

**SUBJECT:** Enforcement Procedures for the Occupational Exposure to  
Bloodborne Pathogens Standard, 29 CFR 1910.1030

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

B. **Scope.** This instruction applies OSHA-wide.

C. **Cancellation.** This instruction cancels OSHA Instruction CPL 2-2.44B, February 27, 1990, (except as noted at M.9. of this instruction).

**D. References.**

1. OSHA Instruction CPL 2.45B, June 15, 1989, Field Operations Manual (FOM).
2. OSHA Instruction ADM 1-1.12B, December 29, 1989, the Integrated Management Information System (IMIS) Forms Manual.
3. Centers for Disease Control Morbidity and Mortality Weekly Report: "Recommendations for Prevention of HIV Transmission in Health Care Settings." August 1987; Vol. 36, No.S-2.
4. Centers for Disease Control Morbidity and Mortality Weekly Report: 1988 Agent Summary Statement for Human Immunodeficiency Virus and Report on Laboratory Acquired Infection with Human Immunodeficiency Virus. April 1, 1988; Vol. 37, No.S-4.
5. Centers for Disease Control Morbidity and Mortality Weekly Report: "Guidelines for Prevention of Transmission of HIV and HBV to Health Care and Public Safety Workers." June 23, 1989; Vol. 38, No. S-6.
6. Centers for Disease Control Morbidity and Mortality Weekly Report: "Update: Universal Precautions for the Prevention of Transmission of HIV, HBV and Other Bloodborne Pathogens in Health Care Settings". June 24, 1988; Vol. 37, No. 24.
7. Centers for Disease Control Morbidity and Mortality Weekly Report: "Public Health Service Statement on Management of Occupational Exposure to Human Immunodeficiency Virus, Including Consideration Regarding Zidovudine Postexposure Use." January 1990; Vol. 139, No.RR2. (See Appendix A.)
8. Centers for Disease Control Morbidity and Mortality Weekly Report: "Protection Against Viral Hepatitis, Recommendations of the Immunization Practices from the Advisory Committee." February 1990, Vol. 39, No. S-2. (See Appendix B.)
9. U.S. Department of Health and Human Services: "Biosafety in Microbiological and Biomedical Laboratories," Publication No. (NIH) 88-8395, May 1988.

- E. **Action.** OSHA Regional Administrators and Area Directors shall use the guidelines in this instruction to ensure uniform enforcement of the Bloodborne Pathogens Standard and as necessary to assist the Regional Administrators and Area Directors in enforcing the Bloodborne Pathogens Standard.
- F. **Federal Program Change.** This instruction describes a Federal program change which affects State programs. Each Regional Administrator shall:
1. Ensure that this change is promptly forwarded to each State designee, using a format consistent with the Plan Change Two-Way Memorandum in Appendix P of OSHA Instruction STP 2.22A CH-3.
  2. Explain the technical content of this change to the State designee as requested.
  3. Ensure that State designees are asked to acknowledge receipt of this Federal program change in writing to the Regional Administrator as soon as the State's intention is known, but not later than 70 calendar days after the date of issuance (10 days for mailing and 60 days for response). This acknowledgment must include the State's intention to follow OSHA's policies and procedures described in this instruction, or a description of the State's alternative policy and/or procedure which, is "at least as effective" as the Federal policy.
  4. Ensure that the State designees submit a plan supplement, in accordance with OSHA Instruction STP 2.22A, Ch-3, as appropriate, following the established schedule that is agreed upon by the State and Regional Administrator to submit non-Field Operations Manual/Technical Manual Federal Program Changes.
    - a. If a State intends to follow the revised inspection procedures described in this instruction, the State must submit a revised version of this instruction, adapted as appropriate to reference State law, regulations and administrative structure, or a cover sheet describing how references in this instruction correspond to the State's structure. The State's acknowledgment letter may fulfill the plan supplement requirement if the appropriate documentation is provided.
    - b. If the State adopts an alternative to Federal enforcement inspection procedures, the State's plan supplement must identify and provide a rationale for all substantial differences from Federal procedures in order for OSHA to judge whether a different State procedure is as effective as the comparable procedure.
  5. After Regional review of the State plan supplement and resolution of any comments thereon, forward the submission to the National Office in accordance with established procedures. The Regional Administrator shall provide a judgment on the relative effectiveness of each substantial difference in the State plan change and an overall assessment thereon with a recommendation for approval or disapproval by the Assistant Secretary.
  6. Advise State designees that the State is also responsible for extending coverage under its procedures for addressing occupational exposure to bloodborne pathogens to the public sector, such as police, firefighters, ambulance and other emergency response employees.

7. Review policies, instructions, and guidelines issued from the State to determine that changes have been communicated to State program personnel.

G. **Background.** In September 1986, OSHA was petitioned by various unions representing health care employees to develop an emergency temporary standard to protect employees from occupational exposure to bloodborne diseases. The agency decided to pursue the development of a Section 6(b) of the Act standard and published a proposed rule on May 30, 1989.

1. The agency also concluded that the risk of contracting the hepatitis B virus (HBV) and human immunodeficiency virus (HIV) among members of various occupations within the health care sector required an immediate response and therefore issued OSHA Instruction CPL 2-2.44, January 19, 1988. That instruction was canceled by CPL 2-2.44A, August 15, 1988, and subsequently, CPL 2-2.44B was issued February 27, 1990.
2. On December 6, 1991, the agency issued its final regulation on occupational exposure to bloodborne pathogens (29 CFR 1910.1030). Based on a review of the information in the rulemaking record, OSHA has determined that employees face a significant health risk as the result of occupational exposure to blood and other potentially infectious materials (OPIM) because they may contain bloodborne pathogens. These pathogens include HBV which causes Hepatitis B, a serious liver disease, and HIV, which causes Acquired Immunodeficiency Syndrome (AIDS). The agency further concludes that this hazard can be minimized or eliminated using a combination of engineering and work practice controls, personal protective clothing and equipment, training, medical surveillance, hepatitis B vaccination, signs, and labels, and other provisions.

#### H. **Inspection Scheduling, and Scope.**

1. Inspection scheduling shall be conducted in accordance with the procedures outlined in the FOM, Chapter II, and for Federal agencies, Chapter XIII, except as modified in paragraphs 2., 3., and 4 below.
2. All inspections, programmed or unprogrammed, shall include, if appropriate, a review of the employer's exposure control plan and employee interviews to assess compliance with the standard.
3. Expansion of an inspection to areas involving the hazard of occupational exposure to body fluids (including onsite health care units and emergency response or first aid personnel) shall be performed when:
  - a. The exposure control plan or employee interviews indicate deficiencies in complying with OSHA requirements, as set forth in 29 CFR 1910.1030 or this instruction.
  - b. Relevant formal employee complaints are received which are specifically related to occupational exposure to blood or OPIM.

- c. A fatality/catastrophe inspection is conducted as the result of occupational exposure to blood or OPIM.
  4. Regional Offices may develop and implement local emphasis programs as a supplement to complaint-generated inspection activities. (See the FOM, Chapter II.)
- I. **General Inspection Procedures.** The procedures given in the FOM, Chapter III, shall be followed except as modified in the following sections:
1. Where appropriate, the facility administrator, infection control director or occupational health nurse, "in service" education (i.e., training) director, and head of central services and/or housekeeping shall be included in the opening conference or interviewed early in the inspection.
  2. If the facility maintains a file of "incident reports" or a first aid log on injuries (e.g., needlesticks), this shall be reviewed as it may contain injuries not included on the OSHA 200 log.
  3. Compliance officers shall take necessary precautions to avoid direct contact with body fluids and shall not participate in activities that will require them to come into contact with body fluids, needles or other sharp instruments contaminated with blood. To evaluate such activities, compliance officers normally shall establish the existence of hazards and adequacy of work practices through employee interviews and shall observe them at a safe distance.
  4. On occasions when entry into potentially hazardous areas are judged necessary, the compliance officer shall be properly equipped as required by the facility as well as by his/her own professional judgment, after consultation with the supervisor.
  5. Compliance officers shall use appropriate caution when entering patient care areas of the facility. When such visits are judged necessary for determining actual conditions in the facility, the privacy of patients shall be respected. Photographs of patients normally will not be necessary and in no event shall identifiable photographs be taken without their consent.
- J. **Recording of Exposure Incidents.** For OSHA 300 recordkeeping purposes, an occupational bloodborne pathogens exposure incident (e.g., needlestick, laceration, or splash) shall be classified as an injury since it is usually the result of an instantaneous event or exposure. It shall be recorded if it meets one of the following recordability requirements:
1. The incident is a work-related injury that involves loss of consciousness, transfer to another job, or restriction of work or motion.
  2. The incident results in the recommendation of medical treatment beyond first aid (e.g., gamma globulin, hepatitis B immune globulin, hepatitis B vaccine, or zidovudine) regardless of dosage.

3. The incident results in a diagnosis of seroconversion. The serological status of the employee shall not be recorded on the OSHA 200. If a case of seroconversion is known, it shall be recorded on the OSHA 200 as an injury (e.g., "needlestick" rather than "seroconversion") in the following manner:
  - a. If the date of the event or exposure is known, the original injury shall be recorded with the date of the event or exposure in column B.
  - b. If there are multiple events or exposures, the most recent injury shall be recorded with the date that seroconversion is determined in column B.

**K. Multi-Employer Worksite.** The following citation guidelines apply in multi-employer worksites (See FOM, Chapter V, F.):

1. Employers shall be cited for violations of the standard to which their own employees are exposed.
2. They shall also be cited for violations to which employees of other employers on their premises are exposed to the extent that they control the hazard. For example, they shall be cited for not providing personal protective equipment to unprotected employees of other employers on their premises.
3. Physicians who are members of professional corporations are generally considered to be employees of that corporation. Therefore, the corporation may be cited for violations affecting those physicians, such as failure to provide the hepatitis B vaccine. Also, the hospitals where they work may be cited for violations to which they are exposed.
4. No citation shall be issued where the only persons exposed are physicians who are sole practitioners or partners, and thus not employees under the Occupational Safety and Health Act.

**L. Federal Agency Facilities.** Agencies of the Federal Government are covered by this instruction.

**M. Clarification of the Standard on Occupational Exposure to Bloodborne Pathogens, 29 CFR 1910.1030.** The guidance that follows relates to specific provisions of 29 CFR 1910.1030 and is provided to assist compliance officers in conducting inspections where the standard may be applicable:

NOTE: Compliance officers shall refer to 29 CFR 1910.1030 regulatory text and preamble for further information.

1. Scope and Application - 29 CFR 1910.1030(a). This section defines the range of employees covered by the standard.
  - a. Since there is no population that is risk free for HIV or HBV infectivity, any employee who has occupational exposure to blood or other potentially infectious material will be included within the scope of this standard.

b. Although a list is included below of a number of job classifications that may be associated with tasks that have occupational exposure to blood and other potentially infectious materials, the scope of this standard is in no way limited to employees in these jobs. The hazard of exposure to infectious materials affects employees in many types of employment and is not restricted to the healthcare industry. At the same time, employees in the following jobs are not automatically covered unless they have occupational exposure:

- Employees of clinical and diagnostic laboratories;
- Housekeepers in health care facilities;
- Tissue bank personnel;
- Employees in blood banks and plasma centers who collect, transport, and test blood;
- Employees assigned to provide emergency first aid;
- Dentists, dental hygienists, dental assistants and laboratory technicians;
- Staff of institutions for the developmentally disabled;
- Hospice employees;
- Home health care workers;
- Staff of nursing homes and long-term care facilities;
- Employees of funeral homes and mortuaries;
- HIV and HBV research laboratory and production facility workers;
- Employees handling regulated waste;
- Medical equipment service and repair personnel;
- Personnel in hospital laundries or commercial laundries that service health care or public safety institutions;
- Freestanding clinic employees (e.g., hemodialysis clinics, urgent care clinics, health maintenance organization (HMO) clinics, and family planning clinics);
- Employees in clinics in industrial, educational, correctional facilities (e.g., those who collect blood, and clean and dress wounds);
- Physicians, physician's assistants, nurses, nurse practitioners, and other health care employees in clinics and physicians' offices;
- Emergency medical technicians, paramedics, and other emergency medical service providers; and
- Firefighters, law enforcement and correctional officers (employees in the private sector, the Federal Government, a State, or local government in a State that has an OSHA-approved State plan).

**INSPECTION GUIDELINES.** The scope section of this standard states that it "applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b)." The compliance officer must take careful note of the phrase "as defined by paragraph (b)" when determining coverage.

1. Definitions of particular importance that the compliance officer must clearly understand before beginning an inspection are Blood, Bloodborne Pathogens,

Contaminated, Exposure Incident, Occupational Exposure, Other Potentially Infectious Materials, and Regulated Waste. If you must determine whether or not an employee in either a health care or a non-health care setting is covered by this standard, knowledge of the definitions will be useful.

NOTES:

1. Part-time, temporary, and health care workers known as "per diem" employees and are covered by this standard.

2. If an employee is trained in first aid and identified by the employer as responsible to provide medical assistance as part of his/her job duties, that employee is covered by the standard

3. Employees in the construction and maritime industries who have occupational exposure to blood or OPIM are covered by the standard.

2. Definitions - 29 CFR 1910.1030(b). The following provides further clarifications of some definitions found in this section:

- a. "Blood": The term "human blood components" includes plasma, platelets, and serosanguineous fluids (e.g., exudates from wounds).
- b. "Bloodborne Pathogens": While HBV and HIV are specifically identified in the standard, the term includes any pathogenic microorganism that is present in human blood and can infect and cause disease in persons who are exposed to blood containing the pathogen. Other examples include hepatitis C, malaria, syphilis, babesiosis, brucellosis, leptospirosis, arboviral infections, relapsing fever, Creutzfeld-Jakob disease, Human T-lymphotrophic Virus Type 1, and viral hemorrhagic fever.
- c. "Exposure Incident": "Non-intact skin" includes skin with dermatitis, hang nails, cuts, abrasions, chafing, etc.
- d. "Occupational Exposure": The term "reasonably anticipated" includes the potential for exposure as well as actual exposure. Lack of history of blood exposures among first aid personnel of a particular manufacturing site, for instance, does not preclude coverage.

NOTE: This definition does not cover "good Samaritan" acts which result in exposure to blood or other potentially infectious materials from assisting a fellow employee, although OSHA encourages employers to offer follow-up procedures in such cases.

- e. "Other Potentially Infectious Materials"(OPIM): Coverage under this definition also extends to blood and tissues of animals that are deliberately infected with HIV or HBV.
- f. "Parenteral": This definition includes human bites that break the skin, which are most likely to occur in violent situations such as may be encountered by prison personnel and police and in emergency rooms or psychiatric wards.
- g. "Regulated Waste": This definition is covered in detail at M.4.d.(3) of this instruction.

3. Exposure Control Plan - 29 CFR 1910.1030(c). This section requires the employer to identify those tasks and procedures in which occupational exposure may occur and to identify the positions whose duties include those tasks and procedures identified with occupational exposure. The exposure control plan required by section (c)(1) is a key provision of the standard because it requires the employer to identify the individuals who will receive the training, protective equipment, vaccination, and other benefits of the standard.

## **INSPECTION AND CITATION GUIDELINES.**

The compliance officer shall review the facility's written exposure control plan. While the plan may be part of a larger document, such as one addressing all health and safety hazards in the workplace, in order for the plan to be accessible to employees, it must be a cohesive entity by itself or there must be a guiding document which states the overall policy goals and references the elements of existing separate policies that comprise the plan.

The compliance officer shall determine whether the plan is reviewed annually and updated to reflect significant modifications in tasks or procedures which may result in occupational exposure as required in section (c)(1)(iv).

### **An exposure control plan shall contain:**

- a. Sections (c)(1)(ii)(A) and (c)(2)(i). The exposure determination requires employers to identify and document:
  - (1) Those job classifications in which all employees have occupational exposure, and
  - (2) Those job classifications in which some employees have occupational exposure.
    - (a) In the latter case, the specific tasks and procedures, or groups of closely related tasks and procedures, which are associated with occupational exposure must be delineated. For example, only some of the employees in a hospital laundry room might be assigned the task of handling contaminated laundry.
    - (b) The tasks and procedures that are included must be related; i.e., they must share a common activity such as "vascular access procedures," "handling of contaminated sharps," or "handling of deceased persons," etc.
  - (3) The exposure determination shall have been made without taking into consideration the use of personal protective clothing or equipment.
- b. **Section (c)(1)(ii)(B).** The **schedule and method of implementation** for sections (d)-(h) in a manner appropriate to the circumstances of the particular workplace must be addressed in the exposure control plan. An annotated copy of the final standard may be adequate for small facilities. An employer may state on a copy of the final standard when and how he/she will implement the provisions of the standard. Larger facilities could develop a broad facility-wide program incorporating provisions from the standard that apply to their establishments.

- c. Section (c)(1)(ii)(C). The exposure control plan shall include the procedure for evaluating the circumstances surrounding exposure incidents, including an evaluation of the policies and "failures of control" at the time of the exposure incident. Also to be considered are the engineering controls and work practices in place, as well as protective equipment or clothing used, at the time of the exposure incident.
- d. Section (c)(1)(iii). The location of the plan maybe adapted to the circumstances of a particular workplace provided that the employee can access a copy at the workplace, during the workshift (e.g., if the plan is maintained solely on computer, employees must be trained to operate the computer). In accordance with 29 CFR 1910.20, a hard copy of the exposure control plan shall be made available to the employee within 15 working days of the employee's request.
- e. Sections (c)(2)(i)(A) and (B). As previously discussed in the exposure control plan, the employer is required to list the job classifications covered by the plan. The list is part of the exposure determination. If a job classification, task, or procedure with occupational exposure is omitted from the list, but all employees in the job or performing the task or procedure have been included in all other aspects of the plan (i.e., vaccinations, training, etc.), it is to be considered a de minimis violation.

**Methods of Compliance - 29 CFR 1910.1030(d).** Section (d) sets forth the methods by which employers shall protect their employees from the hazards of bloodborne pathogens and comply with this standard through the use of universal precautions, engineering controls, work practice controls, personal protective equipment, proper housekeeping and handling of regulated waste.

- a. Universal Precautions - (d)(1). Universal precautions are OSHA's accepted method of control to protect employees from exposure to all human blood and OPIM. The term "universal precautions" refers to a concept of bloodborne disease control which requires that all human blood and OPIM be treated as if known to be infectious for HIV, HBV, or other bloodborne pathogens regardless of the perceived "low risk" of a patient or patient population.
  - (1) Another method of infection control is called Body Substance Isolation (BSI). This method defines all body fluids and substances as infectious. BSI incorporates not only the fluids and materials covered by this standard but expands coverage to include all body fluids and substances.
  - (2) BSI is an acceptable alternative to universal precautions provided facilities utilizing BSI adhere to all other provisions of this standard.

**CITATION GUIDELINES.** If the employer has a policy of treating the blood or OPIM of some patients as potentially infectious and the blood or OPIM of others (e.g., the elderly or children) as not infectious, a violation of this provision exists.

**M.4.b. Engineering Controls and Work Practices - (d)(2).** This section requires the employer to institute engineering and work practice controls as the primary means of eliminating or minimizing employee exposure. In those circumstances in which occupational exposure remains after institution of engineering and work practice controls, employers must provide, and ensure that employees use, personal protective equipment as additional protection.

**INSPECTION GUIDELINES.** The **compliance officer shall determine** through interviews or observation of work involving the use of needles whether proper engineering controls and work practices (such as immediate disposal of used needles into a sharps container) are used.

Most preferable is the use of devices, which offer an alternative to needles being used to perform the procedure. Examples of devices include stopcocks (on-off switch), needle-protected systems or needleless systems, which can be used in place of open needles to connect intravenous lines. Other devices, which are integral to the syringe, such as self-sheathing needles, allow both hands to remain behind the needle and require very little manipulation to isolate the needle safely.

When a **health care worker must recap**, such as during intermittent administration of various drugs during certain procedures, and when it is not feasible to use self-sheathing needle syringes, the employee must use some type of device that protects the hand or allows a safe one-handed recapping method. A proper one-handed scoop method is a work practice, which may also be used in these circumstances. (See M.4.b.(3)(b) of this instruction on section (d)(2)(vii) for details.)

The **compliance officer shall evaluate** the work practices used by health care providers to determine that they ensure the effectiveness of engineering controls. For example, some devices provide a fixed barrier between the hands and the needle after use. While some finger/hand shields available on the market offer full protection of the hand holding the needle sheath from accidental puncture, some do not. They may leave much of the hand area uncovered and are not considered acceptable protection for use in two-handed recapping procedure. Both the shield and the cap must be constructed so that an employee is not exposed to puncture from a needle protruding from the side or end of the cap.

The compliance officer should note that sharps may include more than the traditional needles or scalpels. They also include anything that might produce a puncture wound, which would expose employees to blood or OPIM (e.g., the ends of contaminated orthodontia wires or broken glass).

**CITATION GUIDELINES** Section (d)(2) shall be cited for failure to use engineering/work practice controls. A citation for the appropriate section of (g)(2)(vii) shall be grouped with it, if the compliance officer determines that inadequate training caused the failure to use such controls.

- Citations shall be issued if engineering or work practice controls are not used to eliminate or minimize employee exposure.
- While employers do not automatically have to institute the most sophisticated engineering controls (e.g., needleless IV connectors, self-sheathing needles), it is the employer's responsibility to evaluate the effectiveness of existing controls and to review the feasibility of instituting more advanced engineering controls.

**M.4.b.(1) Section (d)(2)(ii).** This section requires that engineering controls be examined and maintained or replaced on a regular schedule to ensure their effectiveness. Regularly scheduled inspections are required to confirm, for instance, that engineering controls such as protective shields have not been removed or broken, that sharps disposal containers are being replaced in sufficiently frequent intervals and that other physical, mechanical or replacement-dependent controls function as intended.

**CITATION GUIDELINES.** It is the employer's responsibility to regularly examine and repair and/or replace engineering controls as often as necessary to ensure that each control is maintained and that it provides the protection intended. If the compliance officer finds that there is no system for regular checking of the engineering controls, section (d)(2)(ii) shall be cited.

- If there is a check system, but the compliance officer finds, for example, that the biosafety cabinet is not functional, filters are overloaded (in research laboratories or production facilities), disposal containers are overfilled, or a hematron splash shield is broken or missing, section (d)(2)(ii) shall be cited as if an effective monitoring system would have uncovered the deficiency.
- Additionally, if there is unprotected employee exposure, section (d)(2)(i) shall be cited for failure to use Personal protective equipment after institution of engineering controls.

**M.4.b.(2) Sections (d)(2)(iii) through (d)(2)(vi).** These sections **require employers to provide hand washing facilities** which are readily accessible to employees. Hand washing with soap and at least tepid running water must be performed as soon as feasible, particularly in cases of gross contamination, to adequately flush contaminated material from the skin.

(a) Section (d)(2)(iv). This section allows the use of **alternative hand washing methods** as an interim measure when soap and water are not a feasible means of washing the hands or other parts of the body. Antiseptic hand cleaner used in conjunction with clean cloth or paper towels, or antiseptic towelettes are examples of alternative methods.

1. When these types of alternatives are used, employees shall wash their hands (or other affected area) with soap and running water as soon as feasible thereafter.
2. The compliance officer may see these types of alternative washing methods used by ambulance-based paramedics and emergency medical technicians (EMT's), firefighters, police, and mobile blood collection personnel who are exposed to blood or OPIM with no means of washing up with running water.

**M.4.b.(2)(b) Section (d)(2)(v).** This section requires **employers to ensure that employees wash their hands** immediately or as soon as feasible after removal of gloves or other PPE. There is no requirement for hand washing upon leaving the work area unless contact with blood or OPIM has occurred or gloves/PPE have been removed.

**CITATION GUIDELINES.** If the compliance officer finds that required hand washing facilities are not being provided, section (d)(2)(iii) shall be cited unless the employer demonstrates that hand washing facilities are not feasible. If infeasibility is demonstrated, section (d)(2)(iv) shall be cited when the required alternatives are not used. If hand washing is not performed by the employees after exposures or removal of gloves, sections (d)(2)(iv), (v), or (vi) shall be cited. This may be grouped with the pertinent training sections of (g)(2) if employees have not been adequately trained in hand washing procedures.

- At a fixed establishment, if employees need to perform hand washing, they must have a location for washing available at a reasonable distance from their normal work area; i.e., no further than what would be considered reasonable for location of restrooms.
- If an employee must thread his/her way through doorways and/or stairs to wash with appropriate frequency so that there is a reasonable chance of resultant environmental surface contamination, a violation of section (d)(2)(iii) exists.

**M.4.b.(3) Section (d)(2)(vii).** **Shearing or breaking of contaminated needles** is completely prohibited by this section. Bending, recapping, or removing contaminated needles by hand is prohibited as a general practice. However, certain circumstances may exist in which these actions are necessary; e.g., when performing blood gas analyses, inoculating a blood culture bottle, administering incremental doses of a medication such as an anesthetic to the same patient, or removing the needle from a phlebotomy collection apparatus (e.g., vacutainer).

- (a) In these procedures, if the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical procedure, recapping is allowed by some method other than the traditional two-handed procedure; e.g., by means of resheathing instruments or forceps.
- (b) The use of the properly performed one – hand scoop method (in which the hand holding the sharp is used to scoop up the cap from a flat surface) for recapping is a recognized and acceptable method. The scoop method must be performed in a safe manner, and it must be limited to situations in which recapping is necessary.
- (c) An acceptable means of demonstrating that no alternative is feasible would be a written justification included as part of the exposure control plan and stating that the particular medical procedure requires, for example, the bending of the needle and the use of forceps to accomplish this.

Section (d)(2)(viii). Since reusable sharps, such as large bore needles, scalpels, and saws, pose the same percutaneous exposure hazard as disposable sharps, they must be contained in a manner that eliminates or minimizes the hazard until they are reprocessed. Therefore, the containers for reusable sharps must meet the same requirements as containers for disposable sharps (See M.4.d.(3)(b) of this instruction on section (d)(4)(iii)(A)(1).), with the exception that they are not required to be closable since it is anticipated that containers used for collecting and holding reusable sharps will, themselves, be reused. (See M.4.d.(2)(e) of this instruction on section (d)(4)(ii)(E) for the manner in which these reusable sharps are to be stored and processed, and M.4.d.(3)(g) on section (d)(4)(iii)(A)(4) on the requirements form cleaning and processing of these reusable containers.)

**M.4.b.(5) Sections (d)(2)(ix) and (x).** These sections are intended primarily to **eliminate or minimize indirect transmission of HBV** from contaminated environmental surfaces.

- (a) Hand cream is not considered a "cosmetic" and is permitted. It should be noted:
  - 1. Some petroleum-based hand creams can adversely affect glove integrity, and
  - 2. The hand washing requirements of section (d)(2)(v) and (d)(2)(vi) shall be followed.
- (b) The term "work area" means the area where work involving exposure or potential exposure to blood or OPIM exists, along with the potential contamination of surfaces. Employees are permitted to eat and drink in an ambulance cab, for example, as long as the employer has implemented procedures to permit employees to wash up and change contaminated clothing prior to entering the ambulance cab, and to ensure that
- (c) patients and contaminated material remain behind the separating partition.

**INSPECTION GUIDELINES.** In addition to direct contamination of food or drink by blood or OPIM, the compliance officer must keep in mind that containers of food and beverage may also become contaminated, resulting in unsuspected contamination of the hands. The key to this section is whether food and drink may be contaminated by such processes as leakage/spilling of specimen containers, contact with contaminated items, or the performance of activities (e.g., laboratory analysis) that could generate splashes, sprays, or droplets of blood or OPIM.

**CITATION GUIDELINES.** Deficiencies of sections (d)(2)(iv) through (x) shall be cited in conjunction with the appropriate section of (g)(2) if inadequate training exists.

**M.4.b.(6) Section (d)(2)(xi).** The intent of this section is not only to **decrease the chances of direct employee exposure** through spraying or splashing of infectious materials onto employees, but also to reduce contamination of surfaces in the general work area.

- (a) Surgical power tools, lasers, and electrocautery devices may generate aerosols. OSHA does not believe that the data currently support the mandatory use of respiratory protection for exposure to aerosols, nor is there an effective engineering control to address aerosol exposure or approved respirator and filter cartridges.
- (b) Particularly hazardous is the use of sprays, brushes, and high pressure in equipment lines.
- (c) Typically, spattering or generation of droplets would necessitate use of eye protection and mask or a face shield. (See M.4.c.(8) of this instruction on section (d)(3)(x).)

**CITATION GUIDELINES.** A citation shall normally be issued for section (d)(2)(xi) if cleaning procedures unnecessarily cause splashing, spraying, spattering, and generation of droplets of blood or OPIM.

**M.4.b.(7) Section (d)(2)(xii).** While this section **prohibits mouth pipetting/suctioning**, the agency allows a recognized emergency care method of clearing an infant's airways called "DeLee suctioning" in the following situation:

- (a) In an emergency,
- (b) When no other method is available; and
- (c) Provided that a trap which prevents suctioned fluid from reaching the employee's mouth is inserted in-line between the infant and the employee.

**Section (d)(2)(xiii)-(d)(2)(xiii)(C).** These sections deal with the **containerization and labeling of specimens** with the intent to eliminate or minimize the possibility of inadvertent employee contact with blood or OPIM which have leaked out of the container, contaminated exterior surfaces of the container, and/or surrounding surfaces. The labeling requirement warns employees that these substances are present so that proper handling precautions can be taken.

- (a) The labeling exemption listed in section d)(2)(xiii)(A) applies to facilities, which handle all specimens (not just those specimens which contain blood or OPIM) with universal precautions.
  1. This exemption applies only while these specimens remain within the facility.
  2. All employees who will have contact with the specimens must be trained to handle all specimens with universal precautions.
  3. If the specimens leave the facility (e.g., during transport, shipment, or disposal) a label or red color-coding would be required.

**M.4.b.(8)(b) Extracted teeth** are subject to the containerization and labeling provisions of the standard.

- (c) The use of pneumatic tube systems for transport of small materials in hospitals now includes transmittal of laboratory specimens and other more fragile items. The primary concern in the transportation of clinical specimens in a pneumatic tube system is leakage of the specimen into the carrier and potentially into the system tubing. Some systems have virtually eliminated breakage as a cause of leakage by means of padded inserts for carriers and soft delivery of the carrier. Leakage generally results from improper packaging and/or the use of primary containers that do not prevent leakage during transport.
1. All workers who might potentially open a carrier shall be trained to
  2. regard the contents as biohazardous in nature. Employees who open biohazard carriers shall wear gloves in accordance with section (d)(3) when removing specimens from the tube system carrier, as it may be contaminated with leakage. They shall be trained in decontamination of the carrier and, if need be, the tube system in accordance with section (g)(2).
  3. All precautions and standards for manual transport of specimens also apply to the automated transport of specimens: containerization and tagging, or labeling.

INSPECTION GUIDELINES. The compliance officer must observe or document work practices to determine whether a secondary container is being used when necessary. If a bloody glove contaminates the outside of a primary container while the employee is placing a specimen, the employee would need to use a secondary container. Also, primary containers, which may be punctured by their contents, including such items as pointed bone slivers, must be placed in a puncture-resistant container.

M.4.b.(9) Section (d)(2)(xiv). When it is not possible to decontaminate equipment prior to servicing or shipping (e.g., highly technical or sensitive equipment and/or limited access to contaminated parts), at least partial decontamination, such as flushing lines and wiping the exterior, shall be accomplished.

INSPECTION AND CITATION GUIDELINES. The compliance officer shall ensure that the employer's program makes provision for the required equipment labels. A label shall be attached to equipment stating which portions of the equipment remain contaminated in order to inform downstream servicing/repair employees of the hazard and precautions they need to take.

- (a) Before citing (d)(2)(xiv), the compliance officer shall document that equipment is being shipped and/or serviced.
- (b) Compliance officers shall observe or document work practices used when employees are decontaminating equipment. See M.4.b.(6) of this instruction on section (d)(2)(xi) for use of high pressure equipment.)
- (c) When decontaminating reusable equipment that is heavily soiled, the employee will have to perform some prewashing before proceeding with

decontamination because most disinfectants/sterilants cannot sufficiently penetrate the organic material that may remain on such heavily soiled equipment. (See M.4.d.(2)(e) of this instruction for details.)

**M.4.c. Personal Protective Equipment - (d)(3).** PPE must be used to prevent blood or OPIM from passing through to, or contacting the employees' work or street clothes, undergarments, skin, eyes, mouth, or other mucous membranes, unless engineering controls and work practices have eliminated occupational exposure.

- (1) Section (d)(3)(i). The type and amount of PPE shall be chosen to protect against contact with blood or OPIM based upon the type of exposure and quantity of these substances, which can be reasonably anticipated to be encountered during the performance of a task or procedure.

INSPECTION AND CITATION GUIDELINES. The financial responsibility for purchasing and providing PPE rests with the employer. The employer is not obligated under this standard to provide general work clothes to employees, but is responsible for providing PPE. If laboratory coats or uniforms are intended to protect the employee's body from contamination, they are to be provided by the employer.

- (a) Laboratory coats, uniforms and the like that are used as PPE shall be laundered by the employer and not sent home with the employee for cleaning. (See M.4.c.(4) of this instruction on section (d)(3)(iv).)

**M.4.c.(1)(b) Scrubs** are usually **worn** in a manner similar to street clothing, and should be covered by appropriate gowns, aprons or laboratory coats when splashes to skin or clothing are anticipated.

1. If a pullover scrub (as opposed to scrubs with snap closures) becomes minimally contaminated, employees should be trained in accordance with section (g)(2)(vii)(G) to remove the pull-over 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.
2. 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 them 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.
  - (a) A gown which is frequently ripped or falls apart would not be considered "appropriate PPE".
  - (b) Resuscitator devices are to be readily available and accessible to employees who can reasonably be expected to resuscitate a patient.
    1. Emergency ventilation devices also fall under the scope of PPE and hence must be provided by the employer for use in resuscitation (e.g., masks, mouthpieces, resuscitation bags, shields or overlay barriers)

**M.4.c.(1)(d) 2 Improper use of these devices** shall be cited as a violation of section (d)(3)(ii). In addition, section (g)(2)(vii)(G) which requires employees to be trained in the types, proper use, location, etc., of the PPE shall be cited if inadequate training exists. Improper use includes failure to follow the manufacturer's instructions and/or accepted medical practice.

NOTE: The American Society for Testing Materials is currently testing and evaluating methods to be used for assessing the quality of PPE that is available for medical use.

(2) Section (d)(3)(ii). This section requires the use of PPE. It also provides for a limited exemption from the use of PPE, based on situations in which use of PPE would prevent the proper delivery of health care or public safety services, or would pose an increased hazard to the personal safety of the worker. The following represents examples of when such a situation could occur:

- (a) A sudden change in patient status occurs such as when an apparently stable patient unexpectedly begins to hemorrhage profusely, putting the patient's life in immediate jeopardy;
- (b) A firefighter rescues an individual who is not breathing from a burning building and discovers that his/her resuscitation equipment is lost/damaged and he/she must administer CPR;

M.4.c.(2)(c) A bleeding suspect unexpectedly attacks a police officer with a knife, threatening the safety of the officer and/or co-workers.

NOTE: An employee's decision not to use PPE is to be made on a case-by-case basis and must have been prompted by legitimate and truly extenuating circumstances. In such cases, no citation shall be issued when the employee temporarily and briefly abandons use of PPE. This does not relieve the employer of the responsibility to ensure that PPE is readily accessible at all times. The employer shall document why PPE was not used in each case and evaluate the circumstances surrounding the incident to reduce the likelihood of a future unprotected incident.

**CITATION GUIDELINES.** Section (d)(3)(ii) shall be cited if PPE is not being used properly. Improper use would include wearing the wrong PPE (e.g., wearing a laboratory coat when a rubber apron is needed) or wearing the wrong size PPE.

- In addition, section (g)(2)(vii)(G) shall also be cited if the employees have not been adequately trained.
- Unless all elements of the exemption, including the documentation requirement are met, the employer shall not receive the benefit of this exemption and section (d)(3)(ii) shall be cited.

(3) Section (d)(3)(iii). This section requires that the employer provide PPE in appropriate sizes and accessible locations. In addition, 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. The compliance

officer shall review the employer's program and, through employee interviews, ensure that these provisions have been met.

**CITATION GUIDELINES.** If PPE is not provided, the compliance officer shall cite section (d)(3)(i). If PPE is not readily available, the compliance officer shall cite section d)(3)(iii). For example, the clothing of paramedics out on an emergency call may become blood-soaked. If they are unable to change before the next emergency call because a second set of clothing is located at the ambulance's home base, and the ambulance does not return to base for prolonged periods, a violation of section (d)(3)(iii) would exist.

- If it is common practice that PPE is not utilized during certain situations or procedures where exposure to blood or OPIM is anticipated, then a violation of section (d)(3)(ii) would exist. If inaccessibility of PPE exists, section (d)(3)(iii) shall also be cited.

**M.4.c.(4) Section (d)(3)(iv).** It is the **employer's responsibility** not only to provide PPE, but also to clean, maintain, and/or dispose of it.

- (a) While many employees have traditionally provided and laundered their own uniforms or laboratory coats or the like, if the item's intended function is to
- (b)
- (c) Act as PPE, then it is the employer's responsibility to provide, clean, repair, replace, and/or dispose of it.
- (d) Home laundering is not permitted since the employer cannot guarantee that proper handling or laundering procedures are being followed; it could also lead to the migration of contaminants to the home.
- (e) If the employee wishes to choose, wear, and maintain his/her own uniform or laboratory coat, then he/she would need to don additional employer-handled and employer-controlled PPE when performing tasks where it is reasonable to anticipate exposure to blood or OPIM.

**CITATION GUIDELINES.** If PPE is not cleaned/ laundered/disposed of by the employer, or if the employer cleans the PPE but there is a charge to the employee, then section (d)(3)(iv) shall be cited. If PPE is not repaired and/or replaced by the employer at no cost to the employee then section (d)(3)(v) shall be cited.

- If PPE is not removed when penetrated by blood or OPIM, the compliance officer shall cite section (d)(3)(vi).
- If the PPE is not changed, and additional PPE was available, section (g)(2)(vii)(G) may also be cited if employees have not been adequately trained.

**M.4.c.(5) Section (d)(3)(vii).** To **minimize migration of contamination** beyond the work area, employees who are provided designated lunchrooms or break rooms are permitted to

eat/ drink/smoke in these areas as long as the employees wash up and change any contaminated clothing prior to entry.

**INSPECTION AND CITATION GUIDELINES.** The "work area" shall be evaluated on a case-by-case basis. While it is not the intent of the standard to require employees to change PPE when traveling from one hospital laboratory area to another, the compliance officer shall evaluate on a case-by-case basis whether the employee received adequate training in accordance with section (g)(2)(vii)(F) to ensure that no surface contamination occurs during the employee's movement. A violation would exist for the following:

- An employee wearing contaminated gloves exits from a pathology laboratory to use a public telephone located in a public hallway of the hospital. Under such circumstances, it can be reasonably anticipated that another employee, without benefit of gloves or knowledge of the potential surface contamination, could use the phone and unwittingly become contaminated.

M.4.c.(6) Section (d)(3)(ix)(A)-(C). These sections discuss the use of gloves. Gloves of appropriate sizes must be made available in accordance with section (d)(3)(iii). Studies have shown that gloves provide a barrier, but that neither vinyl nor latex procedure gloves are completely impermeable. Thus, hand washing after glove removal is required.

- (a) Disposable gloves shall be replaced as soon as practical when contaminated. Sometimes critical procedures (i.e., surgery, delivery) cannot be interrupted to change gloves. The key words to evaluate are "practical" and "feasible".
- (b) Disinfecting agents may cause deterioration of the glove material; washing with surfactants could result in "wicking" or enhanced penetration of liquids into the glove via undetected pores thereby transporting potentially infectious materials into contact with the hand. For this reason, disposable (single use) gloves may not be washed and reused.
- (c) The compliance officer should note that certain solutions, such as iodine, may cause discoloration of gloves without affecting their integrity and function.
- (d) Gloves shall be used where there is reasonable anticipation of employee hand contact with blood, OPIM, mucous membranes, or nonintact skin; when performing vascular access procedures; or when handling or touching contaminated surfaces or items.

M.4.c.(7) Section (d)(3)(ix)(D). The exemption regarding the use of gloves during phlebotomy procedures applies only to employees of volunteer donor blood collection centers, and does not apply to phlebotomy conducted in other settings such as plasmapheresis centers or hospitals.

**INSPECTION GUIDELINES.** Where an employer in a volunteer donor blood collection center does not require routine gloving for all phlebotomies, the compliance officer shall document that the employer has fulfilled the requirements of sections (d)(3)(ix)(D)(1) through (d)(3)(ix)(D)(4)(iii), and that employees have received the training necessary to make an informed decision on the wearing of gloves.

**CITATION GUIDELINES.** Section (d)(3)(ix)(D) shall not be cited. Rather, the other sections of (d)(3) shall be cited if such an employer violates them and if the employer has not demonstrated fulfillment of all the requirements of the exemptions.

(8) Section (d)(3)(x). This section requires **protection for** the mucous membranes of the face and **upper respiratory tract** from droplet spattering. Minimum protection would consist of a mask in conjunction with eye glasses with solid side shields or a chin length face shield.

- (a) The employer would not necessarily have to provide prescription eyewear for employees. They could provide and mandate the use of side shields, goggles, and/or protective face shields, and provide proper training in decontamination procedures.
- (b) During microsurgery, when it is not reasonably anticipated that there would be any spattering, it would not constitute a violation for the surgeon, while observing surgery through a microscope, not to wear other eye protection.

**M.4.c.(9) Sections (d)(3)(xi)-(xii). Use of protective body clothing**, such as gowns, aprons, laboratory coats, clinic jackets, surgical caps, or shoe covers, and the degree to which such PPE must resist penetration, are performance based. The employer must evaluate the task and the type of exposure expected and, based on the determination, select the "appropriate" personal protective clothing in accordance with section (d)(3)(i). For example, laboratory coats or gowns with long sleeves shall be used for procedures in which exposure of the forearm to blood or OPIM is reasonably anticipated to occur.

**INSPECTION GUIDELINES.** The compliance officer will need to evaluate the task being performed and the degree of anticipated exposure by direct observation, employee interview, or review of written standard operating procedures.

NOTE: There are no currently available standardized methods of testing and classification of performance specifications for resistance of clothing to biological hazards.

- (d) Housekeeping - (d)(4). The term "worksites" in this section refers not only to permanent fixed facilities such as hospitals, dental/medical offices, clinics, etc., but also covers temporary non-fixed workplaces. Examples of such facilities include but are not limited to ambulances, bloodmobiles, temporary blood collection centers, and any other non-fixed worksites, which have a reasonable possibility of becoming contaminated with blood or OPIM.

**M.4.d.(1) Section (d)(4)(i). Cleaning schedules and methods** will vary according to the factors outlined in this section. While extraordinary attempts to disinfect or sterilize environmental surfaces such as walls or floors are rarely indicated, routine cleaning and removal of soil are required.

- (a) The employer must determine and implement an appropriate written schedule of cleaning and decontamination based upon the location within the facility (e.g., surgical operatory versus patient room). The schedule will be based upon type of surface to be cleaned (e.g., hard-surfaced flooring versus carpeting), type of soil present (e.g., gross contamination versus minor splattering), and procedures being performed (e.g., laboratory analyses versus normal patient care).
- (b) The particular disinfectant used, as well as the frequency with which it is used, will depend upon the circumstances in which the housekeeping task occurs.

**INSPECTION AND CITATION GUIDELINES.** Compliance officers should consult the Environmental Protection Agency (EPA) lists of registered sterilants (representing the highest level of antimicrobial activity which destroys all viruses), tuberculocidal disinfectants (effective against tuberculosis bacteria and the specific viruses named on the product label as well as the hepatitis B virus), and antimicrobials with HIV efficacy claims for verification the disinfectant used is appropriate. These lists are available from the Regional bloodborne pathogens coordinators.

NOTE: Products registered by the EPA as HIV-effective are not necessarily tuberculocidal and are therefore not necessarily effective against HBV which is more resistant to inactivation than is HIV. To determine the overall effectiveness of a particular product with an HIV efficacy claim for use in a cleanup (where HBV or other bloodborne pathogens are also of concern), the compliance officer must compare the listing of HIV-effective products with the other two listings to check if they overlap for the product of interest.

**M.4.d.(2) Section (d)(4)(ii).** Since **environmental contamination** is an effective method of disease transmission for HBV section (d)(4)(ii) provides the minimum requirements for the cleaning and decontamination of equipment and environmental and working surfaces that come into contact with blood or OPIM. The CDC states that HBV can survive for at least one week in dried blood on environmental surfaces or contaminated needles and instruments.

- (a) In section (d)(4)(ii)(A), cleaning of contaminated work surfaces after completion of procedures is required to ensure that employees are not unwittingly exposed to blood or OPIM remaining on a surface from previous procedures.
- (b) Where procedures are performed on a continual basis throughout a shift or a day, as may be the case with a clinical laboratory technician performing blood analyses, the agency doesn't intent for the work surface to be decontaminated before the technician can proceed to the next analysis. Contaminated work surfaces should be decontaminated after the procedures are completed which, in the above example, would include a set of analyses. The completion of procedures might also occur when the employee is going to leave the work area for a period of time.

**M.4.d.(2)(a)2 Decontamination** is not automatically required after each patient care procedure, rather only after **procedures resulting in surface contamination**.

3. There may be some instances in which "immediate" decontamination of overt contamination and spills may not be practical as with, for example, an operating table during surgery.
  4. The third instance of mandated work surface decontamination is to be performed at the end of the work shift if the work surface may have become contaminated since the last cleaning by, for example, setting down contaminated instruments or specimens. This requirement is based upon the existence of a contaminated work surface rather than a particular worksite location. It does not, for example, encompass desks, countertops, and so forth that remain uncontaminated.
- (b) The use of protective coverings described in section (d)(4)(ii)(B) is an acceptable alternative for protecting items and surfaces against contamination and is particularly useful in situations in which a piece of equipment would be difficult to decontaminate but could be protected by a cover.
1. If this option is chosen, the covering must be removed and replaced at the stated minimum intervals; e.g., as soon as feasible following overt contamination or at the end of a workshift if they may have become contaminated during the shift.

**M.4.d.(2)(b) 2 More stringent decontamination rules**, such as cleaning equipment or changing coverings between patients, may be prudent infection control policy but do not fall under OSHA's jurisdictional mandate to safeguard employee (not patient) health.

- (c) Section d(4)(ii)(C) requires both the inspection and decontamination on a regularly scheduled basis of cans, bins, pails, which are intended for reuse.
1. Since these containers may be used in a manner which presents the potential for their becoming contaminated with blood or OPIM, they must be cleaned immediately or as soon as feasible upon visible contamination. For example, a reusable metal trash bin may be lined with a disposable plastic regulated waste bag, which leaks and contaminates the can. In addition, regular decontamination will prevent the can from leaking, spilling, or contaminating the outside of successive bags.
  2. Disinfection of these containers is not necessary to ensure their safety for their intended use; it may be possible to achieve their proper decontamination by means of a soap and water wash.
    1. Since contaminated broken glass is capable of inflicting percutaneous injury and direct inoculation of bloodborne pathogens into the bloodstream, section (d)(4)(ii)(D) stipulates that broken glassware, which may be contaminated shall not be picked up directly with the hands. The tools, which are used in cleanup must be properly decontaminated or discarded after use and the broken glass placed in a sharps container and employees

must be given specific information and training with respect to this task in accordance with the requirements of section (g)(2). Vacuum cleaners are not appropriate for cleanup of contaminated broken glass.

M.4.d.(2)(e) Section (d)(4)(ii)(E) prohibits employers from allowing employees to place their hands into containers whose contents include reusable sharps contaminated with blood or OPIM. (See M.4.d.(3)(g) of this instruction on section (d)(4)(iii)(A)(4).)

NOTE: The final standard recognizes that proper decontamination of reusable equipment, such as glassware or hand instruments, cannot be achieved in the presence of organic debris (e.g., blood). It interferes with the efficacy of the disinfecting/sterilizing process and the number of products, which can successfully penetrate a heavy bio-burden is limited.

(f) Violations of sections (d)(4)(ii) and (d)(4)(ii)(A)-(E) may result from a failure to adequately train employees in proper housekeeping procedures. If the compliance officer determines this is the case, violations should be grouped with the appropriate section(s) of (g)(2).

(3) Regulated Waste - (d)(4)(iii). This section requires regulated waste to be properly contained and disposed of, so as not to become a means of transmission of disease to workers.

M.4.d.(3)(a) To eliminate the implication that OSHA has determined the "infectivity" of certain medical wastes, the bloodborne pathogens standard uses the term "regulated waste" to refer to the following categories of waste which require special handling, at a minimum:

1. Liquid or semi-liquid blood or OPIM.
2. Items contaminated with blood or OPIM and which would release these substances 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.
5. Pathological and microbiological wastes containing blood or OPIM.

**INSPECTION AND CITATION GUIDELINES.** The compliance officer shall not use the actual volume of blood as the determining factor as to whether or not a particular material is to be considered regulated waste. Ten ml of blood on a disposable bed sheet appears as a spot (not regulated waste) while the same amount of blood on a cotton ball would likely cause saturation and dripping (regulated waste). Similarly, an item may adequately contain these materials when in a static state yet liberate them when compacted in the waste container.

- Rather, the potential for dripping of liquid blood or OPIM, or flaking off of dried blood or OPIM should be considered.

- Under no circumstances should a bag of waste be squeezed or shaken to determine this. The compliance officer shall exercise professional judgment to make a determination based on visual factors such as a pool of liquid in the bottom of the container or dried blood flaking or falling off during handling, or based on employee interviews.

NOTES 1: The compliance officer should keep in mind that while OSHA specifies certain features of the regulated waste containers, including appropriate tagging, the ultimate disposal method (landfilling, incinerating, and so forth) for medical waste falls under the purview of the EPA and possibly State and local regulations.

NOTE 2. The EPA's Standard for the Tracking and Management of Medical Waste and a number of State regulations consider used needles to be regulated medical waste regardless of the presence of infectious agents. Failing information to the contrary, the compliance officer should consider a used needle to be contaminated.

**M.4.d.(3)(b) Section (d)(4)(iii)(A)(1).** The **construction of the sharps' containers** must meet at least four criteria, two of which will be easily discernible. The compliance officer shall examine a container, preferably empty, to check that it is closable and color-coded or labeled.

- Sharps containers are made from a variety of products, from cardboard to plastic. As long as they meet the definition of a sharps container, the compliance officer should consider them to be acceptable no matter what the composition.

**M.4.d.(3)(b)2** At the time of publication of this instruction, the American Biological Safety Association was in the process of developing a **standard for puncture-resistance** of sharps disposal **containers**.

- a. If questions arise, the compliance officer shall consult the manufacturer's literature or contact the manufacturer directly to determine if the container is leak-proof on the sides and bottom, as well as puncture resistant.
  - b. If the container is considered puncture-resistant by the manufacturer, but there is evidence, through observation or employee statements that sharps have been protruding through a container, section (d)(4)(iii)(A)(1)(ii) shall be cited.
3. The sharps container should not create additional hazards. Some sharps containers have unwinders that are used to separate needles from syringes.

If this situation is encountered, the compliance officer shall determine if the circumstances warrant needle removal. If they do not, section (d)(2)(vii)(A), which prohibits needle removal unless no alternative is feasible or it is required by a specific medical procedure, shall be cited.

- b. If needle removal must be accomplished, the employee shall be trained in the correct procedure as required by (g)(2)(vii)(F).

**M.4.d.(3)(b)4** The needle sheath is not to be considered a "waste container" because it is viewed as a temporary measure. Self-sheathing needle products must be disposed of in a sharps container.

- a. Some self-sheathing devices contain a fast-curing colored liquid adhesive which is released completion of administration of a substance through the needle. This product is intended to permanently adhere all components of the syringe needle and needle sheath, rendering the syringe and needle assembly inoperable and incapable of causing injury.
- b. These devices shall still be disposed of in sharps containers since there is no guarantee of correct usage or proper functioning of the device.

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

1. Section (d)(4)(iii)(A)(2)(i). The compliance officer shall ensure that the sharps container is as close as feasible to where sharps are used or can be reasonably anticipated to be found.

**M.4.d.(3)(c)1** If an employee must **travel to a remote location to discard a sharp**, it will increase the possibility of an accidental needlestick and increase the chances that needles and sharps will be improperly discarded and create potential hazards for other staff members.

- a. Areas such as correctional facilities, psychiatric units, or pediatric units may have difficulty placing containers in the immediate use area. If a mobile cart is used by health care workers in these units, an alternative would be to lock a sharps container in the cart.
  - b. The determination of whether or not the container is as close as feasible shall be made on a case-by-case basis. After interviewing employees, if the compliance officer believes there is a better location for the container, management shall be given the opportunity to explain the present location of the container. The acceptability of the new site shall also be discussed. The compliance officer shall then decide if a violation of this section exists.
3. Laundries shall also have sharp containers easily accessible due to the incidence of needles being mixed with laundry. Facilities that handle shipments of waste which may contain contaminated sharps, shall also have sharps containers available in the event a package accidentally opens and releases sharps.

M.4.d.(3)(d) Section (d)(4)(iii)(A)(2)(iii). The compliance officer shall ensure the employer's exposure control plan specifies how and when the sharps containers will be replaced and that the program is followed.

1. The employer's plan must include the method by which sharps containers will be determined to need to be replaced, such as sharps containers which have a transparent window or are at a height which allows employees to see if the container needs to be replaced.
2. If the employer has a plan but it is not followed, a citation for inadequate training on work practices, (g)(2)(vii)(F), shall be grouped with this section if a training violation exists.

- (e) Section (d)(4)(iii)(A)(3)(i) and (ii). If work practice violations of these sections exist (e.g., not closing the container prior to movement or not placing the container in a secondary container if leakage is possible), they shall be grouped with (g)(2)(vii)(F) if employees have not received adequate training.
- (f) Section (d)(4)(iii)(A)(3)(ii)(B). It is reasonable to presume that some sharps containers will contain residual liquids. If the container cannot be sealed to prevent leakage, it must be placed in a secondary container.
- (g) Section (d)(4)(iii)(A)(4). A reusable sharps container system will be acceptable if it does not expose employees to the risk of percutaneous injury system involving the manual opening, emptying, or cleaning of the containers will be allowed. The only acceptable system is a fully automated container cleaning system that eliminates employee exposure to sharps.

**M.4.d.(3)(h) Section (d)(4)(iii)(B).** While this section **requires that regulated waste containers be closable**, simply being closed does not ensure that wastes will be contained. Waste-containing bags may break and spill their contents, including liquid blood, while, for example, being loaded onto incinerator hoppers, thus contaminating both the employees and the work area.

1. Also, small medical offices, which generate only a small volume of regulated waste may place that waste in a large holding container until the container is filled. In such a case, the design of the container must be such that it is able to retain the waste over an extended period of time between pick-ups by a specialized waste service.
2. The compliance officer should, therefore, check for visual signs of leakage of fluids during handling, storage, transport, or shipping.
3. Any failures to comply with the container construction requirements would be cited under this section. If the compliance officer determines that the employee was not properly trained to recognize the problem or use the containers correctly, a citation for the appropriate section of (g)(2) should be grouped with violations of paragraph (d).

**M.4.d.(3)(i) Sections (d)(4)(iii)(B)(1)(iii) and (2)(iii).** Regulated waste containers are required to be labeled with the biohazard symbol or color coded to warn employees who may have contact with the containers of the potential hazard posed by their contents.

1. Even if a facility considers all of its waste to be regulated waste, the waste containers must still bear the required label or color-coding in order to protect new employees, who would not normally come into contact with wastes, and employees from outside the facility. This requirement is in contrast to the labeling alternative allowed when laundries use universal precautions for the handling of all soiled laundry. (See M.4.d.(4)(a) of this instruction on section (d)(4)(iv)(A)(2).)
2. Regulated waste that has been decontaminated need not be labeled or color-coded. The compliance officer in such a case shall verify that the employer's exposure control plan states the decontamination procedures to be followed.

- a. a In order to ensure that the decontamination process is successful, the employer must monitor factors such as the content, volume, density, configuration, and organic content of the load of waste. (See M.7.a.(2) of this instruction on section (g)(1)(i)(I).)
- b. b The temperature needed for the complete breakdown of plastics, as required by EPA, is sufficient to decontaminate regulated waste.

**M.4.d.(3)(i)2 c Autoclave efficiency** can be verified by means of biological or chemical indicators. While most disposal bags used will contain an indicative color strip, if this is not the case a review may be made of the documentation kept for the sterilizer. Such documentation should include:

- (1) date, time, and operator of each run,
- (2) type and approximate amount of waste tracked,
- (3) post-treatment reading of temperature-sensitive tape,
- (4) dates and results of calibration of the sterilizer, and
- (5) results of routine spore testing.

- d. For a more detailed discussion of chemical decontamination, see guidelines at M.4.d.(1) of this instruction.

3 Although these sections contain **label requirements, failure to label** can also be cited under section (g)(1)(i).

(j) Section (d)(4)(iii)(B)(2). A second container is required when outside contamination of the first waste container occurs. This provision does not requires double-bagging in such circumstances as a waste container being splashed with blood during surgery or autopsy, when a container has been handled by an employee with bloody gloves, or when a waste bag leaks blood or OPIM onto an adjacent bag.

**M.4.d.(4) Laundry - (d)(4)(iv).** This section **reduces employee exposure** to bloodborne pathogens by reducing the amount of manual handling of contaminated laundry. Restricting the sorting to the laundry area will also reduce contamination of additional surfaces.

**INSPECTION AND CITATION GUIDELINES.** Sections (d)(4)(iv)(A) and (A)(1) limit the handling of laundry to removal and bagging or containerization. The training of the employees assigned to these tasks.

(a) Section (d)(4)(iv)(A)(2). The employer has been given the choice, by this section, to either:

- 1. Label or color-code according to section (g)(1)(i), or
  - 2. Utilize universal precautions in the handling of all soiled laundry.
- a. If universal precautions are used for handling all soiled laundry, the employer may use an alternative color or label for the bags/containers, as

long as all employees are trained to recognize them as containing soiled laundry which requires the use of universal precautions.

- b. Training violations would be cited under the appropriate section of (g)(2)(vii).
- c. Refer to M.4.d.(4)(d) on section (d)(4)(iv)(C) for labeling when laundry is shipped off-site.

**M.4.d.(4)(b) Section (d)(4)(iv)(A)(3).** The **material for the bags or containers** used in laundry collection must prevent soak-through or leakage of fluids to the exterior, if the contaminated laundry is wet and presents a reasonable likelihood of soak-through or leakage. Not all contaminated laundry must be placed in such bags or containers. Laundry wet enough to leak or soak through and expose workers handling the bags/ containers to blood or OPIM are required to be put into these containers.

- (c) Section (d)(4)(iv)(B). Employees having direct contact with contaminated laundry must wear protective gloves and any other appropriate personal protective equipment, in order to prevent or reduce contact exposure to blood or OPIM. Any other personal protective equipment required must be determined on a case-by-case basis. Gowns, aprons, eyewear, and masks may be necessary to prevent employee exposure.
- (d) Section (d)(4)(iv)(C). The generator of the laundry must have determined if the facility to which it is shipped utilizes universal precautions. If not, all bags or containers of contaminated laundry must be labeled or color-coded in accordance with section (g)(1)(i). In this instance, if the generator of the laundry chooses to color-code rather than label, the color of the bag must be red.

**INSPECTION AND CITATION GUIDELINES.** The compliance officer shall check the employer's program to determine if laundry is shipped to another facility for cleaning and shall evaluate the methods used to ship contaminated laundry (CL) to a facility that does not utilize universal precautions in the handling of all soiled laundry. The following are unacceptable shipment methods and constitute violations of this section: M.4.d.(4)(d)

- 1 The CL is not shipped labeled or in a red bag. Section (d)(4)(iv)(C) would be cited and grouped with the applicable subsection of (g)(1)(i).
- 2 The CL is shipped with an improper label. Section (d)(4)(iv)(C) would be cited and grouped with the applicable subsections of (g)(1)(i)(B),(C), and (D).
- 3 The CL is shipped in a bag color-coded for in-house use (in a color other than red). Section (d)(4)(iv)(C) would be cited and grouped with section (g)(1)(i)(E).

5. **HIV and HBV Research Laboratories and Production Facilities** 29 CFR 1910.1030(e). This section includes additional requirements that must be met by research

laboratories and production facilities engaged in the culture, production, concentration, and manipulation of HIV and HBV.

Research laboratory means a laboratory, which produces or uses research laboratory scale amounts of HIV or HBV. Although research laboratories may not have the volume found in production facilities, they deal with solutions containing higher viral titers than those normally found in patients' blood. Academic research laboratories are included in this definition. Laboratories that conduct research unrelated to HIV or HBV on blood and other body fluids, or who use unconcentrated blood or blood components as the source of HIV or HBV, are not considered research laboratories for the purpose of this section.

Production facilities are those engaged in industrial scale, large volume, or high concentration production of HIV or HBV.

NOTE 1: Employers in such a facilities remain responsible for complying with the entire standard. Requirements stated elsewhere in the standard are not repeated.

NOTE 2: These requirements are based largely on information from published guidelines of the Centers for Disease Control (CDC) and the National Institutes of Health (NIH) (See D.9. of this instruction, "Biosafety in Microbiological and Biomedical Laboratories.")

**INSPECTION AND CITATION GUIDELINES.** The compliance officer shall review the covered facility's plan, interview a sufficient number of employees, and observe work practices as necessary to determine if the requirements of this section are met. Care shall be taken to ensure the compliance officer understands the special practices and precautions in place at the facility, so that the compliance officer is not placed at risk. Specific requirements include:

a. Section (e)(2)(i). The term "regulated waste" refers to the OSHA definition as found in section (b) of this standard. The purpose of decontaminating regulated waste is to prevent the accidental exposure of other employees to the concentrated virus.

b. Sections (e)(2)(ii)(A) through (M). Sections (A), (C), and (D) limit access to the laboratory and warn of the hazards associated with bloodborne pathogens. The compliance officer must review the written policies and procedures to determine if they are adequate to ensure that unauthorized individuals are not placed at risk nor that they can distract or otherwise interfere with the work of the authorized employees. Interviews with employees should be used to determine if the policies are followed.

(1) **Section (e)(2)(ii)(E).** The "**other physical containment device**" must be sufficient to ensure that virus-containing material will be kept away from the worker's mucous membranes, unprotected skin, and breathing zone.

**(2) Sections (e)(2)(ii)(H) and (I).** These sections **prevent the spread of contamination to other work areas**. Section (I) allows for an alternative to a HEPA filter as long as it is of equivalent or superior efficiency. HEPA filters may be ineffective in humid atmospheres.

- (a) The employer must also have made provisions for routine maintenance and/or replacement of all filters and traps.
- (b) If the compliance officer suspects that the engineering controls are failing to prevent the spread of the virus, the manufacturer should be contacted to establish the limits and required maintenance of the filters and traps.

**(3) Section (e)(2)(ii)(J).** The compliance officer shall determine if the **use of needles and syringes is kept to a minimum** and that they are properly handled as required, paying particular attention to establishing if the puncture-resistant containers are properly autoclaved or decontaminated before being discarded, reused, or incinerated.

**(4) Section (e) (2)(ii)(M)** The compliance officer shall take any necessary additional procedures that are developed to **protect employees in situations unique** to a research/production facility. The biosafety manual required by this section shall be reviewed and updated annually or more often if necessary. The facility will thus be required to review its procedures and determine if they are adequate to protect workers.

c. Section (e)(2)(iii). Specific containment equipment is required by this section to minimize or eliminate exposure to the viruses.

(1) If the compliance officer determines that biological safety cabinets (BSC) have been chosen as the means of containment, they must be certified (Class I, Class II, or Class III) when installed or moved, and at least annually.

(a) The compliance officer shall check that a dated tag is affixed to the BSC indicating who performed the certification. Alternatively, a certification report

(1) attesting to a minimum inward face velocity of at least 75 linear feet per minute and the integrity of the HEPA filters shall be reviewed by the compliance officer. The report must be dated and signed by the trained technician performing the measurements and integrity tests.

(2) In the alternative, appropriate combinations of PPE or physical containment devices (examples listed in the standard) will be accepted.

**(d) Sections (e)(3)(i) and (e)(4)(iii).** **The hand washing facility** must be supplied with at least tepid water, soap, and hand towels. The eyewash must supply a sufficient quantity of water to completely flush the eyes. A 15-minute supply of

continuous free-flowing water is acceptable. The hands must be free to hold the eyelids open to aid in the complete flushing of the eyes. Portable facilities are acceptable only if they meet these requirements.

e. **Section (e)(4)** covers additional requirements for **production facilities** only. The requirement in section (e)(4)(v) minimizes the potential for accidental exposure to other employees from the transport of culture fluids, plastic ware, and other contaminated equipment.

f. **Section (e)(5)** The additional **training requirements** are specified in section (g)(2)(ix). Any violations found would be cited under that section of the standard. (See M.7.b.(5) of this instruction for details.)

6. **Hepatitis B Vaccination and Post Exposure Evaluation and Follow-up** - 29 CFR 1910.1030(f). This section provides a means to protect employees from infection caused by the hepatitis B virus by requiring employers to make the hepatitis B vaccination available to employees with occupational exposure to blood or OPIM. It also ensures that employees receive appropriate medical follow-up after each specific exposure incident. Appendix D provides general algorithms for these requirements.

a. **General - (f)(1)**. This section refers to the hepatitis B vaccination as both the hepatitis B vaccine and vaccination series. These are to be made available to all **occupationally exposed employees**. In addition, a post-evaluation and a follow-up procedure are to be made available to all employees who experience an exposure incident. While it is OSHA's intent to have the employer remove, as much as possible, obstacles to the employee's acceptance of the vaccine, the term "made available" emphasizes that it is the employee's option to participate in the vaccination and follow-up programs.

**INSPECTION GUIDELINES.** The compliance officer shall examine the employer's program to determine if the vaccination series and post-exposure follow-up procedures meet the requirements of section (f)(1)(ii).

(1) Section (f)(1)(ii)(A). The term "**no cost to the employee**" means no "out of pocket" expense to the employee.

(a) The employer may not require the employee to use his/her health care insurance to pay for the series unless the employer pays all of the cost of the health insurance and unless there is no cost to the employee in the form of deductibles, co-payments, or other expenses. Even partial employee contribution to the insurance premium means the employee could be affected by a rise in the total premium caused by insurance company reaction to widespread hepatitis B vaccinations and is therefore unacceptable.

(b) The employer may not institute a program in which the employee pays the original cost of the vaccine and is reimbursed by the employer if she/he remains employed for a specified period of time.

- (c) An "amortization contract" which requires employees to reimburse the employer for the cost of the vaccination should they leave his/her employ prior to a specified period of time is similarly prohibited.
- (2) Section (f)(1)(ii)(B). The term "**reasonable time and place**" requires the medical procedures and evaluations to be convenient to the employee. They shall be offered during normally scheduled work hours. If participation requires travel away from the worksite, the employer must bear the cost.
- (3) Section (f)(1)(ii)(C). The compliance officer may have to **contact** the Regional bloodborne pathogens **coordinator** to determine if the State board of nursing licensing allows licensed health care professionals other than physicians to carry out the procedures required by section (f).
- (4) Section (f)(1)(ii)(D). This section takes into consideration the changing nature of medical treatment relating to bloodborne pathogens. The CDC is the U.S. Public Health Service (USPHS) agency responsible for issuing guidelines and making recommendations regarding infectious agents. **OSHA will accept the CDC guidelines** current at the time of the evaluation or procedure. Copies of the current guidelines can be obtained by contacting the Regional bloodborne pathogens' coordinator or CDC. (See Appendices A and B.)

NOTE: This section requires that the current USPHS/CDC guidelines be followed for all vaccinations, evaluations, and follow-up procedures. Any additional requirements (such as obtaining a written health care professional's opinion) specified in section (f) must also be met.

- (5) Section (f)(1)(iii) requires that all laboratory tests be conducted by an **accredited laboratory**. The compliance officer must determine by means of employer documentation (e.g., certificate) that the laboratory is accredited by a national accrediting body (such as CDC or College of American Pathologists) or equivalent State agency which participates in a recognized quality assurance program.
- c. Hepatitis B Vaccination - (f)(2). The compliance officer shall determine whether or not all occupationally exposed employees have the hepatitis B vaccination series made available to them after training required by section (g)(2)(vii)(I) and within 10 working days of their initial assignment.

The term "made available" includes the health care professional's evaluation and arranging for the administration of the first dose of the hepatitis B vaccination series to begin within the 10 days. This includes all employees with reasonably anticipated occupational exposure, regardless of how often the exposure may occur. Part-time and temporary employees are included in this coverage. The vaccine does not have to be made available if the employer documents

(1) the exemption(s) set forth in section (f)(2), or (2) the signature of the employee on the mandatory declination form. (See Appendix A of 29 CFR 1910.1030.)

- (1) Section (f)(2)(i) states the **circumstances under which an employer is exempted** from making the vaccination available. If, (a) the complete hepatitis B vaccination series was previously received, or (b) antibody testing shows the employee to be immune, or (c) the vaccine cannot be given for medical reasons, the series does not have to be made available. If the employer claims one of these exemptions, it must be documented in the employee's medical record.
    - (a) The hepatitis B vaccination must be given in the standard dose and through the standard route of administration as recommended in the USPHS/CDC guidelines. At the time of publication of this standard, intradermal inoculation of 0.1 of the normal dose of the hepatitis B vaccine is not recommended by the USPHS and therefore is not an acceptable administration method.
    - (b) Current USPHS guidelines do not recommend routine post-vaccination testing. Therefore, employers are not currently required to routinely test immune status after vaccination has been completed.
  - (2) Section (f)(2)(ii). **Prevaccination screening** for antibody status cannot be required of an employee, although if an employer wishes, he/she can make it available at no cost to employees. An employee may decline the prescreening, and the employer must still make the vaccination series available to the employee.
  - (3) Section (f)(2)(iii). The **signing of the hepatitis B vaccine declination** form by the employee, at the time the vaccination is made available, does not relieve the employer from the requirement to provide the vaccine at a later date if the employee so chooses.
  - (4) Section (f)(2)(iv). Although the declination form set forth in 29 CFR 1910.1030, Appendix A, does not have to be reproduced, the **declination** statement used by the employer must contain the **same language** as that found in Appendix A--no words may be added or subtracted.
  - (5) Section (f)(2)(v). At the time of this publication, the possible need for **booster doses** of the hepatitis B vaccine is **still being assessed**. There is no current requirement to provide boosters unless the USPHS recommends it at a later date.
- c. Post-Exposure Evaluation and Follow-up - (f)(3). This section requires the employer to make immediately available a confidential medical evaluation and follow-up to an employee reporting an exposure incident.

NOTE: Employees who do not fall within the scope of this standard may still experience a specific exposure incident at work that is unrelated to the performance of their job duties. In such a case, OSHA strongly encourages their employer to offer them the follow-up procedures set forth in this section.

**INSPECTION GUIDELINES.** The compliance officer must determine if the employer's plan provides for immediate and confidential procedures. At sites where an exposure incident has occurred it should be determined if the procedures were properly followed through interviews, incident report reviews, and, if necessary, medical records reviews.

- The word "immediately" is used in the standard to emphasize the importance of prompt medical evaluation and prophylaxis. An exact time was not given in the standard since medical knowledge concerning the effectiveness of post-exposure prophylactic measures is constantly changing. OSHA requires the evaluation and follow-up procedures to be given as soon as possible after exposure.
  - If the compliance officer believes that an employer is not properly following accepted post-exposure procedures, or needs specific information about current accepted procedures, the Regional bloodborne pathogens coordinator should be contacted. A health care professional in the National Office will then be consulted.
  - The employer must also have established a system that maintains the required medical records in a way that protects the confidentiality of the employee's identity and test results. If the employer has contracted with a clinic or other health care facility to provide the follow-up programs, the confidentiality requirements must be part of the contract.
1. Section (f)(3)(i). Documentation of the circumstances surrounding an exposure incident will help the employer and the compliance officer determine, for example, if PPE is being used or if training is lacking.
  2. Section (f)(3)(ii). This section requires the employer to identify the source individual in an exposure incident, unless this is infeasible. The employer must document in writing the identity of, or infeasibility of identifying, the source individual. Examples of when it may not be feasible to identify the source individual include incidents of needlesticks by unmarked syringes left in laundry or those involving blood samples which are not properly labeled, as well as prohibition by State or local law.
    1. Section (f)(3)(ii)(A). This section requires testing of the source individual's blood after consent is obtained. The employer must ask for consent from the source individual or anyone legally authorized to give consent on his/her behalf. If consent is not obtained, the employer must document this in writing. The compliance officer shall ensure that the employer's plan includes this provision.

1. For those jurisdictions that do not require consent of the individual, available blood must be tested. The term "if available" applies to blood samples that have already been drawn from the source individual.
  2. OSHA does not require redrawing of blood specifically for HBV and HIV testing without consent of the source individual.
1. Section (f)(3)(ii)(C). This section does **not authorize the employer to be informed** of the results of source individual or exposed employee testing. However, the results of the source individual's testing must be made available to the exposed employee.
    1. The boundary between employer and health care professional may be blurred in a medical setting in which, for example, the physician is both the employer and the evaluating health care professional. In such cases, the compliance officer shall ensure that requirements for consent and confidentiality have been followed.
    2. "Applicable laws and regulations concerning disclosure" refers to State and Federal laws that specifically cover medical privacy and confidentiality.
  - (c) Section (f)(3)(iii). The compliance program offers covered employees all of the listed requirements, in the event of an exposure incident. Counseling and evaluation of reported illnesses is not dependent on the employee's electing to have baseline HBV and HIV serological testing.
    1. Section (f)(3)(iii)(A). Although the consent of the employee must also be obtained before collection of blood and before hepatitis B serological testing, the 90-day holding requirement in section (f)(3)(iii)(B) does not apply.
    2. Section (f)(3)(iii)(B). This section allows employees the opportunity for future testing without the need for an immediate decision.
      - a. Employees involved in an exposure incident have at least 90 days following baseline blood collection to decide if they wish to have their blood tested for HIV.
      - b. Employers are required to preserve the blood the employee consented to have drawn, if it was not tested for HIV initially, for at least the 90-day period. Compliance officers shall check if the employer contracts for post-exposure follow-up, the contractor has been informed of the 90-day requirement.

(d) Section (f)(3)(iv). See Appendices A and B for CDC's current guidelines on **management of occupational exposure** to HIV and HBV.

- d. Information Provided to the Health Care Professional (f)(4). This section requires the employer to provide information to the health care professional responsible for the employee's hepatitis B vaccination and post-exposure incident follow-up.

INSPECTION GUIDELINES. The compliance officer must determine if the employer's plan includes providing a copy of this standard to the health care professional responsible for the employee's hepatitis B vaccination.

- (1) In the case of an exposure incident, the plan must provide for the transmission of the information required by (f)(4)(ii)(A-C) and (E) to the health care professional. The information required by (f)(4)(ii)(D) must be provided only if available.
  - (2) The employer does not have a specific right to know the actual results of the source individual's blood testing, but must ensure that the information is provided to the evaluating health care professional.
  - (3) If the evaluating health care professional is also the employer, the information must still be in the employee's record and made available at the time of a post-exposure incident. All applicable laws and standards of confidentiality apply in this situation.
- e. Health Care Professional's Written Opinion - (f)(5). The **employer is required to obtain and provide a written opinion** to the employee within 15 working days of completion of the original evaluation. Employer access is allowed to the health care professional's written opinion.
- (1) Section (f)(5)(i) limits the health care professional's written opinion to very specific information regarding the employee's hepatitis B vaccine status, including indication for vaccine and whether such vaccination was completed.
  - (2) Section (f)(5)(ii) requires documentation that a post-exposure evaluation was performed and that the exposed employee was informed of the results as well as any medical conditions resulting from exposure which require further evaluation and treatment.

**7. Employee Information and Training - 1910.1030(g).** Section (g) ensures that employees receive sufficient warning through labels, signs, and training to eliminate or minimize their exposure to bloodborne pathogens.

- a. Labels - (g)(1). Labels must be provided on containers of regulated waste, on refrigerators and freezers that are used to store blood or OPIM, and on containers used to store, dispose of, transport, or ship blood or OPIM. This requirement alerts employees to possible exposure since the nature of the material or contents will not always be readily identifiable as blood or OPIM. (See Appendix E.)

NOTE: This does not preempt either the U.S. Postal Service labeling requirements (39 CFR Part III) or the Department of Transportation's Hazardous Materials Regulations (49 CFR Parts 171-180).

**INSPECTION AND CITATION GUIDELINES.** The compliance officer shall determine that the warning labels in the facility are used as required by sections (g)(1)(i)(A) through (D) and include the term "BIOHAZARD". OSHA does not require nor prohibit the use of warning signs or labels indicating source individuals' or specimens' known infectivity status although, in accordance with universal precautions, the agency strongly recommends against such warning signs.

- (1) Sections (g)(1)(i)(E) through (G). These sections list exemptions from the labeling requirements, which are additional to those exemptions listed for specimens in section (d)(2)(xiii)(A) and for laundry in section (d)(4)(iv)(A)(2). (See M.4.b.(8)(a) and M.4.d.(4)(a) of this instruction.)
    - (a) Blood and blood products bearing an identifying label as specified by the Food and Drug Administration, which have been screened for HBV and HIV antibodies and released for transfusion or other clinical uses, are exempted from the labeling requirements.
    - (b) When blood is being drawn or laboratory procedures are being performed on blood samples, then the individual containers housing the blood or OPIM do not have to be labeled provided the larger container into which they are placed for storage, transport, shipment, or disposal (e.g., test tube rack) is labeled.
  - (2) Section (g)(1)(i)(I). Regulated waste that has been decontaminated by incineration autoclaving, or chemical means, prior to disposal is not required to bear the BIOHAZARD warning label.
    - (a) Decontamination is discussed in M.4.d.(3)(i)(2) of this instruction.
    - (b) Failure to ensure adequate decontamination procedures prior to removal of the hazard label shall be cited under (g)(1)(i)(A), since the material would still be regulated waste.
- b. Information and Training - (g)(2). All employees with occupational exposure must receive initial and annual training on the hazards associated with blood and OPIM, and the protective measures to be taken to minimize the risk of occupational exposure. Retraining shall take place when changes in procedures or tasks occur, which affect occupational exposure. While the provisions for employee training are performance oriented, with flexibility allowed to tailor the program to, for example, the employee's background and responsibilities, the categories of information listed in section (g)(2)(vii) must be covered at a minimum. These requirements include some site-specific information.

**INSPECTION GUIDELINES.** The compliance officer shall verify that the training is provided at the time of initial employment or on or before June 4, 1992, and at least annually thereafter. Whenever a change in an employee's responsibilities, procedures, or work situation is such that an employee's occupational exposure is affected, training must again be provided. "At the time of initial assignment to tasks where occupational exposure may take place" means that employees shall be trained prior to being placed in positions where occupational exposure may occur.

- Employees who received training on bloodborne pathogens within the year preceding March 6, 1992, shall receive information on the sections of the standard which were not included in their training. The annual retraining for these employees shall be provided within one year of their original training.
  - Part-time and temporary employees, and health care employees known as "per diem" employees are covered and are also to be trained on company time.
  - The compliance officer shall interview a representative number of employees from different work areas to determine that the training (including written material, oral presentations, films, videos, computer programs, or audiotapes) was presented in a manner that was appropriate to the employee's education, literacy level, and language. He should also ask if the trainer was able to answer questions as needed. If an employee is only proficient in a foreign language, the trainer or an interpreter must convey the information in that foreign language.
1. Sections (g)(2)(vii)(B) and (C). These sections require that HIV and HBV and other bloodborne diseases be described. The employer must convey the idea that a number of bloodborne diseases other than HIV and HBV exist, such as hepatitis C or syphilis. At the same time, the employer need not cover such uncommon diseases as Cruetzfeld-Jacob disease unless, for example, it is appropriate for employees working in a research facility with that particular virus.
  2. Section (g)(2)(vii)(J). The word "emergency" in this section refers to blood exposure outside the normal scope of work. This does not refer to hospital emergency rooms or emergency medical technicians' work.
  3. Section (g)(2)(vii)(N). This section requires that there be an opportunity for interactive questions and answers with the person conducting the training session.
    - (a) Training the employees solely by means of a film or video without the opportunity for a discussion period would constitute a violation of this section.

- (b) Similarly, a generic computer program, even an interactive one, is not considered appropriate unless the employer supplements such training with the site-specific information required (e.g., the location of the exposure control plan and the procedures to be followed if an exposure incident occurs) and a person is accessible for interaction.

(4) Section (g)(2)(viii). The person conducting the training is required to 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. In addition to demonstrating expertise in the area of the occupational hazard of bloodborne pathogens, the trainer must be familiar with the manner in which the elements in the training program relate to the particular workplace.

- (a) The compliance officer shall verify the competency of the trainer based on the completion of specialized courses, degree programs, or work experience, if he/she determines that deficiencies in training exist.
- (b) Possible trainers include a variety of health care professionals such as infection control practitioners, nurse practitioners, registered nurses, physician's assistants, or emergency medical technicians.
- (c) Non-health care professionals, such as industrial hygienists, epidemiologists, or professional trainers, may conduct the training provided they can demonstrate evidence of specialized training in the area of bloodborne pathogens.
- (d) In some workplaces, such as dental or physicians' offices, the individual employer may conduct the training provided he or she is familiar with bloodborne pathogen exposure control and the subject matter required by sections (g)(2)-(viii)(A) through (N).

(5) Section (g)(2)(ix)(A)-(C). "Standard microbiological practices" in these sections refer to procedures outlined in "Biosafety in Microbiological and Biomedical Laboratories." (See D.9. of this instruction.)

- (a) The requirement that "proficiency" be demonstrated means that employees who are experienced laboratorians may not need to be retrained in accordance with these sections.
- (b) Education such as a graduate degree in the study of HIV or HBV, or another closely related subject area with a period of related laboratory research experience, would also constitute "proficiency".
- (c) The employer is responsible for evaluating the employee's proficiency and for documenting the mechanism used to determine proficiency.

8. Recordkeeping - 1910.1030(h). Records are required to be kept for each employee covered by this standard for training, as well as for medical evaluations, treatment, and surveillance.

- (a) Medical records required by section (h)(1) will be of particular importance to the health care professional in determining vaccination status and courses of treatment to follow in the event of an exposure incident. Although the employer is required to establish and maintain medical records, he/she may contract for the services of a health care professional located off-site and that person or company may retain the records.

NOTE: While section (h)(1)(iii) requires that medical records are to be kept confidential, section (h)(1)(iii)(B) stipulates that disclosure is permitted when required by this standard or other Federal, State, or local regulations.

**INSPECTION GUIDELINES.** All medical records required to be kept by this standard are also required to be made available to OSHA. The compliance officer must protect the confidentiality of these records. If they are copied for the case file, the provisions of 29 CFR 1913.10 must be followed.

- The compliance officer shall review the employer's recordkeeping program to ensure that the required information is collected, and provision has been made to ensure the confidentiality of the medical records in accordance with 29 CFR 1910.20.

b. Section (h)(2) requires accurate recordkeeping of training sessions, including titles of the employees who attend. The records are necessary to assist the employer and OSHA in determining whether the training program adequately addresses the risks involved in each job. Additionally, this information is helpful in tracking the relationship between exposure incidents (e.g., needlesticks) and various jobs and the corresponding level of training.

(1) Training records may be stored on-site and therefore the actual documents will be easily accessible for review. In order to ensure that the employee training is complete, all the components of the program required by section (g)(2)(vii) must be covered.

(2) Training records are not considered to be confidential and may be maintained in any file. They must be retained for 3 years from the training date.

9. Dates - 1910.1030(i). The effective dates of the requirements of the standard appear in Appendix F of this instruction.

NOTE: OSHA Instruction CPL 2-2.44B shall remain in effect until the effective dates of the requirements of 29 CFR 1910.1030.

## **N. Interface with Other Standards.**

- (1) The hazard communication standard, 29 CFR 1910.1200, applies only to the hazards of chemicals in the workplace and does not apply to biological hazards such as bloodborne diseases.
- (2) Records concerning employee exposure to bloodborne pathogens and records about HIV and/or HBV status are considered employee medical records within the meaning of 29 CFR 1910.20. Under 29 CFR 1913.10, the compliance officer may review these records for purposes of determining compliance with 29 CFR 1910.20.
- (3) Generally, the respiratory protection standard, 29 CFR 1910.134 does not apply since there are no respirators approved for biohazards. However, placing respirators in areas where they could be contaminated by body fluids constitutes a violation of 29 CFR 1910.134 (b)(6).
- (4) The Hazardous Waste Operations and Emergency Response (HAZWOPER) standard, 29 CFR 1910.120, covers three groups of employees. They are workers at uncontrolled hazardous waste remediation sites; workers at Resource Conservation and Recovery Act (RCRA) permitted hazardous waste treatment, storage, and disposal facilities; and those workers expected to respond to emergencies caused by the uncontrolled release of a hazardous substance.
  - a. The definition of hazardous substance includes any biological agent or infectious material, which may cause disease or death. There are potential scenarios where the bloodborne and HAZWOPER standards may interface such as:
    - (1) Workers involved in cleanup operations at hazardous waste sites involving infectious waste;
    - (2) Workers responding to an emergency caused by the uncontrolled release of infectious material; e.g., a transportation accident; and
    - (3) Workers at RCRA permitted incinerators that burn infectious waste.
  - b. Employers of employees engaged in these types of activities must comply with the requirements in 29 CFR 1910.120 as well as the bloodborne pathogens standard. If there is a conflict or overlap, the provision that is more protective of employee safety and health applies.

**O. Recording in the IMIS.** Current instructions for completing the appropriate inspection classification boxes on the OSHA-1, Inspection Report, as found in the IMIS Manual, shall be applied when recording bloodborne pathogens inspections:

1. 1. For any inspection which includes an evaluation of the hazards of bloodborne pathogens, Item 42 of the OSHA-1 shall be recorded as follows: N 02 Blood
2. If local emphasis programs are approved at a later date, Item 25C of the OSHA-1 shall be completed with the appropriate value.

**P. Referrals.** When a complaint or inquiry regarding occupational exposure to bloodborne disease in a State or local government facility is received in a State without an OSHA approved State plan, the Regional Administrator should refer it to the appropriate State public health agency or local health agency with jurisdiction over the facility.

Dorothy L. Strunk  
Acting Assistant Secretary

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## APPENDIX A

Centers for Disease Control  
Atlanta, Georgia

Public Health Service Statement on Management of Occupational Exposure to Human Immunodeficiency Virus, Including Considerations Regarding Zidovudine Postexposure Use [Reprinted from Morbidity and Mortality Weekly Report 39(Suppl. RR-1): 1-14, Jan. 26, 1990]

### INTRODUCTION

CDC has issued guidelines to reduce the risk of human immunodeficiency virus (HIV) infection among health-care workers, emergency-response and public-safety workers, and others who might be exposed to HIV while performing job duties (1-4). The safety practices outlined in these guidelines remain the primary means of preventing occupational acquisition of HIV infection (5). Additionally, some physicians and some institutions have offered the option of using zidovudine (azidothymidine, AZT, ZDV, Retrovir) after occupational exposure to HIV (6). Data collected in an ongoing CDC surveillance project of health-care workers who have been occupationally exposed to blood from HIV-infected patients (7) indicate that during the period April-December 1989, 13 (8.6%) of 151 newly enrolled participants began a postexposure regimen of zidovudine.

This report reviews Public Health Service (PHS) recommendations for postexposure management of workers who have occupational exposures that may place them at risk of acquiring HIV infection, provides background information on zidovudine and experience with zidovudine postexposure prophylaxis, and presents considerations relevant to a decision to offer postexposure prophylaxis.

### DEFINITION OF OCCUPATIONAL EXPOSURE

For purposes of this document, an occupational exposure (i.e., exposure that occurs during the performance of job duties) that may place a worker at risk of HIV infection is defined as a percutaneous injury (e.g., a needlestick or cut with a sharp object), contact of mucous membranes, or contact of skin (especially when the exposed skin is chapped, abraded, or afflicted with dermatitis or the contact is prolonged or involving an extensive area) with blood, tissues, or other body fluids to which universal precautions apply, including: a) semen, vaginal secretions, or other body fluids contaminated with visible blood, because these substances have been implicated in the transmission of HIV infection (2); b) cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, and amniotic fluid, because the risk of transmission of HIV from these fluids has not yet been determined (2); and

c) laboratory specimens that contain HIV (e.g., suspensions of concentrated virus).

## PHS RECOMMENDATIONS FOR MANAGEMENT OF PERSONS AFTER OCCUPATIONAL EXPOSURES THAT MAY PLACE THEM AT RISK OF ACQUIRING HIV INFECTION

Employers should make available to workers a system for promptly initiating evaluation, counseling, and follow-up after a reported occupational exposure that may place the worker at risk of acquiring HIV infection. Workers should be educated to report exposures immediately after they occur, because certain interventions that may be appropriate, e.g., prophylaxis against hepatitis B, must be initiated promptly to be effective (3,8,9). Workers who might reasonably be considered at risk of occupational exposure to HIV should be familiarized with the principles of postexposure management as part of job orientation and ongoing job training.

If an exposure occurs, the circumstances should be recorded in the worker's confidential medical record. Relevant information includes the following:

- date and time of exposure
- job duty being performed by worker at time of exposure
- details of exposure, including amount of fluid or material, type of fluid or material, and severity of exposure (e.g., for a percutaneous exposure, depth of injury and whether fluid was injected; for a skin or mucous-membrane exposure, the extent and duration of contact and the condition of the skin, e.g., chapped, abraded, intact)
- description of source of exposure--including, if known, whether the source material contained HIV or HBV
- details about counseling, postexposure management, and follow-up

After an occupational exposure, both the exposed worker and the source individual should be evaluated to determine the possible need for the exposed worker to receive prophylaxis against hepatitis B according to previously published CDC recommendations (3,8,9). Because of the potentially severe consequences of hepatitis B virus infection, hepatitis B vaccine, which is both safe and highly effective (10), should be offered to any susceptible health-care worker who has an occupational exposure and has not previously been vaccinated with hepatitis B vaccine. Hepatitis B immune globulin may also be indicated, particularly if the source patient or material is found to be positive for hepatitis B surface antigen (HBsAg) (3,8,9).

In addition, the source individual should be informed of the incident and, if consent is obtained, tested for serologic evidence of HIV infection. If consent cannot be obtained (e.g., patient is unconscious),

policies should be developed for testing source individuals in compliance with applicable state and local laws. Confidentiality of the source individual should be maintained at all times.

If the source individual has AIDS, is known to be HIV-seropositive, or refuses testing, the worker should be evaluated clinically and serologically for evidence of HIV infection as soon as possible after the exposure (baseline) and if seronegative, should be retested periodically for a minimum of 6 months after exposure (e.g., 6 weeks, 12 weeks, and 6 months after exposure) to determine whether HIV infection has occurred. The worker should be advised to report and seek medical evaluation for any acute illness that occurs during the follow-up period. Such illness, particularly if characterized by fever, rash, myalgia, fatigue, malaise, or lymphadenopathy, may be indicative of acute HIV infection, drug reaction, or another medical condition. During the follow-up period, especially the first 6-12 weeks after the exposure when most infected persons are expected to seroconvert, exposed workers should follow PHS recommendations for preventing transmission of HIV. These recommendations include refraining from blood, semen, or organ donation and abstaining from or using measures to prevent HIV transmission during sexual intercourse (11-14). In addition, in countries such as the United States where safe and effective alternatives to breast-feeding are available, exposed women should not breast-feed infants during the follow-up period in order to prevent the infant's possible exposure to HIV in breast milk. During all phases of follow-up, confidentiality of the worker should be protected.

If the source individual is HIV-seronegative and has no clinical manifestations of AIDS or HIV infection, no further HIV follow-up of the exposed worker is necessary unless epidemiologic evidence suggests that the source individual may have recently been exposed to HIV or if testing is desired by the worker or recommended by the health-care provider. In these instances, the guidelines may be followed as described above.

If the source individual cannot be identified, decisions regarding appropriate follow-up should be individualized, based on factors such as whether potential sources are likely to include a person at increased risk of HIV infection.

The employer should make serologic testing available to all workers who are concerned about possible infection with HIV through an occupational exposure. Appropriate psychological counseling may be indicated as well.

## **ZIDOVUDINE**

Zidovudine is a thymidine analogue that has been shown in vitro to inhibit replication of some retroviruses, including HIV, by interfering with the action of viral ribonucleic acid (RNA)-dependent deoxyribonucleic acid (DNA) polymerase (reverse transcriptase) and possibly also by other Mechanisms (15).

In a double-blind, placebo-controlled trial, zidovudine was shown to

increase the length and quality of life of patients with advanced HIV infection and AIDS (16). Largely on the basis of the results of this trial, zidovudine was approved for marketing by the Food and Drug Administration (FDA) and is indicated for treatment of adults with symptomatic HIV infection, including AIDS, who have a history of cytologically confirmed *Pneumocystis carinii* pneumonia or an absolute CD4 lymphocyte count of less than 200/mm<sup>3</sup>. The dose of zidovudine originally approved for oral use by patients who have AIDS and advanced symptomatic HIV infection was 200 mg every 4 hours. On January 16, 1990, FDA approved a change in the labeling that now recommends administering the drug at 600 mg/day (100 mg every 4 hours) after a patient has received 1 month of zidovudine therapy at a dose of 1,200 mg/day (200 mg every 4 hours).

Later studies (National Institute of Allergy and Infectious Diseases (NIAID) AIDS Clinical Trial Group Protocols #016 and #019) have indicated that zidovudine can delay disease progression in patients with less advanced HIV infection (patients with an absolute CD4 count of less than 500/mm<sup>3</sup>, whether symptomatic or asymptomatic) (NIAID Administrative Report: "AIDS Clinical Trials Alert," August 29, 1989).

### **Toxicity**

Among patients who have AIDS or symptomatic HIV infection and who are treated with zidovudine, the most frequently reported adverse events are granulocytopenia and anemia. Other adverse events that affect greater than or equal to 5% of zidovudine recipients include one or more of the following: headache, nausea, insomnia, myalgia, diaphoresis, fever, malaise, anorexia, diarrhea, dyspepsia, vomiting, dyspnea, rash, and taste abnormalities (17). Occurrences less commonly reported in the published literature include polymyositis, peripheral neuropathy, and seizures.

Among 3,200 patients with asymptomatic HIV infection treated in NIAID protocol #019 with placebo or with zidovudine doses of either 1,500 mg or 500 mg daily (either 300 mg or 100 mg given every 4 hours, five times daily), investigators have reported the following toxicity after a median of 44 weeks of therapy: in the 1,500-mg/day group, approximately 12% of the subjects developed moderate to severe hematologic toxicity, defined as hemoglobin of less than 8 g/l, granulocytes of less than 750/mm<sup>3</sup>, or platelets of less than 50,000/mm<sup>3</sup>. In the 500-mg/day group, this toxicity occurred at a rate of about 3%, compared with approximately 2% in the placebo group. Nausea was rarely reported in the placebo group; however, 3%-5% of zidovudine recipients, irrespective of dose group, experienced moderate to severe nausea. No statistically significant difference was observed between zidovudine dose and placebo for any other moderate to severe clinical adverse experiences (NIAID Administrative Report: "AIDS Clinical Trials Alert," August 29, 1989).

Preliminary data from a study sponsored by the Burroughs-Wellcome Company of health-care workers who received 200 mg of zidovudine or placebo every 4 hours for 6 weeks after occupational exposure to HIV

indicate that adverse effects most frequently consisted of nausea and vomiting. In no instance did the prescribing physician discontinue a participant's study drug or placebo because of hematologic or other serious toxicity; however, during the therapy period, 14 (28.6%) of 49 participants who received zidovudine had a hemoglobin concentration between 9.5 and 12 g/l, compared with one (2.9%) of 35 participants in the placebo group. Seven (14.3%) of the 49 participants who received zidovudine, compared with one (2.9%) of the 35 placebo recipients, elected to discontinue therapy because of subjective, reversible symptoms, including nausea, vomiting, fatigue, headache, myalgia, or cough.

Several anecdotal reports of short-term toxicity among health-care workers receiving zidovudine have been received by PHS. Symptoms include fever, myalgia, fatigue, nausea, and vomiting. Single reports have been received of severe anemia, reversible peripheral neuropathy, and transient clinical hepatitis.

Although the risk of acute zidovudine toxicity for exposed health-care workers cannot be determined from this limited information, data from the NIAID protocol #019 trial and from the Burroughs-Wellcome study of exposed health-care workers suggest that the risk of acute toxicity associated with short-term use of the drug is lower than the risk observed during long-term therapy of symptomatic HIV-infected individuals.

For healthy persons not infected with HIV, the risk of long-term toxicity, including teratogenic and carcinogenic effects, related to a course of zidovudine is not known. It is not known whether zidovudine can cause fetal harm when administered to a pregnant woman or whether it can affect reproductive capacity (17). To assess the safety of zidovudine use during pregnancy, the Burroughs-Wellcome Company has developed a registry to evaluate pregnancy outcomes of women who took zidovudine during pregnancy. Physicians are encouraged to register such persons by telephoning the pregnancy registry, (919) 248-8465 (collect) or 1-800-722-9292. It is also not known whether zidovudine is excreted in human milk. However, because of the potential for adverse side effects among breast-fed infants, as well as the potential for transmission of HIV if the mother is infected, mothers should be instructed to discontinue breast-feeding whether or not they are receiving zidovudine (17).

In other studies conducted by the Burroughs-Wellcome Company (Appendix I), vaginal tumors, including carcinomas, were observed in mice and rats receiving zidovudine at doses that the FDA has determined resulted in plasma levels in mice approximately equal to human plasma levels at the dose originally approved for treatment of persons with symptomatic HIV infection (200 mg every 4 hours). In rats, the plasma levels were determined by the FDA to be about 10 times higher than human plasma levels achieved with the originally approved dose. The results of these rodent carcinogenicity studies are of uncertain predictive value for humans.

## Studies of Zidovudine Postexposure Prophylaxis Involving Animals

Data involving studies of laboratory animals (Appendix II) are limited and must be interpreted with caution, as they have most often been derived by using nonhuman retroviruses having pathogenic mechanisms different from the pathogenesis of HIV infection in humans. In one study using HIV in a mouse model, zidovudine prophylaxis was begun 24 hours before intrathymic injection of a large inoculum of HIV and continued for 2 weeks thereafter. HIV infection was not prevented in any of the animals studied, although the course of infection was modified. It is not known whether prophylaxis would be effective in conditions that more closely resemble occupational exposures, i.e., zidovudine begun after exposure, with the exposure consisting of a percutaneous injection of a lower inoculum of HIV. Data from animal studies are inadequate to support or reject the hypothesis that zidovudine may be effective prophylaxis for persons who have been occupationally exposed to HIV.

## Studies of Zidovudine Postexposure Prophylaxis Involving Humans

The efficacy of zidovudine prophylaxis for humans after exposure to HIV cannot be assessed because of insufficient data. The Burroughs-Wellcome Company recently sponsored a double-blind, placebo-controlled study to evaluate 6 weeks of zidovudine prophylaxis (200 mg orally every 4 hours) involving health-care workers who had experienced occupational percutaneous, mucous-membrane, or nonintact-skin exposures to HIV-infected blood. Of 84 workers who initially enrolled in the study (49 of whom were given zidovudine), none developed HIV infection after at least 6 months of follow-up. The risk of transmission of HIV per episode of percutaneous exposure to HIV-infected blood is, on the average, approximately 0.4% (7). Thus, the absence of seroconversions in this small group of participants is not unexpected, regardless of whether they took zidovudine. Enrollment in this study was terminated in June 1989.

NIAID has enrolled three persons in an ongoing open trial of zidovudine prophylaxis after a "massive exposure" to HIV. The first person received a blood transfusion from an HIV-infected donor, was started on zidovudine 7 days after exposure, and was culture-positive for HIV 4 months after completing 6 weeks of chemotherapy. The second person was exposed to a high concentration of HIV on abraded skin in a research laboratory, was started on zidovudine within 24 hours postexposure, and remains HIV-seronegative after 11 months. The risk of seroconversion after this type of laboratory exposure is unknown. The third person was exposed to a high concentration of HIV on broken skin in a research laboratory, was started on zidovudine within 24 hours after the exposure, and is HIV-seronegative 3 months after the exposure. The risk of seroconversion after this type of laboratory exposure also is unknown. All individuals were able to complete a 6-week course of therapy (200 mg orally every 4 hours) without clinically significant adverse effects. Information regarding enrollment in this study can be obtained by calling the NIAID study coordinator at (800) 537-9978.

## **Prophylaxis Schedules Currently Used After Occupational Exposure**

Various regimens have been prescribed for zidovudine prophylaxis after occupational exposure. No data are available to enable investigators to determine the efficacy or compare the toxicity of these or other regimens. At the National Institutes of Health Clinical Center, workers who elect to receive zidovudine are treated with 200 mg every 4 hours (six times daily) for 6 weeks (6). At San Francisco General Hospital, workers who elect to receive zidovudine are treated with 200 mg every 4 hours (five times daily; no dose is given at 4: 00 a.m.) for 4 weeks (6). Some clinicians have used an initial dose of 400 mg, and others have prescribed treatment courses ranging from 4 days to 4 months. At several institutions, attempts are made to begin prophylaxis within 1 hour after exposure for workers who elect to receive the drug.

## **DISCUSSION**

Data from animal and human studies are inadequate to establish the efficacy or safety of zidovudine for prophylaxis after occupational exposure to HIV. However, some physicians believe that zidovudine should be offered as prophylaxis to persons after certain occupational exposures for the following reasons: the severity of the illness that may result from HIV infection, the documented antiviral effect of zidovudine in the treatment of persons with established HIV infection, the apparent reversibility of acute toxicity in persons taking zidovudine for a brief period, and the suggestion that in some animal studies, zidovudine postexposure may modify the course of some retroviral infections. Other physicians believe that zidovudine should not be recommended for uninfected persons after occupational exposures because of the lack of data demonstrating efficacy in postexposure prophylaxis, the limited data on toxicity in uninfected individuals, and the fact that zidovudine has been shown to be carcinogenic in rats and mice.

At this time, prophylaxis with zidovudine cannot be considered a necessary component of postexposure management. However, workers who might be at risk of occupational exposure to HIV should be informed, as part of job orientation and ongoing job training, of the considerations pertaining to the use of zidovudine for postexposure prophylaxis. The PHS recommends that if a physician decides to offer zidovudine to a worker after an exposure incident, that decision by the physician and the decision by the worker to take zidovudine should take into account the following considerations.

## **Risk of HIV infection after exposure**

Evaluation of the risk of HIV infection after exposure should take into account existing knowledge from prospective studies of exposed workers, which demonstrate that on the average the risk of transmission of HIV per episode of percutaneous exposure (e.g., a needlestick or cut with a sharp object) to HIV-infected blood is approximately 0.4%. These studies also suggest that the risk of HIV transmission per episode of mucous-membrane or skin exposure to HIV-infected blood is less than that after a percutaneous exposure (7,18-21). The risk of HIV transmission after occupational exposure to body fluids other than blood, for which universal precautions are recommended, is unknown. The risk of HIV infection for persons who take zidovudine postexposure prophylaxis cannot be determined at present because of the small number of persons studied.

Risk evaluation should also include an assessment of factors that may increase or decrease the probability of HIV transmission after an individual occupational exposure. These factors are not well understood, but include the likelihood that the source fluid contained HIV and probably also the concentration of HIV in the source fluid, the route of exposure, and the volume of fluid involved. For example, a percutaneous exposure to concentrated HIV in a research laboratory is probably more likely to result in transmission of infection than a similar exposure to HIV-infected blood in a clinical setting. A percutaneous exposure to HIV-infected blood is probably more likely to result in transmission than a mucous-membrane exposure to the same blood. Finally, an exposure to a larger quantity of HIV-infected blood, such as injection of several milliliters, is probably more likely to result in HIV transmission than an exposure to a smaller quantity of the same blood, such as in a needlestick exposure.

## **Interval between exposure and initiation of prophylaxis, if given**

Data from animal studies suggest that prophylaxis against certain retroviral infections other than HIV may be more effective when started within hours after exposure (22,23). Because *in vitro* studies indicate that human HIV infection may be established in human lymphocytes within hours after exposure (24), and epidemiologic studies of exposed health-care workers indicate that acute retroviral illness may occur as early as 2 weeks after exposure (7), it appears that if the decision is made to use postexposure prophylaxis, prophylaxis should be initiated promptly.

## **Counseling and informed consent**

If zidovudine prophylaxis is being considered, the worker should be counseled regarding a) the theoretical rationale for postexposure prophylaxis, b) the risk of occupationally acquired HIV infection due to the exposure, c) the limitations of current knowledge of the efficacy of zidovudine when used as postexposure prophylaxis, d) current knowledge of

the toxicity of zidovudine (including the data from animal and human studies) and the limitations of this knowledge in predicting toxicity in uninfected individuals who take the drug after occupational exposures, and e) the need for postexposure follow-up (including HIV serologic testing), regardless of whether zidovudine is taken. The worker should also be informed that there are diverse opinions among physicians regarding the use of zidovudine for postexposure prophylaxis, and the PHS cannot make a recommendation for or against the use of zidovudine for this purpose because of the limitations of current knowledge.

The duration of follow-up needed to detect evidence of HIV transmission or delayed toxicity among workers who take zidovudine is presently unknown. Workers taking zidovudine postexposure may require follow-up to detect HIV seroconversion for a longer period than that recommended for workers who do not take zidovudine. Regardless of the length of follow-up, mechanisms should be developed to permit workers taking zidovudine to be contacted if future information indicates the need for additional evaluation.

If a physician offers zidovudine as prophylaxis after an occupational exposure and the exposed worker elects to take the drug, the physician or other appropriate health-care provider should obtain written informed consent from the worker for this use of this drug. The consent document should reflect the information presented in the counseling session, as outlined above, emphasizing the need for follow-up medical evaluations and for precautions to prevent the transmission of HIV infection during the follow-up period, including refraining from blood, semen, or organ donation, refraining from breast-feeding, and either abstaining from sexual intercourse or using latex condoms during sexual intercourse, as discussed below.

Considerations regarding sexual intercourse for exposed workers taking zidovudine include 1) the possible risk of teratogenesis associated with zidovudine use, and 2) the risk of transmission of HIV to a sexual partner. The risk of teratogenesis among offspring of either men or women taking zidovudine is unknown. Therefore, men and women of reproductive age who are receiving zidovudine should abstain from, or use effective contraception during, sexual intercourse throughout the time zidovudine is being taken. In addition, to prevent HIV transmission to sexual partners, all exposed workers, including pregnant women, should abstain from, or use latex condoms during, sexual intercourse throughout the follow-up period.

### **Research Needs**

Further data are needed to determine risk factors for occupational exposure to HIV, to evaluate measures for preventing these exposures, and to identify risk factors for HIV transmission after occupational exposure. Appropriate animal models of HIV infection are needed, and animal studies should be conducted under experimental conditions that mimic the circumstances of occupational exposure affecting humans. Studies involving

humans should be conducted to determine whether postexposure prophylaxis with zidovudine or other agents is effective, and, if effective, should define the optimal time that postexposure prophylaxis should be initiated and the optimal duration of prophylaxis. Studies should also assess the toxicity of candidate prophylactic agents, establish the optimal dosage for healthy individuals and for persons with preexisting hepatic or renal dysfunction, and define the duration of follow-up needed to detect evidence of HIV infection in persons receiving prophylaxis. Strains of HIV isolated from treated workers should be monitored to detect development of drug resistance.

### **Expanded Surveillance of Workers with Occupational Exposures to HIV**

CDC has expanded its ongoing surveillance of workers with occupational exposures to HIV (7) to collect additional information on postexposure chemoprophylaxis. No names or other personal identifiers of workers are collected.

Information is collected on the following:

- circumstances associated with exposures
- extent to which zidovudine and other antiretroviral agents are prescribed for postexposure chemoprophylaxis, including dosage and timing
- incidence of associated toxicity
- rate of HIV seroconversion among workers who do and do not receive postexposure chemoprophylaxis

All physicians who provide care to a worker within 1 month after an occupational exposure to HIV, regardless of whether an antiretroviral agent is prescribed, are encouraged to enroll the worker in the CDC surveillance system. Enrollment and follow-up requirements have been simplified; in particular, it is no longer necessary to send blood specimens to CDC for HIV serologic testing unless the enzyme immunoassay (EIA) performed by a licensed local laboratory is reactive or equivocal. CDC will continue, however, to offer EIA testing at no charge on specimens from surveillance participants on request. Additional information and enrollment materials can be obtained from the Hospital Infections Program, Center for Infectious Diseases, Centers for Disease Control, Mail Stop C-10, Atlanta, GA 30333; telephone (404) 639-1644.

- \* To enroll persons who have had a "massive exposure" to HIV in NIAID study of zidovudine prophylaxis, telephone (800) 537-9978.
- \* To report adverse effects associated with zidovudine to FDA, use "Adverse Reaction Report" forms (FDA #1639), obtainable from:
  - Food and Drug Administration
  - Office of Epidemiology and Biostatistics
  - HFD-730
  - Rockville, MD 20857
  - (301) 443-4580.
- \* To enroll an exposed worker in the CDC prospective surveillance system, telephone (404) 639-1644.
- \* To enroll pregnant women who receive zidovudine during pregnancy, contact:
  - Zidovudine in Pregnancy Registry
  - Epidemiology, Information, and Surveillance Division
  - Burroughs-Wellcome Company
  - 3030 Cornwallis Road
  - Research Triangle Park, NC 27709
  - (919) 248-8465 (collect) or (800) 722-9292.

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## **APPENDIX B**

Centers for Disease Control  
Atlanta, Georgia

Protection against Viral Hepatitis: Recommendations of the Immunization Practices Advisory Committee (ACIP) [Reprinted from *Morbidity and Mortality Weekly Report* 39(Suppl. S-2): 1-26, Feb. 9, 1990]

The following statement updates all previous recommendations on protection against viral hepatitis, including use of hepatitis B vaccine and hepatitis B immune globulin for prophylaxis of hepatitis B (MMWR 1985;34: 313-24,329-35 and MMWR 1987;36: 353-66), universal screening of pregnant women to prevent perinatal hepatitis B transmission (MMWR 1988;37: 341-46,51), and use of immune globulin to prevent other types of viral hepatitis (MMWR 1985;34: 313-24,329-35).

## **INTRODUCTION**

The term "viral hepatitis" is commonly used for several clinically similar diseases that are etiologically and epidemiologically distinct (1). Two of these, hepatitis A (formerly called infectious hepatitis) and hepatitis B (formerly called serum hepatitis), have been recognized as separate entities since the early 1940s and can be diagnosed with specific serologic tests. A third category, currently known as non-A, non-B hepatitis, includes two epidemiologically distinct types of hepatitis: parenterally transmitted and enterically transmitted non-A, non-B hepatitis. Parenterally transmitted non-A, non-B hepatitis is associated with both posttransfusion and sporadic cases of acute hepatitis and may be caused by at least two different agents. Part of the genome for one of these agents has recently been cloned, and a candidate serologic assay for antibody to this virus (proposed as hepatitis C virus) has been developed (2,3). Enterically transmitted non-A, non-B hepatitis, which is spread by the fecal-oral route and is different from the types seen in the United States, has been reported in parts of Asia, Africa, and Mexico (4). Another distinct type of hepatitis, delta hepatitis, is an infection dependent on the hepatitis B virus. It may occur as a coinfection with acute hepatitis B infection or as superinfection of a hepatitis B carrier (5).

## **HEPATITIS SURVEILLANCE**

Approximately 28,500 cases of hepatitis A, 23,200 cases of hepatitis B, 2,620 cases of non-A, non-B hepatitis, and 2,470 cases of hepatitis type unspecified were reported in 1988 in the United States. Most cases of each type occur among young adults. Since reporting from many localities is incomplete, the actual number of hepatitis cases occurring annually is thought to be several times the reported number.

## **IMMUNE GLOBULINS**

Immune globulins are important tools for preventing infection and disease before or after exposure to hepatitis viruses. Immune globulins used in medical practice are sterile solutions of antibodies (immunoglobulins) from human plasma. They are prepared by cold ethanol fractionation of large plasma pools and contain 10%-18% protein. In the United States, plasma is primarily obtained from paid donors. Only plasma shown to be free of hepatitis B surface antigen (HBsAg) and antibody to human immunodeficiency virus (HIV) is used to prepare immune globulins.

Immune globulin (IG) (formerly called immune serum globulin, ISG, or gamma globulin) produced in the United States contains antibodies against the hepatitis A virus (anti-HAV) and the Hbsag (anti-HBs). Hepatitis B immune globulin (HBIG) is an IG prepared from plasma containing high titers of anti-HBs.

There is no evidence that hepatitis B virus (HBV), HIV (the causative agent of acquired immunodeficiency syndromes [AIDS]), or other viruses have ever been transmitted by IG or HBIG commercially available in the United States (6). Since late April 1985, all plasma units for preparation of IGs have been screened for antibody to HIV, and reactive units are discarded. No instances of HIV infection or clinical illness have occurred that can be attributed to receiving IG or HBIG, including lots prepared before April 1985. Laboratory studies have shown that the margin of safety based on the removal of HIV infectivity by the fractionation process is extremely high (7). Some HBIG lots prepared before April 1985 have detectable HIV antibody. Shortly after being given HBIG, recipients have occasionally been noted to have low levels of passively acquired HIV antibody, but this reactivity does not persist (8).

Serious adverse effects from IGs administered as recommended have been rare. IGs prepared for intramuscular administration should be used for hepatitis prophylaxis. IGs prepared for intravenous administration to immunodeficient and other selected patients are not intended for hepatitis prophylaxis. IG and HBIG are not contraindicated for pregnant or lactating women.

## **HEPATITIS A**

Hepatitis A is caused by the hepatitis A virus (HAV), a 27-nm ribonucleic acid (RNA) agent that is classified as a picornavirus. Patients with illness caused by HAV characteristically have abrupt onsets of symptoms including fever, malaise, anorexia, nausea, abdominal discomfort, dark urine, and jaundice. Severity is related to age. Among children, most infections are asymptomatic, and illness is usually not accompanied by jaundice. Most infected adults become symptomatically ill with jaundice. The case-fatality rate among reported cases is about 0.6%.

Hepatitis A is primarily transmitted by person-to-person contact, generally through fecal contamination and oral ingestion. Transmission is facilitated by poor personal hygiene, poor sanitation, and intimate

(intra-household or sexual) contact. In recent years, cases of hepatitis A among intravenous drug users, most likely due to person-to-person contact, have been reported with increasing frequency (9). Common-source epidemics from contaminated food and water also occur. Sharing utensils or cigarettes or kissing is not believed to transmit the hepatitis A virus.

The incubation period of hepatitis A is 15-50 days (average 28). High concentrations of HAV (10<sup>8</sup>) particles/g are found in stool specimens from infected persons. Virus in the feces reaches its highest concentration late in the incubation period and early in the prodromal phase of illness, and it diminishes rapidly once jaundice appears. Greatest infectivity is during the 2-week period immediately before the onset of jaundice. Viremia probably occurs during the period that the virus is shed in feces. Virus has not been found in urine. A chronic carrier state with HAV in blood or feces has not been demonstrated. Transmission of HAV by blood transfusion has been reported but is uncommon (10).

The diagnosis of acute hepatitis A is confirmed by finding IgM anti-HAV in serum collected during the acute or early convalescent phase of the disease. IgM anti-HAV, which appears in the convalescent phase of the disease and remains detectable in serum thereafter, confers enduring protection against the disease. Commercial tests are available to detect IgM anti-HAV and total anti-HAV in serum.

Although the incidence of hepatitis A in the United States in the 1980s was lower than that in the 1970s, a 26% increase in incidence was observed between 1983 and 1988. It is still a common infection among older children and young adults. In 1988, 50% of reported cases of hepatitis in this country were attributable to hepatitis A.

### **Recommendations for IG Prophylaxis for Hepatitis A**

Numerous field studies conducted in the past 4 decades confirm that IG given before exposure or during the incubation period of hepatitis A is protective against clinical illness (11-13). Its prophylactic value is greatest (80%-90%) when given early in the incubation period and declines thereafter (13). Recent tests have shown slightly decreased titers of anti-HAV in current IG lots compared with lots tested 8 years previously; however, no differences in IG efficacy have been noted.

### **Preexposure Prophylaxis**

The major group for whom preexposure prophylaxis is recommended is international travelers. The risk of hepatitis A for U.S. citizens traveling abroad varies with living conditions, length of stay, and the incidence of hepatitis A infection in areas visited (14-16). In general, travelers to developed areas of North America, western Europe, Japan, Australia, and New Zealand are at no greater risk of infection than they would be in the United States. For travelers to developing countries, risk of infection increases with duration of travel and is highest for

those who live in or visit rural areas, trek in back country, or frequently eat or drink in settings of poor sanitation. Nevertheless, recent studies have shown that many cases of travel-related hepatitis A occur in travelers with "standard" tourist itineraries, accommodations, and food and beverage consumption behaviors (16 and CDC unpublished data). In developing countries, travelers should minimize their exposure to hepatitis A and other enteric diseases by avoiding potentially contaminated water or food. Travelers should avoid drinking water (or beverages with ice) of unknown purity and eating uncooked shellfish or uncooked fruits or vegetables that they did not prepare.

IG is recommended for all susceptible travelers to developing countries (17). IG is especially important for persons who will be living in or visiting rural areas, eating or drinking in settings of poor or uncertain sanitation, or who will have close contact with local persons (especially young children) in settings with poor sanitary conditions. Persons who plan to reside in developing areas for long periods should receive IG regularly.

For travelers, a single dose of IG of 0.02 ml/kg of body weight is recommended if travel is for <<3 months. For prolonged travel or residence in developing countries, 0.06 ml/kg should be given every 5 months. For persons who require repeated IG prophylaxis, screening for total anti-HAV before travel is useful to define susceptibility and eliminate unnecessary doses of IG for those who are immune. IG produced in developing countries may not meet the standards for purity required in most developed countries. Persons needing repeat doses overseas should use products that meet U.S. license requirements.

### **Postexposure Prophylaxis**

Hepatitis A cannot be reliably diagnosed on clinical presentation alone, and serologic confirmation of index patients is recommended before contacts are treated. Serologic screening of contacts for anti-HAV before they are given IG is not recommended because screening is more costly than IG and would delay its administration.

For postexposure IG prophylaxis, a single intramuscular dose of 0.02 ml/kg is recommended. IG should be given as soon as possible after last exposure; giving IG more than 2 weeks after exposure is not indicated.

Specific recommendations for IG prophylaxis for hepatitis A depend on the nature of the HAV exposure.

1. Close personal contact. IG is recommended for all household and sexual contacts of persons with hepatitis A.
2. Day-care centers. Day-care facilities attended by children in diapers can be important settings for HAV transmission (18-20). IG should be administered to all staff and attendees of day-care centers or

homes if a) one or more children or employees are diagnosed as having hepatitis A, or b) cases are recognized in two or more households of center attendees. When an outbreak (hepatitis cases in three or more families) occurs, IG should also be considered for members of households that have children (center attendees) in diapers. In centers not enrolling children in diapers, IG need only be given to classroom contacts of an index patient.

3. Schools. Contact at elementary and secondary schools is usually not an important means of transmitting hepatitis A. Routine administration of IG is not indicated for pupils and teachers in contact with a patient. However, when an epidemiologic investigation clearly shows the existence of a school- or classroom-centered outbreak, IG may be given to persons who have close contact with patients.
4. Institutions for custodial care. Living conditions in some institutions, such as prisons and facilities for the developmentally disabled, favor transmission of hepatitis A. When outbreaks occur, giving IG to residents and staff who have close contact with patients with hepatitis A may reduce the spread of disease. Depending on the epidemiologic circumstances, prophylaxis can be limited or can involve the entire institution.
5. Hospitals. Routine IG prophylaxis for hospital personnel is not indicated. Rather, sound hygienic practices should be emphasized. Staff education should point out the risk of exposure to hepatitis A and should emphasize precautions regarding direct contact with potentially infective materials (21).

Outbreaks of hepatitis A occur occasionally among hospital staff, usually in association with an unsuspected index patient who is fecally incontinent. Large outbreaks have occurred from contact with infected infants in neonatal intensive care units (10). In outbreaks, prophylaxis of persons exposed to feces of infected patients may be indicated.

6. Offices and factories. Routine IG administration is not indicated under the usual office or factory conditions for persons exposed to a fellow worker with hepatitis A. Experience shows that casual

contact in the work setting does not result in virus transmission.

7. Common-source exposure. IG use might be effective in preventing foodborne or waterborne hepatitis A if exposure is recognized in time. However, IG is not recommended for persons exposed to a common source of hepatitis infection after cases have begun to occur, since the 2-week period during which IG is effective will have been exceeded.

If a food handler is diagnosed as having hepatitis A, common-source transmissions is possible but uncommon. IG should be administered to other food handlers but is usually not recommended for patrons (22). However, IG administration to patrons may be considered if all of the following conditions exist:

- a) the infected person is directly involved in handling, without gloves, foods that will not be cooked before they are eaten, and
- b) the hygienic practices of the food handler are deficient or the food handler has diarrhea, and
- c) patrons can be identified and treated within 2 weeks of exposure.

Situations in which repeated exposures may have occurred, such as in institutional cafeterias, may warrant stronger consideration of IG use.

## **HEPATITIS B**

Hepatitis B infection is caused by the hepatitis B virus (HBV), a 42-nm, double-shelled deoxyribonucleic acid (DNA) virus of the class hepadnaviridae. Several well-defined antigen-antibody systems are associated with HBV infection (Table 1). HBsAg is found on the surface of the virus and is also produced in excess amounts, circulating in blood as 22-nm spherical and tubular particles. HBsAg can be identified in serum 30-60 days after exposure to HBV and persists for variable periods. Anti-HBs develops after a resolved infection and is responsible for long-term immunity. Antibody to the core antigen (anti-HBc) develops in all HBV infections and persists indefinitely. IgM anti-HBc appears early in infection and persists for >>6 months. It is a reliable marker of acute or recent HBV infection. A third antigen, hepatitis B e antigen (HBeAg), may be detected in samples from persons with acute or chronic HBV infection. The presence of HBeAg correlates with viral replication and high infectivity. Antibody to HBeAg (anti-HBe) develops in most HBV infections and correlates with the loss of replicating virus and with lower infectivity.

TABLE 1. Hepatitis nomenclature

	<u>ABBREV.</u>	<u>TERM</u>	<u>COMMENTS</u>
Hepatitis A	HAV	Hepatitis A	Etiologic agent of "infectious" Hepatitis; a picornavirus; single serotype
	Anti-HAV	Antibody to HAV	Detectable at onset of symptoms; Lifetime persistence.
	IgM anti-HAV	IgM class antibody HAV	Indicates recent infection with hepatitis A; detectable for 4-6 months after infection.
Hepatitis B	HBV	Hepatitis B virus	Etiologic agent of "serum" hepatitis; also known as Dane particle.
	HBsAg	Hepatitis B Surface antigen	Surface antigen(s) of HBV detectable in large quantity in serum; several subtypes identified.
	HBeAg	Hepatitis B e antigen	Soluble antigen; correlates with HBV replication, high titer HBV in serum and infectivity of serum.
	HBcAg	Hepatitis B core antigen	No commercial test available.
	Anti-HBs	Antibody to HBsAg	Indicates past infection with and immunity to HBV, passive antibody from HBIG, or immune response from HB vaccine.
	Anti-HBe	Antibody to HBeAg	Presence in serum of HBsAg carrier indicates lower titer of HBV.
	Anti-HBc	Antibody to HBcAg	Indicates prior infection with HBV at some undefined time.
	IgM anti-HBc	IgM class antibody	Indicates recent infection with HBV; detectable for 4-6 mos. After infection.
Delta	HDV	Hepatitis D virus	Agent of delta hepatitis; can cause infection only in presence of HBV.
	HDAg	Delta antigen	Detectable in early acute delta infection
	Anti-HDV	Antibody to delta antigen	Indicates present or past infection with delta virus

TABLE 1. Hepatitis nomenclature---continued

	<u>ABBREVI.</u>	<u>TERM</u>	<u>COMMENTS</u>
Non-A, Non-B Hepatitis	PT-NANB	Parenterally transmitted	Diagnosis by exclusion. At least two candidate viruses, one of which has been proposed as hepatitis C virus; shares epidemiologic features With hepatitis B.
	ET-NANB	Enterically transmitted	Diagnosis by exclusion. Causes large epidemics in Asia, Africa, and Mexico; fecal-oral or waterborne
Immune globulins	IG	Immune globulin previously ISG, immune serum globulin, or Gamma globulin)	Contains antibodies to HAV, low-titer antibodies to HBV.
	HBIG	Hepatitis B immune globulin	Contains high-titer antibodies to HBV

The incubation period of hepatitis B is long (45-160 days; average =120), and the onset of acute disease is generally insidious. Clinical symptoms and signs include anorexia, malaise, nausea, vomiting, abdominal pain, and jaundice. Extrahepatic manifestations of disease--such as skin rashes, arthralgias, and arthritis--can also occur. The case-fatality rate for reported cases is approximately 1.4%.

A variable proportion of individuals infected with HBV will become chronically infected with the virus. The HBV carrier is central to the epidemiology of HBV transmission. A carrier is defined as a person who is either HbsAg-positive on at least two occasions (at least 6 months apart) or who is HBsAg-positive and IgM anti-HBc negative when a single serum specimen is tested. Although the degree of infectivity is best correlated with HBeAg-positivity, any person positive for HBsAg is potentially infectious. The likelihood of becoming chronically infected with HBV varies inversely with the age at which infection occurs. HBV transmitted from HBsAg-positive mothers to their newborns results in HBV carriage for up to 90% of infants. Between 25% and 50% of children infected before 5 years of age become carriers, whereas only 6%-10% of acutely infected adults become carriers.

Carriers and persons with acute infection have the highest concentrations of HBV in blood and serous fluids. A lower concentration is present in other body fluids, such as saliva and semen. Transmission occurs via percutaneous or permucosal routes, and infective blood or body fluids can be introduced at birth, through sexual contact, or by contaminated needles. Infection can also occur in settings of continuous close personal contact (such as in households or among children in institutions for the developmentally disabled), presumably via inapparent or unnoticed contact of infective secretions with skin lesions or mucosal surfaces. Transmission of infection by transfusion of blood or blood products is rare because of routine screening of blood for HBsAg and because of current donor selection procedures. Transmission of HBV from infected health-care workers to patients is uncommon but has been

documented during types of invasive procedures (e.g., oral and gynecologic surgery) (23,24). HBsAg-positive health-care workers need not be restricted from patient contact unless they have been epidemiologically associated with HBV transmission. Rather, they should be educated about the potential mechanisms of HBV transmission. Adherence to aseptic techniques minimizes the risk of transmission. HBV is not transmitted via the fecal-oral route.

Worldwide, HBV infection is a major cause of acute and chronic hepatitis, cirrhosis, and primary hepatocellular carcinoma. The frequency of HBV infection and patterns of transmission vary markedly in different parts of the world. In the United States, Western Europe, and Australia, it is a disease of low endemicity, with infection occurring primarily during adulthood and with only 0.2%-0.9% of the population being chronically infected. In contrast, HBV infection is highly endemic in China and Southeast Asia, most of Africa, most Pacific Islands, parts of the Middle East, and in the Amazon Basin. In these areas, most persons acquire infection at birth or during childhood, and 8%-15% of the population are chronically infected with HBV. In other parts of the world, HBV infection is moderately endemic, with 2%-7% of the population being HBV carriers. Prevention strategies for population in which HBV infection is highly endemic are directed at vaccinating infants with hepatitis B vaccine, usually beginning at birth, to prevent both perinatal and childhood transmission of infection (25). Recommendations for hepatitis B prophylaxis in other areas should be designed to maximize the interruption of HBV transmission in accordance with local patterns of transmission. The recommendations that follow are intended for use in the United States.

### **Hepatitis B Virus Infection in the United States**

Each year, an estimated 300,000 persons, primarily young adults, are infected with HBV. One-quarter become ill with jaundice, more than 10,000 patients require hospitalization, and an average of 250 die of fulminant disease. The United States currently contains an estimated pool of 750,000-1,000,000 infectious carriers. Approximately 25% of carriers develop chronic active hepatitis, which often progresses to cirrhosis. Furthermore, HBV carriers have a risk of developing primary liver cancer that is 12-300 times higher than that of other persons. An estimated 4,000 persons die each year from hepatitis B-related cirrhosis, and more than 800 die from hepatitis B-related liver cancer.

Serologic surveys demonstrate that, although HBV infection is uncommon among adults in the general population, it is highly prevalent in certain groups. Those at risk, based on the prevalence of serologic markers of infection, are described in Table 2. Persons born in areas of high HBV endemicity and their descendants remain at high risk of infection, as do certain populations in which HBV is highly endemic (Alaskan Natives and Pacific Islanders). Certain lifestyles (e.g. homosexual activity, intravenous drug abuse) result in early acquisition

of HBV infection and high rates of infection. Persons who have heterosexual activity with multiple partners are at significant risk of infection. Inmates of prisons have a high prevalence of HBV markers, usually because of parenteral drug abuse before or during imprisonment. Patients in custodial institutions for the developmentally disabled are also at increased risk of having HBV infection. Household contacts and sexual partners of HBV carriers are at an increased risk, as are hemodialysis patients and recipients of certain plasma-derived products that have not been inactivated (e.g., anti-hemophilic factor).

Those at occupational risk of HBV infection include medical and dental workers, related laboratory and support personnel, and public service employees who have contact with blood, as well as staff in institutions or classrooms for the mentally retarded.

### **Hepatitis B Prevention Strategies in the United States**

The incidence of reported acute hepatitis B cases increased steadily over the past decade and reached a peak in 1985 (11.50 cases/105/year), despite the introduction of hepatitis B vaccine 3 years previously. Incidence decreased modestly (18%) by 1988, but still remains higher than a decade ago. This minimal impact of hepatitis B vaccine on disease incidence is attributable to several factors. The sources of infection for most cases include intravenous drug abuse (28%), heterosexual contact with infected persons or multiple partners (22%), and homosexual activity (9%). In addition, 30% of patients with Hepatitis B deny any of the recognized risk factors for infection.

The present strategy for hepatitis B prevention is to vaccinate those individuals at high risk of infection. Most persons receiving vaccine as a result of this strategy have been persons at risk of acquiring HBV infection through occupational exposure, a group that accounts for approximately 4% of cases. The major deterrents to vaccinating the other high-risk groups include their lack of knowledge about the risk of disease and its consequences, the lack of public-sector programs, the cost of vaccine, and the inability to access most of the high-risk populations.

For vaccine to have an impact on the incidence of hepatitis B, a comprehensive strategy must be developed that will provide hepatitis B vaccination to persons before they engage in behaviors or occupations that place them at risk of infection. Universal HBsAg screening of pregnant women was recently recommended to prevent perinatal HBV transmission. The previous recommendations for selective screening failed to identify most HBsAg-positive pregnant women (27). As an alternative to high-risk-group vaccination, universal vaccination of infants and adolescents needs to be examined as a possible strategy to control the transmission of disease.

TABLE 2. Prevalence of hepatitis B serologic markers in various population groups

<u>POPULATION GROUP</u>	<u>Prevalence of serologic markers of HBV infection</u>	
	<u>HBsAg (%)</u>	<u>Any marker (%)</u>
Immigrants/refugees from areas of high HBV endemicity	13	70-85
Alaskan Natives/Pacific Islanders	5-15	40-70
Clients in institutions for the developmentally disabled	10-20	35-80
Users of illicit parenteral drugs	7	60-80
Sexually active homosexual men	6	35-80
Household contacts of HBV carriers	3-6	30-60
Patients of hemodialysis units	3-10	20-80
Health-care workers-frequent blood contact	1-2	15-30
Prisoners (male)	1-8	10-80
Staff of institutions for the developmentally disabled	1	10-25
Heterosexuals with multiple partners	0.5	5-20
Health-care workers--no or infrequent blood contact	0.3	3-10
General population (NHANES II) (*)		
Blacks	0.9	14
Whites	0.2	3

(\*) Second National Health and Nutrition Examination Survey (26).

Two types of products are available for prophylaxis against hepatitis B. Hepatitis B vaccines, first licensed in 1981, provide active immunization against HBV infection, and their use is recommended for both preexposure and postexposure prophylaxis. HBIG provides temporary, passive protection and is indicated only in certain postexposure settings.

## **HBIG**

HBIG is prepared from plasma preselected to contain a high titer of anti-HBs. In the United States, HBIG has an anti-HBs titer of  $\gg 100,000$  by radioimmunoassay (RIA). Human plasma from which HBIG is prepared is screened for antibodies to HIV; in addition, the Cohn fractionation process used to prepare this product inactivates and eliminates HIV from the final product. There is no evidence that the causative agent of AIDS (HIV) has been transmitted by HBIG (6).

## **Hepatitis B Vaccine**

Two types hepatitis B vaccines are currently licensed in the United States. Plasma-derived vaccine consists of a suspension of inactivated, alum-adsorbed, 22-nm, HBsAg particles that have been purified from human plasma by a combination of biophysical (ultracentrifugation) and biochemical procedures. Inactivation is a threefold process using 8M urea, pepsin at pH 2, and 1: ,000 formalin. These treatment steps have been shown to inactivate representatives of all classes of viruses found in human blood, including HIV (28). Plasma-derived vaccine is no longer being produced in the United States, and use is now limited to hemodialysis patients, other immunocompromised hosts, and persons with known allergy to yeast.

Currently licensed recombinant hepatitis B vaccines are produced by *Saccharomyces cerevisiae* (common baker's yeast), into which a plasmid containing the gene for the HBsAg has been inserted. Purified HBsAg is obtained by lysing the yeast cells and separating HBsAg from yeast components by biochemical and biophysical techniques. These vaccines contain more than 95% HBsAg protein. Yeast-derived protein constitutes no more than 5% of the final product.

Hepatitis B vaccines are packaged to contain 10-40 mg HBsAg protein/ml and are adsorbed with aluminum hydroxide (0.5 mg/ml). Thimerosal (1: 20,000 concentration) is added as a preservative.

The recommended series of three intramuscular doses of hepatitis B vaccine induces an adequate antibody response\* in  $\gg 90\%$  of healthy adults and in  $\gg 95\%$  of infants, children, and adolescents from birth through 19 years of age (29-31). The deltoid (arm) is the recommended site for hepatitis B vaccination of adults and children; immunogenicity of vaccine for adults is substantially lower when injections are given in the buttock (32). Larger vaccine doses (two to four times normal adult dose) or an

increased number of doses (four doses) are required to induce protective antibody in a high proportion of hemodialysis patients and may also be necessary for other immunocompromised persons (such as those on immunosuppressive drugs or with HIV infection) (33,34).

(\*) An adequate antibody response is  $\gg 10$  milliInternational Units (mIU)/ml, approximately equivalent to 10 sample ration units (SRU) by RIA or positive by enzyme immunoassay (EIA), measured 1-6 months after completion of the vaccine series.

Field trials of the vaccines licensed in the United States have shown 80%-95% efficacy in preventing infection or clinical hepatitis among susceptible persons (31,35). Protection against illness is virtually complete for persons who develop an adequate antibody response after vaccination. The duration of protection and need for booster doses are not yet fully defined. Between 30% and 50% of persons who develop adequate antibody after three doses of vaccine will lose detectable antibody within 7 years, but protection against viremic infection and clinical disease appears to persist (36-38). Immunogenicity and efficacy of the licensed vaccines for hemodialysis patients are much lower than in normal adults. Protection in this group may last only as long as adequate antibody levels persist (33).

### **Vaccine Usage**

Primary vaccination comprises three intramuscular doses of vaccine, with the second and third doses given 1 and 6 months, respectively, after the first. Adults and older children should be given a full 1.0 ml/dose, while children  $\ll 11$  years of age should usually receive half (0.5 ml) this dose. See Table 3 for complete information on age-specific dosages of currently available vaccines. An alternative schedule of four doses of vaccine given at 0, 1, 2, and 12 months has been approved for one vaccine for postexposure prophylaxis or for more rapid induction of immunity. However, there is no clear evidence that this regimen provides greater protection than the standard three-dose series. Hepatitis B vaccine should be given only in the deltoid muscle for adults and children or in the anterolateral thigh muscle for infants and neonates.

For patients undergoing hemodialysis and for other immunosuppressed patients, higher vaccine doses or increased numbers of doses are required. A special formulation

TABLE 3. Recommended doses and schedules of currently licensed HB vaccines

<u>GROUP</u>	<u>VACCINE</u>					
	Heptavax-B(*),(t)		Recombivax HB(*)		Engerix-B(*s)	
	DOSE (ug) (ml)		DOSE (ug) (ml)		DOSE (ug) (ml)	
Infants of HBV-carrier mothers	10	(0.5)	5	(0.5)	10	(0.5)
Other infants and children <<11 years	10	(0.5)	2.5	(0.25)	10	(0.5)
Children and adolescents 11-19 years	20	(1.0)	5	(0.5)	20	(1.0)
Adults >>19 year	20	(1.0)	10	(1.0)	20	(1.0)
Dialysis patients and other immunocompromised persons	40	(2.0) (*)	40	(1.0) (**)	40	(2.0) (c,tt)

(\*) Usual schedule: three doses at 0, 1, 6 months.

(t) Available only for hemodialysis and other immunocompromised patients and for persons with known allergy to yeast.

(s) Alternative schedule: four doses at 0, 1, 2, 12 months.

(c) Two 1.0-ml doses given at different sites.

(\*\*) Special formulation for dialysis patient.

(tt) Four-dose schedule recommended at 0, 1, 2, 6 months. of one vaccine is now available for such persons (Table 3).

#### Persons with

HIV infection have an impaired response to hepatitis B vaccine. The immunogenicity of higher doses of vaccine is unknown for this group, and firm recommendations on dosage cannot be made at this time (34).

Vaccine doses administered at longer intervals provide equally satisfactory protection, but optimal protection is not conferred until after the third dose. If the vaccine series is interrupted after the first dose, the second and third doses should be given separated by an interval of 3-5 months. Persons who are late for the third dose should be given this dose when convenient. Postvaccination testing is not considered necessary in either situation.

In one study, the response to vaccination by the standard schedule using one or two doses of one vaccine, followed by the remaining doses of a different vaccine, was comparable to the response to vaccination with a single vaccine. Moreover, because the immunogenicities of the available vaccines are similar, it is likely that responses in such situations will be comparable to those induced by any of the vaccines alone.

The immunogenicity of a series of three low doses (0.1 standard dose) of plasma-derived hepatitis B vaccine administered by the intradermal

route has been assessed in several studies. The largest studies of adults show lower rates of developing adequate antibody (80%-90%) and twofold to fourfold lower antibody titer than with intramuscular vaccination with recommended doses (39 and CDC unpublished data). Data on immunogenicity of low doses of recombinant vaccines given intradermally are limited. At this time, intradermal vaccination of adults using low doses of vaccine should be done only under research protocol, with appropriate informed consent and with postvaccination testing to identify persons with inadequate response that would be eligible for revaccination. Intradermal vaccination is not recommended for infants or children.

All hepatitis B vaccines are inactivated (noninfective) products, and there is no evidence of interference with other simultaneously administered vaccines.

Data are not available on the safety of hepatitis B vaccines for the developing fetus. Because the vaccines contain only noninfectious HBsAg particles, there should be no risk to the fetus. In contrast, HBV infection of a pregnant woman may result in severe disease for the mother and chronic infection of the newborn. Therefore, pregnancy or lactation should not be considered a contraindication to the use of this vaccine for persons who are otherwise eligible.

### **Vaccine storage and shipment**

Vaccine should be shipped and stored at 2 C-8 C but not frozen. Freezing destroys the potency of the vaccine.

### **Side effects and adverse reactions**

The most common side effect observed following vaccination with each of the available vaccines has been soreness at the injection site. Postvaccination surveillance for 3 years after licensure of the plasma-derived vaccine showed an association of borderline significance between Guillain-Barre syndrome and receipt of the first vaccine dose (40). The rate of this occurrence was very low (0.5/100,000 vaccinees) and was more than compensated by disease prevented by the vaccine even if Guillain-Barre syndrome is a true side effect. Such postvaccination surveillance information is not available for the recombinant hepatitis B vaccines. Early concerns about safety of plasma-derived vaccine have proven to be unfounded, particularly the concern that infectious agents such as HIV present in the donor plasma pools might contaminate the final product.

### **Effect of vaccination on carriers and immune persons**

Hepatitis B vaccine produces neither therapeutic nor adverse effects for HBV carriers (41). Vaccination of individuals who possess antibodies against HBV from a previous infection is not necessary but will not cause adverse effects. Such individuals will have a postvaccination increase in

their anti-HBs levels. Passively acquired antibody, whether acquired from HBIG or IG administration or from the transplacental route, will not interfere with active immunization (42).

### **Prevaccination serologic testing for susceptibility**

The decision to test potential vaccine recipients for prior infection is primarily a cost-effectiveness issue and should be based on whether the costs of testing balance the costs of vaccine saved by not vaccinating individuals who have already been infected. Estimation of cost-effectiveness of testing depends on three variables: the cost of vaccination, the cost of testing for susceptibility, and the expected prevalence of immune individuals in the group.

Testing in groups with the highest risk of HBV infection (HBV marker prevalence  $\gg 20\%$ , Table 2) is usually cost-effective unless testing costs are extremely high. Cost-effectiveness of screening may be marginal for groups at intermediate risk. For groups with a low expected prevalence of HBV serologic markers, such as health professionals in their training years, prevaccination testing is not cost-effective.

For routine testing, only one antibody test is necessary (either anti-HBc or anti-HBs). Anti-HBc identifies all previously infected persons, both carriers and those who are not carriers, but does not differentiate members of the two groups. Anti-HBs identifies persons previously infected, except for carriers. Neither test has a particular advantage for groups expected to have carrier rates of  $\ll 2\%$ , such as health-care workers. Anti-HBc may be preferred to avoid unnecessary vaccination of carriers for groups with higher carrier rates. If RIA is used to test for anti-HBs, a minimum of 10 sample ratio units should be used to designate immunity (2.1 is the usual designation of a positive test). If EIA is used, the positive level recommended by manufacturers is appropriate.

### **Postvaccination testing for serologic response and revaccination of nonresponders**

Hepatitis B vaccine, when given in the deltoid, produces protective antibody (anti-HBs) in  $\gg 90\%$  of healthy persons. Testing for immunity after vaccination is not recommended routinely but is advised for persons whose subsequent management depends on knowing their immune status (such as dialysis patients and staff). Testing for immunity is also advised for persons from whom a suboptimal response may be anticipated, such as those who have received vaccine in the buttock, persons  $\gg 50$  years of age, and persons known to have HIV infection. Postvaccination testing should also be considered for persons at occupational risk who may have needle-stick exposures necessitating postexposure prophylaxis. When necessary, postvaccination testing should be done between 1 and 6 months after completion of the vaccine series to provide definitive information on response to the vaccine.

Revaccination of persons who do not respond to the primary series (nonresponders) produces adequate antibody in 15%-25% after one additional dose and in 30%-50% after three additional doses when the primary vaccination has been given in the deltoid (36). For persons who did not respond to a primary vaccine series given in the buttock, data suggests that revaccination in the arm induces adequate antibody in >>75%. Revaccination with one or more additional doses should be considered for persons who fail to respond to vaccination in the deltoid and is recommended for those who have failed to respond to vaccination in the buttock.

### **Need for vaccine booster doses**

Available data show that vaccine-induced antibody levels decline steadily with time and that up to 50% of adult vaccinees who respond adequately to vaccine may have low or undetectable antibody levels by 7 years after vaccination. Nevertheless, both adults and children with declining antibody levels are still protected against hepatitis B disease. Current data also suggest excellent protection against disease for 5 years after vaccination among infants born to hepatitis B-carrier mothers. For adults and children with normal immune status, booster doses are not routinely recommended within 7 years after vaccination, nor is routine serologic testing to assess antibody levels necessary for vaccine recipients during this period. For infants born to hepatitis B-carrier mother, booster doses are not necessary within 5 years after vaccination. The possible need for booster doses after longer intervals will be assessed as additional information becomes available.

For hemodialysis patients, for 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, and booster doses should be given when antibody levels decline to <<10 mIU/ml.

### **Groups recommended for preexposure vaccination**

Persons at substantial risk of HBV infection who are demonstrated or judged likely to be susceptible should be vaccinated. They include the following:

1. Persons with occupational risk. HBV infection is a major infectious occupational hazard for health-care and public-safety workers. The risk of acquiring HBV infection from occupational exposures is dependent on the frequency of percutaneous and permucosal exposure to blood or blood products. Any health-care or public-safety worker may be at risk for HBV exposure depending on the tasks that he or she performs. If those tasks involve contact with

blood or blood-contaminated body fluids, such workers should be vaccinated. Vaccination should be considered for other workers depending on the nature of the tasks (43).

Risks among health-care professional vary during the training and working career of each individual but are often highest during the professional training period. For this reason, when possible, vaccination should be completed during training in schools of medicine, dentistry, nursing, laboratory technology, and other allied health professions before workers have their first contact with blood.

2. Clients and staff of institutions for the developmentally disabled. Susceptible clients in institutions for the developmentally disabled should be vaccinated. Staff who work closely with client should also be vaccinated. The risk in institutional environments is associated not only with blood exposure but may also be consequent to bites to bites and contact with skin lesions and other infective secretions. Susceptible clients and staff who live or work in smaller (group) residential settings with known HBV carriers should also receive hepatitis B vaccine. Clients discharged from residential institutions into community settings should be screened for HBsAg so that the community programs may take appropriate measures to prevent HBV transmission. These measures should include both environmental controls and appropriate use of vaccine.

Staff of nonresidential day-care programs (e.g., schools, sheltered workshops for the developmentally disabled) attended by known HBV carriers have a risk of HBV infection comparable to that among health-care workers and therefore should be vaccinated (44). The risk of HBV infection for clients appears to be lower than the risk for staff. Vaccination of client in day-care programs may be considered. Vaccination of classroom contacts is strongly encouraged if a classmate who is an HBV carrier behaves aggressively or has special medical problems that increase the risk of exposure to his/her blood or serous secretions.

3. Hemodialysis patients. Hepatitis B vaccination is recommended for susceptible hemodialysis patients. Although seroconversion rates and anti-HBs titers are lower than those for healthy persons, for those patients who do respond, hepatitis B vaccine will protect them from HBV infection and reduce the

necessity for frequent serologic screening (45). Some studies have shown higher seroconversion rates and antibody titers for patients with uremia who were vaccinated before they required dialysis (46). Identification of patients for vaccination early in the course of the renal disease is encouraged.

4. Sexually active homosexual men. Susceptible sexually active homosexual men should be vaccinated regardless of their age or the duration of their homosexual practices. Persons should be vaccinated as soon as possible after their homosexual activity begins. Homosexual and bisexual men known to have HIV infection should be tested for anti-HBs response after completion of the vaccine series and should be counseled accordingly.
5. Users of illicit injectable drugs. All users of illicit injectable drugs that are susceptible to HBV should be vaccinated as early as possible after their drug abuse begins.
6. Recipients of certain blood products. Patients with clotting disorders who receive clotting-factor concentrates have an increased risk of HBV infection. Vaccination is recommended for these persons, and it should be initiated at the time their specific clotting disorder is identified. Pre vaccination testing is recommended for patients who have already received multiple infusions of these products.
7. Household and sexual contacts of HBV carriers. Household contacts of HBV carriers are at high risk of HBV infection. Sexual contacts appear to be at greatest risk. When HBV carriers are identified through routine screening, screening of donated blood, diagnostic testing in hospitals, prenatal screening, screening of refugees from certain areas, or other screening programs, they should be notified of their status. All household and sexual contacts should be tested and susceptible contacts vaccinated.
8. Adoptees from countries of high HBV endemicity. Families accepting orphans or unaccompanied minors from countries of high or intermediate HBV endemicity should have the children screened for HBsAg. If the children are HBsAg-positive, family members should be vaccinated (47).

9. Other contacts of HBV carriers. Persons in casual contact with carriers in setting such as schools and offices are at minimal risk of HBV infection, and vaccine is not routinely recommended for them. At child-care centers, HBV transmission between children or between children and staff has rarely been documented. Unless special circumstances exist, such as behavior problems (biting or scratching) or medical conditions (sever skin disease) that might facilitate transmission, vaccination of contacts of carriers in child care is not indicated.
10. Populations with high endemicity of HBV infection. In certain U.S. populations, including Alaskan Natives, Pacific Islander, and refugees from HBV-endemic areas, HBV infection is highly endemic, and transmission occurs primarily during childhood. In such groups, universal hepatitis B vaccination of infants is recommended to prevent disease transmission during childhood. In addition, more extensive programs of "catch-up" childhood vaccination should be considered if resources are available.

Immigrants and refugees from areas with highly endemic HBV disease (particularly Africa and eastern Asia) should be screened for HBV markers upon resettlement in the United States. If an HBV carrier is identified, all susceptible household contacts should be vaccinated. Even if no HBV carriers are found within a family, vaccination should be considered for susceptible children <<7 years of age because of the high rate of interfamilial HBV infection that occurs among these children (48). Vaccination is recommended for all infants of women who were born in areas in which infection is highly endemic.

11. Inmates of long-term correctional facilities. The prison environment may provide a favorable setting for the transmission of HBV because of the use of illicit injectable drugs and because of male homosexual practices. Moreover, it provide an access point for vaccination of percutaneous drug abusers. Prison officials should consider undertaking screening and vaccination programs directed at inmates with histories of high-risk behaviors.
12. Sexually active heterosexual persons. Sexually active heterosexual persons with multiple sexual

partners are at increased risk of HBV infection. Risk increases with increasing numbers of sexual partners. Vaccination is recommended for persons who are diagnosed as having recently acquired other sexually transmitted disease, for prostitutes, and for persons who have a history of sexual activity with multiple partners in the previous 6 months.

13. International travelers. Vaccination should be considered for persons who plan to reside for more than 6 months in areas with high levels of endemic HBV and who will have close contact with the local population. Vaccination should also be considered for short-term travelers who are likely to have contact with blood from or sexual contact with residents of areas with high levels of endemic disease. Ideally, hepatitis B vaccination of travelers should begin at least 6 months before travel to allow for completion of the full vaccine series. Nevertheless, a partial series will offer some protection from HBV infection. The alternative four-dose schedule may provide better protection during travel if the first three doses can be delivered before travel (second and third doses given 1 and 2 months, respectively, after first).

### **Postexposure Prophylaxis for Hepatitis B**

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

Various studies have established the relative efficacies of HBIG and/or hepatitis B vaccine in different exposure situations. For an infant with perinatal exposure to an HBsAg-positive and HBeAg-positive mother, a regimen combining one dose of HBIG at birth with the hepatitis B vaccine series started soon after birth is 85%-95% effective in preventing development of the HBV carrier state (35,49-51). Regimens involving either multiple doses of HBIG alone, or the vaccine series alone, have 70%-85% efficacy (52,53).

For accidental percutaneous exposure, only regimens including HBIG and/or IG have been studied. A regimen of two doses of HBIG, one given after exposure and one a month later, is about 75% effective in preventing hepatitis B in this setting (54,55). For sexual exposure, a single dose of HBIG is 75% effective if given within 2 weeks of last sexual exposure (56). The efficacy of IG for postexposure prophylaxis is uncertain. IG

no longer has a role in postexposure prophylaxis of hepatitis B because of the availability of HBIG and the wider use of hepatitis B vaccine.

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

### **Perinatal Exposure and Recommendations**

Transmission of HBV from mother to infant during the perinatal period represents one of the most efficient modes of HBV infection and often leads to severe long-term sequelae. Infants born to HBsAg-positive and HBeAg-positive mother have a 70%-90% chance of acquiring perinatal HBV infection, and 85%-90% of infected infants will become chronic HBV carriers. Estimates are that >>25% of these carriers will die from primary hepatocellular carcinoma (PHC) or cirrhosis of the liver (57). Infants born to HBsAg-positive and HBeAg-negative mother have a lower risk of acquiring perinatal infection; however, such infants have had acute disease, and fatal fulminant hepatitis has been reported (58,59). Based on 1987 data in the United States, an estimated 18,000 births occur to HBsAg-positive women each year, resulting in approximately 4,000 infants who become chronic HBV carriers. Prenatal screening of all pregnant women identifies those who are HBsAg-positive and allows treatment of the newborns with HBIG and hepatitis B vaccine, a regimen that is 85%-95% effective in preventing the development of the HBV chronic carrier state. The following are perinatal recommendations:

1. All pregnant women should be routinely tested for HBsAg during an early prenatal visit in each pregnancy. This testing should be done at the same time that other routine prenatal screening tests are ordered. In special situations (e.g., when acute hepatitis is suspected, when a history of exposure to hepatitis has been reported, or when the mother has a particularly high-risk behavior such as intravenous drug abuse), and additional HBsAg test can be ordered later in the pregnancy. No other HBV marker tests are necessary for the purpose of maternal screening, although HBsAg-positive mother identified during screening may have HBV-related acute or chronic liver disease and should be evaluated by their physicians.
2. If a woman has not been screened prenatally or if test results are not available at the time of admission for delivery, HBsAg testing should be done at the time of admission, or as soon as possible thereafter. If the mother is identified as

HBsAg-positive >>1 month after giving birth, the infant should be tested for HBsAg. If the results are negative, the infant should be given HBIG and hepatitis B vaccine.

3. Following all initial positive tests for HBsAg, a repeat test for HBsAg should be performed on the same specimen, followed by a confirmatory test using a neutralization assay. For women in labor who did not have HBsAg testing during pregnancy and who are found to be HBsAg-positive on first testing, initiation of treatment of their infants should not be delayed by more than 24 hours for repeat or confirmatory testing.
4. Infants born to HBsAg-positive mother should receive HBIG (0.5 ml) intramuscularly once they are physiologically stable, preferably within 12 hours of birth (Table 4). Hepatitis B vaccine should be administered intramuscularly at the appropriate infant dose. The first dose should be given concurrently with HBIG but at a different site. If vaccine is not immediately available, the first dose should be given as soon as possible. Subsequent doses should be given as recommended for the specific vaccine. Testing infants for HBsAg and anti-HBs is recommended when they are 12-15 months of age to monitor the success or failure of therapy. If HBsAg is not detectable and anti-HBs is present, children can be considered protected. Testing for anti-HBc is not useful, since maternal anti-HBc can persist for >>1 year. HBIG and hepatitis B vaccination do not interfere with routine childhood vaccinations. Breast-feeding poses no risk of HBV infection for infants who have begun prophylaxis.
5. Household members and sexual partners of HBV carriers identified through prenatal screening should be tested to determine susceptibility to HBV infection, and, if susceptible, should receive hepatitis B vaccine.

TABLE 4. Hepatitis B virus postexposure recommendations

<u>EXPOSURE</u>	HBIG RECOMMENDED		Vaccine RECOMMENDED	
	<u>DOSE</u>	<u>TIMING</u>	<u>DOSE</u>	<u>TIMING</u>
Perinatal	0.5 ml IM	Within 12 hrs. of birth	0.5 ml IM(*)	Within 12 hrs. of birth
Sexual	0.06 ml/kg IM	Single dose within 14 days of last sexual contact	1.0 ml IM(*)	First dose time of HBIG treatment

(\*) For appropriate age-specific doses of each vaccine, see Table 3. The first dose can be given the same time as the HBIG dose but in a different site; subsequent doses should be given as recommended for specific vaccine.

6. Obstetric and pediatric staff should be notified directly about HBsAg-positive mother so that neonates can receive therapy without delay after birth and follow-up doses of vaccine can be given. Programs to coordinate the activities of persons providing prenatal care, hospital-based obstetrical services, and pediatric well-baby care must be established to assure proper follow-up and treatment both of infants born to HBsAg-positive mothers and of other susceptible household and sexual contacts.
7. In those populations under U.S. jurisdiction in which hepatitis B infection is highly endemic (including certain Alaskan Natives, Pacific Island group and refugees from highly endemic areas accepted for resettlement in the United States), universal vaccination of newborns with hepatitis B vaccine is the recommended strategy for hepatitis B control. HBsAg screening of mothers and use of HBIG for infants born to HBV-carrier mother may be added to routine hepatitis B vaccination when practical, but screening and HBIG alone will not adequately protect children from HBV infection in endemic areas. In such areas, hepatitis B vaccine doses should be integrated into the childhood vaccination schedule. More extensive programs of childhood hepatitis B vaccination should be considered if resources are available.

### **Acute Exposure to Blood That Contains (or Might Contain) HBsAg**

For accidental percutaneous (needle stick, laceration, or bite) or permucosal (ocular or mucous-membrane) exposure to blood, the decision to provide prophylaxis must include consideration of several factors: 1) where the source of the blood is available, b) the HBsAg status of the

source, and c) the hepatitis B vaccination and vaccine-response status of the exposed person. Such exposures usually affect persons for whom hepatitis B vaccine is recommended. For any exposure of a person not previously vaccinated, hepatitis B vaccination is recommended.

Following any such exposure, a blood sample should be obtained from the person who was the source of the exposure and should be tested for HBsAg. The hepatitis B vaccination status and anti-HBs response status (if known) of the exposed person should be reviewed. The outline below and Table 5 summarize prophylaxis for percutaneous or permucosal exposure to blood according to the HBsAg status of the source of exposure and the vaccination status and vaccine response of the exposed person.

For greatest effectiveness, passive prophylaxis with HBIG, when indicated, should be given as soon as possible after exposure (its value beyond 7 days after exposure is unclear).

1. Source of exposure HBsAg-positive

a. Exposed person has not been vaccinated or has not completed vaccination. Hepatitis B vaccination should be initiated. A single dose of HBIG (0.06 ml/kg) should be given as soon as possible after exposure and within 24 hours, if possible. The first dose of hepatitis B vaccine (Table 3) should be given intramuscularly at a separate site (deltoid for adults) and can be given simultaneously with HBIG or within 7 days of exposure. Subsequent doses should be given as recommended for the specific vaccine. If the exposed person has begun but not completed vaccination, one dose of HBIG should be given immediately, and vaccination should be completed as scheduled.

b. Exposed persons has already been vaccinated against hepatitis B, and anti-HBs response status is known.

(1) If the exposed person is known to have had adequate response in the past, the anti-HBs level should be tested unless an adequate level has been demonstrated within the last 24 months. Although current data show that vaccine-induced protection does not decrease as antibody level wanes, most experts consider the following approach to be prudent.

a) If anti-HBs level is adequate, no treatment is necessary.

b) If anti-HBs level is inadequate (\*) a booster dose of hepatitis B vaccine should be given.

(2) If the exposed persons is known not to have responded to the primary vaccine series, the exposed person should be given, either a single dose of HBIG and a dose of hepatitis B vaccine as soon as possible after exposure, or two doses of HBIG (0.06 m/kg), one given as soon as possible after exposure and the second 1 month later. The latter treatment is preferred for those who have failed to respond to at least four doses of vaccine.

(\*) An adequate antibody level is  $\gg 10$  milliInternational Units (mIU)/ml, approximately equivalent to 10 sample ratio units

(SRU) by RIA or positive by EIA.

**TABLE 5. Recommendations for hepatitis B prophylaxis following percutaneous or permucosal exposure**

	<u>Treatment Given When</u>		
	<u>Source Is:</u>	<u>Source Is:</u>	<u>Source not tested:</u>
Exposed person Unvaccinated	HBsAg-positive HBIG x 1 (*) initiate HB vaccine (t)	HBsAg-negative Initiate HB vaccine (t)	? Initiate HB vaccine (t)
Previously vaccinated Known responder	Test exposed for anti-HBs 1. If adequate (s) no treatment 2. If inadequate, HB vaccine booster dose	No treatment	No treatment
Known nonresponder	HBIG x 2 or HBIG x 1 plus 1 dose HB vaccine	No treatment	If known high risk source, may treat as if source were HBsAg-positive
Response unknown	Test exposed for anti-HBs 1. If inadequate, (s) HBIG x 1 plus HB vaccine booster dose 2. If adequate, no treatment	No treatment	Test exposed for anti-HBs  (s), HB vaccine booster dose  no treatment

(\*) HBIG dose 0.06 ml/kg IM.

(t) HB vaccine dose - see Table 3.

(s) Adequate anti-HBs is >>10 SRU by RIA or positive by EIA.

- c. Exposed person has already been vaccinated against hepatitis B, and the anti-HBs response is unknown. The exposed person should be tested for anti-HBs.
  - (1) If the exposed person has adequate antibody, no additional treatment is necessary.
  - (2) If the exposed person has inadequate antibody on testing, one dose of HBIG (0.06 ml/kg) should be given immediately and a standard booster dose of vaccine (Table 3) given at a different site.
2. Source of exposure known and HBsAg-negative
  - a. Exposed person has not been vaccinated or has not

completed vaccination. If unvaccinated, the exposed person should be given the first dose of hepatitis B vaccine within 7 days of exposure, and vaccination should be completed as recommended. If the exposed person has not completed vaccination, vaccination should be completed as scheduled.

b. Exposed person has already been vaccinated against hepatitis B. No treatment is necessary.

3. Source of exposure unknown or not available for testing

a. Exposed person has not been vaccinated or has not completed vaccination. If unvaccinated, the exposed person should be given the first dose of hepatitis B vaccine within 7 days of exposure, and vaccination completed as recommended. If the exposed person has not completed vaccination, vaccination should be completed as scheduled.

b. Exposed person has already been vaccinated against hepatitis B, and anti-HBs response status is known.

(1) If the exposed person is known to have had adequate response in the past, no treatment is necessary.

(2) If the exposed person is known not to have responded to the vaccine, prophylaxis as described earlier in section I.b.(2) under "Source of exposure HBsAg-positive" may be considered if the source of the exposure is known to be at high risk of HBV infection.

c. Exposed person has already been vaccinated against hepatitis B, and the anti-HBs response is unknown. The exposed person should be tested for anti-HBs.

(1) If the exposed person has adequate anti-HBs, no treatment is necessary.

(2) If the exposed person has inadequate anti-HBs, a standard booster dose of vaccine should be given.

## **Sexual Partners of Persons with Acute HBV Infection**

Sexual partners of HBsAg-positive persons are at increased risk of acquiring HBV infection, and HBIG has been shown to be 75% effective in preventing such infections (56). Because data are limited, the period after sexual exposure during which HBIG is effective is unknown, but extrapolation from other settings makes it unlikely that this period would exceed 14 days. Before treatment, testing of sexual partners for susceptibility is recommended if it does not delay treatment beyond 14 days after last exposure. Testing for anti-HBc is the most efficient prescreening test to use in this population.

All susceptible persons whose sexual partners have acute hepatitis B infection or whose sexual partners are discovered to be hepatitis B carriers should receive a single dose of HBIG (0.06 ml/kg) and should begin the hepatitis B vaccine series if prophylaxis can be started with 14 days of the last sexual contact, or if ongoing sexual contact with the infected person will occur. Giving the vaccine with HBIG may improve the efficacy of postexposure treatment. The vaccine has the added advantage of conferring long-lasting protection.

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

### **Household Contacts of Persons with Acute HBV Infection**

Since infants have close contact with primary care givers and they have a higher risk of becoming HBV carriers after acute HBV infection, prophylaxis of an infant <<12 months of age with HBIG (0.5 ml) and hepatitis B vaccine is indicated if the mother or primary care giver has acute HBV infection. Prophylaxis for other household contacts of persons with acute HBV infection is not indicated unless they have had identifiable blood exposure to the index patient, such as by sharing toothbrushes or razors. Such exposures should be treated similarly to sexual exposures. If the index patient becomes an HBV carrier, all household contacts should be given hepatitis B vaccine.

### **DELTA HEPATITIS**

The delta virus (also known as hepatitis D virus [HDV]) is a defective virus that may cause infection only in the presence of active HBV infection. The HDV is a 35- to 37-nm viral particle, consisting of single-stranded RNA (mw 500,000) and an internal protein antigen (delta antigen [HDAg]), coated with HBsAg as the surface protein (5). Infection may occur as either coinfection with HBV or superinfection of an HBV carrier, each of which usually causes an episode of clinical acute hepatitis. Coinfection usually resolves, whereas superinfection

frequently causes chronic HDV infection and chronic active hepatitis. Both types of infection may cause fulminant hepatitis.

HDV infection may be diagnosed by detecting HDAg in serum during early infection and by the appearance of total of IgM-specific delta antibody (anti-HDV) during or after infection. A test for detection of total anti-HDV is commercially available. Other tests (HDAg, IgM anti-HDV) are available only in researched laboratories.

Routes of transmission HDV are similar to those of HBV. In the United States, HDV infection most commonly affects persons at high risk of HBV infection, particularly parenteral drug abusers and persons with hemophilia.

Since HDV is dependent on HBV for replication, prevention of hepatitis B infection, either preexposure or postexposure, will suffice to prevent HDV infection for a person susceptible to hepatitis B. Known episodes of perinatal, sexual, or percutaneous exposure to serum or exposure to persons known to be positive for both HBV and HDV should be treated exactly as such exposures to HBV alone.

Persons who are HBsAg carriers are at risk of HDV infection, especially if they participate in activities that put them at high risk of repeated exposure to HBV (parenteral drug abuse, male homosexual activity). However, at present no products are available that might prevent HDV infection in HBsAg carriers either before or after exposure.

## **NON-A, NON-B HEPATITIS**

### Parenterally Transmitted (PT) Non-A, Non-B Hepatitis

Parenterally transmitted non-a, non-B hepatitis accounts for 20%–40% of acute viral hepatitis in the United States and has epidemiologic characteristics similar to those of hepatitis B (60). Recently, a portion of the genome of a virus thought to be responsible for PT non-A, non-B hepatitis was cloned (2). A candidate serologic assay for antibody to this virus (proposed as hepatitis C virus) has been developed. This assay appears to detect a substantial number of persons with chronic infection and is being evaluated for screening potential blood donors (3). Although PT non-A, non-B hepatitis has traditionally been considered a transfusion-associated disease, most reported cases have not been associated with blood transfusion (61–64). Groups at high risk of acquiring this disease include transfusion recipients, parenteral drug users, an dialysis patients (62,63). Health-care work that entails frequent contact with blood, personal contact with other who have had hepatitis in the past, an contact with infected persons within households have also been documented in some studies as risk factors for acquiring PT non-A, non-B hepatitis (63–65). However, the role of persons-to-person contact in disease transmission has not been well defined, and the importance of sexual activity in the transmission of this type of hepatitis is unclear.

Multiple episode of non-A, non-B hepatitis have been observed among the same individuals and may be due to different bloodborne agents. An average of 50% of patients who have acute PT non-A, non-B hepatitis infection later develop chronic hepatitis (66). Experimental studies of chimpanzees have confirmed the existence of a carrier state, which may be present in 1%-3% of the population (67,68).

The risk and consequences of perinatal transmission of PT non-A, non-B hepatitis are not well defined. Only one small study has been published in which infants born of 12 women who had acute PT non-A, non-B hepatitis during pregnancy were followed. Six infants developed transient alanine aminotransferase (ALT) elevations at 4-8 weeks of age (69).

The results have been equivocal in several studies attempting to assess the value of prophylaxis with IGs against PT non-A, non-B hepatitis (70-72). For persons with percutaneous exposure to blood from a patient with PT non-A, non-B hepatitis, it may be reasonable to administer IG (0.06 ml.kg) as soon as possible after exposure. In other circumstances, no specific recommendations can be made.

### **Enterically Transmitted (ET) Non-A, Non-B Hepatitis**

A distinct type of non-A, non-B hepatitis acquired by the fecal-oral route was first identified through investigations of large waterborne epidemics in developing countries. This ET non-A, non-B hepatitis, which has occurred in epidemics or sporadically in parts of Asia, North and West Africa, and Mexico, is serologically distinct from other known hepatitis viruses (4,73). Young to middle-aged adults are most often affected, with an unusually high mortality rate among pregnant women. The disease has been transmitted to experimental animals, and candidates viruses have been identified; however, no serologic tests have yet been developed (74).

ET non-A, non-B hepatitis has not been recognized as an endemic disease in the United States or Western Europe, and it is unknown whether the causative agent is present in these areas. Cases have been documented, however, among persons returning from travel to countries in which this disease occurs (75).

Travelers to areas having ET non-A, non-B hepatitis may be at some risk of acquiring this disease by close contact with infected persons or by consuming contaminated food or water. There is no evidence that U.S.-manufactured IG will prevent this infection. As with hepatitis A and other enteric infection, the best means of preventing ET non-A, non-B hepatitis is avoiding potentially contaminated food or water.

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References 70 through 75 may be obtained by writing to the Hepatitis Branch, Division of Viral and Rickettsial Diseases, Center for Infectious Diseases, Mailstop A33, Centers for Disease Control, Atlanta, Ga. 30333.

Biological safety cabinets are among the most effective, as well as the most commonly used, primary containment devices in laboratories working with infectious agents. Each of the three types--Class I, II, III--has performance characteristics which are described in this appendix. In addition to the design, construction, and performance standards for vertical laminar flow biological safety cabinets (Class II), the National Sanitation Foundation has also developed a list of such products which meet the reference standard. Utilization of this standard<sup>80</sup> and list should be the first step in selection and procurement of a biological safety cabinet.

Class I and II biological safety cabinets, when used in conjunction with good microbiological techniques, provide an effective partial containment system for safe manipulation of moderate and high-risk microorganisms (i.e., Biosafety Level 2 and 3 agents). Both Class I and II biological safety cabinets have comparable inward face velocities (75 linear feet per minute) and provide comparable levels of containment in protecting the laboratory worker and the immediate laboratory environment from infectious aerosols generated within the cabinet.

It is imperative that Class I and II biological safety cabinets are tested and certified in situ at the time of installation within the laboratory, at any time the BSC is moved, and at least annually thereafter. Certification at location other than the final site may attest to the performance capability of the individual cabinet or model, but does not supersede the critical certification prior to use in the laboratory.

As with any other piece of laboratory equipment, personnel must be trained in the proper use of the biological safety cabinets. Of particular note are those activities which may disrupt the inward directional airflow through the work opening of Class I and II cabinets. Repeated insertion and withdrawal of the workers' arms in and from the work chamber, opening and closing doors to the laboratory or isolation cubicle, improper placement or operation of materials or equipment within the work chamber, or brisk walking past the BSC while it is in use are demonstrated causes of the escape of aerosolized particles from within the cabinet. Strict adherence to recommended practices for the use of biological safety cabinets is as important in attaining the maximum containment capability of the equipment as is the mechanical performance of the equipment itself.

Horizontal laminar flow "clean benches" are present in a number of clinical, pharmacy, and laboratory facilities. These "clean benches" provide a high quality environment within the work chamber for manipulation of nonhazardous materials. Caution: Since the operator sits in the immediate downstream exhaust from the "clean bench", this equipment must never be used for the handling of toxic, infectious, or sensitizing materials.

The Class I biological safety cabinet is an open-fronted, negative-pressure, ventilated cabinet with a minimum inward face velocity

at the work opening of at least 75 feet per minute. The exhaust air from the cabinet is filtered by a high efficiency particulate air (HEPA) filter. This cabinet may be used in three operational modes: with a full-width open front, with an installed front closure panel not equipped with gloves, and with an installed front closure panel equipped with arm-length rubber gloves.

The Class II vertical laminar-flow biological cabinet is an open-fronted, ventilated cabinet with an average inward face velocity at the work opening of at least 75 feet per minute. This cabinet provides a HEPA-filtered, recirculated mass airflow within the work space. The exhaust air from the cabinet is also filtered by HEPA filters. Design, construction, and performance standards for Class II cabinets have been developed by and are available from the National Sanitation Foundation, Ann Arbor, Michigan.<sup>80</sup>

The Class III cabinet is a totally enclosed ventilated cabinet of gas-tight construction. Operations within the Class II cabinet are conducted through attached rubber gloves. When in use, the Class III cabinet is maintained under negative air pressure of at least 0.5 inches water gauge. Supply air is drawn into the cabinet through HEPA filters. The cabinet exhaust air is filtered by two HEPA filters, installed in series, before discharge outside of the facility. The exhaust fan for the Class III cabinet is generally separate from the exhaust fans of the facility's ventilation system.

Personnel protection provided by Class I and Class II cabinets is dependent on the inward airflow. Since the face velocities are similar, they generally provide an equivalent level of personnel protection. The use of these cabinets alone, however, is not appropriate for containment of highest-risk infectious agents because aerosols may accidentally escape through the open front.

The use of a Class II cabinet in the microbiological laboratory offer the additional capability and advantage of protecting materials contained within it from extraneous airborne contaminants. This capability is provided by the HEP-filtered, recirculated mass airflow within the work space.

The Class III cabinet provides the highest level of personnel and product protection. This protection is provided by the physical isolation of the space in which the infectious agent is maintained. When these cabinets are required, all procedures involving infectious agents are contained within them. Several Class III cabinets are there fore typically set up as an interconnected system. All equipment required by the laboratory activity, such as incubators, refrigerators, and centrifuges, must be an integral part of the cabinet system. Double-doored autoclaves and chemical dunk tanks are also attached to the cabinet system to allow supplies and equipment to be safely introduced and removed.

Personnel protection equivalent to that provided by Class III cabinets can also be obtained with a personnel suit areas and Class I or Class II cabinets. This is one in which the laboratory worker is protected from a potentially contaminated environment by a one-piece positive pressure suit ventilated by a life-support system. This area is entered through an airlock fitted with airtight doors. A chemical shower is provided to decontaminate the surfaces of the suit as the worker leaves the area. The exhaust air from the suit area is filtered by two HEPA filter units installed in series.

Source: "Biosafety in Microbiological and Biomedical Laboratories," U.W. Department of Health and Human Services, Publication No. (NIH) 88-8395, May 1988.

Item	NO LABEL		RED COLOR-CODED		
	REQUIRED	BIOHAZARD LABEL	CONTAINER		
Regulated waste container		X	or	X	
Reusable contaminated sharps.		X	or	X	
Refrigerator/freezer holding blood or other potentially infectious material (opim).		X			
Containers used for storage, transport, or shipping of blood or opim.		X	or	X	
Blood/blood products released for clinical use.	X				
Individual specimen containers of blood or opim remaining in facility.	X (1)	or	X	or	X
Specimens shipped from the primary facility to another facility.		X	or	X	
Individual containers of blood or opim placed in labeled container during storage,	X				



ITEM	EFFECTIVE DATE	60 DAYS	90 DAYS	120 DAYS
Standard	3/6/92			
Exposure Control Plan		5/5/92		
Information and Training			6/4/92	
Recordkeeping			6/4/92	
Engineering/Work Practice Controls				7/6/92
Personal Protective Equipment				7/6/92
Housekeeping				7/6/92
HB Vaccination and Post-Exposure Follow-up				7/6/92
Labels and Signs				7/6/92

(1) OSHA Instruction CPL 2.244B shall remain in effect for complain inspections until the effective dates of the requirements of 29 CFR 1910.1030.

(\*) U.S. Government Printing Office: 1992--312-410/64773