEATURE EVALUATION FORM

SAFETY SYRINGES

Date: _____ Department: _____ Occupation: _____
Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

agree ..... disagree

DURING USE:

1. The safety feature can be activated using a one-handed technique	1	2	3	4	5	N/A
2. The safety feature **does not** obstruct vision of the tip of the sharp	1	2	3	4	5	N/A
3. Use of this product requires you to use the safety feature	1	2	3	4	5	N/A
4. This product does not require more time to use than a non-safety device	1	2	3	4	5	N/A
5. The safety feature works well with a wide variety of hand sizes	1	2	3	4	5	N/A
6. The device is easy to handle while wearing gloves	1	2	3	4	5	N/A
7. This device **does not** interfere with uses that do not require a needle	1	2	3	4	5	N/A
8. This device offers a good view of any aspirated fluid	1	2	3	4	5	N/A
9. This device will work with all required syringe and needle sizes	1	2	3	4	5	N/A
10. This device provides a better alternative to traditional recapping	1	2	3	4	5	N/A

AFTER USE:

11. There is a clear and unmistakable change (audible or visible) that occurs when the safety feature is activated	1	2	3	4	5	N/A
12. The safety feature operates reliably	1	2	3	4	5	N/A
13. The exposed sharp is permanently blunted or covered after use and prior to disposal	1	2	3	4	5	N/A
14. This device is no more difficult to process after use than non-safety devices	1	2	3	4	5	N/A

TRAINING:

15. The user **does not** need extensive training for correct operation	1	2	3	4	5	N/A
16. The design of the device suggests proper use	1	2	3	4	5	N/A
17. It is **not** easy to skip a crucial step in proper use of the device	1	2	3	4	5	N/A

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

APPENDIX U

SAFETY FEATURE EVALUATION FORM

I.V. ACCESS DEVICES

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

		agree ..... disagree					
1.	The safety feature can be activated using a one-handed technique	1	2	3	4	5	N/A
2.	The safety feature **does not** interfere with normal use of this product	1	2	3	4	5	N/A
3.	Use of this product requires you to use the safety feature	1	2	3	4	5	N/A
4.	This product **does not** require more time to use than a non-safety device	1	2	3	4	5	N/A
5.	The safety feature works well with a wide variety of hand sizes	1	2	3	4	5	N/A
6.	The device allows for rapid visualization of flashback in the catheter or chamber	1	2	3	4	5	N/A
7.	Use of this product **does not** increase the number of sticks to the patient	1	2	3	4	5	N/A
8.	The product stops the flow of blood after the needle is removed from the catheter (or after the butterfly is inserted) and just prior to line connections or hep-lock capping	1	2	3	4	5	N/A
9.	A clear and unmistakable change (either audible or visible) occurs when the safety feature is activated	1	2	3	4	5	N/A
10.	The safety feature operates reliably	1	2	3	4	5	N/A
11.	The exposed sharp is blunted or covered after use and prior to disposal	1	2	3	4	5	N/A
12.	The product **does not** need extensive training to be operated correctly	1	2	3	4	5	N/A

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

SAFETY FEATURE EVALUATION FORM

SHARPS DISPOSAL CONTAINERS

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

		agree ..... disagree					
1.	The container's shape, its markings, or its color, imply danger	1	2	3	4	5	N/A
2.	The implied warning of danger can be seen from the angle at which people commonly view it (very short people, people in wheel chairs, children, etc)	1	2	3	4	5	N/A
3.	The implied warning can be universally understood by visitors, children, and patients	1	2	3	4	5	N/A
4.	The container's purpose is self-explanatory and easily understood by a worker who may be pressed for time or unfamiliar with the hospital setting	1	2	3	4	5	N/A
5.	The container can accept sharps from any direction desired	1	2	3	4	5	N/A
6.	The container can accept all sizes and shapes of sharps	1	2	3	4	5	N/A
7.	The container allows single handed operation. (Only the hand holding the sharp should be near the container opening)	1	2	3	4	5	N/A
8.	It is difficult to reach in and remove a sharp	1	2	3	4	5	N/A
9.	Sharps can go into the container without getting caught on the opening	1	2	3	4	5	N/A
10.	Sharps can go into the container without getting caught on any molded shapes in the interior	1	2	3	4	5	N/A
11.	The container is puncture resistant	1	2	3	4	5	N/A
12.	When the container is dropped or turned upside down (even before it is permanently closed) sharps stay inside	1	2	3	4	5	N/A
13.	The user can determine easily, from various viewing angles, when the container is full	1	2	3	4	5	N/A
14.	When the container is to be used free-standing (no mounting bracket), it is stable and unlikely to tip over	1	2	3	4	5	N/A
15.	It is safe to close the container. (Sharps should not protrude into the path of hands attempting to close the container)	1	2	3	4	5	N/A
16.	The container closes securely. (e.g. if the closure requires glue, it may not work if the surfaces are soiled or wet.)	1	2	3	4	5	N/A
17.	The product has handles which allow you to safely transport a full container	1	2	3	4	5	N/A
18.	The product **does not** require extensive training to operate correctly	1	2	3	4	5	N/A

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

APPENDIX U

SAFETY FEATURE EVALUATION FORM

I.V. CONNECTORS

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

		agree ..... disagree					
1.	Use of this connector eliminates the need for exposed needles in connections	1	2	3	4	5	N/A
2.	The safety feature **does not** interfere with normal use of this product	1	2	3	4	5	N/A
3.	Use of this product requires you to use the safety feature	1	2	3	4	5	N/A
4.	This product **does not** require more time to use than a non-safety device	1	2	3	4	5	N/A
5.	The safety feature works well with a wide variety of hand sizes	1	2	3	4	5	N/A
6.	The safety feature allows you to collect blood directly into a vacuum tube, eliminating the need for needles	1	2	3	4	5	N/A
7.	The connector can be secured (locked) to Y-sites, hep-locks, and central lines	1	2	3	4	5	N/A
8.	A clear and unmistakable change (either audible or visible) occurs when the safety feature is activated	1	2	3	4	5	N/A
9.	The safety feature operates reliably	1	2	3	4	5	N/A
10.	The exposed sharp is blunted or covered after use and prior to disposal	1	2	3	4	5	N/A
11.	The product **does not** need extensive training to be operated correctly	1	2	3	4	5	N/A

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

APPENDIX U

SAFETY FEATURE EVALUATION FORM

VACUUM TUBE BLOOD COLLECTION SYSTEMS

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

		agree ..... disagree					
1.	The safety feature can be activated using a one-handed technique	1	2	3	4	5	N/A
2.	The safety feature **does not** interfere with normal use of this product	1	2	3	4	5	N/A
3.	Use of this product requires you to use the safety feature	1	2	3	4	5	N/A
4.	This product **does not** require more time to use than a non-safety device	1	2	3	4	5	N/A
5.	The safety feature works well with a wide variety of hand sizes	1	2	3	4	5	N/A
6.	The safety feature works with a butterfly	1	2	3	4	5	N/A
7.	A clear and unmistakable change (either audible or visible) occurs when the safety feature is activated	1	2	3	4	5	N/A
8.	The safety feature operates reliably	1	2	3	4	5	N/A
9.	The exposed sharp is blunted or covered after use and prior to disposal	1	2	3	4	5	N/A
10.	The inner vacuum tube needle (rubber sleeved needle) **does not** present a danger of exposure	1	2	3	4	5	N/A
11.	The product **does not** need extensive training to be operated correctly	1	2	3	4	5	N/A

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

APPENDIX U

SAFETY FEATURE EVALUATION FORM

E. R. SHARPS DISPOSAL CONTAINERS

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

	agree ..... disagree
1. The container's shape, its markings, or its color, imply danger which can be understood by visitors, children, and patients	1 2 3 4 5 N/A
2. The implied warning of danger can be seen from the angle at which people commonly view it (very short people, people in wheel chairs, children, etc)	1 2 3 4 5 N/A
3. The container can be placed in a location that is easily accessible during emergency procedures	1 2 3 4 5 N/A
4. The container's purpose is self-explanatory and easily understood by a worker who may be pressed for time or unfamiliar with the hospital setting	1 2 3 4 5 N/A
5. The container can accept sharps from any direction desired	1 2 3 4 5 N/A
6. The container can accept all sizes and shapes of sharps	1 2 3 4 5 N/A
7. The container is temporarily closable, and will not spill contents (even after being dropped down a flight of stairs)	1 2 3 4 5 N/A
8. The container allows single handed operation. (Only the hand holding the sharp should be near the container opening)	1 2 3 4 5 N/A
9. It is difficult to reach in and remove a sharp	1 2 3 4 5 N/A
10. Sharps can go into the container without getting caught on the opening or any molded shapes in the interior	1 2 3 4 5 N/A
11. The container can be placed within arm's reach	1 2 3 4 5 N/A
12. The container is puncture resistant	1 2 3 4 5 N/A
13. When the container is dropped or turned upside down (even before it is permanently closed) sharps stay inside	1 2 3 4 5 N/A
14. The user can determine easily, from various viewing angles, when the container is full	1 2 3 4 5 N/A
15. When the container is to be used free-standing (no mounting bracket), it is stable and unlikely to tip over	1 2 3 4 5 N/A
16. The container is large enough to accept all sizes and shapes of sharps, including 50 ml preloaded syringes	1 2 3 4 5 N/A
17. It is safe to close the container. (Sharps should not protrude into the path of hands attempting to close the container)	1 2 3 4 5 N/A
18. The container closes securely under all circumstances	1 2 3 4 5 N/A
19. The product has handles which allow you to safely transport a full container	1 2 3 4 5 N/A
20. The product **does not** require extensive training to operate correctly	1 2 3 4 5 N/A

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

SAFETY FEATURE EVALUATION FORM

SAFETY DENTAL SYRINGES

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

		agree ..... disagree					
1.	The safety feature can be activated using a one-handed technique	1	2	3	4	5	N/A
2.	The safety feature **does not** obstruct vision of the tip of the sharp and the intraoral injection site	1	2	3	4	5	N/A
3.	Use of this product requires you to use the safety feature	1	2	3	4	5	N/A
4.	This product **does not** require more time to use than a non-safety device	1	2	3	4	5	N/A
5.	The safety feature works well with a wide variety of hand sizes	1	2	3	4	5	N/A
6.	The device is easy to handle while wearing gloves	1	2	3	4	5	N/A
7.	The device is easy to handle when wet	1	2	3	4	5	N/A
8.	This device accepts standard anesthetic carpules and does not hinder carpule changing	1	2	3	4	5	N/A
9.	The safety feature **does not** restrict visibility of carpule contents intraorally	1	2	3	4	5	N/A
10.	This device accepts standard dental needles of all common lengths and gauges, and does not interfere with needle changing	1	2	3	4	5	N/A
11.	The device provides a better alternative to traditional recapping	1	2	3	4	5	N/A
12.	Sterilization of this device is as easy as a standard dental syringe	1	2	3	4	5	N/A
13.	For syringes with integral needles only: The needle on this syringe **will not** break while bending and repositioning in the tissue	1	2	3	4	5	N/A
14.	This device is no more difficult to break down after use for sterilization than a standard dental syringe	1	2	3	4	5	N/A
15.	The safety feature operates reliably	1	2	3	4	5	N/A
16.	The exposed sharp is permanently blunted or covered after use and prior to disposal	1	2	3	4	5	N/A
17.	There is a clear and unmistakable change (either visible or audible) that occurs when the safety feature is activated	1	2	3	4	5	N/A
18.	The user **does not** need extensive training to operate the product correctly	1	2	3	4	5	N/A
19.	The design of the device allows for easy removal of the needle from the syringe	1	2	3	4	5	N/A
20.	The design of the device allows for easy removal of the carpule from the syringe	1	2	3	4	5	N/A

SAFETY FEATURE EVALUATION FORM

HOME USE SHARPS DISPOSAL CONTAINERS

Date: _____ Department: _____ Occupation: _____

Product: _____ Number of times used: _____

Please **circle** the most appropriate answer for each question. Not applicable (N/A) may be used if the question does not apply to this particular product.

	agree ..... disagree					
The container is puncture resistant	1	2	3	4	5	N/A
The container is stable	1	2	3	4	5	N/A
There is a handle which is robust, comfortable to carry, and compact	1	2	3	4	5	N/A
The container allows single handed use	1	2	3	4	5	N/A
The user can access the container from any direction	1	2	3	4	5	N/A
It is possible to drop sharps into the container vertically	1	2	3	4	5	N/A
Minimal or no force is required to put sharps into the container	1	2	3	4	5	N/A
The container opens and closes easily	1	2	3	4	5	N/A
Container closure maintains integrity after repeated use	1	2	3	4	5	N/A
The box accommodates a range of sharps, including 12 cc syringe, butterfly and lancet	1	2	3	4	5	N/A
The size of the container is appropriate to its use	1	2	3	4	5	N/A
No one (including a child) can access the contents of the container to retrieve a sharp	1	2	3	4	5	N/A
Needle/tubing do not get caught on the opening or interior shape	1	2	3	4	5	N/A
There is a temporary lock for transport which is secure but reversible	1	2	3	4	5	N/A
There is a permanent lock for final disposal which is not reversible	1	2	3	4	5	N/A
There is an absorbent lining to collect excess fluid	1	2	3	4	5	N/A
The user can determine the fill level visually	1	2	3	4	5	N/A
There is a signal when the box is 2/3 full	1	2	3	4	5	N/A
The container is appropriately labeled	1	2	3	4	5	N/A
Biohazard of container contents is apparent	1	2	3	4	5	N/A
The box is not threatening to patients	1	2	3	4	5	N/A
Use of this container in no way compromises infection control practices	1	2	3	4	5	N/A

Of the above questions, which three are the most important to **your** safety when using this product?

Are there other questions which you feel should be asked regarding the safety/utility of this product?

A USER-BASED PERFORMANCE STANDARD:

for the design, evaluation, and selection of medical devices

This Performance Standard was developed by the TDICT Project, in conjunction with line healthcare workers and the HIV Office of the Centers for Disease Control. It steps back from device specific criteria to look at overall procedures and the fundamental standards which must be met by all products, in all phases of use. Download a pdf version of this document.

Performance Standard vs. Selection Criteria

Generalized/Generic	Device Specific Applications
Based on Procedure	Based on Device
Encompasses Product Life Cycle	Point of Use Only

MAJOR CATEGORIES

I. PATIENT SAFETY & QUALITY OF CARE

- Is the proposed solution of equal or greater effectiveness?
- Will the device improve patient well-being? (Quality Assurance)
- Does the device increase time needed for given procedure?
- Is the device FDA approved? Is it Class I, II, or III?
- Does the device expose the patient to harmful elements? (Latex, X-rays, Chemicals, Extreme Light or Heat, etc.)
- Does proper use of the device involve unnecessary invasions into the patient's body?

II. USER SAFETY

- Does use of the device require excessive re-training?
- Can most of the re-training be done in a lab or simulated setting?
- Do new users experience a steep learning curve?
- Does the level of expertise of the user affect the learning curve? (Novice vs. Expert user?)
- Does the use of the device change the existing procedure significantly?

- Is the device intrinsically more simple, as opposed to more complex, than the device it will replace?
- Does the device require an action which is counter to prevailing procedures? (Is the correct use of the device intuitive?)
- Does the device increase time needed for the given procedure?
- Is the product self-contained as opposed to an assembly of different parts?
- Does the product need to be disassembled-assembled prior to disposal?
- Does the device fit well in the hand of the user as opposed to being cumbersome?
- Who uses the given product?
- Where and how will failure occur?
- Can product be easily misused, used differently, co-opted for alternate use?
- What are the scenarios for common, uncommon, and inappropriate use?
- If a safety feature exists on the device, is it passively activated? (Effective without user interaction/interference)
- Are the safety cues for the safety feature evident at all times? (Are clicks audible, visual markings noticeable, tactile sensations noticeable through gloves?)

III. USER FIT AND SATISFACTION

- Will use of the device require excessive re-training?
- Can most of the re-training be done in a “lab” setting?
- Do new users experience a steep learning curve?
- Does the level of expertise of the user affect the learning curve? (Novice vs. Expert user?)
- Does the use of the device change the existing procedure significantly?
- Is the device intrinsically more simple as opposed to complex?
- Does the device require an action which is counter to prevailing procedures? (Is the correct use of the device intuitive?)
- Does the device increase time needed for given procedure?
- Is product self-contained as opposed to an assembly of different parts?
- Does product need to be disassembled-assembled prior to disposal?
- Does the device fit well in the hand of the user as opposed to being cumbersome?
- Is the packaging of the device easy to open?
- Does the packaging clearly indicate its contents?
- Does the packaging clearly indicate the correct procedures for use of the device?
- Are recycling or disposal directions clear on the packaging or product?
- Where and how will failure occur?
- Can product be easily misused, used differently, co-opted for alternate use?
- What are the scenarios for common, uncommon, and inappropriate use?

IV. PATIENT FIT AND SATISFACTION

- Will the device improve patient well-being? (Quality Assurance)
- Is the proposed solution of equal or greater effectiveness?
- Does the device increase time needed for given procedure?
- Does the device expose the patient to harmful elements? (Latex, X-rays, Chemicals, Extreme Light or Heat, etc.)
- Does proper use of the device involve unnecessary invasions into the patient’s body?

V. PRODUCT LIFE-CYCLE

- What environmental factors must be considered in product evaluation?
- What is the product life-cycle?
- Are recycling or disposal directions clear on the packaging or product?
- Is product self-contained as opposed to an assembly of different parts?
- Is the packaging excessive or cumbersome?
- Does the device, or its packaging, present any new storage problems?
- Does the device incorporate materials that are non-recyclable in places where recyclable materials would be just as effective?

VI. ADMINISTRATIVE FIT AND SATISFACTION

- Does the cost of the product correlate closely with other similar devices on the market?
- Is the cost prohibitive to widespread use of the product?
- Does the cost of the product appear to be correlated to the expense of production?
- Will implementation of the device require excessive re-training?
- Can most of the re-training be done in a “lab” setting?
- Does the level of expertise of the user affect the learning curve? Novice vs. Expert user?
- Does the use of the device change the existing procedure significantly?
- Is the proposed solution of equal or greater effectiveness?
- Where is the product used?
- What environmental factors must be considered in product evaluation?
- What is the product life-cycle?
- Are recycling or disposal directions clear on the packaging or product?
- Does the device, or its packaging, present any new inventory problems?
- Is the device FDA approved? Is it Class I, II, or III?
- How does the device affect patient well-being? (Quality Assurance)
- Who uses the given product?
- Where and how will failure occur?
- How might product be misused, used differently, co-opted for alternate use?
- What are the scenarios for common, uncommon, and inappropriate use?
- Does the device offer a distinct advantage to the institution using it?

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