





# Infection Control Manual for Ambulatory Care Clinics

**Fourth Edition**

Texas Department of State Health Services

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Commissioner of Health

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First Edition – 1988

Second Edition – 1993

Third Edition – 2001

Fourth Edition – 2009

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# Section 1 Purpose



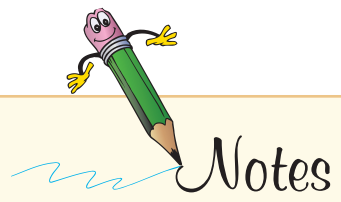


# Section 1: Purpose

## Purpose of This Manual

This infection-control manual has been established to:

1. Provide guidelines, procedures, and an exposure control plan to Department of State Health Services Central and Regional public health employees for preventing the spread of infectious diseases.
2. Serve as resource document for local health departments, contractors and healthcare providers.
3. Promote safer work practices in caring for patients.
4. Indicate what safe work practices and safe devices are recommended, when personal protective equipment is necessary, and how to manage a work-site exposure to blood or other potentially infectious material.
5. Serve as written documentation and reference for agency infection-control policies and guidelines.
6. Serve as a resource for accessing current state and federal laws and recommendations related to employee health and facility infection control.
7. Provide educational resource guidelines for staff development.
8. Assist the Texas Department of State Health Services and public health agencies throughout Texas comply with:
  - ◆ *2007 Guidelines for Isolation Precautions: Preventing Transmission of Infections Agents in Healthcare Settings*, HICPAC, CDC, United States Department of Health and Human Services;
  - ◆ Department of Labor Occupational Safety and Health Administration (OSHA), *29CFR, Part 1910.1030 Occupational Exposure to Bloodborne Pathogens Final Rule 1991*;
  - ◆ Department of Labor Occupational Safety and Health Administration (OSHA), *29CFR, Part 1910 Occupational Safety and Health Administration Occupational Exposure to Bloodborne Pathogens; Needlestick and Other Sharps Injuries Final Rule 2001*;
  - ◆ *DSHS Texas Bloodborne Pathogens Rules Chapter 96 Amended (2006)*;
  - ◆ Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC) *Guidelines for Environmental Infection Control Healthcare Facilities (2003)*;
  - ◆ Department of Health and Human Services Centers for Disease Control and Prevention *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis (2005)*;
  - ◆ Department of Health and Human Services Centers for Disease Control and Prevention *Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Healthcare Settings, 2005*; and
  - ◆ Department of Health and Human Services Centers for Disease Control, *Guidelines for disinfection and sterilization healthcare facilities (2008)*.



**Section 2**  
**Employee Policies**



# Section 2: Employee Policies

## Policy 2.1 Universal/Standard Precautions

Universal/standard precautions will be observed by considering all blood and body fluids as potentially infectious (*OSHA Standards*, Appendix C). New elements of standard precautions include Respiratory Hygiene/Cough Etiquette and Safe Injection Practices (See Appendix D). [http://www.cdc.gov/ncidod/dhqp/gl\\_isolation\\_standard.html](http://www.cdc.gov/ncidod/dhqp/gl_isolation_standard.html)

## Policy 2.2 Hand Washing

All staff must observe good personal hygiene, which includes hand washing. Staff should wash hands before and after each patient contact; before donning and after removing gloves or other personal protective equipment; before preparing and after administering medications or injections; after handling objects contaminated with blood or other potentially infectious materials; after using the toilet, blowing your nose, or covering a sneeze or cough; and before eating, drinking, or handling food.

### Policy 2.2.1 Hand-Washing Facilities

All established clinics must be equipped with hand-washing facilities which are readily accessible to employees.



**Note: Proper hand washing is the single most important means of preventing the spread of infection!**

<u>Procedure</u>	<u>Key Points</u>
1. If possible, remove jewelry from hands and wrists.	Only a minimum amount of jewelry should be worn during clinic care.
2. Wet hands under running water. Avoid touching hands to sink surfaces.	
3. Lather hands well with soap, hand antiseptic, or surface antiseptic from a dispenser. Wash fingers, in between the fingers, under the fingernails, palms, backs of hands, and wrists, for 15 seconds.	Bar soap should be used only if soap dispensers are unavailable. It has been proven that bar soap can harbor bacteria if left undrained. If bar soap is to be used, provide a self-draining soap dish. Run water over the soap briefly before replacing it in the soap dish.  Remove and clean the inside and outside of the soap dispenser when it needs to be refilled. Keep it free of soap build-up.
4. Rinse hands thoroughly.	
5. Dry hands with paper towels.	
6. Use paper towels to turn off the faucet.	

Procedure	Key Points
7. If hands are not soiled with organic debris, use an instant hand sanitizer with at least 60% alcohol.	Hand sanitizers are as effective as soap and water; however, hands should be washed after every 10 uses or as soon as possible.
8. Apply hand lotion as needed.	Frequent hand washing removes skin oil. Using a hand lotion will lubricate the skin and prevent excessive drying and chapping.

➔ **Note:** As parents change diapers on their infant(s) during clinic visits, good hand-washing practices should be reinforced at that time. Soiled diapers should be discarded in rest room waste containers.

Remember to wash hands and any other skin surface with soap and water, or flush mucous membranes with water immediately or as soon as feasible following direct contact with blood or other body substances. Report mucous membrane or non-intact skin contact with blood or other body substances to your supervisor immediately! (See Policy 2.11, “Post-Exposure Management for Occupational Exposure to Blood or Other Potentially Infectious Materials [OPIM].”)

### Policy 2.3 Use of Gloves/Barrier Precautions

Gloves shall be worn when it can be reasonably anticipated the healthcare worker may have hand contact with blood, semen, vaginal secretions, urine, feces, saliva, sputum, vomitus, or any body substance.

➔ **Note:** Throughout the manual, unless otherwise specified, the term “gloves” will refer to disposable latex examination gloves or suitable equivalent such as vinyl gloves or glove liners used underneath the latex gloves, if the employee is allergic to latex. Employees who are allergic to latex should not wear latex gloves or inhale powder from latex gloves worn by other staff.

Procedure	Key Points
1. Gloves shall be used for all procedures where exposure to blood or body substances is expected, including patient care, cleaning equipment and environmental surfaces directly contaminated with such substances, or during any “vascular access procedure.”	Disposable gloves will be made available for all staff to wear when contact with body substances is expected.  Vascular access procedures include such things as phlebotomy and finger or heel sticks.
2. It is recommended that gloves be worn on both hands.	When both hands are gloved, be careful not to contaminate equipment and surfaces while performing patient exams.
3. If cross-contamination of surfaces and equipment is anticipated, one hand should remain ungloved and not used to perform the exam.	Employees should evaluate their working situations to determine appropriate glove use.

Procedure	Key Points
4. Change gloves between patient contacts. Gloves should not be washed or disinfected for continued use. Gloves should not be reused.	Washing gloves with soap may cause “wicking” (i.e., the enhanced penetration of fluids through undetected holes in the gloves). Disinfecting agents will lead to glove deterioration.
5. If the gloves become torn or punctured, discard them and put on a new pair.	Gloves should be checked for tears and should not replace hand washing.
6. If breaks in the skin are present on the hands, additional coverings may be worn under the gloves.	Glove liners, bandages, gauze, or finger cots can help minimize hand irritations.
7. For environmental cleaning purposes, heavier reusable household gloves may be used. They can be washed with soap and water after use and hung to dry.	The light weight examination gloves do not hold up under prolonged exposure to disinfection procedures.
8. Discard the household gloves if they are cracked, peeling, torn, or punctured, or show other signs of deterioration.	

➔ **Note: The use of gloves is not intended to replace good hand-washing practices; rather, it is meant to support and supplement hand washing.**

### Key to Abbreviations Used

- Y = Yes (glove use is mandatory for the procedure)
- N = No (glove use is not required)
- O = Optional (gloves may be worn but are not required)

**Table 1: Procedures and Expected Glove Use**

Procedure	Glove Use
1. Drawing blood	Y
2. Doing finger or heel sticks	Y
3. Giving injections	O
4. Spinning blood in centrifuges	Y
5. Taking temperatures	N
6. Testing urine with dipsticks	Y
7. Doing pap smears and testing for sexually transmitted diseases	Y
8. Pelvic and/or rectal exams	Y
9. Taking blood pressure	N
10. Taking heights, weights	N
11. Doing breast exams	N
12. Changing diapers	Y
13. Doing an oral exam	Y
14. Handling/preparing lab specimens	Y
15. Doing physical exams on children	O

## Infection-Control Techniques

1. Thoroughly wash hands with soap and running water for at least 15 seconds before and after:
  - each contact with each patient,
  - handling a specimen,
  - contact with a potentially contaminated surface, or
  - use of personal protective equipment.
2. Wear personal protective equipment appropriate to the task being performed.
3. Healthcare workers who have exudative lesions/weeping dermatitis or open sores should cover wounds, if possible, and refrain from direct patient care until the condition resolves.
4. Change clothing splashed with blood or body fluids as quickly as feasible.
5. Remember that gloves will not provide protection against needle sticks or other percutaneous injuries. Gloves will, however, help to reduce the amount of blood or body substance entering into a wound, when the needle penetrates the glove.

### Policy 2.4 Use of Additional Personal Protective Equipment

Additional forms of barrier protection such as goggles, masks, and gowns are necessary if splattering of blood or other body fluids is anticipated. Patients with signs or symptoms of infectious tuberculosis disease should wear a surgical or procedure mask; and healthcare workers, visitors and others entering the room of a suspected or confirmed infectious TB disease patient should wear minimum N95 disposable respirators that are user-seal checked.

### Policy 2.5 Provision of Personal Protective Equipment

The employer shall provide, at no cost to the employee, necessary personal protective equipment and clean or replace such items as needed.



**Table 2: Examples of Personal Protective Equipment for Protection from Occupational Exposure to Blood and Body Fluids<sup>1</sup>**

Task/Activity	Disposable			Protective Eye wear
	Gloves	Gown	Mask	
Bleeding control for spurting blood	Yes	Yes	Yes	Yes
Bleeding control with minimal bleeding	Yes	No	No	No
Emergency childbirth	Yes	Yes <sup>2</sup>	Yes	Yes
Blood drawing	Yes	No	No	No
Handling and cleaning instruments with microbial contamination	Yes	Optional	Optional	Optional
Measuring blood pressure	No	No	No	No
Measuring temperature	No	No	No	No
Giving an injection	No <sup>3</sup>	No	No	No

**Policy 2.6 Safety-Engineered Sharps**

Employee will use recommended safety-engineered sharps devices.

**Policy 2.7 Sharps Containers**

Employee will immediately, or as soon as possible, dispose of contaminated sharps into appropriate containers that are placed close to work area.

**Policy 2.8 Employee Immunizations**

All employees will be in compliance with established departmental policies regarding immunizations and TB skin tests.

**Policy 2.8.1 Employer Provision of Vaccines**

- Employee policies outlined in the following documents are to be followed:
  - Appendix A, “DSHS Health Policy Statements,” “Employee Immunization” (9/04).
  - All positions in which the employee’s duties include direct contact with patients, the public, or material from patients with infections will be identified. Specific vaccinations will be incorporated into job descriptions in the “Special instructions” section of Department of State Health Services Immunization Policy OS-3408 3.

<sup>1</sup> Adapted from Centers for Disease Control Guidelines and OSHA standard, Occupational Exposure to Bloodborne Pathogens; Final Rule, December 6, 1991.

<sup>2</sup> Gowns are not needed unless soiling of clothing is likely.

<sup>3</sup> Gloves may be used at an employee’s discretion.

Procedure	Key Points
1. Employee policies outlined in the following documents are to be followed: Appendix A, "DSHS Health Policy Statements," "Employee Immunization" (9/04), and "TB Skin Testing and Management Policy" (2005).	This document outlines requirements for pre-exposure vaccinations and TB screening.
2. All positions in which the employee's duties include direct contact with patients, the public, or material from patients with infections will be identified. Specific vaccination requirements for these positions will be incorporated into the <i>Facility Bloodborne Pathogen Exposure Control Plan</i> .	Because of their direct contact with patients, the public, and material from patients with infections, healthcare workers (physicians, nurses, emergency medical personnel, dental professionals, medical and nursing students, laboratory technicians, hospital volunteers, administrative and clerical staff, hospital and clinic housekeeping staff, and others) are at increased risk for exposure to and possible transmission of TB and vaccine-preventable diseases.
3. Employee vaccination, serology, and/or infection history will be documented and reviewed to identify additional vaccinations or tests which are required.	Vaccination not only protects employees from diseases transmitted by the patients and public they serve, but also protects patients and the public from becoming infected through exposure to healthcare workers.
4. Newly hired employees will be offered required vaccines, serological tests, or TB screening within 10 days of their initial assignment.	Recommended TB screening intervals vary by risk of exposure. Periodic TB screening identifies recent converters who would benefit from preventive therapy and prevents transmissions to clients and staff.
5. Immunization records will not be inserted in personnel records, but will be maintained in separate files to preserve employee confidentiality.	Separate files for immunization records will permit easy access for evaluation as needed. Employee health files can serve this purpose.

For more information regarding employee immunizations, contact your regional immunization program manager, or the DSHS Immunization Division at 1-800-252-9152.

## Policy 2.9 Employee TB Skin Testing

DSHS will provide employees who have worksite risk of exposure to Tuberculosis (TB): Skin testing at specified intervals, appropriate user-tested masks; referral and post exposure follow-up treatment as needed.

(See TB Skin Testing and Management Policy in Appendix A.)

## Policy 2.10 Orientation of Employees

All employees with potential for occupational exposure will be oriented to infection-control guidelines within oyment, as changes occur in policies and practices concerning infection control, and annually thereafter. Documentation of training will be maintained.

### Policy 2.10.1 Employer Provision of Staff Orientation

Staff orientation shall be provided during normal working hours, at no cost to the employees.

Procedure	Key Points
1. All employees should be informed about the risks of significant infection they are exposed to in the occupational setting.	Presentation of the information should be geared to the educational level of the employee.
2. Supervisors will ensure that training sessions are provided to review these infection control guidelines with new employees at their initial assignment and annually thereafter.	General principles of infection control should be included in the discussion.
3. Employees should understand:	
a. the routes of transmission of various infectious diseases, especially those for the bloodborne diseases such as hepatitis B and C and HIV/AIDS;	Diseases to be discussed include, but are not limited to, those listed in Policy 5.1, "Identification/ Isolation of Potentially Infectious Patients." Refer to Appendix D, "Infectious Diseases Information."
b. other relevant epidemiologic aspects of occupationally acquired infectious diseases;	
c. an explanation of the department's bloodborne pathogen exposure control plan as outlined in this manual;	
d. a review of the "OSHA Bloodborne Pathogens Standard;"	Refer to Appendix C, "OSHA Standards." DSHS Bloodborne Pathogen Exposure Control Plan and chapter 96 "Texas Bloodborne Pathogen Rule."
e. the basic principles of standard precautions, and the uses and limitations of personal protective equipment;	
f. strategies to reduce occupational exposure, including the use of engineering controls and work practice controls, and safety-engineered sharps devices;	Topics such as when to use various personal protective equipment and the types of protective items appropriate to the task will be discussed.
g. how to dispose of potentially infectious waste, contaminated clothing, equipment, sharps, and other items such as gloves, etc.;	
h. the protective action to take in the event of spills or personal exposure to tissue or fluids, and the appropriate reporting measures;	
i. the department's <i>Post Exposure Prophylaxis Policy</i> for reporting and managing needlesticks and other direct exposures to blood and other potentially infectious materials;	Refer to Appendix B, "Post-Exposure Management," for a summary of these procedures and the 2005 CDC Post Exposure Prophylaxis Guidelines.
j. an explanation of the signs, labels, or color-coding regarding hazard communication.	
k. staff should be provided training in the use of safety engineered sharps devices.	

Procedure	Key Points
4. Employees at risk should be provided tuberculosis education that includes annual respiratory-protection training in the use of respiratory devices; TB disease signs and symptoms, screening, transmission, and management.	
5. Staff should be given initial orientation, annual training, and updates as needed in the content of the <i>Bloodborne Pathogen Exposure Control Plan</i> and the <i>Infection Control Manual for Ambulatory Care</i> .	
6. Staff should be given information on how to access and use Material Safety Data Sheets for the safe use of chemicals in cleaning and disinfection.	
7. Training records shall be kept to document training received.	Training records will be kept for three years from the date of the training session. These records must be made available to the employee when requested by either the employee or the supervisor.
8. Information to be recorded shall include:	
a. the date(s) of the session and a summary of the course content;	
b. the name(s) and qualifications of the person conducting the training;	
c. the names and employee numbers (e.g., Social Security numbers) of all the persons attending the training session.	
9. Training sessions must include an opportunity for discussion or a question/answer period.	While videotapes and other media may be used to present the basic information, a person qualified to answer questions on the subject matter must be present.

## Policy 2.11 Post-Exposure Management for Occupational Exposure to Blood or Other Potentially Infectious Materials (OPIM)

All accidental exposures of employees or patients to blood, blood products, secretions, or other body substances via percutaneous, parenteral, or mucosal routes shall be reported immediately, and appropriate post-exposure evaluation/treatment initiated, according to departmental policy.

### Policy 2.11.1 Employer Provision of Post-Exposure Management

The employer shall ensure that all medical evaluations, procedures, prophylaxies, and counseling are made available at no cost to the employee and at a reasonable time/place. A licensed healthcare professional will evaluate the exposure and recommend treatment and follow-up as indicated.

Procedure	Key Points
1. All employees should be aware of the risks of acquiring an infection from occupational exposure in a healthcare setting. See Policy 2.8, "Orientation of Employees."	Exposure to bloodborne pathogens is defined as parenteral (needlestick or other punctures of the skin with a used needle or other sharp item), mucous membrane (splatters/aerosols into the eyes, nose, or mouth), or direct contamination of an open wound or non-intact skin with a body substance.
2. All accidental exposures of employees to patient blood or body substances shall be reported to the employee's direct supervisor immediately.	If the direct supervisor is unavailable, the incident shall be reported to the next available supervisor or authorized person (e.g., clinic coordinator, nursing director, regional physician).
3. Regardless of the source of exposure, first aid consists of washing exposed skin site with soap and water or irrigation of exposed eyes with clean water/saline/sterile irrigant.	
4. For DSHS only, the employee or their supervisor must complete the (Accident/ Incident Report) on-line through AccessHR <a href="http://www.accesshr.hhsc.state.tx.us">http://www.accesshr.hhsc.state.tx.us</a> .	See Appendix B, "Post-Exposure Management" for examples of current forms and forms developed specifically for the purpose of documenting an occupational exposure to blood or OPIM.
a. Enter employee number and password.	
b. Click on "Health and Safety."	
c. A drop down menu will show:	
♦ "Add an Accident/Incident"	
♦ "View/Update Accident/Incident"	
♦ "Print Accident/Incident Report"	
d. Click on "Add an Accident/Incident."	
e. Click on the yellow "Add" box and complete form.	
f. Then click on the "Add" on the bottom right hand corner.	
g. The form will automatically forward to AccessHR service center for handling.	
h. A copy will also automatically forward to the employee's supervisor and HHS risk management.	
i. If you need to exit the system prior to completion of the accident form, you may save your work and come back to complete the form at a later time. However, please complete the form as soon as possible after the accident occurs (preferably within 24 hours).	
j. If a supervisor enters an Accident/Incident report on behalf of a non-employee or an unavailable employee, they will need go through the "Manager's Center" menu to choose "Add an Accident/Incident." Then follow the procedure above.	

Procedure	Key Points
5. The employee's supervisor or designee is responsible for coordination of post-exposure management as specified in Appendix B.	The tasks to be coordinated in post-exposure management, include completing the risk assessment, documentation of exposure in AccessHR if the employee has not done so, collecting serological information on the employee and the source (if available), HIV-related counseling, referral to an evaluating healthcare professional as needed, and the providing of appropriate post-exposure prophylaxis within one hour of the incident pending the results of serologic follow-up.
6. Document the route(s) of exposure and the circumstances under which the exposure incident occurred on the AccessHR Accident/ Incident form (On-line at AccessHR); Employee Exposure Assessment form (Appendix B); Checklist for Management of Bloodborne Pathogen (BBP) Exposures (Appendix B); and Bloodborne Pathogens Testing Consent/ Declination form (Appendix B). Also see the information sheet titled "Workers Compensation Accident Reporting for all HHS Agencies" except State Schools and State Hospitals (Appendix B).	This information will be important in risk assessment and management of the exposure incident.
7. If post-exposure therapy for HIV is warranted, the first dose should be administered as soon as possible (within one hour of exposure is ideal).	See Appendix B, "Post-Exposure Management."
8. Post-exposure counseling will be given within 10 calendar days of the exposure.	Check with the HIV program manager for a list of qualified counselors in the area or region.
9. When required for decisions regarding management of hepatitis B prophylaxis, employee hepatitis B surface antibody results should be available within 72 hours.	Postponing testing of the baseline serum will undermine the success of hepatitis B intervention.
10. The employee may refuse all or part of the recommended post-exposure management procedures. Document which step of the process was refused, and have this signed by both the employee and supervisor. Attach this documentation to the appropriate post-exposure form specific for bloodborne pathogens (see Appendix B).	Be certain that the employee understands that refusal to submit a baseline serum for HIV antibodies or have it tested within 10 calendar days of the exposure will result in forfeiture of his/her eligibility for HIV-related workers' compensation. Failure to complete the scheduled follow-up serologic evaluation for HIV will also result in forfeiture of eligibility for HIV-related workers' compensation.
11. The supervisor shall make available, or ensure it is made available, to the evaluating healthcare professional the following information:	The employee has the option to select an evaluating healthcare professional outside the department. The evaluating healthcare professional will review the information provided and determine what prophylaxis may be needed.
a. a copy of the "OSHA Bloodborne Pathogens Standard;"	

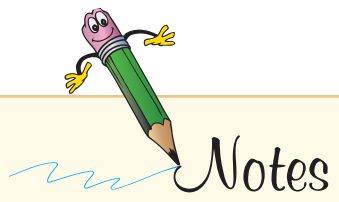
Procedure	Key Points
b. a description of the employee’s duties as they relate to the exposure incident;	
c. documentation of the route(s) of exposure and the circumstances involved;	
d. serologic test results of the source, if available; and	
e. employee health records, such as hepatitis B vaccination and/or serologic status, which may be relevant to the post-exposure treatment.	
12. Test results should remain strictly confidential and be filed in the employee’s health record.	Any test, treatment, or follow-up procedure should be documented, but serologic test results should not be put into the employee’s personnel file.
13. The employer must obtain and provide the employee with a copy of the evaluating healthcare professional’s written report within 15 days of its completion in accordance with “OSHA standard Occupational Exposure to Bloodborne Pathogens; Final Rule” (see Appendix C, “OSHA Standards”).	This report will document the need, if any, for completion of hepatitis B vaccine series, and that the employee has been advised of the evaluation’s results and any medical conditions that may arise as a consequence of exposure.
14. Employee health records will be maintained for the duration of employment plus 30 years thereafter.	

<b>Current Estimates — Risk of Becoming Infected After a Single Needlestick From a Known Positive Source</b>	
Hepatitis B:	2%–40%
Hepatitis C:	1.8%
HIV:	0.3%

Source: Gerberding, Julie, M.D., M.P.H. (Feb. 16, 1995). “Management of Occupational Exposures to Bloodborne Viruses,” *New England Journal of Medicine*;

*Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV and HIV and Recommendations for Postexposure Prophylaxis* Centers for Disease Control (CDC) *Morbidity and Mortality Weekly Report (MMWR) 50 (RR-11); 1-42 (2001, June 29)*; and

*Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposure to HIV and Recommendations for Postexposure Prophylaxis* Centers for Disease Control (CDC) *Morbidity and Mortality Weekly Report (MMWR) 54(RR09); 1-17 (2005, September 30)*





**Section 3**  
**Sterilization and**  
**Disinfection of**  
**Clinic Equipment**



# Section 3: Sterilization and Disinfection of Clinic Equipment

## Policy 3.1 Counters/Sinks/Tables/Trays

All counter tops, sinks, trays, and table tops in patient care areas must be made of impervious materials and should be cleaned routinely with a diluted chlorine-bleach solution or with a disinfectant-detergent registered by the U.S. Environmental Protection Agency (EPA). Surfaces which are likely to be contaminated with blood or body fluids will be cleaned daily, and must be cleaned and disinfected after contamination.

### Policy 3.1.1 Routine Schedule for Cleaning and Disinfection

The facility will maintain a written schedule for cleaning and disinfection, outlining the surfaces and areas to be cleaned, the cleaners or disinfectants used, and the employees involved in the process

Procedure	Key Points
1. Dilute solutions of chlorine bleach, or any disinfectant-detergent formulations labeled as registered by the EPA, can be used for cleaning environmental surfaces.	If using an EPA-registered disinfectant-detergent, follow the manufacturer's instructions for use (see note at end of Policy 3.1).  Remember that the physical removal of microorganisms by scrubbing is just as important as the anti-microbial action of the disinfectant used.
2. If chlorine bleach is to be used for routine cleaning/disinfection, a solution of bleach and water will be mixed and put in a labeled opaque spray bottle. The bleach solution must be mixed at 1:10 concentration.	A 1:10 solution can be used up to a week. See Appendix E, "Principles of Sterilization and Disinfection; Classification of Device, Processes, and Germicidal Products; and Formulas for Mixing Chlorine Bleach."
3. If using a spray disinfectant, leave the disinfectant on the surface for required length of time and then wash off and let dry according to manufacturer's directive.	When spraying wear mask and eye protection. Do not use spray when patients are present.
4. Wear gloves while cleaning.	Rinsing is very important in removing soil and chemical residue. It is especially important when using chlorine-bleach solutions, as residual chlorine can be damaging to metal surfaces.  Reusable gloves should be inspected for tears or holes before using. They should be washed with soap and water and hung to dry after use. Replace the gloves if they are cracked, peeling, torn, etc.

Procedure	Key Points
5. Maintain and consult current “Material Safety Data Sheets” on all products in order to determine appropriate precautions and to prevent hazardous conditions during product applications.	

➔ **Note:** General information on sterilization and disinfection can be found in Appendix E, “Principles of Sterilization and Disinfection.” For a current listing of chemical disinfectants and sterilants registered by the U.S. Environmental Protection Agency, contact any of the OSHA regional offices in Texas. Check the government section in your local telephone directory for the office nearest you.

## Policy 3.2 Cleaning Up Blood and/or Body Secretion Spills

Spills will be cleaned immediately or as soon as feasible, using a 1:10 chlorine-bleach solution or other appropriate EPA-registered disinfectant.

### Policy 3.2.1 Use of Chemical Germicides

Chemical germicides that are registered by the EPA as “hospital disinfectants” and are tuberculocidal are to be used to clean up spills of blood or body secretions. Those disinfectant-detergent formulations not designated as “hospital disinfectants” should be reserved for general cleaning of environmental surfaces. Follow the manufacturer’s instructions for using any EPA disinfectants. The procedures below address cleaning spills with a chlorine-bleach solution.

Procedure	Key Points
1. When using chlorine bleach, a 1:10 solution of chlorine bleach should always be available in a labeled, opaque spray bottle.	The 1:10 solution of chlorine bleach can be used for up to one week. Make sure the dispensers are labeled clearly 1:10 Chlorine-Bleach Solution 1:10. Indicate on the label the date the solution was prepared. See Appendix E, “Principles of Sterilization and Disinfection,” for bleach-solution formulas.
2. Put on household gloves.	
3. Take care not to splash the blood or body secretions into your mouth or eyes. If the circumstances are such that aerosolization may occur, a mask and goggles must be worn.	
4. Cover the spill with disposable absorbent toweling. Apply the disinfectant solution by spraying it or pouring it directly onto the covered area.	When using any disinfectant in concentrated form or in large amounts (such as with spill cleanup), always make sure the area is well ventilated.

Procedure	Key Points
5. Remove the majority of the spill with disposable absorbent toweling. Place towels in heavy-duty garbage bag, and add absorbent material as needed. Dispose of in waste receptacles marked with the BIOHAZARD label.	Heavy-duty garbage bags should be at least 1.2 mil minimum thickness. Examples of absorbent material added to the bags include additional paper towels or kitty litter. See note at the end of Policy 3.2, "Cleaning Up Blood and/or Body Secretion Spills," and see Policy 4.3, "Waste Treatment and Disposal Methods."
6. When dealing with a large spill, reapply disinfectant directly to the cleaned spill area, then remove with absorbent toweling.	Longer contact times are required when more organic matter is present.
7. Equipment used in spill cleanup (tongs, dust pans, brooms with plastic bristles), should be decontaminated with the chlorine-bleach solution, washed with soap and water, and hung to dry.	The reusable household gloves should be washed with soap and water and hung to dry after all the spill clean-up equipment has been decontaminated and washed.
8. After spill cleanup, hands should be washed with soap and water.	
9. Commercial blood spill clean-up kits are available for purchase.	

➔ **Note:** General information on sterilization and disinfection can be found in Appendix E, "Principles of Sterilization and Disinfection."

### Policy 3.3 Exam Tables/Infant Scales

All exam tables and infant scales should be cleaned daily with an appropriate disinfectant solution, and disposable coverings for exam surfaces should be used.

Procedure	Key Points
1. Table paper or absorbent pads will be changed on all exam tables and infant scales after use by each patient.	This decreases the possibility of tables becoming contaminated with secretions, excretions, and/or blood. Unless there is oil on the table, surface disinfection between patients is not necessary.
2. Table paper or absorbent pads with no visible soil or body fluids can be discarded with routine solid waste.	If the paper or absorbent pad becomes contaminated, the soiled covering must be discarded in waste containers identified with color coding or the BIOHAZARD symbol. See Policy 4.5, "Other Clinic Waste," for the specifications of these waste containers.
3. If the table or scales become soiled, remove obvious organic soil with disposable towels and follow instructions in Policy 3.2, "Cleaning Up Blood and/or Body Secretion Spills."	Wear gloves during this cleaning procedure.

Procedure	Key Points
<p>4. All exam tables and infant scales should be cleaned at the end of each day with a chlorine-bleach solution of 1:10 concentration and left on surface for 10 minutes, or use an appropriate EPA-registered low-level disinfectant-detergent for non critical medical equipment according to manufacturer's directive. Surfaces cleaned with chlorine-bleach solutions or germicidal detergents should be left on surface for appropriate length of time and then cleaned with soap and water to remove residue.</p> <p>5. Methods of Sterilization and Disinfection for the list of low-level disinfectant-detergents. See Policy 3.1 "Counters/Sinks/Tables/Trays."</p>	<p>Glutaraldehyde is a high level disinfectant and is NOT appropriate for cleaning surfaces. Hospital low-level disinfectant detergents are an acceptable substitute to chlorine-bleach solution, but are less economical as a routine cleaner. Avoid prolonged contact of metal surfaces with chlorine-bleach solution, as bleach is corrosive and may pit surface. Rinse and dry the treated surface thoroughly.</p>

### Policy 3.4 Thermometers

Mercury thermometer use is not recommended. Digital and ear thermometers must be cleaned according to manufacturer's instructions.

Procedure	Key Points
Digital and Other (Such as Ear) Thermometers	
<p>1. When using thermometers with disposable sleeves or sheaths, use a new sleeve or sheath for each patient.</p> <p>2. Follow manufacturer's instructions for cleaning.</p>	

### Policy 3.5 Devices Used in Procedures Involving Blood

All devices used in procedures involving blood shall be cleaned, disinfected, or discarded after each use, as directed below.

Procedure	Key Points
A. Automatic Lancet Devices	
<p>1. Only safety-engineered disposal lancets should be used. Contaminated lancets should be deposited in appropriate sharps containers immediately after use.</p>	Sharps containers should be placed close to work area and not overfilled.
B. Vacutainer Sleeves	

**Procedure**

- Vacutainer sleeves (blood tube holders) are to be used only one time because they are reported to have a 50-80% contamination after one use and because the health worker is put at risk of a sharps injury during removal of the contaminated needle.

**C. Other Safety-Engineered Devices**

- Plastic or mylar-wrapped capillary tubes, plastic blood tubes, and plastic slides should be used.
- Safety-engineered blood tube holders should be used.
- Safety-engineered syringes and needles should be used.
- The list of safety-engineered devices used in the facility should be updated annually in the "Bloodborne Pathogen Exposure Control Plan."

**D. Glucometers**

- Assign separate glucometers to individual patients. If a glucometer used for one patient must be reused for another patient, the device must be cleaned and disinfected between patients according to manufacturer's guidelines with an EPA-approved disinfectant.

**Key Points**

Figure 1: Blood tube holder (vacutainer sleeve)



Glucometers and other environmental surfaces should be cleaned regularly and whenever contamination with blood or body fluids occurs.

**Policy 3.6 Vaginal Specula**

Reusable specula will be cleaned and autoclaved or receive high-level disinfection as outlined, after each use. Disposable specula will be discarded after use.

**Procedure**

- Immediately after use, the reusable specula can be either put in a container of soap and water that is covered with a lid, or rinsed with warm water and put aside in the sink. The person doing this should wear gloves.
- At the end of the clinic session, disassemble the specula and scrub with soap and water, being careful not to splash. Wear reusable household gloves.
- Rinse the specula with hot water and dry with a paper towel. Reassemble the specula prior to autoclaving or disinfecting.

**Key Points**

Covered containers will help keep children's hands out of the container.

A small brush or toothbrush, only to be used for cleaning equipment, may be helpful in cleaning the specula. Clean the brush thoroughly and allow it to dry after use. Store brushes out of the reach of children.

Air-drying is also acceptable.

Procedure	Key Points
4. Use an autoclave to steam-sterilize the specula. Place the specula side by side in the autoclave chamber. Do not stack them on top of one another.	Single-layer stacking allows the steam to reach all surfaces of the specula. Follow the manufacturer's recommendations for proper loading procedures of the autoclave.
5. Place a chemical test strip in between several of the specula. After the cycle, check to see if the strip has changed color. Do not consider any materials sterile from an autoclave run if the test strips did not change color.	The strip should be placed in the most difficult area for the steam to reach. These special test strips change color when a temperature of 120°C has been maintained for at least 12 minutes. This will provide an immediate indication that high enough temperature was achieved for a minimum period of time, but it does not assure sterility. See Policy 3.11.1, "Autoclaves," for monitoring the effectiveness of the autoclave and for more information.
6. After assessing the color of the tape has changed, remove the specula and restock them in the rooms and exam tables.	After autoclaving, the specula will be sterile. Once they are removed from the autoclave, they will be clean, but not sterile.
7. High-level disinfection may be used as an alternative if the autoclave is not functioning properly, or if an autoclave is not available. Soak the specula in a 2% glutaraldehyde solution, or appropriate disinfectant in a closed container, according to the manufacturer's instructions, to achieve high-level disinfection. Rinse, dry, and restock in exam rooms.	Either autoclaving or high-level disinfection is acceptable. High-level disinfection is an alternative to sterilization when treating objects or instruments that come into contact with mucous membranes. High-level disinfection inactivates viruses, fungi, actively growing bacteria, including tubercle bacilli, but it will not inactivate bacterial endospores. Disadvantages of glutaraldehyde include respiratory irritation from the vapor, pungent and irritating odor, relatively slow mycobactericidal activity, and the chemical coagulates blood and fixes tissue to surfaces. Glutaraldehyde is not an appropriate disinfectant for cleaning surfaces such as counter tops, etc. Glutaraldehyde must be neutralized according to manufacturer's direction prior to disposal of product.
9. The minimum effective concentration (MEC) of high level disinfectants such as glutaraldehyde, must be monitored by testing the solution before each use with records kept on solution effectiveness.	
10. Change drawer lining for specula on a weekly basis.	
11. Disposable specula will be discarded into a waste container marked with the BIOHAZARD label.	These are considered as "other regulated medical waste." See Policy 4.5, "Other Clinic Waste," for more information.



### Policy 3.7 Diaphragm Fitting Rings (DFR)

Diaphragm fitting rings will be disinfected as outlined after each use.

Procedure	Key Points
1. After use, wash the rings with soap and water, then dry. Wear gloves.	The employee will wear gloves and goggles to prevent contact with body fluids and disinfectant solution.
2. Immerse rings in currently recommended percentage glutaraldehyde solution, or other high-level disinfectant according to manufacturer's instructions, to achieve high-level disinfection. Disinfect the rings in a closed container. Wear gloves and goggles when working with glutaraldehyde. Rinse diaphragm rings according to manufacturer's directions after removal from high level disinfectant.	A 2% glutaraldehyde solution is an acceptable high-level disinfectant. Followers manufacturer's direction for checking solution effectiveness before each use.

### Policy 3.8 TB Sputum-Collection Equipment

All sputum-collection equipment will be disinfected as outlined after each use.

Procedure	Key Points
1. Self-collected sputum specimen outside the building will not require use of equipment other than sputum specimen collection cup and mask for healthcare provider (See policy 5.2 for information on the use of gloves, masks, and safe collection of sputum specimen in the absence of Airborne Infection Isolation (AI) environmental controls.)	Refer to Appendix E, "Methods of Sterilization and Disinfection," for more information.
2. Medical instruments and equipment that do not touch the patient or touch only the in-tact skin of patients who have TB disease are not usually involved in transmission of <i>M. tuberculosis</i> .	
3. Tuberculocidal is not required for low-level disinfectants used to clean or disinfect minimally soiled non critical items and environmental surfaces such as floors, walls, and other surfaces in a TB/healthcare clinic.	

## Policy 3.9 Otoscope/Ophthalmoscope:


The plastic attachments are to be cleaned and disinfected as outlined after each use.

Procedure	Key Points
1. After the piece is removed from the instrument, clean off visible organic matter with a cotton swab. Wash the piece with soap and water, and dry it.	Certain substances, such as pus and blood, neutralize the disinfectant. Soap and water assure emulsification and dispersion of these substances. Drying assures there is no dilution of the disinfectant from water left on the pieces.
2. Place the cleaned piece(s) in 70% alcohol for 10 minutes.	Either ethanol or isopropyl alcohol is acceptable for use as a disinfectant, but check to make sure that the plastic materials are compatible with alcohol.
3. Remove the pieces from the alcohol, rinse well with water, dry, and store in a dry container.	
4. If there is not time to soak the piece(s) between patients, the pieces can be cleaned by first washing with soap and water, then taking an alcohol prep or an alcohol-soaked cotton ball and wiping the piece thoroughly, then rinsing with water and drying. Then, at the end of each day, complete steps 1–3.	See Policy 6.3, “Cotton Balls.”
5. Disposable specula are preferred for ear and nose exams and as single-use items should be discarded after completing each patient’s exam.	These may be discarded as routine clinic waste, provided that there is no visible blood present on the specula. If blood is present, these should be discarded into a waste receptacle marked with the BIOHAZARD label.

## Policy 3.10 Blood-Pressure Equipment

Stethoscope earpieces should be cleaned after each use unless only one person is using the stethoscope. Blood-pressure cuffs should be kept clean and free from obvious debris.

Procedure	Key Points
1. Earpieces on stethoscopes should be cleaned by using cotton soaked with 70% alcohol or an alcohol swab each time a different person uses the stethoscope. See Policy 6.3, “Cotton Balls.”	Ideally, the earpieces should be washed with soap and water first to remove obvious debris. This may not be practical in most situations. An alternative procedure would be to use a cotton swab to remove visible organic material and follow with alcohol.
2. The bell of the stethoscope should be wiped with 70% alcohol or an alcohol swab after use with each patient.	
3. Wash the blood-pressure cuffs when they appear to be dirty or when they become soiled with a body substance.	How often they are washed depends on how much they are used.

Procedure	Key Points
4. Blood-pressure cuffs may be washed in regular laundry detergent after first removing the bladder. The cuffs can be soaked in a sink with detergent and washed by hand, or they can be washed in a machine.	<p data-bbox="922 233 1484 264">Figure 2: Blood pressure cuff and stethoscope.</p> 

## Policy 3.11 Autoclave Operation

Clinic autoclaves will be operated and maintained according to manufacturer's instructions to assure proper function.

### Policy 3.11.1 Autoclaves

Clinic autoclaves will be monitored periodically to determine that they are functioning properly (i.e., achieving sterile conditions).

Procedure	Key Points
<ol style="list-style-type: none"> <li>1. Make sure that the autoclave is loaded according to the following guidelines:               <ol style="list-style-type: none"> <li>a. Do not overload or crowd items into the chamber.</li> <li>b. Do not allow material to come into contact with the sides or the door of the chamber.</li> <li>c. Separate items or arrange them loosely in the chamber.</li> <li>d. When wrapped and non-wrapped items are loaded together, autoclave them using the run time and temperature guidelines for wrapped items.</li> </ol> </li> </ol>	<p data-bbox="922 894 1484 957">This will ensure that steam reaches all materials adequately during the run.</p>
<ol style="list-style-type: none"> <li>2. Do not use an autoclave that is not working properly. Make alternate arrangements for sterilizing materials while the equipment is being repaired.</li> </ol>	
<ol style="list-style-type: none"> <li>3. Follow the manufacturer's instructions regarding care and maintenance of the autoclave.</li> </ol>	<p data-bbox="922 1451 1484 1482">Check to make sure the drain is kept clear.</p>
<ol style="list-style-type: none"> <li>4. Testing procedures for monitoring autoclave performance utilize both physical and biological parameters.</li> </ol>	<p data-bbox="922 1524 1484 1747">Use special test strips that change color when a temperature of 121°C has been maintained for at least 12 minutes. This will provide an immediate indication that a high enough temperature was achieved for a minimum period of time, but it does not assure sterility. Do not consider any materials sterile if the test strips did not change color.</p>

Procedure	Key Points
<p>a. Physical Parameters Autoclave performance will be monitored each time the equipment is used by including chemical test strips with the load. In addition, log books will be maintained to record the date, type of load, temperature achieved, and length of time at achieved temperature.</p>	
<p>b. Biological Parameters Autoclave performance will be monitored using a biological or equivalent indicator system, such as a spore test, on a quarterly basis, or more frequently, as needed. In the autoclave log, note the time and date of the run and the results of the spore test.</p>	

**Table 3: General Guidelines for Run Times and Temperatures**

Wrapped Items	Non-Wrapped Items
132°C (270°F): 10 minutes	132°C (270°F): 5 minutes
121°C (250°F): 30 minutes	121°C (250°F): 10 minutes

### Policy 3.12 Refrigerators and Freezers



Refrigerators and freezers used to store or contain blood or other potentially infectious materials (OPIM) must have a fluorescent orange or orange-red warning label including the BIOHAZARD symbol and word in a contrasting color. These refrigerators and freezers must not be used for food storage or vaccine storage.

Procedure	Key Points
<p>Refrigerators should be kept clean at all times. They can be wiped out with liquid dish soap and warm water.</p>	<p>Be sure to include refrigerator cleaning in the written schedule for routine cleaning and disinfection (housekeeping schedule).</p>
<p>Refrigerator should be kept at appropriate storage temperature.</p>	

Figure 3: BIOHAZARD symbol for refrigerators containing blood and OPIM.

### Policy 3.13 Centrifuges

Centrifuges will be given a general cleaning once a month. All centrifuges will be cleaned immediately following contamination with blood or other potentially infectious material (OPIM) (see Appendix F).

### Policy 3.13.1 Hazard Communication for Contaminated Equipment

BIOHAZARD signs or labels must be posted on contaminated equipment if the equipment cannot be decontaminated immediately.

Procedure	Key Points
1. Centrifuges will be cleaned routinely, once a month, using a chlorine-bleach solution of 1:10 concentration or an EPA-registered disinfectant.	Always unplug the centrifuge prior to cleaning. Do not immerse the unit in water. Always follow the manufacturer's recommendations for cleaning procedures.
2. Wear gloves when cleaning centrifuges.	The gloves will protect the hands from soil and chemical contact.
3. A cloth, small brush, or cotton swab may be needed to get to hard-to-reach areas inside the centrifuge. Rinse with water after using chlorine-bleach solutions.	Remember that if chlorine bleach is used, these solutions can be corrosive to metal surfaces, so rinsing becomes especially important. Cotton swabs should be discarded into clinic trash after use. The cloths and brushes should be cleaned thoroughly and allowed to dry.
4. If the centrifuge (or any piece of equipment) becomes contaminated with blood or other body fluids, clean the spill up right away.	Spills of blood or OPIM should be decontaminated first with a 1:10 solution of chlorine bleach. See Policy 3.2, "Cleaning Up Blood and/or Body-Secretion Spills."
5. If tubes of blood or OPIM leak or break during centrifuge operation, close the centrifuge, leave the room for 30 minutes, and post a warning sign on the door.	A hazardous aerosol will be created if blood or OPIM spills while the centrifuge is spinning. See Appendix F, "Clinic Laboratory Information" for centrifuge precautions.
6. If contaminated equipment cannot be disinfected and cleaned immediately after a spill, a sign or BIOHAZARD label must be posted on the equipment to alert employees that a spill has occurred.	The sign should be readily visible and should indicate which parts of the equipment are contaminated.
7. If a blood tube or hematocrit (HCT) tube breaks in the centrifuge, use long forceps to remove broken glass. Wear gloves. If a large blood spill results from a tube breaking (where blood has created a pool), soak up the blood using a disposable paper towel, then spray and clean with a 1:10 chlorine bleach solution, let the solution set 10 minutes, then rinse with water.	For disposal of paper towels used to soak up a pool of blood, see Policy 3.2, "Cleaning Up Blood and/or Body-Secretion Spills." Keep contact time to a minimum as chlorine-bleach solution is corrosive to metals. Rinse metal surfaces thoroughly. Never use your hands to manually slow down or stop the centrifuge from spinning.

### Policy 3.14 Microscopes and Other Laboratory Equipment in the Clinic

Any equipment that becomes contaminated with blood or OPIM must be decontaminated.

Procedure	Key Points
If the microscope or any piece of clinic equipment becomes contaminated, it should be cleaned/disinfected as soon as it is practical to do so.	Any cleaners or disinfectants used must be compatible with the surface to be cleaned. Follow manufacturer's instructions for cleaning microscopes and other delicate equipment.

### Policy 3.14.1 Hazard Communication for Contaminated Equipment

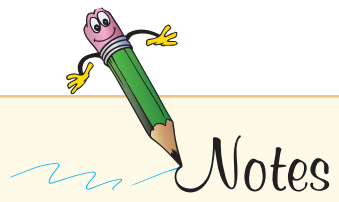
BIOHAZARD signs or labels must be posted on contaminated equipment if the equipment cannot be decontaminated immediately.

Procedure	Key Points
If the instrument cannot be readily cleaned after contamination with blood or OPIM, a BIOHAZARD sign and label must be posted on the instrument prior to cleanup.	The sign must be readily visible and must indicate which parts of the instrument are contaminated.
The BIOHAZARD sign and label must be attached to contaminated equipment that requires disassembly for the cleaning/disinfecting process or for repairs.	This is important to alert all who handle the equipment, especially off-site repair technicians, as to the nature and extent of the contamination.

### Policy 3.15 Ultraviolet Germicidal Irradiation (UVGI) Lights

UVGI lights are to be dusted weekly or, if not used often, each time before use. (See Policy 5.2, “Collection of Sputum Specimen,” Appendix A “TB Skin Testing and Management Policy,” and Appendix D “Management of Patients with Confirmed or Suspected TB”).

Procedure	Key Points
1. Turn off the UVGI light before cleaning it.	UVGI light can cause sunburn and can damage the retina.
2. Lights and UVGI bulbs should be dusted weekly with a clean dry cloth. If used infrequently, dust before use.	Dust on the bulbs interferes with proper function by reducing the amount of effective UVGI radiation.
3. UVGI lights should be turned on as specified in Policy 5.2, “Collection of Sputum Specimen.”	UVGI lights should be on when the room is occupied. The light can be turned off if the room is unoccupied for extended periods of time.
4. UVGI lights must be installed according to the manufacturer’s recommendations so the light is directed away from patients. Once installed, the UVGI tube should not be visible from any normal position in the room.	Signs should be posted near UVGI lamps: “CAUTION. Ultraviolet energy. Protect eyes and skin.”







**Section 4**  
**Disposal of Regulated  
Medical Waste**



# Section 4: Disposal of Regulated Medical Waste

## Policy 4.1 Management of Medical Waste

Medical waste generated within the facility which has a high potential risk for causing infection if improperly handled or treated will be managed in accordance with:

1. *Definition, Treatment, and Disposition of Special Waste from Healthcare Related Facilities (Regulated Medical Waste)*, 25 Texas Administrative Code (TAC) 1.131–1.137
2. OSHA standard, *Occupational Exposure to Bloodborne Pathogens*; Formal Rule, 29 CFR 1910.1030, (see Appendix C) as a good practice standard and
3. Texas Commission on Environmental Quality (TCEQ) 30 TAC Part 1 Chapter 330 Subchapter Y.

### Policy 4.1.1 Summary of Regulated Medical Waste Management Requirements

1. Sharps and other regulated medical waste shall be collected in approved containers.
2. Waste may be treated on-site or shipped off-site for treatment and disposal. Records must be maintained documenting on-site treatment, and treated waste must be labeled as such. (TAC 30 Part 1, Chapter 330, Subchapter Y) (TAC 25 Part 1, Chapter 1, Subchapter K).
3. Waste shipped off-site for disposal must be packaged properly and documentation of the shipment, treatment, and disposal must be maintained. (TAC 30 Part 1, Chapter 330, Subchapter Y) (TAC 25 Part 1, Chapter 1, Subchapter K).
4. The TCEQ rules allow for the individual transportation of medical waste of less than fifty pounds per month by personal vehicle.

### Policy 4.1.2 Definitions of Regulated Medical Waste

1. Animal Waste — includes carcasses, body parts, whole bulk blood and blood products of animals, and bedding of animals intentionally exposed to pathogens.
2. Bulk Blood and Blood Products — includes all human blood, serum, plasma, and other blood components of 100 ml or more in volume.
3. Microbiological Waste — includes cultures and stocks of infectious agents and associated biologicals; cultures of specimens from laboratories; discarded live and attenuated vaccines; disposable culture dishes; and disposable devices used to transfer, inoculate, and mix cultures.
4. Pathological Waste — includes, but is not limited to, human materials removed during surgery, labor and delivery, autopsy or biopsy, products of spontaneous or induced human abortions regardless of the period of gestation, laboratory specimens of blood and tissue after completion of laboratory examination, and anatomical remains.

5. Sharps — includes all hypodermic needles; hypodermic syringes with needles attached. When contaminated, scalpel blades; razor blades and disposable razors used in surgery, labor, and delivery, or other medical procedures; Pasteur pipettes; and broken glass from laboratories. HCT tubes and microscope slides are also managed as sharps.
6. (See other definitions TAC 25, 1.132).

## Policy 4.2 Collection of Waste

All sharps and other regulated medical wastes shall be properly collected as outlined below. All sharps will be disposed of in specially designated puncture-resistant containers as outlined below (see Appendix C, “OSHA Standards”).

➔ **Note:** Under no circumstances will hand entry into puncture-resistant containers for sharps be allowed.

Figure 1: Contaminated sharps container.



### Policy 4.2.1 Sharps Collection

Procedure	Key Points
1. Sharps containers shall be puncture-resistant, closable, leak-proof on sides and bottom, color-coded or labeled clearly with the BIOHAZARD symbol.	The BIOHAZARD label must be predominantly fluorescent orange or orange-red with letters or symbols in a contrasting color.
2. Sharps containers will be placed in clinic settings. All sharps will be placed in these containers immediately after use.	Place the containers in the areas where sharps are used. When not in use, these containers must be placed out of the reach of children.

Procedure	Key Points
3. Contaminated needles shall not be recapped, bent, sheared, broken, or separated by hand from syringes. Needles and syringes must be discarded into the sharps container as a unit.	Twisting, bending, or separating contaminated needles by hand increases the possibility of injury and occupational exposure. One-hand disposal of sharps is recommended.
4. Broken glassware shall not be picked up directly by hand. Use appropriate mechanical means.	Decontaminate and wash equipment as needed after use in picking up contaminated glass.
5. Sharps containers will be replaced when they are three-fourths full.	Sharps containers must be kept upright, replaced routinely, and not be overfilled.
6. Sharps must be placed in a marked, puncture resistant rigid container designed for sharps. If the container is not leakproof as defined in 49 Code of Federal Regulations 173.23(f), the container must be placed in a plastic bag that is marked with a BIOHAZARD symbol of color-coded.	Storage of medical waste must follow the Texas Commission on Environmental Quality, chapter 30.

 **Notes:**

- 1. Under no circumstances are children to be left unattended or unsupervised in clinic areas or in any area where sharps are used.**
- 2. For specific questions regarding special medical waste, contact the Municipal Solid Wastes and Permitting Division, Texas Commission on Environmental Quality.**
- 3. See Appendix G, "Special Waste Treatment and Disposal," for the EPA brochure, *Disposal Tips for Home Healthcare*. This brochure is available from:**  
  
**RCRA Docket (5305)**  
**U.S. Environmental Protection Agency**  
**401 M Street, S.W.**  
**Washington, D.C. 20460**  
**or phone: 1-800-424-9346 or TDD 1-800-553-7672.**

### **Policy 4.2.2 Collection of Other Regulated Medical Waste**

All regulated medical waste shall be treated and disposed of as outlined below (see Appendix C, "OSHA Standards"). Also, refer to TAC Title 25, Part 1, Subchapter K, and TAC Title 30, Part 1, Chapter 330, Subchapter Y.

Procedure	Key Points
1. All other regulated waste shall be placed in containers which are closable and constructed to contain all contents and prevent leakage of fluids during handling, storage, transport, and shipping.	Receptacles designated for special waste should be set up in the clinics, readily accessible for staff use.
2. Containers must be labeled or color-coded in accordance with paragraph (g)(1)(i) of the Bloodborne Pathogen Standard (see Appendix C, "OSHA Standards").	The BIOHAZARD label must be predominantly fluorescent orange or orange-red with letters or symbols in a contrasting color. A red bag or container may be substituted for labels.

Procedure	Key Points
3. Containers must be closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.	
4. If outside contamination of the regulated waste container occurs, it shall be placed in a second container which meets the same specifications as the first.	Wear gloves and use mechanical devices as necessary to prevent contaminating or injuring the hands.
5. Clinical personnel, not janitorial staff, shall manage the proper disposal of sharps and other regulated medical waste.	Janitorial staff should be trained to recognize medical waste containers and know that clinical personnel will manage the medical waste.

➔ **Note: Sharps containers and other medical waste awaiting transport must be kept in a secure location.**

### Policy 4.3 Waste Treatment and Disposal Methods

All regulated medical waste shall be treated as outlined below and in Appendix G, “Special Waste Treatment and Disposal.”

➔ **Note: Sharps containers and other regulated medical waste are required to be released only to registered transporters of untreated medical waste who provide a signed receipt for each shipment.**

**Table 4: Treatment Methods for Microbiological Waste**

Procedure	Key Points
1. Steam Sterilization	BIOHAZARD bags may be used for both steam sterilization and chemical disinfection. They should be placed in a regular black trash bag prior to being placed in the trash.
a. Autoclave containers for at least 30 minutes at 121°C at 15 psi.	
b. Label the containers “Treated — Steam-Sterilized.”	
2. Chemical Disinfection	
a. Treat the waste with a 1:10 dilution of chlorine bleach for a minimum of three minutes.	Note: Discarded live and attenuated vaccines and other biologicals, if unacceptable for exchange, are considered microbiological waste. Unopened vials of vaccine need to be returned to the DSHS Pharmacy. Check with the pharmacy on specifics regarding return and exchange of vaccines and biologicals. The pharmacy can be reached at (512) 458-7500.
b. Pour the bleach solution off prior to disposal.	
c. Label waste as “Treated — Chemical.”	
d. If using another EPA-registered liquid disinfectant, follow the manufacturer’s instructions.	

\* These containers must be segregated from the regular trash and transported to the sanitary landfill without being compacted.

**Table 5: Treatment Methods for Pathological Waste**

<b>Procedure</b>	<b>Key Points</b>
1. Removing pathological waste in glass tubes or on slides	Follow the procedures for treatment and disposal of sharps.
a. Place in puncture-resistant containers for treatment.	
b. Treat using steam sterilization, chemical disinfection, or encapsulation.	
c. Follow disposal procedures for sharps.	
2. Disposing of small amounts of tissue, blood, and body fluids removed during clinical procedures	
a. Grind and flush into a sanitary sewer system.	Local sewage-discharge requirements must be met.
b. Treat using steam-sterilization or chemical disinfection. Refer to Policy 4.3, "Waste Treatment and Disposal Methods."	Incineration and thermal inactivation are also accepted methods of treatment.
3. Handling organs or body parts	
a. Organs or body parts must be incinerated or interred.	

**Table 6: Treatment Methods for Bulk Blood and Blood Products**

<b>Procedure</b>	<b>Key Points</b>
1. Blood or Blood Products	
a. Discharge to sanitary sewer. Blood and blood products can be discharged into a sanitary sewer system without prior treatment.	Local sewage-discharge requirements must be met. Check with your local wastewater officials.
b. Steam sterilization and chemical disinfection are acceptable.	Thermal inactivation and incineration are also accepted methods of treatment.
♦ Label waste as "Treated — Steam-Sterilized" or "Treated — Chemical."	
♦ This waste can be sent to the sanitary landfill after treatment.	
c. Dispose of items that are saturated with blood or body fluids so that liquid flows freely or drips without compression must be treated prior to disposal in a sanitary landfill.	


## Policy 4.4 Record-Keeping Requirements

<b>Procedure</b>	<b>Key Points</b>
1. Waste Treated On-Site	
a. Records must be kept to document quantities treated on-site and the process used.	

Procedure	Key Points
<ul style="list-style-type: none"> <li>Small-quantity generators must record date of treatment, amount of waste treated, method/conditions of treatment, and the printed name and initials of the person performing the treatment.</li> </ul>	A small-quantity generator generates less than or equal to 50 pounds per calendar month.
<ul style="list-style-type: none"> <li>Large-quantity generators must record all items listed for small-quantity generators and have a written procedure for the process used, keep an account of any tests performed to monitor any equipment, as well as a description of chemicals used and their preparation.</li> </ul>	A large-quantity generator generates more than 50 pounds per calendar month.
<p>2. Waste Treated Off-Site Clinics that ship untreated special waste directly from the premises via a registered transporter must obtain a written receipt from the transporter for the shipment. These receipts must be kept on file for at least three years from the date of the shipment.</p>	Check with your waste-management company for specific details. See Appendix H, "Special Waste Treatment and Disposal."

### Policy 4.5 Non-Infectious Clinic Waste and Office Waste

Waste which is generated within the facility and which does not have a high potential for causing infection does not require special precautions concerning handling and disposal.

 **Note: Urine dipsticks and empty urine-specimen cups may be placed in the regular trash. These items do not meet the definition of special waste from healthcare related facilities or OSHA's definition of a bloodborne pathogen.**

Procedure	Key Points
1. Exam rooms, clinic areas, and laboratories should have trash cans lined with heavy-duty plastic trash bags.	Bags of 1.2 mil thickness are less likely to tear and leak. They are used to contain absorbent towels and other disposable clinic supplies stained with small amounts of blood (less than 100 ml) or other organic debris.
2. All clinic waste that has not been identified as potentially infectious under Policy 4.1.2, "Definitions of Regulated Medical Waste," should be placed into these lined trash cans.	Disposable items such as paper gowns, drape sheets, exam-table paper, applicators, swabs, tongue blades, used dressings and bandages, urine dipsticks, disposable gloves, cotton balls, hemocult cards, and disposable speculums, if contaminated with <100 ml blood or other potentially infectious materials, fall into this category.



### Procedure

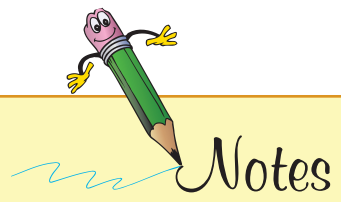
3. Clinic trash cans, when filled, should be emptied by taking the plastic-bag lining and the receptacle out with the trash as a unit. Add a new plastic bag to the trash can.
4. If the waste receptacle becomes contaminated, clean and disinfect it using a 1:10 solution of chlorine bleach.

### Key Points

Removal of non-infectious waste from clinic areas may be assigned to the janitorial staff. Make certain that both the clinic personnel and janitorial staff understand that no one is to reach directly into clinic trash receptacles with their bare hands.

This non-infectious waste may be placed with the regular trash.

This should be done as soon as possible.



**Section 5**  
**Isolation of Potentially  
Infectious Patients**



# Section 5: Isolation of Potentially Infectious Patients

## Policy 5.1 Identification/Isolation of Potentially Infectious Patients

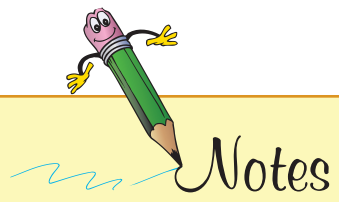
In an effort to prevent the transmission of disease, patients with a suspected or confirmed infectious disease that is transmitted by droplet spread or direct contact will be isolated from the general clinic population.

Procedure	Key Points
<p>1. All staff in the clinic should have a basic knowledge of the common communicable diseases that may be present in the clinic. Patients suspected of having the following illnesses should be isolated:</p> <ul style="list-style-type: none"><li>• Bacterial meningitis</li><li>• Chickenpox</li><li>• Diphtheria</li><li>• Gastroenteritis</li><li>• Influenza</li><li>• Measles</li><li>• Mumps</li><li>• Pertussis</li><li>• Rashes of unknown source</li><li>• Rubella</li><li>• Tuberculosis</li><li>• Upper respiratory infections (especially with fever and productive cough)</li></ul>	<p>This information should be included as part of the employee's orientation program. See Policy 2.8, "Orientation of Employees." See also Appendix D "Incubation Period and Duration of Communicability of Common Infectious Diseases" and "2007 Guidelines for Isolation Precautions: Preventing Transmission of Infections Agents in Health Care Settings."</p>
<p>2. When a patient suspected of having one of the above illnesses comes to the clinic, the nurse in charge should be notified, and the patient should be taken out of the waiting room immediately and put in an exam room or office away from other patients. Patients who are coughing are required to wear a mask.</p>	<p>It is not intended that clinic staff diagnose illness, but rather that they should be aware of indications that the patient may be infectious. It is particularly important to be aware of persons with rash-associated illness in maternity clinics. Clerical and other support staff should tell the nurse in charge if they suspect a patient is infectious.</p>
<p>3. Whenever possible, these patients should be seen immediately.</p>	
<p>4. Whenever possible, schedule clinics for immunosuppressed patients early in the day.</p>	<p>This strategy will help to minimize these patients' risk of exposure to infectious agents.</p>

## Policy 5.2 Collection of Sputum Specimen

Collection of sputum will be done in a way to minimize possible exposure of staff and patients.

Procedure	Key Points
<b>Self-Produced TB Sputum Collection</b>	
<p>1. Appropriate precautions should be taken when working with patients suspected or confirmed with TB disease. Environmental controls include technologies for the removal or inactivation of airborne <i>M. tuberculosis</i>. The technologies include local exhaust ventilation (booth), general negative-pressure room, HEPA filtration, and Ultraviolet germicidal irradiation (UVGI) as described in <i>MMWR Recommendations and Reports</i>, December 30, 2005 Department of Health and Human Services Center for Disease Control and Prevention Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Healthcare Settings, 2005. If the above listed Airborne Infection Isolation environmental controls are not available, the sputum specimen can be collected safely outside of a building, away from other persons, windows, and ventilation intakes, with the healthcare worker wearing an N-95 disposable respirator during sputum collection.</p>	<p>If used infrequently, the UVGI light must be dusted before each collection. See Policy 3.15, "UVGI Lights." UVGI lights are remarkably effective in killing airborne tubercle bacilli and serve as a supplement to ventilation in cleaning the air. Airflow in the room should be gentle enough to not cause dust dispersal. The direction of the airflow should be away from occupied areas and air intakes.</p> <p>Air cleaning technologies for Airborne Infection Isolation must be designed, installed and monitored for efficacy at specified time intervals by qualified environmental specialists.</p>
<p>2. Be sure to give the patient full instructions or any necessary information on collecting the specimen before proceeding. The patient should be in the airborne infection isolation room alone when the sputum is collected. It is important, however, to check on the patient to be sure that the sputum is being collected correctly and to see if the patient has any questions.</p>	<p>Encourage patients to come in for sputum collection in the morning, as this will increase the likelihood of obtaining a good specimen from a more productive cough.</p>
<p>3. TB patients, if not known to be sputum-negative, who are coughing in the clinic should always be given tissues and asked to cover their mouths when coughing. They should be asked to wear a surgical/procedure masks. If possible place patient in a separate room while waiting and provide clinic services for this patient as soon as possible.</p>	<p>Do not schedule a TB clinic prior to or simultaneously with clinics for immunocompromised patients.</p> <p>The Texas Department of State Health Services Communicable Disease Control Group is reviewing information on the efficacy of masks and particulate respirators. Check with the regional TB program manager for current recommendations.</p>







**Section 6**

**Storage and Handling of  
Equipment, Supplies, and  
Biological Specimens**



# Section 6: Storage and Handling of Equipment, Supplies, and Biological Specimens

## Policy 6.1 Equipment and Supplies

All equipment and supplies, including those in boxes, will be stored in properly designated storage areas.

## Policy 6.2 Sterile Equipment

All expiration dates on sterile equipment will be checked on a defined schedule with documentation of checking.

For DSHS clinics only: Outdated equipment and supplies will be returned to regional headquarters for exchange.

## Policy 6.3 Cotton Balls

Cotton balls will not be stored in alcohol unless they are to be used that day. Commercially packaged alcohol sponges may be used but are more costly.

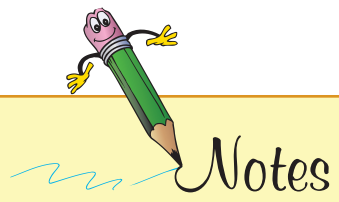
Procedure	Key Points
1. Unpack supplies when received and place them on shelves or in cabinets immediately.	As an aid to rotating stock supplies, place the new supplies towards the back of the shelf and move the older supplies towards the front.
2. Keep supplies off the floor to avoid contamination from soil and bacteria.	
3. Cotton balls are to be soaked with 70% alcohol at the time they are used. Only a one-day supply should be put into a container and moistened with alcohol. Discard the leftover ones at the end of the day.	Unless the solution is changed daily, the alcohol begins to lose its effectiveness. Alcohol is the most convenient chemical germicide for use in this situation, but other germicides may be used, provided they are chemically compatible with the surface to be wiped and are not too irritating to the skin.

## Policy 6.4 Specimen Storage, Handling, and Transport

Laboratory specimens of blood or other potentially infectious materials (OPIM) shall be handled in accordance with the provisions of the OSHA *Bloodborne Pathogens* standard (see Appendix C, “OSHA Standards”).

Procedure	Key Points
1. Specimens of blood or OPIM must be placed in containers which prevent leakage during collection, handling, storage, processing, or transport.	Triple containers, required by postal regulations, are supplied by the DSHS Laboratory Services Section. All containers must be closed tightly prior to shipping the specimens.
2. Be sure to add enough absorbent material to absorb the entire contents of the primary container in case of breakage or leakage.	See Appendix F, "Guidelines for Submission of Laboratory Specimens" for packing instructions.
3. The outer container used for storing or shipping specimens must be color-coded or labeled with the BIOHAZARD symbol and word.	The OSHA Bloodborne Pathogens standard states that the BIOHAZARD label is to be affixed to all containers of specimens leaving the facility for testing. The BIOHAZARD label is not placed on outer containers sent through U.S. mail. Postal regulations have priority over OSHA regulations in this case. Contact other carriers for their specific protocols.
4. All procedures involving blood or OPIM must be performed in such a manner as to minimize splashing, spraying, spattering, and the creation of aerosols of these materials.	
5. Mouth pipetting/suctioning of blood or OPIM is prohibited.	
6. Specimens must also be in leakproof containers separate from vaccines or other biologicals during storage in the refrigerator. The containers should be disinfected at least once a week with a 1:10 solution of chlorine bleach or other EPA-registered hospital disinfectant.	Clinical staff not housekeeping staff, will disinfect the leak proof containers weekly, and document disinfection.

➔ **Note:** General information on sterilization and disinfection can be found in Appendix E, "Principles of Sterilization and Disinfection." For a current listing of chemical disinfectants and sterilants registered by the U.S. Environmental Protection Agency, contact any of the OSHA regional offices in Texas. Check the government section in your telephone directory for the office nearest you.





**Section 7**  
**Miscellaneous Activities**  
**in Clinic Settings**





# Section 7: Miscellaneous Activities in Clinic Settings

## Policy 7.1 Laundry

Clinic smocks, laboratory coats, or other reusable personal protective equipment made of cloth will be cleaned and repaired at no cost to the employee.

Procedure	Key Points
1. Reusable personal protective equipment made of cloth will be laundered and repaired, as needed, at no cost to the employee.	
2. Employees must remove their clinic coats or smocks before leaving the clinic or lab area.	Employees cannot take clinic coats or smocks home to be cleaned.
3. A container that is labeled with the BIOHAZARD symbol and word, or color-coded, must be available to collect clothing contaminated with blood or OPIM.	If the contaminated clothing is wet and leakage is possible, the container must be leakproof.
4. Employees will use universal precautions when handling contaminated laundry.	Gloves and other personal protective equipment will be necessary when handling contaminated laundry.
5. If using a contract service for laundry, BIOHAZARD labeling and color-coding provisions will apply, especially if the off-site contract service does not use universal precautions.	See Appendix C, "OSHA Standards," for labeling and color-coding instructions.

## Policy 7.2 Toys

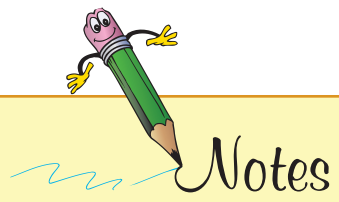
All toys provided for patients to play with will be washable and will be kept clean.

Procedure	Key Points
1. Toys should be cleaned with soap and water and dried as needed during the course of the day.	
2. At the end of each day, all toys that have been used will be washed with soap and water, rinsed, and dried.	Do not use toys that can't be washed. Be sure to include this cleaning process in the written schedule for routine cleaning and housekeeping.
3. Toys that are used in the clinics must be safe, easily maintained, and kept clean. They must be made of impervious materials.	
4. Throughout the day, make sure that clinic toys do not clutter the entrances, exits, hallways, and walkways.	Avoid toys with sharp edges, lead-based paints, beads, heavy hard balls that can be thrown, cloth toys, or toys with small removable parts.

## Policy 7.3 Food

Employee food will be stored separately from vaccines, biologicals, medications, and specimens.

Procedure	Key Points
1. Food and biologicals will not be stored in the same refrigerator. Food cannot be stored in a refrigerator along with specimens.	See Appendix C, "OSHA Standards."
2. Food shall not be eaten in the clinic or laboratory areas.	The following activities are also not permitted in the patient-treatment areas or laboratory areas: <ul style="list-style-type: none"><li>• smoking or drinking,</li><li>• applying cosmetics or lip balm, or</li><li>• handling contact lenses.</li></ul>





Appendix A  
**DSHS Health Policy  
Statements**



<b>Employee Immunizations</b>		<b>Policy Number</b>	OS-3408
		<b>Effective Date</b>	September 1, 2004
		<b>Revision Date</b>	
		<b>Subject Matter</b>	
		<b>Approval Authority</b>	Chief Operating Officer
		<b>Signed by: Randy Fritz, MPA</b>	
<b>1.0</b>	<b>Purpose</b>		
<p>Because of their direct contact with patients and the public and material from patients with infections, healthcare workers who are employees of DSHS are at increased risk for exposure to and possible transmission of vaccine-preventable diseases. It is the purpose of this policy to minimize such risks whenever possible.</p>			
<b>2.0</b>	<b>Policy</b>		
<p>All employees will have immunizations that are necessary to maintain immunity or show immunity to specific diseases. This is an essential part of prevention and infection control programs for healthcare workers. Vaccination not only protects employees from diseases transmitted by the patients and public they serve but also protects patients and the public from becoming infected through exposure to healthcare workers. Consistent immunization programs can significantly reduce the number of susceptible employees in health departments and can reduce employee absenteeism during flu season.</p>			
<b>3.0</b>	<b>Definitions</b>		
<b>3.1</b>	<p><b>Healthcare Workers</b> — Medical or non-medical, paid or volunteer, full or part-time, student or non-student, with or without patient-care responsibilities -- who work in public or private facilities that provide healthcare or services to patients. This includes physicians, nurses, pharmacists, emergency medical personnel, dental professionals, medical and nursing students, laboratory technicians, hospital volunteers, administrative and clerical staff, hospital and clinic housekeeping and maintenance staff, and others.</p>		
<b>4.0</b>	<b>Persons Affected</b>		
<ul style="list-style-type: none"> <li>• Employees who have direct contact with patients or the public</li> <li>• Employees performing tasks involving exposure to blood or blood-contaminated body fluids</li> <li>• Employees performing tasks involving exposure to soil or animals or who routinely work outdoors</li> <li>• Volunteers only if their duties involve direct healthcare of a patient or exposure to patients' blood or body substances</li> <li>• Laboratory employees</li> <li>• Unit Managers/Section Managers/Regional Administrators/Hospital Superintendents</li> </ul>			
<b>5.0</b>	<b>Responsibilities</b>		
	<b>Employee Group</b>	<b>Vaccine Requirement</b>	
<b>5.1</b>	<p>Employees who have direct contact with patients or the public, particularly employees of WIC, STD/HIV, TB, and Immunization clinics; outreach workers; inspectors; investigators; and receptionists, clerical staff, hospital and clinic housekeeping staff, and security personnel who contact with the public on a regular basis</p>	<ul style="list-style-type: none"> <li>• MMR (2 doses or evidence of immunity to measles, mumps, and rubella)</li> <li>• Varicella (2 doses, reliable history of disease, or evidence of immunity to chickenpox)</li> <li>• Influenza (1 dose annually)</li> </ul>	

5.2	Employees performing tasks involving exposure to blood or blood-contaminated body fluids, for example: nurses; physicians; lab and medical technicians; dentists and dental assistants	<ul style="list-style-type: none"> <li>• Hepatitis B (documentation of 3 doses. Unvaccinated new employees must complete a 3-dose series and post-vaccination test showing immunity. If test result is negative, up to 3 additional doses of vaccine may be required)</li> </ul>
5.3	Employees performing tasks involving exposure to soil or animals or who routinely work outdoors	<ul style="list-style-type: none"> <li>• Tetanus-diphtheria (Td) (complete series with one booster dose every 10 years)</li> </ul>
5.4	Laboratory employees	<ul style="list-style-type: none"> <li>• Follow lab policy</li> </ul>
<p>NOTE: Positions identified as having an immunization requirement may choose to undergo immune-status tests. These tests for DSHS employees are available through the DSHS Laboratory at 1100 West 49th Street, Austin, at no charge to the employee but must be coordinated through the Immunization Division (512) 458-7284. Employees with a previous history of a complete hepatitis B vaccination series do not have to be tested unless an exposure occurs.</p> <p><b>Medical Contraindications</b></p> <p>Employees who have certain medical conditions can not receive some vaccines due to the potential risk to their health. Individuals who cannot receive these vaccines and who are not already immune to the disease(s) may not be hired for positions that have an immunization requirement. Employees should consult with their physician who is most familiar with their health status regarding required vaccines and contraindications.</p>		
<p><b>All Vaccines</b></p> <p>Anyone who has had an anaphylactic reaction to a previous dose of any vaccine should never receive that vaccine again.</p> <p><b>MMR Vaccine</b></p> <ul style="list-style-type: none"> <li>• Pregnancy.</li> <li>• Known severe immunodeficiency.</li> <li>• Varicella Vaccine</li> <li>• Substantial suppression of cellular immunity.</li> <li>• Influenza Vaccine</li> <li>• Severe allergic reaction to a previous dose of vaccine including egg protein</li> </ul>		
<p><b>Opting Out of Immunizations Required Under this Policy</b></p> <p>Positions identified under this policy as having an immunization requirement may not opt out with the exception of hepatitis B vaccine. Hepatitis B vaccine guidelines are provided by OSHA and employees may decline that vaccine by signing a waiver after being fully informed of their risks. Employees selected for positions that have an immunization requirement must either show proof of their immunization history or have their immune-status tested. The Americans with Disabilities Act does not provide for reasonable accommodation in these circumstances.</p> <p>The waiver for the hepatitis B vaccine must include the following wording taken directly from OSHA standards:</p> <p>“I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.”</p>		



<b>5.5</b>	<b>Recommendation to all employees</b>
	<p>All employees should consider staying current with the following immunizations:</p> <ul style="list-style-type: none"> <li>• MMR (2 doses or evidence of immunity to measles, mumps, and rubella);</li> <li>• Varicella (2 doses, reliable history of disease, or evidence of immunity to chickenpox);</li> <li>• Td (complete series with one booster dose every 10 years);</li> <li>• Influenza (1 dose annually); and</li> <li>• Pneumococcal (1 dose for persons &gt; 65, 1 or more doses for persons at increased risk).</li> </ul>
<b>5.6</b>	<b>Unit Managers/Section Managers/Regional Administrators/Hospital Superintendents</b>
	<p><b>Will be responsible for:</b></p> <ul style="list-style-type: none"> <li>• identifying to which specific positions these requirements apply;</li> <li>• incorporating vaccine requirements into individual job descriptions;</li> <li>• screening new employees for compliance with vaccine requirements;</li> <li>• establishing a system for tracking employee immunization records within their programs and assuring ongoing compliance;</li> <li>• encouraging participation in annual employee immunization clinics held across the state; and ensuring that the following statement is included in each job description: "Compliance with DSHS Immunization Policy required-serologic evidence of immunity to, or documented evidence of vaccination against, measles, mumps, rubella, varicella (chickenpox), and annual vaccination against influenza."</li> </ul>
<b>5.7</b>	<b>Facilities/Laboratories</b>
	<p>Facilities that maintain infection control staff and operate laboratories may adopt policies above and beyond these minimum standards that are specific and targeted towards protecting employees with risks not identified in this policy. Facilities that house patients must also have a policy regarding infection control among their patients. The Immunization Division will provide consultation services to facilities in order to identify the needs of specific patient groups upon request to ensure that policies and procedures are in alignment with medical recommendations.</p>
<b>6.0</b>	<b>Procedure</b>
	<p>Policy is self-explanatory and no procedures are necessary.</p>
<b>7.0</b>	<b>Issuance and Revision History</b>

<b>Date</b>	<b>Action</b>	<b>Section</b>
9/12/2004	New policy.	

## TB Skin Testing and Management Policy

**Table 7: TB Frequency Testing**

Risk Classifications for healthcare settings that serve communities with high incidence of tuberculosis (TB) and recommended frequency of screening for *Mycobacterium tuberculosis* infection among healthcare workers (HCWs)\*

Setting	Risk classification <sup>†</sup>		
	Low Risk	Medium Risk	Potential ongoing transmission <sup>§</sup>
Inpatient <200 beds	<3 TB patients/year	≥3 TB patients/year	Evidence of ongoing <i>M. tuberculosis</i> transmission, regardless of setting
Inpatient ≥200 beds	<6 TB patients/year	≥6 TB patients/year	
Outpatient; and nontraditional facility-based	<3 TB patients/year	≥3 TB patients/year	
TB treatment facilities	Settings in which <ul style="list-style-type: none"> <li>• persons who will be treated have been demonstrated to have latent TB infection (LTBI) and not TB disease</li> <li>• a system is in place to promptly detect and triage persons who have signs or symptoms of TB disease to a setting in which persons with TB disease are treated</li> <li>• no cough-inducing or aerosol-generating procedures are performed</li> </ul>	Settings in which <ul style="list-style-type: none"> <li>• persons with TB disease are encountered</li> <li>• criteria for low risk is not otherwise met</li> </ul>	
Laboratories	Laboratories in which clinical specimens that might contain <i>M. tuberculosis</i> are not manipulated	Laboratories in which clinical specimens that might contain <i>M. tuberculosis</i> are manipulated	
<b>Recommendations for Screening Frequency</b>			
Baseline two-step TST or one BAMT <sup>¶</sup>	Yes, for all HCWs upon hire	Yes, for all HCWs upon hire	Yes, for all HCWs upon hire
Serial TST or BAMT screening of HCWs	No**	Every 12 months <sup>††</sup>	As needed in the investigation of potential ongoing transmission <sup>§§</sup>
TST or BAMT for HCWs upon unprotected exposure to <i>M. tuberculosis</i>	Perform a contact investigation (i.e., administer one TST as soon as possible at the time of exposure, and, if the TST result is negative, place another TST 8–10 weeks after the end of exposure to <i>M. tuberculosis</i> ) <sup>¶¶</sup>		

**Risk Classifications for healthcare settings that serve communities with high incidence of tuberculosis (TB) and recommended frequency of screening for *Mycobacterium tuberculosis* infection among healthcare workers (HCWs)\***

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- \* Healthcare workers (HCWs) refers to all paid and unpaid persons working in healthcare settings who have the potential for exposure to *M. tuberculosis* through air space shared with persons with TB disease.
- † Settings that serve communities with a high incidence of TB disease or that treat populations at high risk (e.g., those with human immunodeficiency virus infection or other immunocompromising conditions) or that treat patients with drug-resistant TB disease might need to be classified as medium risk, even if they meet the low-risk criteria.
- § A classification of potential ongoing transmission should be applied to a specific group of HCWs or to a specific area of the healthcare setting in which evidence of ongoing transmission is apparent, if such a group or area can be identified. Otherwise, a classification of potential ongoing transmission should be applied to the entire setting. This classification should be temporary and warrants immediate investigation and corrective steps after a determination has been made that ongoing transmission has ceased. The setting should be reclassified as medium risk, and the recommended time frame for this medium risk classification is at least one year.
- ¶ All HCWs should have a baseline two-step tuberculin skin test (TST) or one blood assay for *M. tuberculosis* (BAMT) result at each new healthcare setting even if the setting is determined to be low risk. In certain settings, a choice might be made to not perform baseline TB screening or serial TB screening for HCWs who 1) will never be in contact with or have shared air space with patients who have TB disease (e.g., telephone operators who work in a separate building from patients) or 2) will never be in contact with clinical specimens that might contain *M. tuberculosis*. Establishment of a reliable baseline result can be beneficial if subsequent screening is needed after an unexpected exposure to *M. tuberculosis*.
- \*\* HCWs whose duties do not include contact with patients or TB specimens do not need to be included in the serial TB screening program.
- †† The frequency of testing for infection with *M. tuberculosis* will be determined by the risk assessment for the setting.
- §§ During an investigation of potential ongoing transmission of *M. tuberculosis*, testing for *M. tuberculosis* infection would be performed every 8–10 weeks until lapses in infection controls have been corrected and no further evidence of ongoing transmission is apparent.
- ¶¶ Procedures for contact investigations should not be confused with two-step TST, which is used for newly hired HCWs.



**Appendix B**  
**Post-Exposure**  
**Management**



<b>Occupational Exposure to Blood or Other Potentially Infectious Material</b>	Policy Number	OS-3412
	Effective Date	December 1, 2007
	Revision Date	
	Subject Matter	Infectious Disease Surveillance and Epidemiology Branch Manager
	Approval Authority	Chief Operating Officer
	Signed by: Dee Porter	

**1.0 Purpose**

The purpose of this policy is to assure that the Texas Department of State Health Services (DSHS) is in compliance with [Texas Administrative Code, Chapter 96, Bloodborne Pathogen Control \(Amended 2006\)](#), analogous to the [OSHA Bloodborne Standard, 29 CFR 1910.1030 \(1991\)](#) and the U. S. Public Health Service Department of Health and Human Services Centers for Disease Control and Prevention Recommendations (updated 2005), for the timely management of an occupational exposure to Bloodborne Pathogens or Other Potentially Infectious Materials.

<http://www.sos.state.tx.us/tac/index.shtml>

<http://www.osha.gov/SLTC/bloodborne pathogens/postexposure.html>

**2.0 Policy**

It is the policy of the Texas Department of State Health Services to provide post exposure evaluation and follow up healthcare in accordance with current [U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Post Exposure Prophylaxis](#) to all employees with occupational exposures to bloodborne pathogens or other potentially infectious materials.

**3.0 Definitions**

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

**Non-Intact Skin** - A condition in which the integrity of the skin is breached, such as with a cut, scratch, or puncture wound or exudative weeping lesions. Unapparent exposures occur when blood or body fluids make skin contact in exposed skin that is chapped, abraded, afflicted with dermatitis, or has micro-lacerations.

**Occupational Exposure** - A specific eye, mouth, or other mucous membrane, nonintact skin or parenteral contact with blood or other potentially infectious material which results from an employee performing their duties [19 CFR 1910.1030 (b)]. Those conditions that constitute a possible exposure to a Bloodborne disease include a needlestick or other penetrating puncture of the skin with a used needle or other contaminated item; or either a splash or aerosol into the eyes, nose, mouth; or any significant contamination of an open wound or other non-intact skin with blood or body fluids [25 TAC 96.101 (c) (17)].

**Other Potentially Infectious Materials** - The following human body fluids: (1) semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, amniotic fluid; saliva in dental procedures; any fluid that is visibly contaminated with blood; and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) any unfixed tissue or organ from a human (living or dead); (3) HIV-containing cell or tissue cultures, organ cultures, and HIV/ HBV/ containing culture medium or other solutions, and blood or body tissues from experimental animals infected with HIV or HBV [29 CFR 1910.1030].

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

**Non-Intact Skin** — A condition in which the integrity of the skin is breached, such as with a cut, scratch, or puncture wound or exudative weeping lesions. Unapparent exposures occur when blood or body fluids make skin contact in exposed skin that is chapped, abraded, afflicted with dermatitis, or has micro-lacerations.

#### 4.0 Persons Affected

- DSHS Executive Leadership;
- Employees at risk for bloodborne pathogen exposure:
- Physicians,
  - ◆ nursing staff,
  - ◆ WIC staff,
  - ◆ laboratory staff,
  - ◆ dentists and dental staff,
  - ◆ utility/housekeeping staff,
  - ◆ regional direct care staff,
  - ◆ maintenance workers, and
  - ◆ other auxiliary staff across the agency;
- Supervisor (or designee) of exposed employee;
- Treating Physician.

#### 5.0 Responsibilities

**DSHS Executive Leadership** — Shall require that all employee exposures to bloodborne pathogens are reported immediately to supervisor or designee; that the employee shall be referred for free risk assessment and Post Exposure Prophylaxis if needed within 1-2 hours of exposure; that the employee and source person (if permission granted) shall be tested for HIV, HCV, and HBV if status is unknown.

**Exposed Employee** — Shall immediately wash needlesticks/sharps injuries with soap and water or flush exposed nose, mouth or skin with water, or irrigate exposed eyes with water, saline, or sterile irrigant; report the exposure to his/her supervisor or designee; follow guidelines for submitting blood samples and seeking a risk assessment to a referred source of healthcare; and submit a completed Accident/Incident Report on AccessHR.

**Supervisor or Designee** — Shall ensure that exposed employee is provided first aid to the exposure site, that blood samples are collected from employee and source person and then immediately refer exposed employee to a licensed healthcare professional (physician) for risk assessment and treatment as needed.

**Physician** — Shall evaluate the exposure, order Post Exposure Prophylaxis within 1-2 hours of exposure when needed, and provide follow-up according to the U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV Recommendations for Postexposure Prophylaxis.

#### 6.0 Procedures

1. The exposed employee will wash needlestick/other sharps injury site with soap and water; or flush areas of splashes to nose, mouth or skin with water; or irrigate eye splashes with clean water, saline, or sterile eye irrigants.
2. Exposed employee shall notify supervisor or designee as soon as possible.
3. Exposed employ will seek a source of health according to referral guidelines of work site.
4. Exposed employee shall complete the (Accident/Incident Report) on AccessHR Web site (The form will automatically forward to AccessHR for processing, also copies will automatically forward to employee's supervisor and HHS Risk Management.
5. The Supervisor or designee shall ensure that first aid is applied to site of exposure as described in # 1.
6. Supervisor or designee shall immediately refer exposed employee to a healthcare provider for a confidential risk assessment and follow up according to work site guidelines:



- **Central Campus:** Contact the supervisor or designee who will refer the employee to hospital emergency department or urgent care provider. This may also be the Physician on Call or another DSHS physician.
  - **Public Health Service Regions:** Supervisor or designee will refer the employee to hospital emergency department or urgent care provider according to regional guidelines.
  - **DSHS Hospitals:** Contact Resource Person as designated by specific site.
7. A supervisor enters an Employee Accident/Incident report in AccessHR on behalf of an employee through the "Manager's Center" menu. (A copy of report will automatically be forwarded to the Director of HHS Enterprise Risk Management).
  8. The confidential medical evaluation provided to the exposed employee will include the following:
    - Ensure that initial first aid has been provided to exposure site.
    - Documentation of the route of exposure and how the exposure occurred.
    - Identification and documentation of the source individual, unless identification is infeasible or prohibited by state or local law
    - After obtaining consent, unless the law allows testing without consent, the blood of the source individual shall be tested for HIV/HBV/HCV infectivity.
    - The results of testing of the source individual shall be made available to the exposed employee with the employee informed about the applicable laws and regulations concerning disclosure of the identity and infectivity of the source individual.
    - After obtaining consent, the exposed employee's blood shall be collected for HIV/HBV/HCV testing.
    - The exposed employee's blood sample shall be preserved for at least 90 days to allow the baseline sample to be tested during this waiting period.
    - The employee will be provided a health care professional's written opinion within 15 days concerning the exposure incident.
  9. The employee shall be offered timely (within one (1) to two (2) hours) post exposure prophylaxis if needed, in accordance with the current recommendations of the U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Post Exposure Prophylaxis (September 30, 2005) and according to the U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis (June 29, 2001)..
 

[http://www.ucsf.edu/hivcntr/Clinical\\_Resources/PEPGuidelines.html](http://www.ucsf.edu/hivcntr/Clinical_Resources/PEPGuidelines.html)

<http://www.osha.gov/SLTC/bloodborne pathogens/postexposure.html>

The National HIV/AIDS Clinicians' Post-Exposure Prophylaxis Hot line 1-888-933-3413 is available for post-exposure physician consultation for conducting risk assessments.

24 hours a day – 7days a week
  10. When the exposed employee is referred to a healthcare professional outside of DSHS, the healthcare professional will be provided the following (as provided through the Employee Checklist for Management of Bloodborne Pathogen (BBP) Exposure form and the Employee Assessment form):
    - A copy of the Exposure Control Plan;
    - A description of the exposed employee's duties as they relate to the exposure incident;
    - Documentation of the route(s) of exposure and circumstances under which the exposure occurred;
    - Results of the source individual's blood tests (if available); and
    - Medical records relevant to the appropriate treatment of the employee.
  11. As mandated by OSHA (Federal Register Dec. 6, 1991 and outlined in DSHS Bloodborne Pathogen Exposure Control Plan) Healthcare professionals shall be instructed to limit their written opinions to

- Whether the hepatitis B vaccine is indicated;
  - Whether the employee has received the vaccine;
  - The evaluation following an exposure incident;
  - Whether the employee has been informed of the results of the evaluation;
  - Whether the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment (all other findings or diagnosis shall remain confidential and shall not be included in the written report); and
  - Whether the healthcare professional’s written opinion is provided to the employee within 15 days of completion of the evaluation.
12. The employee shall be given appropriate counseling concerning infection status, results and interpretations of tests, and precautions to take during the period after the exposure incident. The employee shall also be informed about what potential illnesses can develop and to seek early medical evaluation and subsequent treatment.
13. When a supervisor (or designee) enters an Employee Accident/Incident report in AccessHR on behalf of an employee he should submit a Supervisor’s Investigation of Employee Accident/Incident report of a sharps injury to the Texas Department of Insurance Division of Workers Compensation and to the State Office of Risk Management.
- In order for an employee to qualify for workers’ compensation benefits for illness due to occupational exposure to HIV, the employee must provide his/her supervisor with a written statement of the date and circumstances of the exposure incident within 24 hours of date of the exposure incident (The AccessHR Accident/Incident report). It must be documented additionally that the employee had test results that indicated an absence of Bloodborne pathogen infection within 10 days of the exposure.
  - If an employee declines to be tested within the 10 days period, this shall be documented on applicable forms..
14. The supervisor must complete and submit a Contaminated Sharps Injury Reporting form to the Infectious Disease Control Unit of DSHS.

**Postexposure Resources:**

- DSHS Physician On Call ..... (512) 468-4710 (cell phone)
- ..... (512) 235-4895 (pager)
- ..... (512) 458-7111 (answering service after hours)
- Regan Rychetsky ..... (512) 424-6985
- HHS Enterprise Director of Risk Management..... (512) 896-6622 (Alpha/Numeric Pager)
- AccessHR <http://AccessHR.hhsc.state.tx.us/> ..... 1 (888)-894-4747
- Texas Department of Insurance, Division of Worker’s Compensation . 1 (800) 252-7031  
<http://www.tdi.state.tx.us/wc/indexwc.html>
- The State Office of Risk Management..... (512) 475-1440

**7.0 Revision History**

Date	Action	Section
11/10/2007	New policy	All

# Workers' Compensation Accident Reporting For HHS Agencies (Except State Schools And State Hospitals)

As of August 1, 2005, HHS Agencies no longer file workers' compensation claims directly with the State Office of Risk Management. If a state employee sustains a work related injury they, or their supervisor, will need to file an accident/incident report online through AccessHR. The Web site address is <https://AccessHR.hhsc.state.tx.us>.

- Input your Employee ID and password. If you have logged into AccessHR before, you should have a password. See the menu items on the login page if this is your first login. You will need to establish a password.

Once into the AccessHR system scan the menu items on the left and find Health and Safety.

- Click on Health and Safety. The drop down box will appear
- Choose "Add an Accident/Incident," then click the yellow "Add" box and fill out the form.
- Once the form is complete, click "Add" on the bottom right hand corner, and the form will automatically forward to the AccessHR Service Center for handling. A copy will also automatically forward to the supervisor and HHS risk management.
- If you need to exit the system prior to completion of the accident form, you may save your work and come back to complete the form at a later time. However please complete the form as soon as possible after the accident occurs. (preferably within 24 hours)
- If a supervisor enters an Accident/Incident report on behalf of a non-employee or an unavailable employee, they will need go through the "Manager's Center" menu to choose "Add an Accident/Incident." Then follow the procedure above.

AccessHR Service Center will file all workers' compensation claims for the HHS agencies with the State Office of Risk Management.

If you have questions regarding your rights under the workers' compensation system, or need to find a physician, you may contact the

- Texas Department of Insurance, Division of Workers' Compensation at 1-800-252-7031 or <http://www.tdi.state.tx.us/wc/indexwc.html>;
- The State Office of Risk Management at (512) 475-1440; or
- HHS Risk Management at (512) 424-6985.

## APPENDIX B

If you have any questions, please contact HHS Risk Management at (512) 424-6985.

National HIV/AIDS Clinicians Consultation Center:

National Clinicians' Post Exposure Prophylaxis Hot line 1-888-448-4911

National HIV Telephone Consultation Service Warmline 1-800-933-3413

## Checklist for Management of Bloodborne Pathogen (BBP) Exposures

Date of incident: \_\_\_\_\_ Employee name: \_\_\_\_\_

- 1. Complete "Employee Exposure Assessment Form."
- 2. Determine HBV status.  
 Number of doses of vaccine received: 0 1 2 3 4 5 6  
 Titer documented on: \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  
 NO FURTHER ACTION NECESSARY  
 Chronic non-responder  
 Refer to MMWR, Nov. 22, 1991, page 22, for required prophylaxis.
- 3. Identify source blood.  
 Yes ID No. \_\_\_\_\_  
 Test source blood for HIV. Store remaining blood for 6 months.  
 No Comments \_\_\_\_\_ :
- 4. Notify physician.
- 5. Counsel employee.
- 6. Have consent forms signed.  
 HIV chemoprophylaxis  
 Blood test(s)
- 7. Administer chemoprophylaxis.  
 HIV  
 HBV

Drug	Quantity Provided	Date	Initials
1.			
2.			
3.			

- 8. Draw employee's blood.  
 HIV  
 ALT  
 HBV  
 HCV

	Manufacturer	Lot	Dose	Initials
Vaccine				
HBIG				

APPENDIX B

- 9. Submit blood for testing.
  - Employee - HIV, anti-HBs, HBsAg, RPR, HCV, ALT
  - Source - HIV, HBsAg, HCV, RPR
- 10. Schedule employee follow-up blood test(s).
  - HIV            6 weeks            12 weeks            6 months
  - HCV            6 months
  - ALT            6 months
- 11. Provide results to employee.

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No further action is necessary if employee has not seroconverted to HIV-positive or HCV-positive six months after exposure.

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If employee seroconverts for either HIV or HCV:

- 12. Schedule follow-up medical consultation.
  - No
  - Comments: \_\_\_\_\_
- 13. Test source blood for HCV and AAT if employee has seroconverted and the source blood was not tested for baseline at the time of exposure.
  - Yes
  - No
  - Comments: \_\_\_\_\_

Place the completed form in a sealed envelope labeled “CONFIDENTIAL MEDICAL INFORMATION.” File it separately from the employee’s personnel folder. **Do not place lab results or other confidential medical information in the employee’s personnel file.**

# Recommendations for Follow-Up of Healthcare Workers After Exposure to Bloodborne Pathogens

## I. Occupational Exposure To Hepatitis B

Follow-up for occupational percutaneous or permucosal exposure to blood or body secretions that might contain hepatitis B depends on:

- whether the source of the blood is available;
- the HBsAg status of the source; and
- the hepatitis B vaccination and vaccine-response status of the exposed person.

### A. Source of Exposure Known and HBsAg-Positive

1. If the exposed person has not been vaccinated or has not completed the vaccination series, the hepatitis B vaccination should be initiated. A single dose of HBIG (0.06 ml/kg) should be administered as soon as possible after exposure and within 24 hours, if possible. The first dose of hepatitis B vaccine should be administered intramuscularly at a separate site (deltoid for adults) and can be administered simultaneously with HBIG or within seven days of exposure; subsequent doses should be administered as recommended for the specific vaccine. If the exposed person has begun but has not completed vaccination, one dose of HBIG should be administered immediately and vaccination should be completed as scheduled.
2. If the exposed person has already been vaccinated against hepatitis B, and the anti-HBs response status is known:
  - a. If the exposed person is known to have had an adequate response in the past, the anti-HBs level should be tested unless an adequate level has been demonstrated within the past 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:
    - i. If the anti-HBs level is adequate (antibody level > 10 mIU/ml), no treatment is necessary.
    - ii. If the anti-HBs level is inadequate, a booster dose of hepatitis B vaccine should be administered.
  - b. If the exposed person is known to have not responded to the primary vaccine series, he or she should receive either a single dose of HBIG and a dose of hepatitis B vaccine as soon as possible after exposure, or two doses of HBIG (0.06 ml/kg), one as soon as possible after exposure and the second one month later. The latter treatment is referred for those who have not responded to at least four doses of vaccine.
3. If the exposed person has already been vaccinated against hepatitis B and anti-HBs response is unknown, the exposed person should be tested for anti-HBs.

- a. If the exposed person has adequate antibody, no additional treatment is necessary.
  - b. If the exposed person has inadequate antibody, one dose of HBIG (0.06 ml/kg) should be administered immediately, and a standard booster dose of vaccine should be administered at a different site.
- B. Source of Exposure Known and HBs Ag-Negative
1. If the exposed person has not been vaccinated or has not completed vaccination:
    - a. If unvaccinated, the exposed person should be administered the first dose of hepatitis B vaccine within seven days of exposure, and vaccination should be completed as recommended. If the exposed person has not completed vaccination, the vaccination series should be completed as scheduled.
  2. If the exposed person has already been vaccinated against hepatitis B, no treatment is necessary.
- C. Source of Exposure Unknown or Not Available For Testing
1. If the exposed person has not been vaccinated or has not completed vaccination:
    - a. If unvaccinated, the exposed person should be administered the first dose of hepatitis B vaccine with seven days of exposure, and vaccination should be completed as recommended.
    - b. If the exposed person has not completed vaccination, the vaccination series should be completed as scheduled.
  2. If the exposed person has already been vaccinated against hepatitis B, and anti-HBs response status is known:
    - a. If the exposed person is known to have had adequate response in the past, no treatment is necessary.
    - b. If the exposed person is known to have not responded to the vaccine, prophylaxis as described earlier in this outline (see page B-5, I.A.) “Source of Exposure Known and HBsAg-Positive”) may be considered if the source of the exposure is known to be at high risk of HBV infection.
  3. If the 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.
    - a. If the exposed person has adequate anti-HBs, no treatment is necessary.
    - b. If the exposed person has inadequate anti-HBs, a standard booster dose of vaccine should be administered.

Table 1 summarizes the 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.

Records on tested sources and employees should be kept in accordance with established Texas Department of State Health Services policies. Laboratory results from HIV-antibody testing, hepatitis-B testing, or any other test must remain confidential and never be placed in personnel files.



**Table 8: Recommendations for Hepatitis B Prophylaxis Following Percutaneous Exposure****I. Source HbsAg-positive**

Exposed person	Treatment when source is found to be HBsAg-positive
Unvaccinated	<ul style="list-style-type: none"> <li>• Administer HBIG x 1* and initiate Hepatitis B vaccine**</li> </ul>
Previously vaccinated known responder	<ul style="list-style-type: none"> <li>• Test exposed for anti-HBs               <ul style="list-style-type: none"> <li>◆ If inadequate, no treatment</li> <li>◆ If inadequate, Hepatitis B vaccine-booster dose</li> </ul> </li> </ul>
Known nonresponder	<ul style="list-style-type: none"> <li>• HBIG x 2 or HBIG x 1, plus 1 dose of Hepatitis B vaccine</li> </ul>
Response unknown	<ul style="list-style-type: none"> <li>• Test exposed person for anti-HB***               <ul style="list-style-type: none"> <li>◆ If inadequate, HBIG x 1, plus Hepatitis B vaccine-booster dose</li> <li>◆ If inadequate, no treatment</li> </ul> </li> </ul>

**II. Source HbsAg-negative**

Exposed person	Treatment when source is found to be HBsAg-negative
Unvaccinated	<ul style="list-style-type: none"> <li>• Initiate Hepatitis B vaccine</li> </ul>
Previously vaccinated known responder	<ul style="list-style-type: none"> <li>• No treatment</li> </ul>
Known nonresponder	<ul style="list-style-type: none"> <li>• No treatment</li> </ul>
Response unknown	<ul style="list-style-type: none"> <li>• No treatment</li> </ul>

**III. Source unknown or not tested**

Exposed person	Treatment when source is found to be Unknown or not tested
Unvaccinated	<ul style="list-style-type: none"> <li>• Initiate Hepatitis B vaccine</li> </ul>
Previously vaccinated known responder	<ul style="list-style-type: none"> <li>• No treatment</li> </ul>
Known nonresponder	<ul style="list-style-type: none"> <li>• If known high-risk source, may treat as if source were HBsAg-positive</li> </ul>
Response unknown	<ul style="list-style-type: none"> <li>• Test exposed person for anti-HBs. If inadequate, Hepatitis B vaccine-booster dose               <ul style="list-style-type: none"> <li>◆ If inadequate, no treatment</li> </ul> </li> </ul>

**II. Occupational Exposure to Hepatitis C****A. Employee with History of Hepatitis C Infection (HCV)**

1. If the employee gives a history of infection or has documentation of HCV-positive status, no testing of either the source or the employee is necessary.

**B. Source of Exposure Known and Anti-HCV-Antibody-Positive**

1. The exposed employee should be tested at the time of initial exposure or as soon as possible after initial exposure for anti-HCV antibody and ALT (alanine aminotrans-ferase) activity.
2. Repeat testing for anti-HCV antibody and ALT activity should be done six months after exposure.
3. All anti-HCV results reported as repeatedly reactive by enzyme immunoassay (EIA) should be confirmed by supplemental anti-HCV testing.
4. No post-exposure prophylaxis is available for hepatitis C; immune globulin is not recommended.

C. Source of Exposure Unknown or Cannot be Tested

1. Follow the guidelines in II. B. above, “Source of Exposure Known and Anti-HCV-Antibody-Positive.”

D. Source of Exposure Known and Can be Tested

1. The source should be tested for anti-HCV antibody as soon as possible after initial exposure. If positive, guidelines in II. B. above, “Source of Exposure Known and Anti-ACV-Antibody-Positive,” should be followed. If the source tests negative for anti-HCV antibody, no further follow-up for hepatitis C is necessary for the employee.

E. Summary Recommendations

1. No post-exposure prophylaxis is available for hepatitis C; immune globulin is not recommended.
2. Institutions should provide to healthcare workers accurate and up-to-date information on the risk and prevention of all bloodborne pathogens, including hepatitis C.
3. Institutions should consider implementing policies and procedures for follow-up of healthcare workers after percutaneous or permucosal exposure to anti-HCV-positive blood. Such policies might include baseline testing of the source for anti-HCV and baseline and six-month follow-up testing of the person exposed for anti-HCV and ALT activity. All anti-HCV results reported as repeatedly reactive by EIA should be confirmed by supplemental anti-HCV testing.
4. There are currently no recommendations regarding restriction of healthcare workers with hepatitis C. The risk of transmission from an infected worker to a patient appears to be very low. Furthermore, there are no serologic assays that can determine infectivity nor are there data to determine the threshold concentration of virus required for transmission. As recommended for all healthcare workers, those who are anti-HCV-positive should follow strict aseptic technique and standard (universal) precautions, including appropriate use of hand washing, protective barriers, and care in the use and disposal of needles and other sharp instruments.

**III. Occupational Exposure to HIV**

A. Employee with History of HIV Infection

1. If the employee gives a history of HIV infection or has documentation of HIV-positive status, no testing of either the source or the employee is necessary.

B. Source of HIV Exposure Known

1. If the source of exposure is known, he/she should be assessed clinically and epidemiologically to determine the risk or likelihood of HIV infection. The source should be informed of the exposure and be asked to be tested. It should be stressed to the source that the results will be kept confidential. If the source has no clinical evidence of infection, is HIV-antibody-negative, and has no history of high-risk behavior, no further follow-up of source is indicated.
2. The exposed healthcare worker should be counseled that the source could be infected even though results are negative. The healthcare worker needs to understand that negative results are not reliable for behaviors that occurred within the past six weeks to three months. The decision to start/continue prophylaxis treatment should not be based on source test results alone.

### C. Testing the Exposed Employee

1. The exposed employee should be tested within 10 days (although 72 hours is preferable) of initial exposure.
2. Repeat testing should then be done six weeks, 12 weeks, and six months after exposure.

### D. Source of HIV Exposure Unknown and Miscellaneous

1. If the source has evidence of possible HIV infection, a confirmed positive HIV-antibody test, a history of high-risk behavior, cannot be tested, refuses to be tested, or is unknown, then the following steps should be taken:
  - a. The exposed individual should be evaluated clinically for evidence of HIV infection, and HIV antibody testing should be recommended as soon as possible after the exposure. Refusal to submit a specimen must be documented. The exposed individual should be advised to report and seek medical evaluation for any acute febrile illness that occurs within 12 weeks after exposure. Such an illness, particularly one characterized by fever, rash, or lymphadenopathy, may be indicative of recent HIV infection.
  - b. If the exposed individual's baseline test is negative for HIV antibody, he/she should have repeat testing for HIV antibody in six weeks, 12 weeks, and again in six months. Again, refusal to submit a specimen must be documented. Risk behavior during each testing interim must be assessed and documented.
  - c. Both the source, if known, and the exposed individual should be counseled.
  - d. If the source is unknown, decisions regarding appropriate follow-up should be individualized. Serologic testing should be made available by the employer to all workers who may be concerned they have been infected with HIV through an occupational exposure.
  - e. Post-exposure counseling should be given within two weeks of exposure and should include information on the potential risk of infection and specific measures to prevent transmission.

### E. Medical Protocol for the Management of Occupational Exposure to HIV

1. *Post-exposure prophylaxis (PEP) should be initiated within one hour of exposure, if possible.*
2. The attending physician should review available information on occupational-exposure forms submitted by the employee, determine the extent and time of the exposure, and consult a copy of the Exposure Assessment Form (see page C-19). If a fax machine is readily available, this information can be faxed to the attending physician by the supervisor. If not, the supervisor can provide the information on the form over the telephone.

- F. If status of the source of exposure is unknown, initiating PEP should be determined on a case-by-case basis. Initiating PEP should be based on the exposure risk and likelihood of HIV infection in the source. Every effort should be made to determine this information; however, the physician's decision to offer or recommend PEP should depend on the type of exposure. PEP should not be delayed while waiting for information regarding the source. Information concerning what testing the involved specimen was submitted for might give some insight regarding the likelihood of HIV being found in that specimen. Blood specimens which are the source of an exposure will be tested for HIV (antibody

and antigen) and hepatitis B and C. If there is not enough of the source blood to test, information should be gathered from the submitter and another blood sample obtained, if possible.

1. *The attending physician should initiate prophylaxis promptly (if appropriate and accepted), preferably within 1-2 hours after exposure. Because the interval after which there is no benefit from PEP is not defined, prophylaxis after 24 hours should depend on the type of exposure (e.g., high risk, increased risk, no increased risk).* (See Table 2 on following pages for defining criteria.) The recommended length of therapy is four weeks. Medications should not be provided if the exposed employee's HIV status is positive. Each health department should develop a plan to obtain medications within 24 hours, as needed.

#### G. Chemoprophylaxis

1. If medications are ordered, blood should be drawn for baseline laboratory tests of exposed individual to monitor drug toxicity, if chemoprophylaxis is chosen as an option.
2. Laboratory testing which should be performed is as follows:
  - a. Complete blood count
  - b. Liver-function tests
  - c. Renal-function tests
  - d. Urinalysis
  - e. Amylase
  - f. Pregnancy test if question of pregnancy
  - g. HIV antibody by ELISA
  - h. Hepatitis B surface antigen and anti-hepatitis B surface antigen
  - i. Hepatitis C antibody (25% of HIV positive patients are also HCV positive)
3. Some of the above tests may be performed by the DSHS Laboratory, and some will be performed by an outside laboratory. These tests should be repeated by the employee's private physician after two weeks on prophylaxis.

#### H. Pregnancy

1. If the employee who has been exposed is pregnant or has any reason to believe that she is in the early stages of pregnancy, *do not provide medications.*
2. The employee should immediately contact her private obstetrician, family practitioner, or the individual on call for these physicians and discuss the situation with him/her. The employee's private obstetrician or family practitioner should make the determination as to whether this employee should be provided post-exposure prophylaxis.
3. The employee's private obstetrician or family practitioner may be referred to the DSHS physician handling the exposure and request that the DSHS physician dispense one or two days of medication. Any additional medication would be provided via a prescription for the employee by the private practitioner.

Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis Centers for Disease Control (CDC) 2005.

**Table 9: Recommended HIV postexposure prophylaxis (PEP) for percutaneous injuries**

Exposure Type	Infection status of source				
	HIV-positive, class 1*	HIV-positive, class 2*	Source of unknown HIV status <sup>†</sup>	Unknown source <sup>§</sup>	HIV-negative
Less severe <sup>¶</sup>	Recommend basic 2-drug PEP	Recommend expanded ≥3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP** for source with HIV risk factors <sup>††</sup>	Generally, no PEP warranted; however, consider basic 2-drug PEP** in settings in which exposure to HIV-infected persons is likely.	No PEP warranted
More Severe <sup>§§</sup>	Recommend expanded 3-drug PEP	Recommend expanded ≥3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP** for source with HIV risk factors <sup>††</sup>	Generally, no PEP warranted; however, consider basic 2-drug PEP** in settings in which exposure to HIV-infected persons is likely.	No PEP warranted

\* HIV-positive, class 1 — asymptomatic HIV infection or known low viral load (e.g., <1,500 ribonucleic acid copies/mL). HIV-positive, class 2 — symptomatic HIV infection, acquired immunodeficiency syndrome, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of PEP should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

† For example, deceased source person with no samples available for HIV testing.

§ For example, a needle from a sharps disposal container.

¶ For example, solid needle or superficial injury.

\*\* The recommendation “consider PEP” indicates that PEP is optional; a decision to initiate PEP should be based on a discussion between the exposed person and the treating clinician regarding the risks versus benefits of PEP.

†† If PEP is offered and administered and the source is later determined to be HIV-negative, PEP should be discontinued.

§§ For example, large-bone hollow needle, deep puncture, visible blood on device, or needle used in patient’s artery or vein.

**Table 10: Recommended HIV postexposure prophylaxis (PEP) for mucous membrane exposures and non intact skin\* exposures**

Exposure Type	Infection status of source				
	HIV-positive, class 1 <sup>†</sup>	HIV-positive, class 2 <sup>†</sup>	Source of unknown HIV status <sup>§</sup>	Unknown source <sup>¶</sup>	HIV-negative
Small volume**	Consider basic 2-drug PEP	Recommend basic 2-drug PEP	Generally, no PEP warranted <sup>§§</sup>	Generally, no PEP warranted;	No PEP warranted
Large volume <sup>¶¶</sup>	Recommend basic 2-drug PEP	Recommend expanded ≥3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP <sup>††</sup> for source with HIV risk factors <sup>§§</sup>	Generally, no PEP warranted; however, consider basic 2-drug PEP <sup>††</sup> in settings in which exposure to HIV-infected persons is likely.	No PEP warranted

\* For skin exposures, follow-up is indicated only if evidence exists of compromised skin integrity (e.g., dermatitis, abrasion, or open wound).

<sup>†</sup> HIV-positive, class 1 — asymptomatic HIV infection or known low viral load (e.g., <1,500 ribonucleic acid copies/mL). HIV-positive, class 2 — symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load. If drug resistance is a concern, obtain expert consultation. Initiation of PEP should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

<sup>§</sup> For example, a needle from a sharps disposal container.

<sup>¶</sup> For example, splash from inappropriately disposed blood.

\*\* For example, a few drops.

<sup>††</sup> The recommendation “consider PEP” indicates that PEP is optional; a decision to initiate PEP should be based on a discussion between the exposed person and the treating clinician regarding the risks versus benefits of PEP.

<sup>§§</sup> If PEP is offered and administered and the source is later determined to be HIV-negative, PEP should be discontinued.

<sup>¶¶</sup> For example, a major blood splash.

**Table 11: Primary side effects and toxicities associated with antiretroviral agents used for HIV postexposure prophylaxis, by class and agent**

Class and agent	Side effect and toxicity
<b>Nucleoside reverse transcriptase inhibitors (NRTI)</b>	<b>Class warning: all NRTIs have the potential to cause lactic acidosis with hepatic steatosis</b>
Zidovudine (Retrovir®; ZDV, AZT)	Anemia, neutropenia, nausea, headache, insomnia, muscle pain, and weakness
Lamivudine (Epivir®, 3TC)	Abdominal pain, nausea, diarrhea, rash, and pancreatitis
Stavudine (Zerit™; d4T)	Peripheral neuropathy, headache, diarrhea, nausea, insomnia, anorexia, pancreatitis, elevated liver function tests (LFTs), anemia, and neutropenia
Didanosine (Videx®; ddl)	Pancreatitis, lactic acidosis, neuropathy, diarrhea, abdominal pain, and nausea
Emtricitabine (Emtriva; FTC)	Headache, nausea, vomiting, diarrhea, and rash. Skin discoloration (mild hyperpigmentation on palms and soles), primarily among nonwhites
<b>Nucleotide analogue reverse transcriptase inhibitor (NtRTI)</b>	<b>Class warning: all NRTIs have the potential to cause lactic acidosis with hepatic steatosis</b>
Tenofovir (Viread®; TDF)	Nausea, diarrhea, vomiting, flatulence, and headache
<b>Nucleoside reverse transcriptase inhibitors (NRTIs)</b>	
Efavirenz (Sustiva®; EFV)	Rash (including cases of Stevens-Johnson syndrome), insomnia, somnolence, dizziness, trouble concentrating, abnormal dreaming, and teratogenicity
<b>Protease inhibitor</b>	

Class and agent	Side effect and toxicity
Indinavir (Crixivan®; NFV)	Diarrhea, nausea, abdominal pain, weakness, and rash
Ritonavir (Norvir®; RTV)	Weakness, diarrhea, nausea, circumoral paresthesia, taste alteration, and elevated cholesterol and triglycerides
Saquinavir (inivase®; SQV)	Diarrhea, abdominal pain, nausea, hyperglycemia, and elevated LFTs
Fosamprenavir (Lexiva®; FOSAPV)	Nausea, diarrhea, rash, circumoral paresthesia, taste alteration, and depression
Atazanavir (Reyataz®; ATV)	Nausea, headache, rash, abdominal pain, diarrhea, vomiting, and indirect hyperbilirubinemia
Lopinavir / ritonavir (Kaletra®; LPV / RTV)	Diarrhea, fatigue, headache, nausea, and increased cholesterol and triblycerides
<b>Fusion inhibitor</b>	
Enfuvirtide (Fuzeon®; T-20)	Local injection site reactions, bacterial pneumonia, insomnia, depression, peripheral neuropathy, and cough

**Sources:** Package inserts; Panel on Clinical Practices for Treatment of HIV Infection. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents — April 7, 2005. Washington, DC; National Institutes of Health; 2005. Available at [http://aidsinfo.nih.gov/guidelines/default\\_db2.asp?id=50](http://aidsinfo.nih.gov/guidelines/default_db2.asp?id=50).





## Employee Exposure Assessment Form

### A. Employee Information

Name: \_\_\_\_\_

Date (form filled out): \_\_\_\_\_

Division/Program: \_\_\_\_\_ Supervisor \_\_\_\_\_

Personal Physician: \_\_\_\_\_ Physician: \_\_\_\_\_

Phone: \_\_\_\_\_

### B. Exposure Information

Date of Exposure (mm/dd/yy): \_\_\_\_\_

Time of Exposure (a.m./p.m.): \_\_\_\_\_

### C. Characteristics of Source Material [check appropriate box(s)]

#### Infectious

- Blood or serum
- Fluid or tissue with visible blood
- Amniotic fluid
- Cerebrospinal fluid
- Pericardial fluid
- Peritoneal fluid
- Pleural fluid
- Semen

#### Non-Infectious (without visible blood)

- Synovial fluid
- Vaginal secretions
- Saliva
- Sputum
- Stool
- Sweat
- Urine
- Vomitus

### D. Characteristics of Exposure (Check as many as apply):

- Percutaneous injuries: Exposed with visibly bloody device or device used in source patient's artery or vein.
- Deep intramuscular injury
- Superficial Injury
- Other: (give brief description on back of this form)

- Muscosal contacts: Large volume (> cc)
- Prolonged contact (> 5 min)
- Small Volume (< cc)
- Brief contact (< 5 min)
- Skin contacts: Skin integrity obviously compromised
- Large volume (> 1cc)
- Prolonged contact (> 5 minutes)
- Extensive area of contact
- Skin intact
- Small volume (< 1cc)
- Small area of contact

**E. Characteristics of Source (Check one):**

- Specimen is from an HIV positive individual who is asymptomatic or known low viral titer.
- Specimen is from an HIV positive individual who is symptomatic patient with acute retroviral syndrome (infected within past few weeks and has a mononucleosis-like illness).
- Specimen is from an HIV positive individual who is preterminal, CD4 < 100 or viral titer > 50,000.
- Specimen has tested HIV negative by ELISA, Western Blot testing.
- HIV Serostatus of the specimen is unknown.

Specimen sent to the lab to be tested for:

**F. Employee Clinical History:**

1. Have you ever been diagnosed with HIV infection in the past (i.e. tested HIV positive)?  
 Yes       No
2. Have you received a hepatitis B immunization/vaccine?  
 Yes       No
3. Are you currently pregnant or have you been trying to conceive a child?  
 Yes       No
4. Have you ever been treated for kidney disease or liver disease or other immune system disorders?

Yes       No

5. Are you presently taking any medications regularly?

Yes       No

If yes, please list:

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6. Do you routinely use illegal drugs such as heroin, cocaine, etc.?

Yes       No

7. Have you ever been in a treatment program to stop the use of illegal drugs?

Yes       No



# Texas Department of State Health Services

## Bloodborne Pathogen Testing Consent/ Declination Form

TO THE EMPLOYEE: Texas law requires that counseling be provided to anyone potentially exposed to human immunodeficiency virus (HIV) and other bloodborne pathogens such as hepatitis B (HBV), or hepatitis C (HCV) during the course of job duties. After being counseled and having all of your questions answered, sign the reverse side of this form to indicate that you understand and consent to testing for HIV and other blood-borne pathogens or that you understand and decline such testing. All tests used a sample of blood taken from your arm.

### HIV tests

The tests currently used by the Texas Department of State Health Services are antibody tests, that is, tests which detect the presence of antibodies to HIV but not the virus itself. If you have been recently exposed to HIV, your body has not yet made the antibodies which can be detected by the tests. You will need an initial test within 10 calendar days after exposure and additional tests at six weeks, twelve (12) weeks and six months.

In addition to the knowledge gained from having the HIV tests performed, a small percentage of tests may give a “false-positive” or a “false-negative” result. A “false positive” result means a test has incorrectly indicated that you are infected with HIV, when in fact, you are not. A “false-negative” result means a test has incorrectly indicated that you are not infected with HIV, when in fact, you are. A small percentage of results can be inconclusive, necessitating retesting.

If the first test is positive, further confirmatory tests shall be performed on that blood sample. You will be considered as infected with HIV, but it does not indicate that you have HIV illness or AIDS now or that you will develop these conditions in the future.

If all your tests results are positive, you are presumed to be infected with HIV, and you will be referred for more extensive counseling and medical evaluation. The test results can also help you make important decisions involving your personal life, professional duties and obligations.

HIV testing is confidential, as provided by Texas law, and disclosure can be made only to the healthcare professional designated to evaluate claims of occupational exposure to blood-borne pathogens, persons

responsible for workers compensation claims and individuals who are specifically authorized by the individual tested or Texas law. Records shall be handled in a confidential manner, and personnel handling records have been advised of the confidentiality of HIV-related information.

## **HCV Tests**

There is no pre-exposure or post-exposure prophylaxis for hepatitis C. If your exposure to blood was percutaneous or permucosal, you will also be tested for antibody to HCV and for alanine aminotransferase. Negative tests will be repeated six months after the exposure. If you seroconvert, you will have the opportunity to seek medical evaluation and treatment for chronic liver disease.

## **HBV**

Hepatitis B is a treatment-preventable blood-borne pathogen and, therefore, more information about it will be provided during the process of evaluating the need for prophylaxis.

## Texas Department of State Health Services Blood-borne Pathogen Testing Consent/Declination Form

TO THE EMPLOYEE: Texas law requires that counseling be provided to anyone potentially exposed to human immunodeficiency virus (HIV) and other blood-borne pathogens such as hepatitis B (HBV), or hepatitis C (HCV) during the course of job duties. After being counseled and having all of your questions answered, sign the reverse side of this form to indicate that you understand and consent to testing for HIV and other blood-borne pathogens or that you understand and decline such testing. All tests used a sample of blood taken from your arm.

### Blood-borne Pathogens Testing Consent/Declination

I have had an opportunity to ask questions, including the risks and benefits of taking these tests. Any questions I had about the tests were answered to my satisfaction. I understand that neither the Texas Department of State Health Services, its employees, nor the State of Texas has warranted the accuracy of the test results.

Information about the tests has been given to me in the following manner:

(Check one)  orally  
 written

(Check one)  I have read the form and I understand its meaning  
 The form has been read to me and I understand its meaning.  
 All the blanks were filled in before I signed this form.

I have been advised of the need to collect my blood due to an occupational exposure incident in which I have been potentially exposed to blood-borne pathogens. Permission to have my blood drawn and tested for the human immunodeficiency virus (HIV), hepatitis B (HBV), hepatitis C (HCV), and alanine aminotransferase activity (AAT) at the expense of my employer is hereby given.

I consent to be tested.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Print Name: \_\_\_\_\_

Witness Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Print Name: \_\_\_\_\_

I decline counseling/testing. I understand:

- a. and accept responsibility for declining counseling/testing procedures;
- b. that if I refuse to be tested within 10 calendar days of the exposure I shall be disqualified for worker's compensation or other similar claims, as specified by Texas law;
- c. that I may agree to have my blood drawn but not tested. I understand that federal standards require that such blood specimen be retained under proper storage conditions for ninety (90) calendar days, during which time I may decide to have testing completed. Unless testing is performed within 10 calendar days after exposure, I shall not qualify for workers' compensation or other similar benefits;

that my failure to sign the consent or declination is in fact a declination and my legal rights will be affected accordingly.

Employee must initial **each** blood-borne pathogen test being declined.

HIV \_\_\_\_\_ HBV \_\_\_\_\_ HCV \_\_\_\_\_ AAT \_\_\_\_\_

Employee Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Print Name: \_\_\_\_\_

Witness Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Print Name: \_\_\_\_\_



# Texas Department of State Health Services Employee Consent/ Declination for Post-Exposure Chemoprophylaxis for Occupational Exposure to HIV

## Recitals

I understand and agree as follows:

1. I may have been exposed to human immunodeficiency virus (HIV), the virus which causes AIDS, in my workplace. The risk of infection from my exposure is not know, however, should HIV infection occur the ultimate outcome is likely to be fatal. I have been offered treatment with one or more of the following medications, (Zidovudine, Lamivudine and Indinavir) or other currently recommended medications which might reduce my risk of infection. I have been advised that there is no guarantee that such drug treatment after HIV exposure will prevent infection. I have also been advised that because strains of HIV are now resistant to Zidovudine, combination treatment with multiple medications may be offered as post-exposure prophylaxis.
2. I have been advised that the treatment by my personal physician should consist of the following:
  - a. My blood will be tested for complete blood count platelet, liver function test, kidney function tests and other tests as determined by my personal physician, including but not limited to a test for antibodies to HIV.
  - b. I have been advised to use contraception during the four weeks of treatment and the four weeks following treatment. If I am currently pregnant or feel that I could be in the early stages of pregnancy, I have consulted with my personal obstetrician or family practitioner to determine if I should be given post-exposure prophylaxis.
  - c. I will be given a one or two day supply of one or more of the following medications: Zidovudine, Lamivudine, or Indinavir or other currently recommended medications (Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HIV and Recommendations for Postexposure Prophylaxis Centers for Disease Control (CDC) Morbidity and Mortality weekly Report (MMWR) 54 (RR09); 1-17 (2005, September 30)) <http://www.osha.gov/SLTC/bloodborne pathogens/postexposure.html> with instructions on how to take this medication.
  - d. I will contact my personal physician immediately to set up an appointment to obtain a prescription for additional medication as needed.
  - e. My personal physician will be responsible for the continuation of therapy, if needed.
  - f. I will consult my personal physician if I develop side effects while taking any of the medication.
3. I understand and hereby acknowledge that there is a risk of serious side effects associated with any and all drugs prescribed with post-exposure prophylaxis including but not limited to the following:

- a. Known side effects of Zidovudine include:  
**Common:** headache, muscle pain, tiredness, loss of appetite, trouble sleeping, nausea.  
**Uncommon:** fever, vomiting, dizziness, diarrhea, anemia, low white blood count, low platelet count, hepatitis (liver inflammation), pancreatitis (pancreas inflammation).
  - b. Known side effects of Lamivudine include:  
**Common:** headache, muscle pain, tiredness, loss of appetite, trouble sleeping, nausea.  
**Uncommon:** fever, vomiting, dizziness, diarrhea, anemia, low white blood count, hepatitis liver inflammation), pancreatitis (pancreas inflammation).
  - c. Known side effect of Indinavir include:  
**Common:** abdominal pain, fatigue, nausea, vomiting, diarrhea, headache, insomnia, changes in taste, abnormal liver tests.  
**Uncommon:** anemia, low white blood count, hepatitis (liver inflammation), kidney stones (nephrolithiasis), pancreatitis (pancreas inflammation).
  - d. Indinavir cannot be taken concurrently with any of the following drugs: Seldane, Hismanal, Halcion, Versed, and Propulsid. Serious and/or life-threatening events could occur if the above medications are taken with Indinavir.
  - e. Treatment side effects are expected to disappear after treatment is stopped, but could be life-threatening or irreversible. I specifically acknowledge, however, that these drugs are new and there is little known about their short-term and long-term side effects when used in combination. New or rare side effects, including cancer, birth defects, or other life-threatening diseases, might develop now or in the future.
4. The risks of drawing blood included temporary discomfort from the needle stick, bruising and rarely, infection.
  5. Knowledge that I could be HIV infected may cause personal psychosocial risks. Being tested for HIV may cause personal anxiety regardless of the test results. Receiving positive test results may cause severe personal anxiety.
  6. Post-exposure prophylaxis treatment will involve knowledge of this incident only to those who need to know. Records recording this incident and the outcome will be kept confidential. I will be the only individual that can give written permission to have these records released. I may be asked for permission to enroll me in the Centers for Disease Control and Prevention's anonymous registry of healthcare workers who receive post-exposure prophylaxis. Enrollment in this registry will not affect my treatment, but may benefit healthcare workers in the future.
  7. I understand that treatment hereunder does not obligate the Texas Department of State Health Services (DSHS) to treat any other conditions affecting me or to treat conditions that might arise after this treatment is completed.
  8. I understand that this treatment is optional and voluntary on my part, I have the right to decline this treatment at any time. If I decide to discontinue treatment, I will notify my personal physician.
  9. Before the medication can be provided, I must consent to the treatment and must release DSHS, their medical staff, and employees, from any and all liability that may result from the treatment.

## Release of All Claims

1. Fully realizing that post-exposure prophylactic treatment may be unsuccessful and that it may have certain side effects including but not limited to those listed above, I request that such treatment be performed, and expressly consent to it.
2. I hereby release and forever discharge the DSHS, their medical staff, and any other persons connected with the such treatment, from all claims, damages, and causes of action that may arise from the performance of the treatment described in this Release, and from other medical care arising from the performance of such treatment, while I am being treated.
3. I agree that no representations have been made to me regarding the success of this treatment, except as may be set forth in this instrument.
4. This Release will be binding on the heirs, legal representatives, and assigns of me.
5. I have read all the terms of this instrument and fully understand that I am signing a complete release to any claim resulting from the performance of the treatment by the DSHS.

### DSHS Physician Administering This Treatment:

I understand that I will receive subsequent treatment from:

Personal Physician Name: \_\_\_\_\_

Personal Physician Address (if available) \_\_\_\_\_

Personal Physician Phone: \_\_\_\_\_

I will report to my personal physician's office: (mm/dd/yy) \_\_\_\_\_

### I Accept Treatment

By signing here, I am consenting to this treatment.

Signature \_\_\_\_\_

Printed Name \_\_\_\_\_

Witness \_\_\_\_\_

Signature \_\_\_\_\_

Printed Name \_\_\_\_\_

Person Obtaining Consent \_\_\_\_\_

Name of Interpreter (if used) \_\_\_\_\_

### I Decline Treatment

By signing here, I am declining this treatment

Signature \_\_\_\_\_

Printed Name \_\_\_\_\_

Witness \_\_\_\_\_

Signature \_\_\_\_\_

Printed Name \_\_\_\_\_

Person Obtaining Consent \_\_\_\_\_

Name of Interpreter (if used) \_\_\_\_\_

**Appendix C**  
**OSHA Standards**



### § 1910.1030 Bloodborne pathogens.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

*HBV* means hepatitis B virus.

*HIV* means human immunodeficiency virus.

*Needleless Systems* means a device that does not use needles for:

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

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

*Other Potentially Infectious Materials* means

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

*Parenteral* means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions. Personal Protective Equipment is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

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

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

microbiological wastes containing blood or other potentially infectious materials.

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

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

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

*Sterilize* means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores. Universal Precautions is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

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

(c) *Exposure Control* —

(1) Exposure Control Plan.

- (i) Each employer having an employee(s) with occupational exposure as defined by paragraph (b) of this section shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure.
- (ii) The Exposure Control Plan shall contain at least the following elements:
  - (A) The exposure determination required by paragraph(c)(2),
  - (B) The schedule and method of implementation for paragraphs (d) Methods of Compliance, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, (g) Communication of Hazards to

Employees, and (h) Recordkeeping, of this standard, and

- (C) The procedure for the evaluation of circumstances surrounding exposure incidents as required by paragraph (f)(3)(i) of this standard.
  - (iii) Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.20(e).
  - (iv) The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure. The review and update of such plans shall also:
    - (A) Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and
    - (B) Document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.
  - (v) An employer, who is required to establish an Exposure Control Plan shall solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan.
  - (vi) The Exposure Control Plan shall be made available to the Assistant Secretary and the Director upon request for examination and copying.
- (2) Exposure determination.
- (i) Each employer who has an employee(s) with occupational exposure as defined by paragraph (b) of this section shall prepare an exposure determination. This exposure determination shall contain the following:
    - (A) A list of all job classifications in which all employees in those job classifications have occupational exposure;
    - (B) A list of job classifications in which some employees have occupational exposure, and



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

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

(d) *Methods of compliance* —

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

(2) Engineering and work practice controls.

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

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

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

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

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

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

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

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

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

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

(A) Puncture resistant;

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

(C) Leakproof on the sides and bottom; and

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

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

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

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

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

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

(A) The container for storage, transport, or shipping shall be labeled or color-coded according to paragraph (g)(1)(i) and closed prior to being stored, transported, or shipped. When a facility utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary provided

- containers are recognizable as containing specimens. This exemption only applies while such specimens / containers remain within the facility. Labeling or color-coding in accordance with paragraph (g)(1)(i) is required when such specimens/containers leave the facility.
- (B) If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of this standard.
- (C) If the specimen could puncture the primary container, the primary container shall be placed within a secondary container which is puncture-resistant in addition to the above characteristics.
- (xiv) Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible.
- (A) A readily observable label in accordance with paragraph (g)(1)(i)(H) shall be attached to the equipment stating which portions remain contaminated.
- (B) The employer shall ensure that this information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken.
- (3) *Personal Protective Equipment* —
- (i) *Provision.* When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, and mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Personal protective equipment will be considered “appropriate” only if it does not permit blood or other potentially infectious materials to pass through to or reach the employee’s work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.
- (ii) *Use.* The employer shall ensure that the employee uses appropriate personal protective equipment unless the employer shows that the employee temporarily and briefly declined to use personal protective equipment when, under rare and extraordinary circumstances, it was the employee’s professional judgment that in the specific instance its use would have prevented the delivery of healthcare or public safety services or would have posed an increased hazard to the safety of the worker or co-worker. When the employee makes this judgement, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future.
- (iii) *Accessibility.* The employer shall ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the worksite or is issued to employees. Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.
- (iv) *Cleaning, Laundering, and Disposal.* The employer shall clean, launder, and dispose of personal protective equipment required by paragraphs (d) and (e) of this standard, at no cost to the employee.
- (v) *Repair and Replacement.* The employer shall repair or replace personal protective equipment as needed to maintain its effectiveness, at no cost to the employee.
- (vi) If a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible.
- (vii) All personal protective equipment shall be removed prior to leaving the work area.
- (viii) When personal protective equipment is removed it shall be placed in an appropriately designated area or container for storage, washing, decontamination or disposal.
- (ix) *Gloves.* Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and

non-intact skin; when performing vascular access procedures except as specified in paragraph (d)(3)(ix)(D); and when handling or touching contaminated items or surfaces.

- (A) Disposable (single use) gloves such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.
- (B) Disposable (single use) gloves shall not be washed or decontaminated for re-use.
- (C) Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.
- (D) If an employer in a volunteer blood donation center judges that routine gloving for all phlebotomies is not necessary then the employer shall:
  - (1) Periodically re-evaluate this policy;
  - (2) Make gloves available to all employees who wish to use them for phlebotomy;
  - (3) Not discourage the use of gloves for phlebotomy; and
  - (4) Require that gloves be used for phlebotomy in the following circumstances:
    - (i) When the employee has cuts, scratches, or other breaks in his or her skin;
    - (ii) When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and
    - (iii) When the employee is receiving training in phlebotomy.
    - (x) *Masks, Eye Protection, and Face Shields.* Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chinlength face

shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

- (xi) *Gowns, Aprons, and Other Protective Body Clothing.* Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments shall be worn in occupational exposure situations. The type and characteristics will depend upon the task and degree of exposure anticipated.
- (xii) Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (e.g., autopsies, orthopaedic surgery).

#### (4) *Housekeeping* —

- (i) General. Employers shall ensure that the worksite is maintained in a clean and sanitary condition. The employer shall determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility, type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area.
- (ii) All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials.
  - (A) Contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning.
  - (B) Protective coverings, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper used to cover equipment

- and environmental surfaces, shall be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the workshift if they may have become contaminated during the shift.
- (C) All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination.
- (D) Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dust pan, tongs, or forceps.
- (E) Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed.
- (iii) *Regulated Waste* —
- (A) Contaminated Sharps Discarding and Containment.
- (1) Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:
- (i) Closable;
  - (ii) Puncture resistant;
  - (iii) Leakproof on sides and bottom; and
  - (iv) Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard.
- (2) During use, containers for contaminated sharps shall be:
- (i) Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries);
  - (ii) Maintained upright throughout use; and
  - (iii) Replaced routinely and not be allowed to overfill.
- (3) When moving containers of contaminated sharps from the area of use, the containers shall be:
- (i) Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping;
  - (ii) Placed in a secondary container if leakage is possible. The second container shall be:
    - (A) Closable;
    - (B) Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and
    - (C) Labeled or color-coded according to paragraph (g)(1)(i) of this standard.
  - (4) Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.
- (B) *Other Regulated Waste Containment* —
- (1) Regulated waste shall be placed in containers which are:
- (i) Closable;
  - (ii) Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;
  - (iii) Labeled or color-coded in accordance with paragraph (g)(1)(i) this standard; and
  - (iv) Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.
- (C) Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.
- (iv) *Laundry*.
- (A) Contaminated laundry shall be handled as little as possible with a minimum of agitation.

- (1) Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.
  - (2) Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.
  - (3) Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through or leakage from the bag or container, the laundry shall be placed and transported in bags or containers which prevent soakthrough and/or leakage of fluids to the exterior.
- (B) The employer shall ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment.
  - (C) When a facility ships contaminated laundry off-site to a second facility which does not utilize Universal Precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded in accordance with paragraph (g)(1)(i).
- (e) *HIV and HBV Research Laboratories and Production Facilities.*
- (1) This paragraph applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. It does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. These requirements apply in addition to the other requirements of the standard.
  - (2) Research laboratories and production facilities shall meet the following criteria:
    - (i) *Standard microbiological practices.* All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.
    - (ii) *Special practices.* (A) Laboratory doors shall be kept closed when work involving HIV or HBV is in progress.
    - (B) Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leakproof, labeled or color-coded container that is closed before being removed from the work area.
    - (C) Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established whereby only persons who have been advised of the potential BIOHAZARD, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms.
    - (D) When other potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal BIOHAZARD symbol shall be posted on all access doors. The hazard warning sign shall comply with paragraph (g)(1)(ii) of this standard.
    - (E) All activities involving other potentially infectious materials shall be conducted in biological safety cabinets or other physical-containment devices within the containment module. No work with these other potentially infectious materials shall be conducted on the open bench.
    - (F) Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area and shall be decontaminated before being laundered.
    - (G) Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with other potentially infectious materials is unavoidable.
    - (H) Before disposal all waste from work areas and from animal rooms shall either be incinerated or decontaminated by a

- method such as autoclaving known to effectively destroy bloodborne pathogens.
- (I) Vacuum lines shall be protected with liquid disinfectant traps and high efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency and which are checked routinely and maintained or replaced as necessary.
  - (J) Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of other potentially infectious materials. Extreme caution shall be used when handling needles and syringes. A needle shall not be bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture resistant container and autoclaved or decontaminated before reuse or disposal.
  - (K) All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.
  - (L) A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or other responsible person.
  - (M) A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.
- (iii) *Containment equipment.* (A) Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols.
  - (B) Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually.
- (3) HIV and HBV research laboratories shall meet the following criteria:
    - (i) Each laboratory shall contain a facility for hand washing and an eye wash facility which is readily available within the work area.
    - (ii) An autoclave for decontamination of regulated waste shall be available.
  - (4) HIV and HBV production facilities shall meet the following criteria:
    - (i) The work areas shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors shall be the basic requirement for entry into the work area from access corridors or other contiguous areas. Physical separation of the high-containment work area from access corridors or other areas or activities may also be provided by a double-doored clothes-change room (showers may be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area.
    - (ii) The surfaces of doors, walls, floors and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.
    - (iii) Each work area shall contain a sink for washing hands and a readily available eye wash facility. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.
    - (iv) Access doors to the work area or containment module shall be self-closing.
    - (v) An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.
    - (vi) A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air

intakes. The proper direction of the airflow shall be verified (i.e., into the work area).

- (5) *Training Requirements.* Additional training requirements for employees in HIV and HBV research laboratories and HIV and HBV production facilities are specified in paragraph (g)(2)(ix).
- (f) *Hepatitis B vaccination and post-exposure evaluation and follow-up* —
- (1) *General.*
- (i) The employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident.
- (ii) The employer shall ensure that all medical evaluations and procedures including the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are:
- (A) Made available at no cost to the employee;
- (B) Made available to the employee at a reasonable time and place;
- (C) Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and
- (D) Provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place, except as specified by this paragraph (f).
- (iii) The employer shall ensure that all laboratory tests are conducted by an accredited laboratory at no cost to the employee.
- (2) *Hepatitis B Vaccination.* (i) Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii) (I) and within 10 working days of initial assignment to all employees who have occupational exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.
- (ii) The employer shall not make participation in a prescreening program a prerequisite for receiving hepatitis B vaccination.
- (iii) If the employee initially declines hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time.
- (iv) The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the statement in appendix A.
- (v) If a routine booster dose(s) of hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii).
- (3) *Post-exposure Evaluation and Follow-up.* Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements:
- (i) Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred;
- (ii) Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;
- (A) The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.
- (B) When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.
- (C) Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.
- (iii) Collection and testing of blood for HBV and HIV serological status;
- (A) The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

- (B) If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.
  - (iv) Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;
  - (v) Counseling; and
  - (vi) Evaluation of reported illnesses.
- (4) *Information Provided to the Healthcare Professional.*
- (i) The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.
  - (ii) The employer shall ensure that the healthcare professional evaluating an employee after an exposure incident is provided the following information:
    - (A) A copy of this regulation;
    - (B) A description of the exposed employee's duties as they relate to the exposure incident;
    - (C) Documentation of the route(s) of exposure and circumstances under which exposure occurred;
    - (D) Results of the source individual's blood testing, if available; and
    - (E) All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer's responsibility to maintain.
- (5) *Healthcare Professional's Written Opinion.* The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.
- (i) The healthcare professional's written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.
  - (ii) The healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information:
    - (A) That the employee has been informed of the results of the evaluation; and
    - (B) That the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.
    - (iii) All other findings or diagnoses shall remain confidential and shall not be included in the written report.
- (6) *Medical recordkeeping.* Medical records required by this standard shall be maintained in accordance with paragraph (h)(1) of this section.
- (g) *Communication of hazards to employees —*
- (1) *Labels and signs —*
    - (i) *Labels.*
      - (A) Warning labels shall be affixed to Occupational Safety and Health Admin., Labor § 1910.1030 containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F) and (G).
      - (B) Labels required by this section shall include the following legend:
      - (C) These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color.
      - (D) Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.
      - (E) Red bags or red containers may be substituted for labels.
      - (F) Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are



- exempted from the labeling requirements of paragraph (g).
- (G) Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.
- (H) Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated.
- (I) Regulated waste that has been decontaminated need not be labeled or color-coded.
- (ii) *Signs.*
- (A) The employer shall post signs at the entrance to work areas specified in paragraph (e), HIV and HBV Research Laboratory and Production Facilities, which shall bear the following legend:
- 
- (Name of the Infectious Agent)  
 (Special requirements for entering the area)  
 (Name, telephone number of the laboratory director or other responsible person.)
- (B) These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color.
- (2) *Information and Training.* (i) Employers shall ensure that all employees with occupational exposure participate in a training program which must be provided at no cost to the employee and during working hours.
- (ii) Training shall be provided as follows:
- (A) At the time of initial assignment to tasks where occupational exposure may take place;
- (B) At least annually thereafter.
- (iii) [Reserved]
- (iv) Annual training for all employees shall be provided within one year of their previous training.
- (v) Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.
- (vi) Material appropriate in content and vocabulary to educational level, literacy, and language of employees shall be used.
- (vii) The training program shall contain at a minimum the following elements:
- (A) An accessible copy of the regulatory text of this standard and an explanation of its contents;
- (B) A general explanation of the epidemiology and symptoms of bloodborne diseases;
- (C) An explanation of the modes of transmission of bloodborne pathogens;
- (D) An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan;
- (E) An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;
- (F) An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment;
- (G) Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment;
- (H) An explanation of the basis for selection of personal protective equipment;
- (I) Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;
- (J) Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;

- (K) An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available;
  - (L) Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;
  - (M) An explanation of the signs and labels and/or color coding required by paragraph (g)(1); and
  - (N) An opportunity for interactive questions and answers with the person conducting the training session.
- (viii) The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.
- (ix) Additional initial training for employees in HIV and HBV laboratories and production facilities. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements.
- (A) The employer shall assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.
  - (B) The employer shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.
  - (C) The employer shall provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The employer shall assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.
- (h) *Recordkeeping* —
- (1) *Medical Records.*
    - (i) The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020.
      - (ii) This record shall include:
        - (A) The name and social security number of the employee;
        - (B) A copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination as required by paragraph (f)(2);
        - (C) A copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3);
        - (D) The employer's copy of the healthcare professional's written opinion as required by paragraph (f)(5); and
        - (E) A copy of the information provided to the healthcare professional as Occupational Safety and Health Admin., Labor § 1910.1030 required by paragraphs (f)(4)(ii)(B)(C) and (D).
      - (iii) Confidentiality. The employer shall ensure that employee medical records required by paragraph (h)(1) are:
        - (A) Kept confidential; and
        - (B) Not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by this section or as may be required by law.
      - (iv) The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020.
    - (2) *Training Records.* (i) Training records shall include the following information:
      - (A) The dates of the training sessions;
      - (B) The contents or a summary of the training sessions;
      - (C) The names and qualifications of persons conducting the training; and

- (D) The names and job titles of all persons attending the training sessions.
- (ii) Training records shall be maintained for 3 years from the date on which the training occurred.
- (3) *Availability.*
- (i) The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.
- (ii) Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee representatives, to the Director, and to the Assistant Secretary.
- (iii) Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.1020.
- (4) *Transfer of Records.*
- (i) The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h).
- (ii) If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director, at least three months prior to their disposal and transmit them to the Director, if required by the Director to do so, within that three month period.
- (i) *Dates —*
- (1) *Effective Date.* The standard shall become effective on March 6, 1992.
- (2) The Exposure Control Plan required by paragraph (c) of this section shall be completed on or before May 5, 1992.
- (3) Paragraph (g)(2) Information and Training and (h) Recordkeeping shall take effect on or before June 4, 1992.
- (4) Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Followup, and (g) (1) Labels and Signs, shall take effect July 6, 1992.
- (5) *Sharps injury log.* (i) The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum:
- (A) The type and brand of device involved in the incident,
- (B) The department or work area where the exposure incident occurred, and
- (C) An explanation of how the incident occurred.
- (ii) The requirement to establish and maintain a sharps injury log shall apply to any employer who is required to maintain a log of occupational injuries and illnesses under 29 CFR 1904.
- (iii) The sharps injury log shall be maintained for the period required by 29 CFR 1904.6.

#### APPENDIX A TO SECTION 1910.1030 — HEPATITIS B VACCINE DECLINATION (MANDATORY)

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

[56 FR 64175, Dec. 6, 1991, as amended at 57 FR 12717, Apr. 3, 1992; 57 FR 29206, July 1, 1992; 61 FR 5508, Feb. 13, 1996; 66 FR 5325, Jan. 18, 2001; 71 FR 16672, 16673, Apr. 3, 2006]

#### § 1910.1020 Access to employee exposure and medical records.

- (a) *Purpose.* The purpose of this section is to provide employees and their designated representatives a right of access to relevant exposure and medical records; and to provide representatives of the Assistant Secretary a right of access to these records in order to fulfill responsibilities under the Occupational Safety and Health Act. Access by employees, their representatives, and the Assistant Secretary is necessary to yield both direct and indirect improvements in the detection, treatment, and prevention of occupational disease. Each employer is responsible for assuring compliance with this section, but the activities

involved in complying with the access to medical records provisions can be carried out, on behalf of the employer, by the physician or other healthcare personnel in charge of employee medical records. Except as expressly provided, nothing in this section is intended to affect existing legal and ethical obligations concerning the maintenance and confidentiality of employee medical information, the duty to disclose information to a patient/employee or any other aspect of the medical-care relationship, or affect existing legal obligations concerning the protection of trade secret information.

- (b) *Scope and application.* (1) This section applies to each general industry, maritime, and construction employer who makes, maintains, contracts for, or has access to employee exposure or medical records, or analyses thereof, pertaining to employees exposed to toxic substances or harmful physical agents.
- (2) This section applies to all employee exposure and medical records, and analyses thereof, of such employees, whether or not the records are mandated by specific occupational safety and health standards.
- (3) This section applies to all employee exposure and medical records, and analyses thereof, made or maintained in any manner, including on an in-house or contractual (e.g., fee-for-service) basis. Each employer shall assure that the preservation and access requirements of this section are complied with regardless of the manner in which records are made or maintained.
- (c) *Definitions.*
- (1) *Access* means the right and opportunity to examine and copy.
- (2) *Analysis using exposure or medical records* means any compilation of data or any statistical study based at least in part on information collected from individual employee exposure or medical records or information collected from health insurance claims records, provided that either the analysis has been reported to the employer or no further work is currently being done by the person responsible for preparing the analysis.
- (3) *Designated representative* means any individual or organization to whom an employee gives written authorization to exercise a right of access. For the purposes of access to employee exposure records and analyses using exposure or medical records, a recognized or certified collective bargaining agent shall be treated automatically as a designated representative without regard to written employee authorization.
- (4) *Employee* means a current employee, a former employee, or an employee being assigned or transferred to work where there will be exposure to toxic substances or harmful physical agents. In the case of a deceased or legally incapacitated employee, the employee's legal representative may directly exercise all the employee's rights under this section.
- (5) *Employee exposure record* means a record containing any of the following kinds of information:
- (i) Environmental (workplace) monitoring or measuring of a toxic substance or harmful physical agent, including personal, area, grab, wipe, or other form of sampling, as well as related collection and analytical methodologies, calculations, and other background data relevant to interpretation of the results obtained;
  - (ii) Biological monitoring results which directly assess the absorption of a toxic substance or harmful physical agent by body systems (e.g., the level of a chemical in the blood, urine, breath, hair, fingernails, etc.) but not including results which assess the biological effect of a substance or agent or which assess an employee's use of alcohol or drugs;
  - (iii) Material safety data sheets indicating that the material may pose a hazard to human health; or
  - (iv) In the absence of the above, a chemical inventory or any other record which reveals where and when used and the identity (e.g., chemical, common, or trade name) of a toxic substance or harmful physical agent.
- (6)
- (i) *Employee medical record* means a record concerning the health status of an employee which is made or maintained by a physician, nurse, or other healthcare personnel, or technician, including:
    - (A) Medical and employment questionnaires or histories (including job description and occupational exposures),
    - (B) The results of medical examinations (pre-employment, pre-assignment, periodic, or episodic) and laboratory tests (including chest and other X-ray examinations taken for the purpose of establishing a base-line or detecting occupational illnesses and all biological

- monitoring not defined as an “employee exposure record”),
- (C) Medical opinions, diagnoses, progress notes, and recommendations,
  - (D) First aid records,
  - (E) Descriptions of treatments and prescriptions, and
  - (F) Employee medical complaints.
- (ii) “Employee medical record” does not include medical information in the form of:
- (A) Physical specimens (e.g., blood or urine samples) which are routinely discarded as a part of normal medical practice, or
  - (B) Records concerning health insurance claims if maintained separately from the employer’s medical program and its records, and not accessible to the employer by employee name or other direct personal identifier (e.g., social security number, payroll number, etc.), or
  - (C) Records created solely in preparation for litigation which are privileged from discovery under the applicable rules of procedure or evidence; or
  - (D) Records concerning voluntary employee assistance programs (alcohol, drug abuse, or personal counseling programs) if maintained separately from the employer’s medical program and its records.
- (7) *Employer* means a current employer, a former employer, or a successor employer.
- (8) *Exposure* or *exposed* means that an employee is subjected to a toxic substance or harmful physical agent in the course of employment through any route of entry (inhalation, ingestion, skin contact or absorption, etc.), and includes past exposure and potential (e.g., accidental or possible) exposure, but does not include situations where the employer can demonstrate that the toxic substance or harmful physical agent is not used, handled, stored, generated, or present in the workplace in any manner different from typical non-occupational situations.
- (9) *Health Professional* means a physician, occupational health nurse, industrial hygienist, toxicologist, or epidemiologist, providing medical or other occupational health services to exposed employees.
- (10) *Record* means any item, collection, or grouping of information regardless of the form or process by which it is maintained (e.g., paper document, microfiche, microfilm, X-ray film, or automated data processing).
- (11) *Specific chemical identity* means a chemical name, Chemical Abstracts Service (CAS) Registry Number, or any other information that reveals the precise chemical designation of the substance.
- (12)
- (i) *Specific written consent* means a written authorization containing the following:
    - (A) The name and signature of the employee authorizing the release of medical information,
    - (B) The date of the written authorization,
    - (C) The name of the individual or organization that is authorized to release the medical information,
    - (D) The name of the designated representative (individual or organization) that is authorized to receive the released information,
    - (E) A general description of the medical information that is authorized to be released,
    - (F) A general description of the purpose for the release of the medical information, and
    - (G) A date or condition upon which the written authorization will expire (if less than one year).
  - (ii) A written authorization does not operate to authorize the release of medical information not in existence on the date of written authorization, unless the release of future information is expressly authorized, and does not operate for more than one year from the date of written authorization.
  - (iii) A written authorization may be revoked in writing prospectively at any time.
- (13) *Toxic substance or harmful physical agent* means any chemical substance, biological agent (bacteria, virus, fungus, etc.), or physical stress (noise, heat, cold, vibration, repetitive motion, ionizing and non-ionizing radiation, hypo - or hyperbaric pressure, etc.) which:
- (i) Is listed in the latest printed edition of the National Institute for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS) which is

incorporated by reference as specified in Sec. 1910.6; or

- (ii) Has yielded positive evidence of an acute or chronic health hazard in testing conducted by, or known to, the employer; or
- (iii) Is the subject of a material safety data sheet kept by or known to the employer indicating that the material may pose a hazard to human health.

(14) *Trade secret* means any confidential formula, pattern, process, device, or information or compilation of information that is used in an employer's business and that gives the employer an opportunity to obtain an advantage over competitors who do not know or use it.

(d) *Preservation of records.* (1) Unless a specific occupational safety and health standard provides a different period of time, each employer shall assure the preservation and retention of records as follows:

- (i) *Employee medical records.* The medical record for each employee shall be preserved and maintained for at least the duration of employment plus thirty (30) years, except that the following types of records need not be retained for any specified period:

(A) Health insurance claims records maintained separately from the employer's medical program and its records,

(B) First aid records (not including medical histories) of one-time treatment and subsequent observation of minor scratches, cuts, burns, splinters, and the like which do not involve medical treatment, loss of consciousness, restriction of work or motion, or transfer to another job, if made on-site by a non-physician and if maintained separately from the employer's medical program and its records, and

(C) The medical records of employees who have worked for less than (1) year for the employer need not be retained beyond the term of employment if they are provided to the employee upon the termination of employment.

- (ii) *Employee exposure records.* Each employee exposure record shall be preserved and maintained for at least thirty (30) years, except that:

(A) Background data to environmental (workplace) monitoring or measuring, such as laboratory reports and worksheets, need only be retained for one (1) year so long as the sampling results, the collection methodology (sampling plan), a description of the analytical and mathematical methods used, and a summary of other background data relevant to interpretation of the results obtained, are retained for at least thirty (30) years; and

(B) Material safety data sheets and paragraph (c)(5)(iv) records concerning the identity of a substance or agent need not be retained for any specified period as long as some record of the identity (chemical name if known) of the substance or agent, where it was used, and when it was used is retained for at least thirty (30) years<sup>1</sup>; and

(C) Biological monitoring results designated as exposure records by specific occupational safety and health standards shall be preserved and maintained as required by the specific standard.

- (iii) *Analyses using exposure or medical records.* Each analysis using exposure or medical records shall be preserved and maintained for at least thirty (30) years.

(2) Nothing in this section is intended to mandate the form, manner, or process by which an employer preserves a record so long as the information contained in the record is preserved and retrievable, except that chest X-ray films shall be preserved in their original state.

(e) *Access to records* —

(1) General.

(i) Whenever an employee or designated representative requests access to a record, the employer shall assure that access is provided in a reasonable time, place, and manner. If the employer cannot reasonably provide access to the record within fifteen (15) working days, the employer shall within the fifteen (15) working days apprise the employee or designated representative requesting the record of the reason for the delay and the earliest date when the record can be made available.

- (ii) The employer may require of the requester only such information as should be readily known to the requester and which may be necessary to

<sup>1</sup> Material safety data sheets must be kept for those chemicals currently in use that are effected by the Hazard Communication Standard in accordance with 29 CFR 1910.1200(g).

locate or identify the records being requested (e.g. dates and locations where the employee worked during the time period in question).

- (iii) Whenever an employee or designated representative requests a copy of a record, the employer shall assure that either:
  - (A) A copy of the record is provided without cost to the employee or representative,
  - (B) The necessary mechanical copying facilities (e.g., photocopying) are made available without cost to the employee or representative for copying the record, or
  - (C) The record is loaned to the employee or representative for a reasonable time to enable a copy to be made.
- (iv) In the case of an original X-ray, the employer may restrict access to on-site examination or make other suitable arrangements for the temporary loan of the X-ray.
- (v) Whenever a record has been previously provided without cost to an employee or designated representative, the employer may charge reasonable, non-discriminatory administrative costs (i.e., search and copying expenses but not including overhead expenses) for a request by the employee or designated representative for additional copies of the record, except that
  - (A) An employer shall not charge for an initial request for a copy of new information that has been added to a record which was previously provided; and
  - (B) An employer shall not charge for an initial request by a recognized or certified collective bargaining agent for a copy of an employee exposure record or an analysis using exposure or medical records.
- (vi) Nothing in this section is intended to preclude employees and collective bargaining agents from collectively bargaining to obtain access to information in addition to that available under this section.

(2) *Employee and designated representative access —*

(i) *Employee Exposure Records.*

(A) Except as limited by paragraph (f) of this section, each employer shall, upon request, assure the access to each employee and designated representative to employee exposure records relevant to the employee. For the purpose

of this section, an exposure record relevant to the employee consists of:

- (1) A record which measures or monitors the amount of a toxic substance or harmful physical agent to which the employee is or has been exposed;
- (2) In the absence of such directly relevant records, such records of other employees with past or present job duties or working conditions related to or similar to those of the employee to the extent necessary to reasonably indicate the amount and nature of the toxic substances or harmful physical agents to which the employee is or has been subjected, and
- (3) Exposure records to the extent necessary to reasonably indicate the amount and nature of the toxic substances or harmful physical agents at workplaces or under working conditions to which the employee is being assigned or transferred.

(B) Requests by designated representatives for unconsented access to employee exposure records shall be in writing and shall specify with reasonable particularity:

- (1) The record requested to be disclosed; and
- (2) The occupational health need for gaining access to these records.

(ii) *Employee medical records.* (A) Each employer shall, upon request, assure the access of each employee to employee medical records of which the employee is the subject, except as provided in paragraph (e)(2)(ii)(D) of this section.

(B) Each employer shall, upon request, assure the access of each designated representative to the employee medical records of any employee who has given the designated representative specific written consent. Appendix A to this section contains a sample form which may be used to establish specific written consent for access to employee medical records.

(C) Whenever access to employee medical records is requested, a physician representing the employer may recommend that the employee or designated representative:

- (1) Consult with the physician for the purposes of reviewing and discussing the records requested,

- (2) Accept a summary of material facts and opinions in lieu of the records requested, or
  - (3) Accept release of the requested records only to a physician or other designated representative.
- (D) Whenever an employee requests access to his or her employee medical records, and a physician representing the employer believes that direct employee access to information contained in the records regarding a specific diagnosis of a terminal illness or a psychiatric condition could be detrimental to the employee's health, the employer may inform the employee that access will only be provided to a designated representative of the employee having specific written consent, and deny the employee's request for direct access to this information only. Where a designated representative with specific written consent requests access to information so withheld, the employer shall assure the access of the designated representative to this information, even when it is known that the designated representative will give the information to the employee.
- (E) A physician, nurse, or other responsible healthcare personnel maintaining employee medical records may delete from requested medical records the identity of a family member, personal friend, or fellow employee who has provided confidential information concerning an employee's health status.
- (iii) Analyses using exposure or medical records.
- (A) Each employer shall, upon request, assure the access of each employee and designated representative to each analysis using exposure or medical records concerning the employee's working conditions or workplace.
  - (B) Whenever access is requested to an analysis which reports the contents of employee medical records by either direct identifier (name, address, social security number, payroll number, etc.) or by information which could reasonably be used under the circumstances indirectly to identify specific employees (exact age, height, weight, race, sex, date of initial employment, job title, etc.), the employer shall assure that personal identifiers are removed before access is provided. If the employer can demonstrate that removal of personal identifiers from an analysis is not feasible, access to the personally identifiable portions of the analysis need not be provided.
- (3) *OSHA access.* (i) Each employer shall, upon request, and without derogation of any rights under the Constitution or the Occupational Safety and Health Act of 1970, 29 U.S.C. 651 "et seq.," that the employer chooses to exercise, assure the prompt access of representatives of the Assistant Secretary of Labor for Occupational Safety and Health to employee exposure and medical records and to analyses using exposure or medical records. Rules of agency practice and procedure governing OSHA access to employee medical records are contained in 29 CFR 1913.10.
- (ii) Whenever OSHA seeks access to personally identifiable employee medical information by presenting to the employer a written access order pursuant to 29 CFR 1913.10(d), the employer shall prominently post a copy of the written access order and its accompanying cover letter for at least fifteen (15) working days.
- (f) *Trade secrets.*
- (1) Except as provided in paragraph (f)(2) of this section, nothing in this section precludes an employer from deleting from records requested by a health professional, employee, or designated representative any trade secret data which discloses manufacturing processes, or discloses the percentage of a chemical substance in mixture, as long as the health professional, employee, or designated representative is notified that information has been deleted. Whenever deletion of trade secret information substantially impairs evaluation of the place where or the time when exposure to a toxic substance or harmful physical agent occurred, the employer shall provide alternative information which is sufficient to permit the requesting party to identify where and when exposure occurred.
  - (2) The employer may withhold the specific chemical identity, including the chemical name and other specific identification of a toxic substance from a disclosable record provided that:
    - (i) The claim that the information withheld is a trade secret can be supported;



- (ii) All other available information on the properties and effects of the toxic substance is disclosed;
  - (iii) The employer informs the requesting party that the specific chemical identity is being withheld as a trade secret; and
  - (iv) The specific chemical identity is made available to health professionals, employees and designated representatives in accordance with the specific applicable provisions of this paragraph.
- (3) Where a treating physician or nurse determines that a medical emergency exists and the specific chemical identity of a toxic substance is necessary for emergency or first-aid treatment, the employer shall immediately disclose the specific chemical identity of a trade secret chemical to the treating physician or nurse, regardless of the existence of a written statement of need or a confidentiality agreement. The employer may require a written statement of need and confidentiality agreement, in accordance with the provisions of paragraphs (f)(4) and (f)(5), as soon as circumstances permit.
- (4) In non-emergency situations, an employer shall, upon request, disclose a specific chemical identity, otherwise permitted to be withheld under paragraph (f)(2) of this section, to a health professional, employee, or designated representative if:
- (i) The request is in writing;
  - (ii) The request describes with reasonable detail one or more of the following occupational health needs for the information:
    - (A) To assess the hazards of the chemicals to which employees will be exposed;
    - (B) To conduct or assess sampling of the workplace atmosphere to determine employee exposure levels;
    - (C) To conduct pre-assignment or periodic medical surveillance of exposed employees;
    - (D) To provide medical treatment to exposed employees;
    - (E) To select or assess appropriate personal protective equipment for exposed employees;
    - (F) To design or assess engineering controls or other protective measures for exposed employees; and
  - (G) To conduct studies to determine the health effects of exposure.
- (iii) The request explains in detail why the disclosure of the specific chemical identity is essential and that, in lieu thereof, the disclosure of the following information would not enable the health professional, employee or designated representative to provide the occupational health services described in paragraph (f)(4)(ii) of this section:
- (A) The properties and effects of the chemical;
  - (B) Measures for controlling workers' exposure to the chemical;
  - (C) Methods of monitoring and analyzing worker exposure to the chemical; and
  - (D) Methods of diagnosing and treating harmful exposures to the chemical;
- (iv) The request includes a description of the procedures to be used to maintain the confidentiality of the disclosed information; and
- (v) The health professional, employee, or designated representative and the employer or contractor of the services of the health professional or designated representative agree in a written confidentiality agreement that the health professional, employee or designated representative will not use the trade secret information for any purpose other than the health need(s) asserted and agree not to release the information under any circumstances other than to OSHA, as provided in paragraph (f)(7) of this section, except as authorized by the terms of the agreement or by the employer.
- (5) The confidentiality agreement authorized by paragraph (f)(4)(iv) of this section:
- (i) May restrict the use of the information to the health purposes indicated in the written statement of need;
  - (ii) May provide for appropriate legal remedies in the event of a breach of the agreement, including stipulation of a reasonable pre-estimate of likely damages; and,
  - (iii) May not include requirements for the posting of a penalty bond.
- (6) Nothing in this section is meant to preclude the parties from pursuing non-contractual remedies to the

- extent permitted by law.
- (7) If the health professional, employee or designated representative receiving the trade secret information decides that there is a need to disclose it to OSHA, the employer who provided the information shall be informed by the health professional prior to, or at the same time as, such disclosure.
- (8) If the employer denies a written request for disclosure of a specific chemical identity, the denial must:
- (i) Be provided to the health professional, employee or designated representative within thirty days of the request;
  - (ii) Be in writing;
  - (iii) Include evidence to support the claim that the specific chemical identity is a trade secret;
  - (iv) State the specific reasons why the request is being denied; and,
  - (v) Explain in detail how alternative information may satisfy the specific medical or occupational health need without revealing the specific chemical identity.
- (9) The health professional, employee, or designated representative whose request for information is denied under paragraph (f)(4) of this section may refer the request and the written denial of the request to OSHA for consideration.
- (10) When a health professional, employee, or designated representative refers a denial to OSHA under paragraph (f)(9) of this section, OSHA shall consider the evidence to determine if:
- (i) The employer has supported the claim that the specific chemical identity is a trade secret;
  - (ii) The health professional employee, or designated representative has supported the claim that there is a medical or occupational health need for the information; and
  - (iii) The health professional, employee or designated representative has demonstrated adequate means to protect the confidentiality.
- (11)
- (i) If OSHA determines that the specific chemical identity requested under paragraph (f)(4) of this section is not a “bona fide” trade secret, or that it is a trade secret but the requesting health professional, employee or designated representatives has a legitimate medical or occupational health need for the information, has executed a written confidentiality agreement, and has shown adequate means for complying with the terms of such agreement, the employer will be subject to citation by OSHA.
  - (ii) If an employer demonstrates to OSHA that the execution of a confidentiality agreement would not provide sufficient protection against the potential harm from the unauthorized disclosure of a trade secret specific chemical identity, the Assistant Secretary may issue such orders or impose such additional limitations or conditions upon the disclosure of the requested chemical information as may be appropriate to assure that the occupational health needs are met without an undue risk of harm to the employer.
- (12) Notwithstanding the existence of a trade secret claim, an employer shall, upon request, disclose to the Assistant Secretary any information which this section requires the employer to make available. Where there is a trade secret claim, such claim shall be made no later than at the time the information is provided to the Assistant Secretary so that suitable determinations of trade secret status can be made and the necessary protections can be implemented.
- (13) Nothing in this paragraph shall be construed as requiring the disclosure under any circumstances of process or percentage of mixture information which is a trade secret.
- (g) *Employee information.*
- (1) Upon an employee’s first entering into employment, and at least annually thereafter, each employer shall inform current employees covered by this section of the following:
    - (i) The existence, location, and availability of any records covered by this section;
    - (ii) The person responsible for maintaining and providing access to records; and
    - (iii) Each employee’s rights of access to these records.
  - (2) Each employer shall keep a copy of this section and its appendices, and make copies readily available, upon request, to employees. The employer shall also distribute to current employees any informational materials concerning this section which are made available to the employer by the Assistant Secretary of Labor for Occupational Safety and Health.
- (h) *Transfer of records.*

- (1) Whenever an employer is ceasing to do business, the employer shall transfer all records subject to this section to the successor employer. The successor employer shall receive and maintain these records.
- (2) Whenever an employer is ceasing to do business and there is no successor employer to receive and maintain the records subject to this standard, the employer shall notify affected current employees of their rights of access to records at least three (3) months prior to the cessation of the employer's business.
- (3) Whenever an employer either is ceasing to do business and there is no successor employer to receive and maintain the records, or intends to dispose of any records required to be preserved for at least thirty (30) years, the employer shall:
  - (i) Transfer the records to the Director of the National Institute for Occupational Safety and Health (NIOSH) if so required by a specific occupational safety and health standard; or
  - (ii) Notify the Director of NIOSH in writing of the impending disposal of records at least three (3) months prior to the disposal of the records.
- (4) Where an employer regularly disposes of records required to be preserved for at least thirty (30) years, the employer may, with at least (3) months notice, notify the Director of NIOSH on an annual basis of the records intended to be disposed of in the coming year.
  - (i) *Appendices.* The information contained in appendices A and B to this section is not intended, by itself, to create any additional obligations not otherwise imposed by this section nor detract from any existing obligation.

[61 FR 5507, Feb. 13, 1996; 61 FR 9227, March 7, 1996; 61 FR 31427, June 20, 1996; 71 FR 16673, April 3, 2006]

<http://www.osha.gov/SLTC/bloodbornepathogens/standards.htm>

Texas Department of State Health Services TAC Chapter 96 Bloodborne Pathogen Rules revised effective July 2006: [http://www.dshs.state.tx.us/idcu/health/bloodborne\\_pathogens/reporting](http://www.dshs.state.tx.us/idcu/health/bloodborne_pathogens/reporting)

## Updates

Occupational Safety and Health Administration  
 Department of Labor 29CFR 1910.1030  
 Occupational Exposure to Bloodborne Pathogens;  
 Needlesticks and Other Sharps Injuries; Final rule.  
 Federal Register/Vol. 66, No. 12/January 28, 2001:



**Appendix D**  
**Infectious Disease**  
**Information**



# To Order From the DSHS Warehouse:

1. Use a copy of the AG-30 form on page 3:
  - a. Fill out the form completely.
  - b. Keep a copy for your records.
  - c. Mail or fax the request directly to:

Warehouse Manager  
Department of State Health Services  
Materials Acquisition & Management Division  
1100 W. 49th St.  
Austin, TX 78756-3199  
Fax: (512) 458-7413, or (512) 458-7707

OR

2. Go to <http://webds.dshs.state.tx.us/mamd/litcat/pdf/ag-30.pdf>  
Follow the instructions for ordering materials from this Web site.

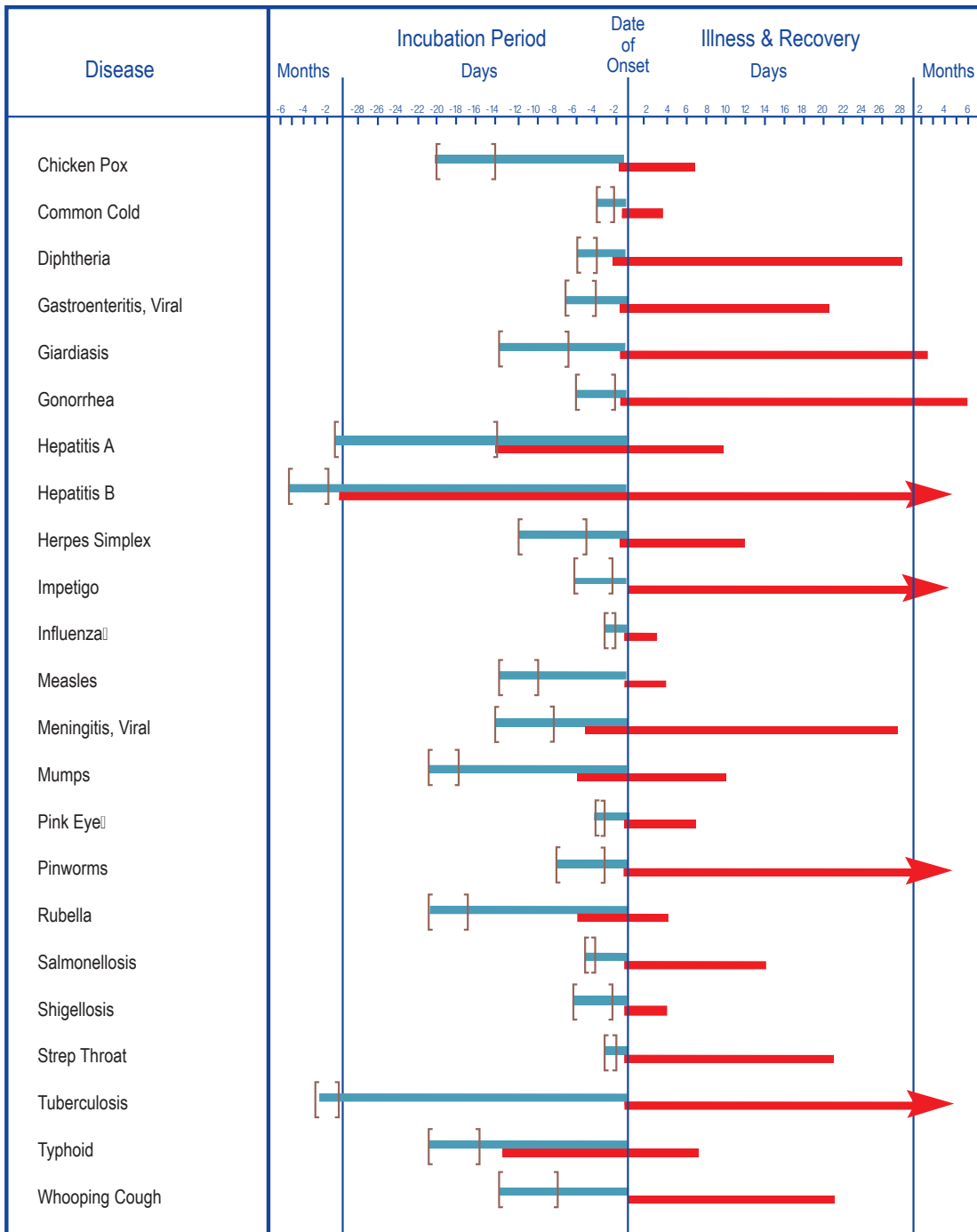
Note that only materials stored at the DSHS Warehouse can be ordered directly from this Web site. Although all the WIC materials are listed on the Online Catalog Shopping Cart, when an item is not available from the DSHS Warehouse, it will not allow you to request a quantity. It will direct you to click at the right for ordering. Click on the > under the “Order Source and Publication” information. These materials are stored by individual DSHS programs, such as WIC.







**Table 12: Incubation Period and Duration of Communicability of Common Infectious Diseases**



[ ] indicate probable period of exposure  
 ■ incubation period  
 ■ communicable period

(Note that communicable period can be shortened for many diseases by appropriate antibiotic treatment. Arrows indicate the possibility of a prolonged carrier state.)

Table 13: The ABC's of Hepatitis

	Hepatitis A (HAV)	Hepatitis B (HBV)	Hepatitis C (HCV)	Hepatitis D (HDV)	Hepatitis E (HEV)
<b>What is it?</b>	HAV is a virus that causes inflammation of the liver. It does not lead to chronic disease.	HAV is a virus that causes inflammation of the liver. It does not lead to chronic disease.	HCV is a virus that causes inflammation of the liver. This infection can lead to cirrhosis and cancer.	HDV is a virus that causes inflammation of the liver. It only infects those persons with HBV.	HEV is a virus that causes inflammation of the liver. It is rare in the U.S. There is no chronic state.
<b>Incubation Period</b>	15 to 50 days. Average 30 days.	4 to 25 weeks. Average 8 to 12 weeks.	2 to 25 weeks. Average 7 to 9 weeks.	4 to 26 weeks.	2 to 9 weeks. Average 40 days.
<b>How is it spread?</b>	Transmitted by fecal/oral route, through close person-to-person contact or ingestion of contaminated food and water.	Contact with infected blood, seminal fluid, and vaginal secretions. Sex contact, contaminated needles, tattoo/body piercing and other sharp instruments. Infected mother to newborn. Human bite.	Contact with infected blood, contaminated IV needles, razors, tattoo/body piercing and other sharp instruments. Infected mother to newborn. It is not easily transmitted through sex.	Contact with infected blood, contaminated needles. Sexual contact with HDV infected person.	Transmitted through fecal/oral route. Outbreaks associated with contaminated water supply in other countries.
<b>Symptoms</b>	May have no symptoms. Adults may have light stools, dark urine, fatigue, fever, and jaundice.	May have no symptoms. Some persons have mild flu-like symptoms, dark urine, light stools, jaundice, fatigue and fever.	Same as HBV.	Same as HBV.	Same as HBV.
<b>Treatment of Chronic Disease</b>	Not applicable.	Interferon is effective in up to 35-45% of those treated.	Interferon is effective in 10-20% of those treated.	Interferon with varying success.	Not Applicable.
<b>Vaccine</b>	Two doses of vaccine to anyone over the age of two.	Three doses may be given to persons of any age.	None.	None.	None.
<b>Who is at risk?</b>	Household or sex contact with an infected person or living in an area with HAV outbreak, travelers to developing countries, homosexual men, and IV drug users.	Infant born to infected mother, having sex with infected person or multiple partners, IV drug users, emergency responders and healthcare workers, homosexual men, and hemodialysis patients.	Anyone who had a blood transfusion before 1990, healthcare workers, IV drug users, hemodialysis patients, infants born to infected mother, and multiple sex partners.	IV drug users, homosexual men, and those having sex with a HDV-infected person.	Travelers to developing countries.
<b>Prevention</b>	Immune Globulin or vaccination. Wash hands after going to the toilet. Clean surfaces contaminated with feces, such as changing tables.	Vaccination and safe sex. Clean up any infected blood with bleach and wear protective gloves. Do not share razors or toothbrushes.	Safe sex. Clean up spilled blood with bleach. Wear gloves when touching blood. Do not share razors or toothbrushes.	Hepatitis B vaccine to prevent HBV infection. Safe sex.	Avoid drinking or using potentially contaminated water.



## 2007 Guidelines for Isolation Precautions: Preventing Transmission of Infections Agents in Health Care Settings, HICPAC, CDC, and United States Department of Health and Human Services

Table 14: Synopsis of Types of Precautions and Patients Requiring the Precautions\*

I. Standard Precautions
<p><b>Standard Precautions</b> combine the major features of Universal Precautions and Body Substance Isolation (BSI) and are based on the principle that all blood, body fluids, secretions, excretions except sweat, non intact skin, and mucous membranes may contain transmissible infectious agents. New elements of Standard Precautions include <i>Respiratory Hygiene/Cough Etiquette</i>, safe injection practices, and the use of masks for the insertion of catheters or injections into spinal or epidural spaces (e.g., myelogram, spinal or epidural anesthesia).</p> <p><b>Respiratory Hygiene/Cough Etiquette</b> is a strategy targeted at patients and accompanying family members and friends with undiagnosed transmissible respiratory infections, and applies to any person with signs of illness including cough, congestion, rhinorrhea, or increased production of respiratory secretions when entering a healthcare facility. The elements of Respiratory Hygiene/Cough Etiquette include: 1) education of healthcare facility staff, patients, and visitors, 2) posted signs, in language(s) appropriate to the population served, with instructions to patients and accompanying family members or friends, 3) source control measures (e.g., covering the mouth/nose with a tissue when coughing and prompt disposal of used tissues, using surgical masks on the coughing person when tolerated and appropriate, 4) hand hygiene after contact with respiratory secretions, and 5) spatial separation, ideally &gt;3 feet, of persons with respiratory infections in common waiting areas when possible.</p> <p>Covering sneezes and coughs and placing masks on coughing patients are proven means of source containment that prevent infected persons from dispersing respiratory secretions into the air. Healthcare personnel are advised to observe Droplet Precautions (i.e., wear a mask) and hand hygiene when examining and caring for patients with signs and symptoms of a respiratory infection. Healthcare personnel who have a respiratory infection are advised to avoid direct patient contact, especially with high-risk patients. If this is not possible, then a mask should be worn while providing patient care.</p> <p><b>Safe Injection Practices.</b> The investigation of four large outbreaks of HBV and HCV among patients in ambulatory care facilities in the United States identified a need to define an reinforced safe injection practices. The four outbreaks occurred in a private medical practice, a pain clinic, an endoscopy clinic, and a hematology/oncology clinic. The primary breaches in infection control practice that contributed to these outbreaks were 1) reinsertion of used needles into a multiple-dose vial or solution container (e.g., saline bag) and 2) use of a single needle/syringe to administer intravenous medication to multiple patients. In one of these outbreaks, preparation of medications in the same workspace where used needle/syringes were dismantled also a contributing factor. These and other outbreaks of viral hepatitis could have been prevented by adherence to basic principles of aseptic technique for the preparation and administration of parenteral medications. These include the use of a sterile, single-use, disposable needle and syringe for each injection given and prevention of contamination of injection equipment and medication.</p> <p>Whenever possible, use of single-dose vials is preferred over multiple-dose vials, especially when medications will be administered to multiple patients. Outbreaks related to unsafe injection practices indicate that some healthcare personnel are unaware of, do not understand, or do not adhere to basic principles of infection control and aseptic technique. A survey of US healthcare workers who provide medication through injection found that 1% to 3% reused the same needle and/or syringe on multiple patients. Among the deficiencies identified in recent outbreaks were a lack of oversight of personnel and failure to follow-up on reported breaches in infection control practices in ambulatory settings. Therefore, to ensure that all healthcare workers understand and adhere to recommended practices, principles of infection control and aseptic technique need to be reinforced in training programs and incorporated into institutional policies that are monitored for adherence.</p>

## II. Transmissions Based Precautions

### Airborne Precautions

In addition to Standard Precautions, use Airborne Precautions for patients known or suspected to have serious illnesses transmitted by airborne droplet nuclei.

Examples of such illnesses include:

- Measles
- Varicella (including disseminated zoster)<sup>†</sup>
- Tuberculosis<sup>‡</sup>

### Droplet Precautions

In addition to Standard Precautions, use Droplet Precautions for patients known or suspected to have serious illnesses transmitted by large particle droplets.

Examples of such illnesses include:

- Invasive *Haemophilus influenzae* type b disease, including meningitis, pneumonia, epiglottitis, and sepsis
- Invasive *Neisseria meningitidis* disease, including meningitis, pneumonia, and sepsis

Other serious bacterial respiratory infections spread by droplet transmission, including:

- Diphtheria (pharyngeal)
- Mycoplasma pneumonia
- Pertussis
- Pneumonic plague
- Streptococcal (group A) pharyngitis, pneumonia, or scarlet fever in infants and young children

Serious viral infections spread by droplet transmission, including:

- Adenovirus<sup>†</sup>
- Influenza
- Mumps
- Parvovirus B19
- Rubella

### Contact Precautions

In addition to Standard Precautions, use Contact Precautions for patients known or suspected to have serious illnesses easily transmitted by direct patient contact or by contact with items in the patient's environment. Examples of such illnesses include:

- Gastrointestinal, respiratory, skin, or wound infections or colonization with multi drug-resistant bacteria judged by the infection control program, based on current state, regional, or national recommendations, to be of special clinical and epidemiologic significance
- Enteric infections with a low infectious dose or prolonged environmental survival, including:
  - ◆ *Clostridium difficile*
  - ◆ For diapered or incontinent patients: enterohemorrhagic *Escherichia coli* O157:H7, *Shigella*, hepatitis A, or rotavirus

- Respiratory syncytial virus, parainfluenza virus, or enteroviral infections in infants and young children
- Skin infections that are highly contagious or that may occur on dry skin, including:
  - ◆ Diphtheria (cutaneous)
  - ◆ Herpes simplex virus (neonatal or mucocutaneous)
  - ◆ Impetigo
  - ◆ Major (noncontained) abscesses, cellulitis, or decubiti
  - ◆ Pediculosis
  - ◆ Scabies
  - ◆ Staphylococcal furunculosis in infants and young children
  - ◆ Zoster (disseminated or in the immunocompromised host)<sup>†</sup>
- Viral/hemorrhagic conjunctivitis
- Viral hemorrhagic infections (Ebola, Lassa, or Marburg)<sup>\*</sup>

## Management of Patients with Confirmed or Suspected Infections TB Disease

Comprehensive infection control guidelines have been published by the Centers for Disease Control and Prevention in the following document: Centers for Disease Control and Prevention. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005. MMWR 2005,54(no. RR-17). For specific, comprehensive information on infection control measures to prevent the transmission of *M. tuberculosis*, please refer to this document. This document can be found at the following Web site: <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm>.

The 2005 CDC guidelines recommend:

- All healthcare setting should have a written TB infection control plan as part of an overall infection control program.
- Every healthcare setting should conduct an initial and ongoing assessment of the risk of transmitting *Mycobacterium tuberculosis* within the setting.
- The risk assessment will determine the risk category of transmitting *M. tuberculosis* as:
  - ◆ low-risk,
  - ◆ medium risk, or
  - ◆ potential ongoing risk/transmission.
- The infection control plan will differ if the setting is one in which:
  - ◆ patients with suspected or confirmed TB disease are expected to be encountered, or
  - ◆ patients with suspected or confirmed TB disease are not expected to be encountered.
- A TB infection control plan is based on three levels of controls:
  - ◆ administrative controls,
  - ◆ environmental controls, and
  - ◆ respiratory-protection controls.

- The risk category for each of the three levels of (low, medium, or potential ongoing transmission) determines which administrative, environmental and respiratory protection measures are needed for the individual healthcare setting.
- The following types of healthcare settings are defined and discussed in (2005)
  - ◆ Inpatient settings in which patients are to be expected to be encountered
    - emergency department
    - ICU
    - surgical suites
    - laboratories
    - bronchoscopy suites
    - sputum induction and inhalation therapy rooms
    - autopsy suites
    - embalming rooms
  - ◆ Outpatient settings
    - TB treatment facilities
    - medical offices and ambulatory care settings
    - dialysis units
    - dental-care settings
  - ◆ Non-traditional settings
    - emergency medical services
    - medical settings in correctional facilities
    - home-based healthcare and outreach settings

The following information contains an outline of general recommendations for managing patients who have suspected or confirmed TB disease, as discussed on pages 16–19 in the 2005 CDC Guidelines. For comprehensive information, please refer to the 2005 CDC Guidelines or the most recent guidelines from CDC.

### Think TB!

The primary risk to healthcare workers is contact with individuals who are not diagnosed or suspected of having infectious TB disease. Healthcare workers in all categories of healthcare settings should maintain a high index of suspicion for patients with signs and symptoms of TB disease and should implement appropriate precautions: prompt triage, airborne precautions, including airborne infection isolation (AII) rooms when available, diagnostic procedures, and prompt initiation of treatment for TB infection or TB disease upon diagnosis.

**Table 15: Management of patients with confirmed or suspected TB**

	Administrative Controls	Environmental Controls	Respiratory Protection Controls
<b>Settings in which patients with suspected or confirmed infectious TB disease are not expected to be encountered</b>			
Triage only: initial evaluation of patients who will transfer to another setting.	Implement written infection-control plan for triage of patients with suspected or confirmed TB disease. Update annually.	Settings in which patients with suspected or confirmed TB disease are rarely seen and not treated do not need an airborne infection isolation (A.I.I.) room.	
	Promptly recognize and transfer patients with suspected or confirmed TB disease to a facility that treats patients with TB disease.	Place in A.I.I. room, if it is available, or hold in a separate room with door closed, away from others, and not in a waiting room.	If the patient has signs or symptoms of infectious TB disease (positive AFB smear result), have patient wear a surgical or procedure mask during transport, in waiting areas, or when others are present.
	Before transfer, hold patient in an area separate from healthcare workers and other persons..	If available, air cleaning technologies can be used to increase the number of air exchanges.	
<b>Inpatient settings, TB expected to be encountered.</b>			
<b>Outpatient settings in which patients with suspected or confirmed infectious TB disease are expected to be encountered.</b>			
	Perform annual risk assessment for the setting.	Environmental controls should be implemented based on the types of activities that are performed.	For healthcare workers, visitors and others entering an A.I.I. room of a patient with settings in which patients with suspected or confirmed TB disease, at least N95 disposable respirators should be worn.
	Develop and implement a written infection control plan.	Patients with suspected or confirmed infectious TB disease requiring transport should be transported as discussed under Emergency Medical Services (See 205, pg. 126).	If the patient has signs or symptoms of infectious TB disease, have the patient wear a surgical or procedure mask, if possible, during transport, in waiting areas, or when others are present.



	Administrative Controls	Environmental Controls	Respiratory Protection Controls
	Provide TB training, education and screening for healthcare workers as part of the infection control plan.		If the risk assessment indicates that respiratory protection is needed, drivers or HCWs who are transporting patients with suspected or confirmed infectious TB disease in an enclosed vehicle should wear at least an N95 disposable respirator. The risk assessment should consider the potential for shared air.
	Establish protocols for problem evaluations.		
	Collaborate with state or local health departments when appropriate.		
<b>Non-Traditional Facility-Based Settings</b>			
Non-traditional facility-based settings include home-based healthcare, outreach, and ambulatory settings. <b>Note:</b> This category includes all Texas Department of State Health Services regional clinics.	Perform an annual risk assessment. Develop and implement a written infection control plan. Provide TB training, education, and screening for HCWs as part of the infection control plan.	Environmental controls should be implemented based on the types of activities that are performed.	If the nontraditional based setting has A.I.I. room(s), all HCWs, visitors, and others entering the A.I.I. room of a patient with suspected or confirmed TB disease should wear N95 disposable respirators.
	Establish protocols for problem evaluation.	Patients with suspected or confirmed infectious TB disease requiring transport should be transported as discussed in the EMS section.	If the patient has signs and symptoms of infectious TB disease, have the patient wear a surgical or procedure mask, if possible, during transport, in waiting areas, or when others are present.
	Patients and household members should be educated regarding the importance of taking medications, respiratory hygiene, cough etiquette, and proper medical evaluation and treatment.	If possible, do not perform cough-inducing procedures unless the appropriate environmental measures are present, or perform these procedures outside.	For HCWs entering the homes of patients with suspected or confirmed infectious TB disease, at least N95 disposable respirators should be worn.
	If possible, postpone transporting patients until they are determined not to have TB disease or to be noninfectious.		For HCWs transporting patients with suspected or confirmed infections TB disease in a vehicle, at least an 95 disposable respirators should be worn.

Table 16: Notifiable Conditions

A – L	When to Report	L – Y	When to Report
Acquired immune deficiency syndrome (AIDS) <sup>1,2</sup>	Within 1 week	Leishmaniasis <sup>3</sup>	Within 1 week
Amebiasis <sup>3</sup>	Within 1 week	Listeriosis <sup>3,4</sup>	Within 1 week
<b>Anthrax<sup>3,4</sup></b>	<b>Call Immediately</b>	Lyme disease <sup>3</sup>	Within 1 week
Arbovirus infection <sup>3,5</sup>	Within 1 week	Malaria <sup>3</sup>	Within 1 week
Asbestosis <sup>6</sup>	Within 1 week	<b>Measles (rubeola)<sup>3</sup></b>	<b>Call Immediately</b>
<b>Botulism, foodborne<sup>3,4</sup></b>	<b>Call Immediately</b>	Meningitis (specify type) <sup>3</sup>	Within 1 week
Botulism, infant, wound, and other <sup>3,4</sup>	Within 1 week	<b>Meningococcal infections, invasive<sup>3,4</sup></b>	<b>Call Immediately</b>
<b>Brucellosis<sup>3,4</sup></b>	<b>Within 1 work day</b>	Mumps <sup>3</sup>	Within 1 week
Campylobacteriosis <sup>3</sup>	Within 1 week	<b>Pertussis<sup>3</sup></b>	<b>Within 1 work day</b>
Cancer <sup>7</sup>	See rules <sup>7</sup>	Pesticide poisoning, acute occupational <sup>6</sup>	Within 1 week
Chancroid <sup>1</sup>	Within 1 week	<b>Plague<sup>3</sup></b>	<b>Call Immediately</b>
Chickenpox (varicella) <sup>8</sup>	Within 1 week	<b>Poliomyelitis, acute paralytic<sup>3</sup></b>	<b>Call Immediately</b>
<i>Chlamydia trachomatis</i> infection <sup>1</sup>	Within 1 week	<b>Q fever<sup>3</sup></b>	<b>Within 1 work day</b>
Contaminated sharps injury <sup>9</sup>	Within 1 month	<b>Rabies, human<sup>3</sup></b>	<b>Call Immediately</b>
<b>Controlled substance overdose<sup>10</sup></b>	<b>Call Immediately</b>	Relapsing fever <sup>3</sup>	Within 1 week
Creutzfeldt-Jakob disease (CJD) <sup>3</sup>	Within 1 week	<b>Rubella (including congenital)<sup>3</sup></b>	<b>Within 1 work day</b>
Cryptosporidiosis <sup>3</sup>	Within 1 week	Salmonellosis, including typhoid fever <sup>3</sup>	Within 1 week
Cyclosporiasis <sup>3</sup>	Within 1 week	<b>Severe Acute Respiratory Syndrome (SARS)<sup>3</sup></b>	<b>Call Immediately</b>
Cysticercosis <sup>3</sup>	Within 1 week	Shigellosis <sup>3</sup>	Within 1 week
Dengue <sup>3</sup>	Within 1 week	Silicosis <sup>6</sup>	Within 1 week
<b>Diphtheria<sup>3</sup></b>	<b>Call Immediately</b>	<b>Smallpox<sup>3</sup></b>	<b>Call Immediately</b>
Drowning/near drowning <sup>11</sup>	Within 10 work days	Spinal cord injury <sup>11</sup>	Within 10 work days
Ehrlichiosis <sup>3</sup>	Within 1 week	Spotted fever group rickettsioses <sup>3</sup>	Within 1 week
Encephalitis (specify etiology) <sup>3</sup>	Within 1 week	<b>Staph. aureus, vancomycin-resistant (VISA and VRSA)<sup>3, 4</sup></b>	<b>Call Immediately</b>
<i>Escherichia coli</i> , enterohemorrhagic <sup>3,4</sup>	Within 1 week	Streptococcal disease (group A, B, S. pneumo), invasive <sup>3</sup>	Within 1 week
Gonorrhea <sup>1</sup>	Within 1 week	Syphilis <sup>1</sup>	Within 1 week
<b>Haemophilus influenzae type b infections, invasive<sup>3</sup></b>	<b>Call Immediately</b>	<i>Taenia solium</i> and undifferentiated <i>Taenia</i> infection <sup>3</sup>	Within 1 week
Hansen's disease (leprosy) <sup>3</sup>	Within 1 week	Tetanus <sup>3</sup>	Within 1 week
Hantavirus infection <sup>3</sup>	Within 1 week	Traumatic brain injury <sup>11</sup>	Within 10 work days
Hemolytic Uremic Syndrome (HUS) <sup>3</sup>	Within 1 week	Trichinosis <sup>3</sup>	Within 1 week

A – L	When to Report	L – Y	When to Report
Hepatitis A (acute) <sup>3</sup>	Within 1 work day	Tuberculosis (includes all M. tuberculosis complex) <sup>12</sup>	Within 1 work day
Hepatitis B, C, D, E, and unspecified (acute) <sup>3</sup>	Within 1 week	Tularemia <sup>3,4</sup>	Call Immediately
Hepatitis B identified prenatally or at delivery (acute & chronic) <sup>3</sup>	Within 1 work day	Typhus <sup>3</sup>	Within 1 week
Hepatitis B, perinatal (HBsAg+ < 24 months old) <sup>3</sup>	Within 1 week	Vibrio infection, including cholera <sup>3,4</sup>	Within 1 work day
Human immunodeficiency virus (HIV) infection <sup>1,2</sup>	Within 1 week	Viral hemorrhagic fever, including Ebola <sup>3</sup>	Call Immediately
Influenza-associated pediatric mortality <sup>3</sup>	Within 1 work day	West Nile Fever <sup>3</sup>	Within 1 week
Lead, child blood, any level & adult blood, any level <sup>6</sup>	Call Immediately	Yellow fever <sup>3</sup>	Call Immediately
Legionellosis <sup>3</sup>	Within 1 week	Yersiniosis <sup>3,4</sup>	Within 1 week
<b>In addition to specified reportable conditions, any outbreak, exotic disease, or unusual group expression of disease that may be of public health concern should be reported by the most expeditious means available.</b>			

<sup>1</sup> Please refer to specific rules and regulations for reporting and who to report to at: <http://www.dshs.state.tx.us/hivstd/reporting/default.shtm>

<sup>2</sup> Labs conducting confirmatory HIV testing are requested to send remaining specimen to a CDC-designated laboratory. Please call (512) 533-3041 for details.

<sup>3</sup> Reporting forms are available at <http://www.dshs.state.tx.us/idcu/investigation/forms/>. Investigation forms at <http://www.dshs.state.tx.us/idcu/investigation/>

Call as indicated for immediately reportable conditions.

<sup>4</sup> Lab isolate must be sent to DSHS lab. Call (512) 458-7598 for specimen submission information.

<sup>5</sup> Reportable Arbovirus infections include neuroinvasive and non-neuroinvasive Cache Valley, California serogroup, Eastern Equine (EEE), Dengue, Powassan, St. Louis Encephalitis (SLE), Venezuelan equine (VEE), West Nile, and Western Equine (WEE)

<sup>6</sup> Please refer to specific rules and regulations for reporting and who to report to at <http://www.dshs.state.tx.us/epitox/default.shtm>

<sup>7</sup> Please refer to specific rules and regulations for reporting and who to report to at <http://www.dshs.state.tx.us/tcr/lawrules.shtm>

<sup>8</sup> Varicella reporting form is at [http://www.dshs.state.tx.us/idcu/health/vaccine\\_preventable\\_diseases/forms/f11\\_11046.pdf](http://www.dshs.state.tx.us/idcu/health/vaccine_preventable_diseases/forms/f11_11046.pdf). Call local health dept for copy with their fax number.

<sup>9</sup> Not applicable to private facilities. Initial reporting forms for Contaminated Sharps at [http://www.dshs.state.tx.us/idcu/health/bloodborne\\_pathogens/reporting/](http://www.dshs.state.tx.us/idcu/health/bloodborne_pathogens/reporting/)

<sup>10</sup> Contact local poison center at 1 (800) 222-1222. For instructions, forms, and fax numbers see <http://www.dshs.state.tx.us/epidemiology/epipoison.shtm>

<sup>11</sup> Please refer to specific rules and regulations for reporting and who to report to at <http://www.dshs.state.tx.us/injury/default.shtm>

<sup>12</sup> Please refer to specific rules and regulations for reporting and who to report to at <http://www.dshs.state.tx.us/idcu/disease/tb/>

### Call Immediately 24/7 Phone Numbers

Information for your local or regional health department can be found at:

<http://www.dshs.state.tx.us/regions/default.shtm>

Department of State Health Services

Business Hours 1 (800) 252-8239/After Hours Physician On Call (512) 458-7111

E59-11364 (Rev. 01/08)

Several Texas laws (Health & Safety Code, Chapters 81, 84, and 87) require specific information regarding notifiable conditions be provided to the Texas Department of State Health Services (DSHS). Healthcare providers, hospitals, laboratories, schools, and others are required to report patients who are suspected of having a notifiable condition ( Chapter 97, Title 25, Texas Administrative Code).

## General Instructions

- **WHAT:** The table below lists notifiable conditions in Texas. In addition to these conditions, **any outbreaks, exotic diseases, and unusual group expressions of disease** must be reported. All diseases shall be reported by name, age, sex, race/ethnicity, DOB, address, telephone number, disease, date of onset, method of diagnosis, and name, address, and telephone number of physician.
- **WHEN:** The *Reportable Conditions List* indicates when to report each condition. Cases or suspected cases of illness considered to be **public health emergencies, outbreaks, exotic diseases,** and unusual group expressions of disease must be reported to the local health department or DSHS **immediately**. Other diseases for which there must be a quick public health response must be reported **within one working day**. All other conditions must be reported to the local health department or DSHS **within one week**.
- **HOW:** Most notifiable conditions, or other illnesses that may be of public health significance, should be reported directly to the local or health service regions. Paper reporting forms can be obtained by calling your local or health service region or by download (Epi-2 for more detailed single case medical care provider reports or Epi-1 for less detailed multiple reports). As a last resort or in case of emergency, reports can be made by telephone to the state office at (800) 252-8239 or (512) 458-7111. Calling (512) 458-7111 after hours will reach the physician/epidemiologist-on-call.

## Special Instructions

- Acquired immune deficiency syndrome (AIDS) should only be reported once following the initial physician diagnosis. The report date, type and results of tests including a CD4 + T lymphocyte cell count below 200 cells per microliter/percentage < 14% must also be included with the report.
- **Chancroid, Chlamydia trachomatous infection, gonorrhea, human immunodeficiency virus (HIV) infection, and syphilis** reports must also include the report date, type and results of tests, including a CD4 + T lymphocyte cell count below 200 cells per microliter/percentage < 14% for HIV infection.
- **Meningitis** types include aseptic/viral, bacterial (specify etiology), fungal, parasitic, and other.
- Invasive streptococcal disease, invasive meningococcal infection, or invasive Haemophilus influenzae type b infections refers to isolates from normally sterile sites and includes meningitis, septicemia, cellulitis, epiglottitis, osteomyelitis, pericarditis, septic arthritis, and necrotizing fasciitis.

For more information, call the Infectious Disease Control Unit (IDCU) at (800) 252-8239 and press 1).

## Laboratories

*Reportable Laboratory Results* ( PDF File: 36.4 KB)

*DSHS Quarterly Antibiotic Resistant Isolate Reporting Form* ( PDF File: 112 KB)

Laboratory Services Section Forms, Including G-2A and G-2B

Laboratories, blood banks, mobile units, and other facilities in which a laboratory examination of a blood specimen is made are required to report **patients with a CD4 + T lymphocyte cell count below 200 cells per microliter or CD4 + T lymphocyte percentage less than 14%.**

Immediately report isolates of vancomycin-resistant *Staphylococcus aureus* (VRSA) and vancomycin-resistant coagulase negative Staphylococcus species by calling (800) 252-8239 or faxing (512) 458-7616. Isolates of VRSA and vancomycin-resistant coagulase negative Staphylococcus species shall be submitted to the Laboratory Services Section, 1100 West 49th Street, Austin, Texas 78756-3199. Isolates of vancomycin-resistant Enterococcus (VRE) species and penicillin-resistant Streptococcus pneumoniae shall be reported to the DSHS Infectious Disease Control Unit on at least a quarterly basis.

All reports of **VRSA, vancomycin-resistant coagulase-negative Staphylococcus species, VRE, and penicillin-resistant Streptococcus pneumoniae** shall include patient name, date of birth or age, sex, city of submitter, anatomic site of culture, date of culture, and minimum inhibitory concentration (MIC) if available. For VRE, name the species of Enterococcus.

In addition, numeric totals of all isolates of Enterococcus species and all isolates of Streptococcus pneumoniae shall be reported to the DSHS Infectious Disease Epidemiology and Surveillance Division no later than the last working day of March, June, September, and December.

Laboratories shall submit all *Neisseria meningitides* isolates from normally sterile sites to the Texas Department of State Health Services, Laboratory Services Section, 1100 West 49th Street, Austin, TX 78756-3199.



**APPENDIX E**  
**Principles of Sterilization  
and Disinfection**





**Table 17: Inactivation of Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV) by Disinfectants**

Disinfectant	Concentration Inactivating 10 <sup>6</sup> HBV, 10 min., 20° C	Concentration Inactivating 10 <sup>6</sup> HIV, ≤ 10 min., 20° C
Chlorine dioxide	ND	ND+
Ethyl alcohol	ND	50%
Formalin	ND	ND+
Glutaraldehyde	2%	ND+
Glutaraldehyde-phenate	0.13% Glutaraldehyde–0.44% phenol	ND
Hydrogen peroxide	ND	0.3%
Iodophor	80 ppm	ND+
Isopropyl alcohol	70%	35%
Paraformaldehyde	ND	0.5%
Phenolic	ND	0.5%
Quarternary ammonium	ND	ND+
Sodium hypochlorite	500 ppm	50 ppm

ND No data

\* Data from Bond et al.

\*\* Data from Martin et al.

+ Other investigators have used reverse transcriptase activity and/or virus infectivity assays to determine the activity of other disinfectants against HIV.

Other disinfectants that inactivate HIV include 1:200 dilution of chlorine dioxide, 1% formalin, 0.25% iodophor, 0.08% quarternary ammonium compound, and glutaraldehyde.

**Table 18: Classification of Devices, Processes, and Germicidal Products**

Device Classification	Spaulding Process Classification	EPA Product Classification
Critical (Enters sterile tissue or vascular system): Implants, scalpels, needles, other surgical instruments, etc.	Sterilization.  Sporicidal chemical; prolonged contact.	ND+ Sterilant/disinfectant.
Semicritical (Touches mucous membranes): Flexible endoscopes, laryngoscopes, endotracheal tubes, and other similar instruments.	High-Level Disinfection. Sporocidal chemical; short contact.	Sterilant/disinfectant.
Noncritical (Touches intact skin): Stethoscopes, tabletops, floors, etc.	Intermediate-Level Disinfection.	Hospital disinfectant with label claim for tuberculocidal activity.
	Low-Level Disinfection.	Hospital disinfectant without label claim for tuberculocidal activity. <sup>+</sup>

<sup>+</sup> Modified from Favero MS, Bond WW: Chemical disinfection of medical and surgical materials. In: Block SS, ed: Disinfection, sterilization and preservation, ed 4, Philadelphia, 1991 Lea & Febiger.

[http://www.infectioncontroldiscovery.com/articles/410/410\\_111clean.html](http://www.infectioncontroldiscovery.com/articles/410/410_111clean.html)

**Table 19: Methods Of Sterilization and Disinfection**

Object	Sterilization		Disinfection		
	Procedure	Exposure Time	Procedure	Procedure	Procedure
	<b>Critical Items</b> (will enter tissue or vascular system or blood will flow through them)		<b>High Level</b> (semicritical items; [except dental] will come in contact with mucous membrane or nonintact skin)	<b>Intermediate Level</b> some semicritical items <sup>1</sup> and noncritical items)	<b>Low Level</b> (noncritical items; will come in contact with intact skin)
			(exposure time 12–30 min. at 20° C) <sup>2,3</sup>	(exposure time ≥ 1 min.) <sup>9</sup>	(exposure time ≥ 1 min.) <sup>9</sup>
Smooth, hard surface <sup>1,4</sup>	A B C D E F G H	MR MR MR 10 h at 20--25°C NA 6 h 12 M at 50-56°C 3-8 H	D E F H I <sup>8</sup> J	K L <sup>5</sup> M N	K L M N O
Rubber tubing and catheters <sup>3,4</sup>	A B C D E F G H	MR MR MR 10 h at 20--25°C NA 6 h 12 M at 50-56°C 3-8 H	D E F H I <sup>8</sup> J		
Polyethylene tubing and catheters <sup>3,4,7</sup>	A B C D E F G H	MR MR MR 10 h at 20--25°C NA 6 h 12 M at 50-56°C 3-8 H	D E F H I <sup>8</sup> J		
Lensed instruments <sup>4</sup>	B C D E F G H	MR MR 10 h at 20--25°C NA 6 h 12 M at 50-56°C 3-8 H	D E F H I <sup>8</sup> J		
Thermometers (oral and rectal) <sup>8</sup>				K <sup>8</sup>	
Hinged instruments <sup>4</sup>	A B C D E F G H	MR MR 10 h at 20--25°C NA 6 h 12 M at 50-56°C 3-8 H	D E F H I <sup>8</sup> J		

Modified from 8. 10. 11. 616.

- A – Heat sterilization, including steam or hot air (see manufacturer’s recommendations, steam sterilization processing time from 3–30 minutes, see Table 10)
- B – Ethylene oxide gas (see manufacturer’s recommendations, generally 1–6 hours processing time plus aeration time of 8–12 hours at 50–60°C)
- C – Hydrogen peroxide gas plasma (see manufacturer’s recommendations, processing time between 45–72 minutes; endoscopes or medical devices with lumens >40 cm or a diameter <3 mm cannot be processed at this time in the United States)
- D – Glutaraldehyde-based formulations ( $\geq 2\%$  glutaraldehyde caution should be exercised with all glutaraldehyde formulations when further in-use dilution is anticipated); glutaraldehyde (0.95%) and 1.64% phenol/phenate
- E – Ortho-phthalaldehyde 0.55%
- F – Hydrogen peroxide 7.5% (will corrode copper, zinc, and brass)
- G – Peracetic acid, concentration variable but 2% or greater is sporicidal
- H – Hydrogen peroxide (7.35%) and 0.23% peracetic acid; hydrogen peroxide 1% and peracetic acid 0.08% (will corrode metal instruments)
- I – Wet pasteurization at 70°C for 30 minutes after detergent cleaning
- J – Hypochlorite, single-use chlorine generated on-site by electrolyzing saline containing more than 650–675 active free chlorine (will corrode metal instruments)
- K – Ethyl or isopropyl alcohol (70–90%)
- L – Sodium hypochlorite (5.25–6.15% household bleach diluted 1:500 provides 100 ppm available chlorine)
- M – Phenolic germicidal detergent solution (follow product label for use-dilution)
- N – Iodophor germicidal detergent solution (follow product label for use-dilution)
- O – Quaternary ammonium germicidal detergent solution (follow product label for use-dilution)
- MR – Manufacturer’s recommendations
- NA – Not applicable

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<sup>1</sup> See text for discussion of hydrotherapy

<sup>2</sup> The longer the exposure to a disinfectant, the more likely it is that all microorganisms will be eliminated. Ten-minute exposure is not adequate to disinfect many objects, especially those which are difficult to clean, because they have narrow channels or other areas that can harbor organic material and bacteria. Twenty-minute exposure at 20°C is the minimum time needed to reliably kill *M. tuberculosis* and nontuberculous mycobacteria with a 2% glutaraldehyde. With the exception of >2% glutaraldehydes, follow the FDA-cleared high-level disinfection claim. Some high-level disinfectants have a reduced exposure time (e.g., ortho-Phthalaldehyde at 12 minutes at 20°C) because of their rapid activity against mycobacteria or reduced exposure time due to increased mycobactericidal activity at elevated temperature (2.5% glutaraldehyde at 5 minutes at 35°C)..

<sup>3</sup> Tubing must be completely filled for disinfection. Care must be taken to avoid entrapment of air bubbles during immersion.

<sup>4</sup> Material compatibility should be investigated when appropriate

<sup>5</sup> A concentration of 1000 ppm available chlorine should be considered where cultures or concentrated preparations of microorganisms have spilled (5.25% to 6.15% household bleach diluted 1:50 provides > 1000 ppm available chlorine). This solution may corrode some surfaces.

<sup>6</sup> Pasteurization (washer-disinfector) of respiratory therapy or anesthesia equipment is a recognized alternative to high-level disinfection. Some data challenge the efficacy of some pasteurization units.

<sup>7</sup> Thermostability should be investigated when appropriate.

<sup>8</sup> Do not mix rectal and oral thermometers at any stage of handling or processing.

<sup>9</sup> By law, all applicable label instructions on EPA-registered products must be followed. If the user selects exposure conditions that differ from those on the EPA-registered products label, the user assumes liability from any injuries resulting from off-label use and is potentially subject to enforcement action under FIFRA.

**Table 20: Formulas for Mixing Chlorine-Bleach Solution**

<b>1:100 Concentration<sup>1</sup></b>					
<b>Metric Measurement Volumes</b>			<b>Approximate Household Measurement Volumes</b>		
<b>Bleach</b>	<b>Water</b>	<b>Total</b>	<b>Bleach</b>	<b>Water</b>	<b>Total</b>
2.5 mL	247.5 mL	250 mL	2/3 tsp	1¼ cup	10 oz
5 mL	495 mL	500 mL	1¼ tsp	2½ cups	20 oz
10 mL	990 mL	1 L	2 tsp	1 qt	1 qt
20 mL	1980 mL	2 L	4 tsp	2 qts	2 qts
<b>1:10 CONCENTRATION<sup>2</sup></b>					
<b>Metric Measurement Volumes</b>			<b>Approximate Household Measurement Volumes</b>		
<b>Bleach</b>	<b>Water</b>	<b>Total</b>	<b>Bleach</b>	<b>Water</b>	<b>Total</b>
25 mL	225 mL	250 mL	2 Tbsp	1 cup + 2 Tbsp	10 oz
50 mL	450 mL	500 mL	¼ cup	2¼ cups	20 oz
100 mL	900 mL	1 L	6 Tbsp	3½ cups	1 qt
200 mL	1800 mL	2 L	¾ cup	7 cups	2 qts
<b>Desired Chlorine Concentration<sup>3</sup></b>					
	<b>5000 ppm</b>	<b>1000 ppm</b>	<b>500 ppm</b>	<b>100 ppm</b>	
Dilution of bleach (5.25% NaCl) prepared fresh for use within 24 hours	1:10	1:50	1:100	1:500	
Dilution of bleach (5.25% NaCl) prepared fresh and used for 1–30 days	1:5	1:25	1:50	1:250	

<sup>1</sup> This solution is used for general cleaning of non-porous environmental surfaces on a routine basis. The solution must be made fresh daily because the active ingredient is lost more rapidly in very dilute solutions than in the more concentrated solution.

<sup>2</sup> This solution is used to decontaminate and disinfect non-porous environmental surfaces when a spill of blood, body fluids or feces has occurred. The solution can be made up once a week and dispensed from an opaque spray bottle which has been clearly labeled.

<sup>3</sup> To maintain the chlorine concentration, the bleach solution must be stored in a closed, opaque plastic container. Over a one-month period, the chlorine level will be reduced 40% to 50%. Therefore, for long-term storage, the beginning concentration should be twice as strong as the desired final concentration.

**Appendix F**  
**Clinic Laboratory**  
**Information**



# Manual of Reference Services

## Guidelines for Specimen Collection and Submission

### Telephone Inquiries

Telephone inquiries should be directed to:

(512) 458-7578 for lab results, or

(512) 458-7598 for inquiries about guidelines for the submission, collection, and handling of specimens.

We examine specimens as carefully and rapidly as possible; however, we do not sacrifice accuracy for speed. Please consider the following information before making a telephone inquiry:

- Lab reporting results are given only to the original submitter.
- Upon receipt of the specimen at the Laboratory, most testing will be completed in one to three days; however, newborn screening tests take 3-6 days.
- Confirmation of findings in certain bacteriological examinations may necessitate a short delay in reporting results.
- If specimens must go to another reference center, the report will be delayed for at least two weeks.

Of course, emergency matters may be pursued at any time.

### Reference Services

If reference services are needed but are not provided in this laboratory system, the Laboratory uses the services of the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia or in Ft. Collins, Colorado. When a particular test is available only from CDC, submitters should send the specimen DSHS requisition form, along with a patient history, to the Texas Department of State Health Services for forwarding to the CDC.

### Submission of Specimens

Please exercise care when submitting specimens and requesting tests. Services are offered only in keeping with departmental policies, licensure, and mission; therefore, services may be withdrawn in case of misuse or improper specimen submission. Submission of proper specimens under optimum conditions is very important. Accurate tests seldom can be performed on poor specimens.

The Laboratory enforces the principles of Good Laboratory Practices. The submitter is responsible for ensuring expiration dating on media. We will monitor the interval between the collection and the receipt of time-sensitive specimens (newborn screening, bacteriological water, gonorrhea).

## Guidelines for Specific Types of Specimens

### Prenatal Triple Screen Collection and Packing Instructions

#### General Instructions:

1. Submit a G-1C form for each patient with corresponding specimen tube.
2. Retain a copy of the G-1C submission form for your records.
3. Clearly label each specimen with the patient's first and last name as written on the G-1C specimen submission form. Pre-printed patient labels used for specimen identification **MUST** match the patient's name on the submission form.
4. Specimens must be triple-contained.

#### Special Requirements:

Required Specimen Type: 2 mL of serum in blue top tube specific for Triple Screen Testing.

#### Special Instructions:

1. Specimen must be collected from patients between 15.0 and 20.9 gestational weeks, preferably 16-18 weeks. Serum specimen must be collected prior to amniocentesis.
2. Allow samples to clot completely before centrifugation; remove serum from clot within 2 hours of collection. Immediately transfer serum to special blue top tube provided by DSHS and freeze (-20° or lower degrees C or lower). Batching of specimens for shipment is recommended.
3. Specimens **MUST** be kept frozen until shipping is initiated. Ship specimens overnight on dry ice **OR** with adequate ice packs so that specimens arrive at DSHS laboratory cold. Specimens received at room temperature will be unsatisfactory for testing.
4. Do **NOT** ship ANY prenatal triple screen specimens on Fridays or prior to a Federally observed holiday (for holiday delivery).

#### Instructions for Shipping Biological substance, Category Bs:

To ensure proper packaging, please follow these instructions. See also the Triple Screen Packing Diagram below.

1. Obtain enough dry ice to keep the specimens frozen or enough ice packs to keep specimens cold for the duration of the shipment.
2. Place the serum specimens in the blue top tube provided by DSHS laboratory, then place them in a BIOHAZARD bag and seal. Place BIOHAZARD bag, containing the specimens, inside a canister provided by DSHS and place up to 4 canisters in the bottom of the Styrofoam box.
3. Fill the Styrofoam box with dry ice or ice packs. Ensure canisters are completely covered with dry ice or ice packs, and secured.
4. Place the lid on the Styrofoam box. *Make sure the date and time is documented on the G-1C form when specimens are removed from the freezer.*



5. Place the completed G-1C form(s) in a plastic zip lock bag. Then place the plastic zip lock bag on top of the closed Styrofoam box and seal the fiberboard box.
6. Secure the outer fiberboard box with packing tape.
7. Ensure that a diamond-shaped UN 3373 label is on exterior of the fiberboard box, when shipping biological substance, Category Bs.
8. Dry ice is considered a “dangerous good.” If using dry ice:
  - a. Use less than 5 lbs of dry ice.
  - b. Mark the blank box and write “dry ice” in the **Special Instructions** section of the air bill.
  - c. Attach a diamond-shaped dry ice label on the package with the number “9” and “UN1845” on it. This label must include the amount of dry ice used. Ensure that this is legible and does not overlap any other label on the fiberboard box.
9. Fill out Section 1 of the air bill that is provided by DSHS and place it inside the sleeve and attach to the top of the sealed fiberboard box.

➔ **Note: Make sure that your Styrofoam box is not airtight, if using dry ice!**

By following these instructions when shipping biological substance, Category Bs, your responsibility should be fulfilled.

### Shipping Instructions:

Check elsewhere in this section for specific test instructions and information about tube types.

For questions about shipping of triple screen specimens, call (800) 687-4363 or (512) 458-7138.

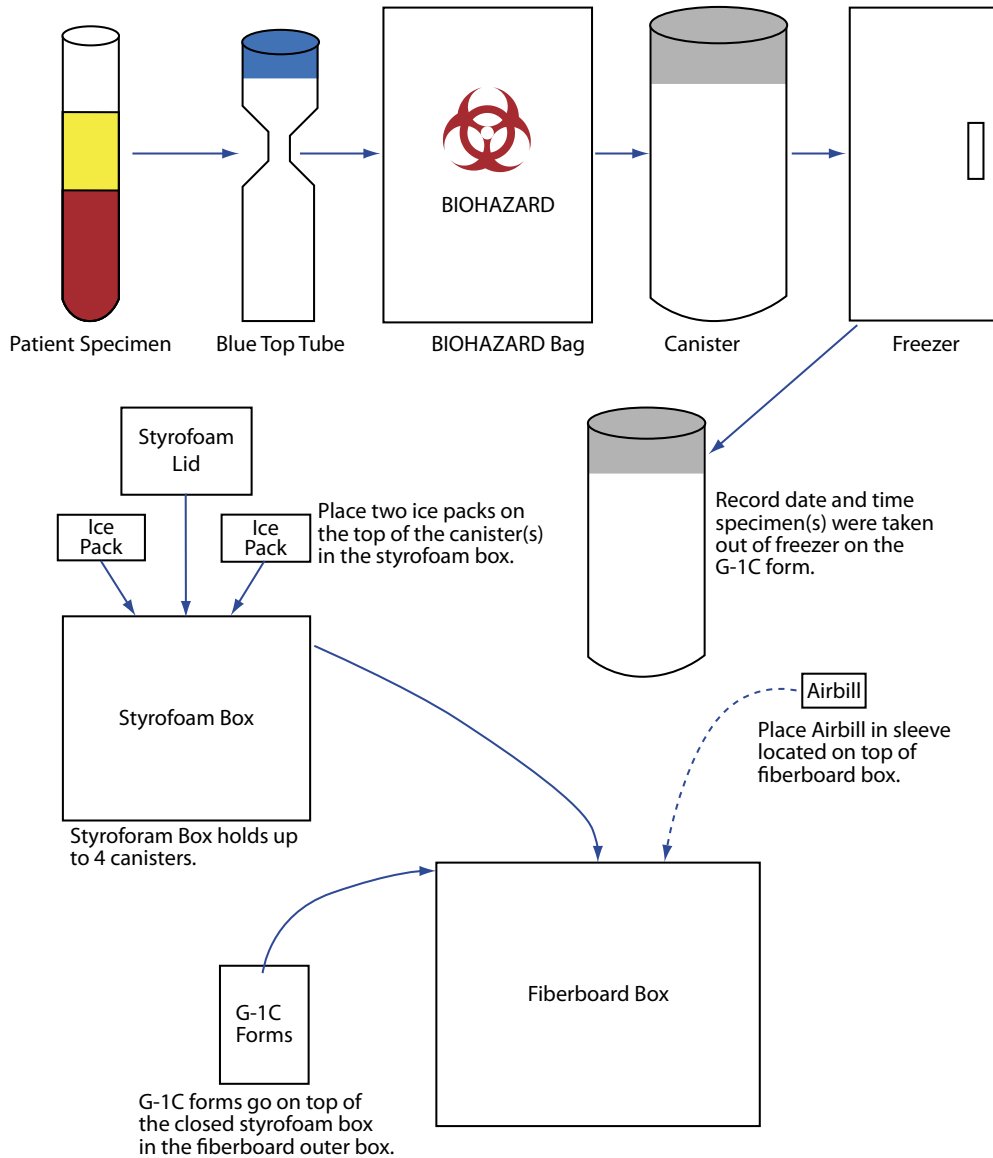
For blue top specimen tubes, non-dry ice cold boxes, and shipping containers, call (512) 458-7661.

## Collection and Shipping of Triple Screen Specimens:

1. Collect whole blood from patients for triple screen testing who are between 15.0-20.9 weeks of gestational age.
2. Centrifuge specimen and separate serum from RBC within 2 hours.
3. Place 2 ml of serum in 3 ml blue top tube provided by DSHS Laboratory.
4. Place specimens in BIOHAZARD bags and place in canisters.  
Multiple specimens may be contained inside the canisters.  
FREEZE canister(s) containing specimens IMMEDIATELY.
5. **After specimens are frozen:**  
Batch specimens and ship once or twice a week.  
Do not ship on Fridays or the day before Federal holidays.
6. Place up to four canisters with frozen specimens in the bottom of the Styrofoam box.
7. Place and secure ice packs or place dry ice on top of canisters.

8. Close the Styrofoam box.
9. Place the Styrofoam box inside the fiberboard box.
10. Before sealing the fiberboard box, record time and date on each G1-C form for each specimen removed from the freezer.
11. Place requisition forms on top of the Styrofoam box, but inside fiberboard box. Seal fiberboard box.
12. Place an air bill provided by the Prenatal Testing Laboratory inside the shipping sleeve and attach to top of the sealed fiberboard box and ship specimens overnight.

Figure 5: Triple Screen Packing Diagram



## Serological Testing

The DSHS Laboratory does not provide blood collection tubes, except for those who are under contract or are eligible under the Texas Health Steps (THSteps) Program; therefore, physicians should have a supply of vacuum tubes for the collection of blood specimens for serological testing. They may either be serum tubes, silicon coated (red-top tubes), or Serum Separator tubes with clot activator and gel for serum separation (red gray or “tiger” top tubes). Assays will require at least 5mls of whole blood in a tube. General specimens handling requirements are listed below, however, they differ with each assay, so please refer to the test requested in the Lab Tests for Diseases/Agents section of this manual.

Serum samples that are to be tested fresh may be stored for up to two hours at 2-8°C in the presence of clots. Serum may be separated from the clot by centrifugation and transferred to a sterile tube with a screw-cap (make sure that the seal is tight to prevent leakage). Serum separated from the clot may be stored at 2-8°C up to 48 hours. After 48 hours, or for shipping, the serum must be frozen at -20°C and sent on dry ice. Temperature level during entire shipment should be no warmer than -20°C. Pack specimens in compliance with government regulations covering the transportation of etiologic agents. To prevent hemolysis in the specimens avoid: bacterial contamination, the presence of water or chemicals in syringes or tubes, or rough treatment. Avoid extremely high temperatures, such as may occur in mail vans and drop boxes in the summer, and **never freeze whole blood**.

### How to collect serum sample using serum separator tubes with clot activator:

1. Gently invert tube 5 times to mix clot activator with blood.
2. Allow blood to clot for a minimum of 30 minutes in a vertical position. Observe a dense clot.
3. Centrifuge at full speed (between 1100 and 1300g) for 10 minutes for swing-head unit or 15 minutes for fixed angle units. Barrier will form, separating serum specimen from clot.
4. Transport spun tube to the laboratory.

A single result is significant in a few serological tests, such as immune status testing. In many cases, single results will be more misleading than helpful. Therefore, the Laboratory’s policy requires paired specimens, that is two blood specimens collected from two to three weeks apart for most diseases. Collecting the first specimens as soon as possible after the onset of the disease is essential. Single specimens will be accepted for syphilis and HIV serology, immune status testing (i.e. Rubella in pregnant women), and IgM antibody tests. Single specimens may also be submitted for systemic mycoses when a chronic infection is underway.

**Table 21: DSHS Laboratory - Serology Specimen Acceptance Criteria (effective 01/01/08)**

Testing Requirements			Shipping Requirements		
Analyte	Test	Testing Specimen Type	Shipping Requirement	Received Within	Temp
Hepatitis A	Hep A Total Ab EIA	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Hepatitis A	Hep A IgM EIA	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Hepatitis B	Hep B Core Total Ab EIA	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower

APPENDIX F

Testing Requirements			Shipping Requirements		
Analyte	Test	Testing Specimen Type	Shipping Requirement	Received Within	Temp
Hepatitis B	Hep B Core IgM EIA	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Hepatitis B	Hep B Surf Ag EIA	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Hepatitis B	Hep B Surf Ab EIA	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Hepatitis B	Hep B Surf Ag neut EIA	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Hepatitis B	Hep B Ag EIA	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Hepatitis B	Hep Be Ab EIA	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Rubella (screen - Family planning)	IgG, screen EIA	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Cytomegalovirus (CMV)	IgG/IgM EIA	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Lyme disease	Poly IgG & IgM/IgM EIA	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Rubella	IgG/IgM EIA	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Rubeola (Measles)	IgG EIA & IgM EIA	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Varicella Zoster (VZV)	IgG EIA Screen	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Hantavirus	IgG/IgM EIA	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
West Nile/SLE	IgM - MIA	Serum/CSF	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
West Nile/SLE	IgG/IgM EIA	Serum/CSF	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Mumps	IgM EIA	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Mumps	IgM IFA	Serum	Cold (tested within 7 d) Frozen/dry ice	2 days >2 d up to 7 d	2-8°C -20° or lower
Legionellosis	IgG IFA	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Toxoplasma	IgG IFA	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Cat Scratch Fever	IgG IFA	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Ehrlichia	IgG IFA	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Rickettsial panel (RMSF, typhus)	IgG IFA	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Q Fever	IgG IFA	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower

Testing Requirements			Shipping Requirements		
Analyte	Test	Testing Specimen Type	Shipping Requirement	Received Within	Temp
Aspergillosis	Immunodiffusion	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Fungal ID	Immunodiffusion	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Fungal CF panel	CFT	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Brucellosis	MAT	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Tularemia	MAT	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Plague (Human)	PHI	Serum	Cold Frozen/dry ice	2 days >2 days	2-8°C -20° or lower
Plague (Zoonosis)	PHI	Nobuto strips (dried blood)	Ambient temp Frozen/dry ice	3 months >3 months	Ambient temp -20° or lower
HIV-1/HIV-2 PLUS O screen	EIA	Whole blood (red top tube)	Ambient temp	7 days	up to 37°C
		Serum/Plasma	Frozen/dry ice	>7 days	-20° or lower
HIV - 1 screen	rLAV EIA	Dried Blood Spot	Ambient temp	7 days	≤37°C
			Cold or Frozen/dry ice	>7 days	2-8°C/-20° or lower
HIV - 1 confirmation	Western Blot	Whole blood (red top tube)	Ambient temp	7 days	up to 37°C
		Dried Blood Spot	Ambient temp	7 days	up to 37°C
			Cold or Frozen/dry ice	> 7 days	2-8°C/-20° or lower
HIV - 1 confirmation	Western Blot only	Oral Fluid	Ambient temp	up to 21 days	up to 37°C
HIV - 1 confirmation only	Western Blot only	Serum/Plasma	Frozen/dry ice	>7 days	-20° or lower
Hepatitis C	EIA - Serum	Whole blood (red top tube)	Ambient temp	7 days	up to 37°C
		Serum/Plasma	Frozen/dry ice	>7 days	-20° or lower
Hepatitis C	RIBA - Serum	Serum	send out to LabCorp		
Syphilis	RPR Card test	Whole blood (red top tube)	Abient temp	5 days	up to 45°C
		Serum	Cold	>5 days	2-8°C
Syphilis - confirmation	TP-PA	Whole blood (red top tube)	Ambient temp	5 days	up to 45°C
		Serum	Cold	<5 days	2-8°C
Syphilis - confirmation	FTA - ABS	Serum	Cold Frozen/dry ice	5 days >5 days	2-8°C -20° or lower

## Sputum

When submitting sputum, be certain that it is from the deeper portion of the lungs. Often saliva only is submitted, and this is usually unsatisfactory. The Laboratory in Austin provides reference and primary culturing work in mycobacteriology and mycology.

## Fecal specimens for bacteriological culturing

Fecal specimens for bacteriological culturing will be accepted only under special circumstances and with prior approval (512) 458-7318. When approved, these specimens must be submitted in Cary-Blair transport medium. Instruction sheet and medium available upon request. Call (512) 458-7661.

### Fecal specimens for intestinal parasites

The examination of fecal specimens for intestinal parasites is still viewed as a reference service and will be offered to any public health clinic, but prior arrangement is required for all other specimens (512-458-7318). The specimens must not be sent in the bacteriological preservative. The specimen should be divided into two portions, one being placed into a vial of 10% Formalin, the second being placed into a vial of PVA (polyvinyl alcohol). The Laboratory provides kits to qualified providers. Call (512) 458-7661.

### Fecal specimens for viral isolation

Fecal specimens for viral isolation must not be chemically preserved. Instead, fresh, unpreserved stools must be submitted. Any viral isolation specimen should be maintained at refrigerator temperatures (4-8° C) between the time of collection and the time of receipt in the laboratory. If the expected time between collection and receipt in the laboratory will be greater than 72 hours, freeze specimens after collection and ship on dry ice.

### Rabies specimens

The DSHS Laboratory recommends shipping rabies specimens by bus. Guidelines for shipping rabies specimens are as follows:

- Specimens must be shipped in a sealed, sturdy double container; a Styrofoam container inside a cardboard box works well.
- Place completed Rabies Submission Form (G-9) in a separate plastic bag to keep the form dry.
- Enclose sufficient absorbent material to keep all moisture within the container.
- Specimens should not be frozen because freezing delays and frequently compromises the examination.
- Use sufficient cold packs, to maintain a cool environment, even with a delay of one full day. Wet ice is not recommended. If ice must be used, double bag to prevent leakage. zip lock bags are recommended.

**State law requires telephone notification to this Laboratory  
before shipment of rabies specimens:  
1 (800) 252-8163**

**Table 22: Specimen Management for Infrequently Encountered Organisms**

Specimen Management for Infrequently Encountered Organisms			
Organism (disease)	Specimen of choice	Transport issues	Comments
<i>Bartonella sp</i> (cat scratch fever)	Blood, tissue, lymph node aspirate	1 wk at 4°C; indefinitely at -70°C	May see organisms in or on erythrocytes with Giemsa stain. Use Warthin Starry silver stain for tissue. SPS is toxic.
<i>Borrelia burgdorferi</i> (Lyme disease)	Skin biopsy at lesion periphery, blood, CSF	Keep tissue moist and sterile; hand carry to laboratory if possible.	Consider PCR in addition to culture. Culture yield is low. Warthin-Starry silver stain tissue. AO and Giemsa for blood and CSF.

Organism (disease)	Specimen of choice	Transport issues	Comments
<i>Borrelia sp.</i> (relapsing fever)	Blood smear (blood)	Hand carry to laboratory if possible.	Use direct wet mount in saline for dark-field microscopy. Stain with Wright's or Giemsa stain. Blood culture is unreliable.
<i>Brucella sp.</i>	Blood, bone marrow	Transport at room temperature; pediatric lysis-centrifugation tube is helpful.	Routine blood culture bottles are useful if held 30 days. Blind subculture may be necessary. Joint fluid culture in arthritis. Notify laboratory if <i>Brucella</i> suspected.
<i>Klebsiella granulomatis</i> (granuloma inguinale; donovanosis)	Tissue, subsurface scrapings	Transport at room temperature.	Mostly a tropical disease. Stain with Wright's or Giemsa stain. Epithelium alone is adequate. Organism cannot be cultured.
<i>Coxiella</i> (Q fever), <i>Rickettsia</i> (spotted fevers; typhus)	Serum, blood, tissue	Blood and tissue are frozen at -70°C	Refer isolation to reference laboratory. Serologic diagnosis is preferred.
<i>Ehrlichia sp.</i>	Blood smear, skin biopsy, blood (with heparin or EDTA anticoagulant), CSF, serum	Material for culture sent on ice; keep tissue moist and sterile; hold at 4 to 20°C until tested or at -70°C for shipment; transport on ice or frozen for PCR test.	Serologic diagnosis preferred. Fix smear in methanol. Tissue stained with FA or Gimenez stain. Refer isolate to reference laboratory. CSF for direct examination and PCR.
<i>Francisella sp.</i> (tularemia) <sup>b</sup>	Lymph node aspirate, scrapings, lesion biopsy, blood, sputum	Rapid transport to laboratory or freeze; ship on dry ice.	Send to reference laboratory. Serologic testing helpful. Gram stain of tissue is not productive. IFA available. Culture effective 10% of the time.
<i>Leptospira sp.</i>	Serum, blood (citrate containing anticoagulants should not be used), CSF (1st wk), urine (after 1st wk)	Blood <1 h; urine, <1 h or dilute 1:10 in 1% bovine serum albumin and store at 4-20°C or neutralize with sodium bicarbonate	Serologic testing most helpful. Acidic urine is detrimental. Dark-field microscopy and direct FA available. Warthin-Starry silver stain for tissue.
<i>Streptobacillus sp.</i> (rat bite fever; Haverhill fever)	Blood, aspirates of joint fluid	High-volume bottle preferred	Do not refrigerate. Requires blood, serum, or ascitic fluid for growth. SPS is inhibitory. AO staining is helpful.

## Guidelines for Specimen Shipping and Mailing

### Shipping Overview

Submitters are responsible for shipping specimens in conformity with all safety and labeling regulations. Be aware that many commercial carriers no longer accept specimens. When using any carrier, including the bus service or the U.S. Postal Service (USPS), package specimens to avoid leakage or breakage. All specimen mailing containers supplied by the Laboratory meet USPS and Department of Transportation (DOT) requirements for the shipment of biological substance, Category Bs. Specimens must be packed in triple containment with sufficient absorbent material enclosed to absorb the entire volume of liquid. The container used must meet current DOT and USPS regulations.

- Shipment of infectious agents requires specialized training and United Nations (UN)-approved packaging that the Lab does not provide.

**ALWAYS EXERT THE MAXIMUM PROTECTION FOR THE SAKE OF THOSE WHO HANDLE THE PARCELS AND TO AVOID JEOPARDIZING THE SYSTEM FOR SHIPPING SPECIMENS.**

**The Laboratory policy is: ALL blood specimens in a container will be considered broken if one tube in that container is broken during shipment.**

### Mailing Containers/Completion of Forms

The Laboratory provides specimen mailing containers and labels to physicians and public health laboratories and water sample containers to any citizen upon request. The containers are the property of the State of Texas and must not be used for any purpose other than the shipment of specimens to the DSHS laboratory. The mailing containers and labels meet current DOT and USPS regulations for shipping biological substance, Category Bs.

- Shipping infectious specimens requires special mailing containers that the Lab does not supply.
- **DSHS request form must be included with every specimen in the same container.**

**Forms should be completed as follows:**

- Use **BOLD CAPITAL BLOCK LETTERS** to complete all information that is requested on the form.
- If the patient is Medicaid eligible, you *must* provide the Medicaid number.
- For THSteps (EPSDT) specimens, you *must* provide the Medicaid number.
- Date of Birth, Date of Collection, and test request are required.
- **Unidentified or improperly identified specimens are unsatisfactory and they will not be tested.**

We will test specimens identified by number only; however, we will not report the results until a patient's name is provided. Good laboratory practice recommends, and our federal license requires, the patient's name on the specimen vial.

**THE PATIENT'S NAME ON THE SPECIMEN REQUISITION FORM AND THE SPECIMEN MUST BE THE SAME. IF THEY ARE NOT THE SAME, THE SPECIMEN WILL NOT BE TESTED.**



## Submission of Specimens through the U.S. Postal System

The requirements for the submission of biological substance, Category Bs through the U.S. Postal Services system are:

1. Definition: “Biological substance, Category B means any human or animal material; including excreta, secreta, blood and its components; tissue and tissue fluids; being transported for diagnostic or investigational purposes”;
2. Quantity: 50 ml or less per mail piece. Two or more primary receptacles may be included per mail piece;
3. Secondary container (liner) must contain sufficient absorbent materials to absorb the entire contents of primary containers in case of breakage or leakage; and
4. Outer mailer must be properly labeled.
5. Mailing unit must pass current shipping regulations for biological substance, Category Bs.

EFFECTIVE IMMEDIATELY, THE TEXAS DEPARTMENT OF STATE HEALTH SERVICES LABORATORY WILL ONLY SUPPLY MAILING CONTAINERS FOR CLINICAL Biological substance, Category BS. USE OF DSHS CONTAINERS WILL INSURE COMPLIANCE WITH USPS AND DOT REQUIREMENTS.

Following is the definition of an acceptable triple container:

1. Primary receptacle: a bottle or tube in which the specimen is collected or held such as a feces bottle, test tube, or tube (vacutainer) of blood or serum; leak proof and securely sealed; surrounded by absorbent material capable of taking up the entire contents of the primary receptacle(s); held within the secondary container.
2. Secondary container: leak proof, securely sealed; placed within the strong outer mailer; BIOHAZARD sticker affixed;
3. Outer mailer or container: constructed of fiberboard or other equivalent material; clearly and durably marked “Biological Substance Category B.”

Packaging and Labeling of  
Biological substance, Category B

**(Do Not Put Any Patient Information on Outer or  
Secondary Containers or Lids)**

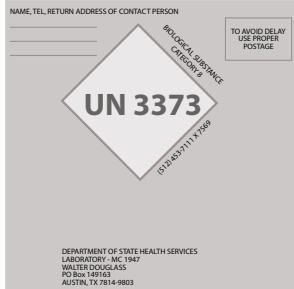
# Packaging and Labeling of Clinical Diagnostic Samples

(Do Not Put Any Patient Information on Outer or Secondary Containers or Lids)

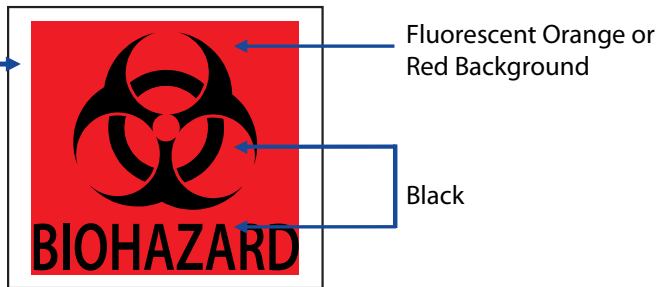
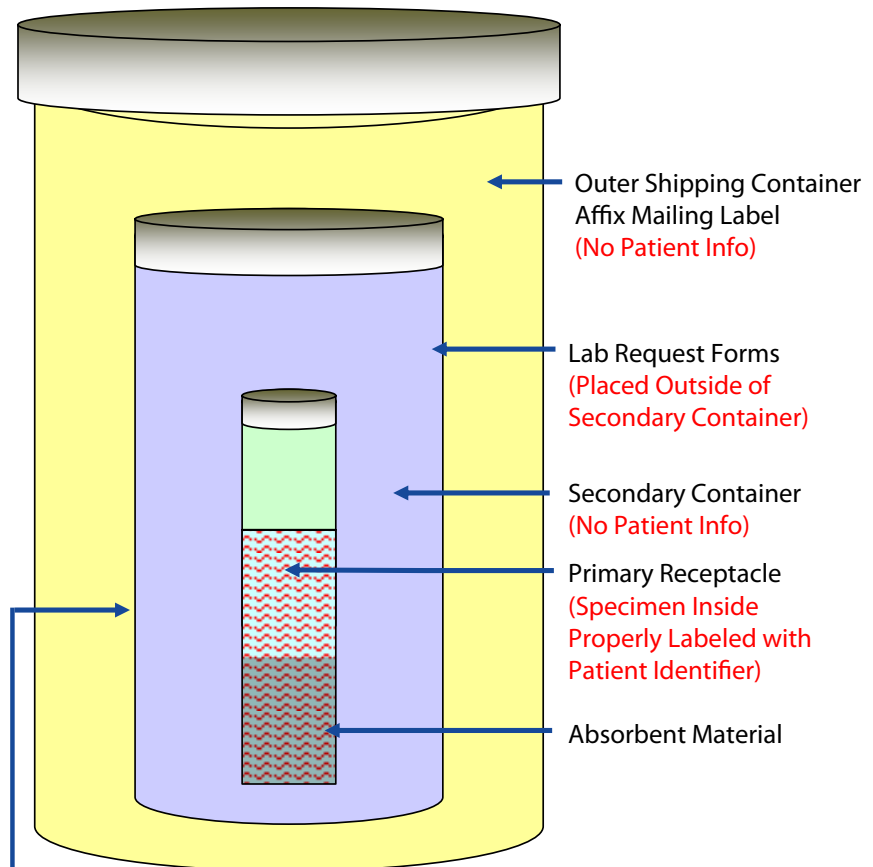
Outer Shipping Container:  
Fiberboard Cylinder with  
metal screw cap

Secondary Container:  
Plastic Liner with screw cap

Primary Receptacle:  
Specimen tube



(Mailing Label)



BIOHAZARD Label should be on Secondary Container.  
DO NOT put BIOHAZARD Label on Outer Container.

## Packaging and Shipment of Blood Tubes

Containers are available in three sizes for blood specimens. You may order for: one specimen, four specimens, and seven specimens.

In order to insure the satisfactory receipt and proper testing of your specimens in our laboratory, it is necessary to:

1. **label each tube of blood or serum with the name of the patient exactly the way it is written on the laboratory request form;**
2. put absorbent material, such as paper towels, around each tube, sufficient to absorb the entire contents of the tubes, prior to placing the tubes in the secondary plastic liner;
3. wrap the properly completed laboratory request form(s) — must have the name of patient and a correct return address — around the secondary plastic liner. Place the secondary container in the fiberboard cylinder; and
4. attach the proper mailing label (and postage, if required) to the outside container before the specimens are mailed.

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\* Excerpt from the *Texas Department of Health Bureau of Laboratories Safety Manual*, August 1996 ed.

## Instructions for Packing Blood Tubes for Shipment

The number of blood tubes broken in transit can be greatly reduced or eliminated by using appropriate packaging and following these simple instructions.



1. Assemble components.



2. Place absorbent into bottom of liner.



3. Wrap tubes in paper towels.



4. Place tubes in liner.



5. Place absorbent on top of tubes and screw on plastic liner cap.



6. Place lab form around the outside of the liner. Place liner in cardboard mailer. Screw on appropriate, well fitting metal cap. Include return address and contact telephone number on label.

**Note:** Only use mailers approved for biological substance, Category B.

Questions on proper packaging and shipment of blood tubes should be directed to the Specimen Acquisition Branch at (512) 458-7598.

### General Instructions:

1. Submit a G-1B form for each patient with corresponding specimen tube.
2. Retain a copy of the G-1B submission form for your records.

3. Clearly label each specimen with the patient's first and last name as written on the G-1B specimen submission form. Pre-printed patient labels used for specimen identification **MUST** match the patient's name on the submission form.
4. Specimens must be triple-contained.

### Special Requirements:

**Required Specimen Type:** Collect specimens for cholesterol and lipid profiles in a red top tube. Remove serum from clot within 2 hours of collection. Transfer at least 1 ml of serum to another plastic transport tube. Plastic transport tube can be a plain blood collection tube.

Collect specimens for glucose testing in gray top tubes. Plasma must be separated from red blood cells within 24 hours from time of collection.

### Special Instructions:

1. Allow samples to clot completely before centrifugation. Immediately transfer serum/plasma to transport tube and freeze ( $-20^{\circ}$  C or lower). Batching of specimens for shipment is recommended.
2. Specimens **MUST** be kept frozen until shipping is initiated. Ship specimens overnight on dry ice **OR** with adequate ice packs so that specimens arrive at DSHS laboratory cold. Specimens received at room temperature will be unsatisfactory for testing.
3. Do **NOT** ship ANY cholesterol, lipid profile or glucose specimens on Fridays or prior to a federally observed holiday.

### Instructions for Shipping Biological substance, Category Bs:

To ensure proper packaging, please follow these instructions:

1. Obtain enough dry ice to keep the specimens frozen or enough ice packs to keep specimens cold for the duration of the shipment.
2. Place the frozen specimen(s) in mailing canister and seal. Place up to four canisters in the bottom of the Styrofoam box.
3. Fill the Styrofoam box with dry ice or ice packs. Ensure canisters are completely covered with dry ice or ice packs, and secured.
4. Place the lid on the Styrofoam box. *Make sure each G-1B form documents the date and time on when specimens are removed from the freezer. Please circle "freezer" to indicate specimens were removed from the freezer not the "fridge."*
5. Place the completed G-1B form(s) in a plastic zip lock bag. Then place the plastic zip lock bag on top of the closed Styrofoam box and seal the fiberboard box.
6. Secure the outer fiberboard box with packing tape.
7. Ensure that a diamond-shaped UN 3373 label is on the exterior of the fiberboard box, when shipping biological substance, Category Bs.
8. Dry ice is considered a "dangerous good." If using dry ice:
  - a. Use less than 5 lbs of dry ice.

- b. Mark the blank box and write “dry ice” in the Special Instructions section of the air bill.
- c. Attach a diamond-shaped dry ice label on the package with the number “9” and “UN1845” on it. This label must include the amount of dry ice used. Ensure that this is legible and does not overlap any other label on the fiberboard box.

9. Fill out the air bill and place it inside the sleeve and attach to the top of the sealed fiberboard box.

**NOTE:** If overnight carrier does not make regular pick-ups at your facility, call the carrier and let them know you need a pick-up.

DHL: (800) 225-5345

UPS: (800) 742-5877

 **NOTE: IF USING DRY ICE MAKE SURE THAT YOUR STYROFOAM BOX IS NOT AIRTIGHT!**

By following these instructions when shipping biological substance, Category Bs, your responsibility should be fulfilled.

### Shipping Instructions:

Check elsewhere in this section for specific test instructions and information about tube types.

For questions about shipment of cholesterol, lipid and glucose specimens, call (512) 458-7111 ext. 2414.

For non-dry ice cold boxes and shipping containers, call (512) 458-7661.

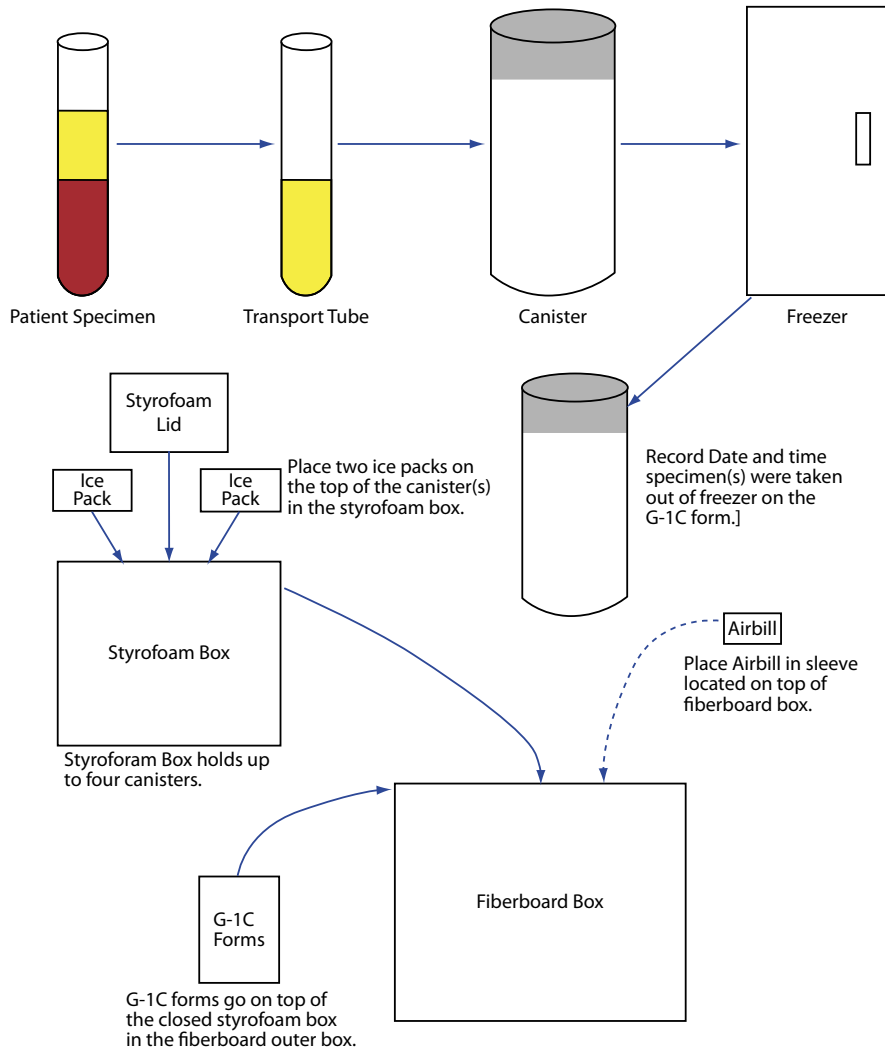
For cholesterol, lipid profile or glucose specimens, prepaid air bills are provided for THSteps specimens only. For all other cholesterol, lipid profile and glucose specimens the provider must pay the shipping costs, using a carrier of their choice.

## Collection and Shipping of Cholesterol, Lipid Profile and Glucose

1. Collect specimens for cholesterol and lipid profile testing in red top tubes.
2. Collect specimens for glucose testing in gray top tube containing sodium fluoride/potassium oxalate.
3. Cholesterol and lipid profile specimens: Centrifuge and separate serum within in 2 hours.
4. Glucose specimens: Centrifuge and separate plasma within 24 hours from time of collection.
5. Transfer serum/plasma into plastic transport container.
6. Place specimen(s) in canisters.  
Multiple specimens may be contained inside the canisters.  
FREEZE canister(s) containing specimens IMMEDIATELY
7. **After specimens are frozen:**  
Batch specimens and ship once or twice a week.  
Do not ship on Fridays or the day before federal holidays.
8. Place up to four canisters with frozen specimens in the bottom of the Styrofoam box.
9. Place and secure ice packs or place dry ice on top of canisters

10. Close the Styrofoam box
11. Place the Styrofoam box inside the fiberboard box.
12. Before sealing the fiberboard box, record each G1-B form the time and date each specimen was removed from the freezer. Circle "freezer" to indicate specimens were removed from the freezer.
13. Place requisition forms on top of the Styrofoam box, but inside fiberboard box. Seal fiberboard box.
14. Place an air bill inside the shipping sleeve and attach to top of the sealed fiberboard box and ship specimens overnight.

Figure 6: Cholesterol Lipid and Glucose Packing Diagram



### RHOGAM (HDN) Packing and Shipping Instructions

#### General Instructions:

1. Submit a G-1B form for each patient with corresponding specimen tube.
2. Retain a copy of the G-1B submission form for your records.

3. Clearly label each specimen with the patient's first and last name as written on the G-1B specimen submission form. Pre-printed patient labels used for specimen identification MUST match the patient's name on the submission form.
4. Specimens must be triple-contained.

**Special Requirements:**

Required Specimen Type: Collect specimens for RhoGAM (HDN Screening) in a red top tube. DSHS Laboratory must receive specimens within 24 hours from time of collection. Specimens not received at DSHS Laboratory within 24 hours should be stored at 1° to 10°C and shipped cold.

**Special Instructions:**

1. Ship specimens overnight at ambient temperature.
2. Specimens not received within 24 hours from time of collection must be shipped overnight with enough cold packs to maintain refrigerated temperature until arrival at DSHS Laboratory.
3. Do not freeze.
4. Do NOT ship ANY RhoGAM specimens on Fridays or prior to a federally observed holiday.

**Instructions for Shipping Biological substance, Category Bs:**

1. To ensure proper packaging, please follow these instructions:
2. Package and ship specimens overnight at ambient temperature.
3. For specimens requiring overnight cold shipment, package with enough ice packs to maintain refrigerated temperature for the duration of the shipment.
4. Record the date and time each specimen was removed from the refrigerator on the G-1B form.
5. Please circle "FRIDGE" on the G-1B form to indicate specimens were removed from the refrigerator.

**Shipping Instructions:**

For specific test instructions, see the Manual of Reference Services section on Lab Tests for Diseases/Agents.

See sections above for information about tube types.

For questions about shipment of RhoGAM (HDN screening) specimens, call (512) 458-7111 ext. 2414.

Shipping containers for cold shipment are available upon request, call (512) 458-7661.

For (HDN) RhoGAM specimens, prepaid air bills are provided for Title V specimens only. For all other RhoGAM (HDN) specimens, the provider must pay the shipping costs using a carrier of their choice.



## Precautions for Using Laboratory Equipment and Devices\*

### Centrifuges

Centrifugation, if improperly used, can create serious hazards from mechanical failure and the generation of biohazardous materials or toxic chemicals. A mechanical failure, such as a broken drive shaft, a faulty bearing, or a disintegrated rotor, can produce high-velocity hazardous fragments. If these fragments escape the protective housing of the centrifuge, they can produce traumatic injury to personnel.

- Mechanical failure can be minimized by meticulous observance of the manufacturer's instructions and utilization of periodic rotor inspection service.
- Aerosols can be avoided by observing sound laboratory practices and using appropriate centrifuge safety equipment and containment hoods or cabinets.
- Shields, trunnion cups, and centrifuge tubes should be properly balanced. Ensure that matched sets of trunnion cups, shields, and adapters do not become mixed. If the components are not inscribed with their weights by the manufacturer, colored stains can be applied for identification to avoid confusion. When the tubes are balanced, the shields, trunnion cups, and adapters, including any disinfectant solution or water added for balancing, should be included in the procedure. The basic concern is that the centers of gravity of the tubes are equidistant from the axis of rotation. To illustrate the importance of this, two identical tubes containing 20 g of mercury and 20 g of water, respectively, will balance perfectly on the scales; however, their performance in motion is totally different, leading to violent vibration with all its attendant hazards. This is especially important to consider when centrifuging gradients containing cesium salts.

Figure 7: Centrifuge



## G-11 Clinic Laboratory Information

- Screw caps, or other tight-fitting skirted caps that fit outside the rim of the centrifuge tube are safer to use than plug-in closures. Even screw-capped bottles are not without risk; if the rim is soiled and seals imperfectly, fluid will escape down the outside of the tubes.
- Aluminum foil should not be used to cap centrifuge tubes because it detaches or ruptures and does not prevent aerosols.
- Do not use cotton plugs when centrifuging BIOHAZARDOUS materials. Instead, use rubber stoppers or other tight-fitting plastic, rubber, or metal caps or closures.
- Heat-sealed tubes should be used when centrifuging highly toxic or pathogenic materials or concentrating infectious agents, (e.g., viruses).
- Continuous-flow rotors, particularly the steam driven Sharples™ designed for cream separation, are notorious generators of aerosols and must be enclosed in well ventilated hoods, if used with infectious agents.
- The frequency of use, maximum g-force exposure, washing, etching, abrasion, and method of storage affect the life expectancy of glass centrifuge tubes and bottles.
- The stresses developed during these processes are cumulative in Pyrex™ glass despite its excellent chemical resistance. When used with proper adapters and cushions, it can withstand moderate speeds.
- Corex™ glass has four to six times the strength of conventional glass, greater resistance to alkalis and acids, scratching, and etching, and is unaffected by temperatures up to 300°C. In proper adapters, Corex™ tubes may be used at relatively high speeds.
- Before using glass centrifuge tubes, eliminate those with cracks, severe etching, scratches, and chipped rims.
- While plastic tubes and bottles resist breakage, they may begin to show signs of deterioration (crazing, cracking, or spotting) after several runs as a result of the interaction of centrifugal forces, chemical effects from samples and cleaning solutions, and autoclaving cycles of heat and pressure. Tubes showing these signs should be discarded. Note that celluloid (cellulose nitrate) centrifuge tubes are highly flammable, prone to shrinkage with age, can distort on boiling, and can be highly explosive in an autoclave.

## G-12 Rotor Use and Maintenance

It is generally recommended that medium- and high-speed rotors be accelerated to a low speed before allowing them to reach higher programmed speeds. The detection of imbalances, (e.g., missing or mis-hung swinging buckets, unfastened rotor covers, and unaligned drive shafts) at low speed can prevent serious accidents at higher speeds.

High-speed rotor heads are prone to metal fatigue and, where there is a chance that they may be used on more than one machine, each rotor should be accompanied by its own logbook indicating the number of hours run at top speeds. Failure to observe this precaution and to institute replacement after recommended periods of use can result in dangerous and expensive disintegration. Frequent inspection, cleaning and drying are important to ensure absence of corrosion or other damage that may

lead to the development of cracks. Many high-speed rotors, including the zonal rotors for preparative ultracentrifuges, are made of aluminum. Precautions must be exercised to avoid their deterioration and corrosion. For example, alkalis (e.g., Radiacwash™ and Count-Off™), halide salt solutions, and many acids should not come in contact with these rotors as they may remove the anodizing that protects the rotor from pitting. For gradient separations in aluminum rotors, sucrose solutions are recommended. Some rotors also contain cores of Noryl™ which deteriorate in the presence of certain solvents, including benzene, chloroform, petroleum ether, and propylene glycol. In general, titanium rotors are preferred.

Caution should be exercised as to what chemicals, including disinfectants, are permitted to contact component materials that are subject to deterioration.

If the rotor is treated with a disinfectant, it should be rinsed with clean water and dried as soon as the disinfectant has adequately decontaminated the rotor.

Before using a rotor, inspect it carefully for the presence of contaminants, salt deposits, or cracks.

Rinse out buckets/rotor cavity after each run. Use special brushes and detergent. Dry thoroughly and grease gaskets and threads according to manufacturer's recommendations.

Always run all swing-out buckets. Open and inspect all buckets before and after use.

Remove condensation ice from rotor chamber at frequent intervals.

### **G-13 Clinic Laboratory Information**

Rubber "O" rings and tube closures must be examined for deterioration and must be kept lubricated with material recommended by the makers. This provision is especially important for the use of zonal rotors.

Where tubes of different materials are provided (e.g., celluloid, polypropylene, stainless steel), care must be taken to employ tube closures designed specifically for the type of tube in use. These caps are often similar in appearance, but are prone to leakage if applied to tubes of the wrong material. When properly designed tubes and rotors are well maintained and handled, leakage should never occur.

When service is required, the centrifuge must be decontaminated before allowing service personnel to repair it. In the event of a centrifuge malfunction and/or spill which may create hazardous aerosols, air-circulating equipment should be shut down, (e.g., air conditioners, fans, fume hoods, biological safety cabinets) and the room should be vacated by all personnel for a suitable period (at least 30 minutes) to allow the aerosol to dissipate. Broken glass should then be cleaned up promptly and contaminated areas properly decontaminated. Remember that if contaminated materials have reached the chamber, the pump oil will be contaminated as well. The person using the centrifuge, along with the principal investigator in charge of the lab, is responsible for ensuring that clean-up and decontamination is achieved. Maintenance service may be refused on centrifuges which appear to be improperly used and/or contaminated.

**Table 23: U.S. Department of Labor Occupational Safety and Health Administration Labeling Requirements**

Item	No Label Needed if Universal Precautions Are Used and Specific Use of Container or Item Is Known to All Employees		BIOHAZARD Label		Red Container
Regulated waste container (e.g., contaminated sharps container)			X	or	X
Reusable contaminated sharps container (e.g., surgical instruments soaking in a tray)			X	or	X
Refrigerator/freezer holding blood or other potentially infectious material			X		
Containers used for storage, transport or shipping of blood			X	or	X
Blood/blood products for clinical use	No labels required				
Individual specimen containers of blood or other potentially infectious materials remaining in facility	X		X	or	X
Contaminated equipment needed service (e.g., dialysis equipment; suction apparatus)			X		
			Plus a label specifying where the contamination exists		
Specimens and regulated waste shipped from the primary facility to another facility for service or disposal			X	or	X
Contaminated laundry	X*	or	X	or	X
Contaminated laundry sent to another facility that does not use Universal Precautions			X	or	X

Federal Register: November 1, 2006 (Volume 71, Number 211)  
[Rules and Regulations]  
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From the Federal Register Online via GPO Access [wais.access.gpo.gov]  
[DOCID:fr01no06-5]

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## POSTAL SERVICE

39 CFR Part 111

New Standards for Mailing Sharps and Other Regulated Medical Waste Containers

AGENCY: Postal Service.

ACTION: Final rule.

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**SUMMARY:** The Postal Service revises the standards for mailing sharps and other regulated medical waste containers. The new standards include improvements to the packaging, the package testing, and the process for authorizing and suspending authorization.

**DATES:** Effective Date: November 9, 2006.

**FOR FURTHER INFORMATION CONTACT:** Bert Olsen, 202-268-7276.

### SUPPLEMENTARY INFORMATION:

#### Background

We published a proposed rule in the Federal Register (71 FR 19840, April 18, 2006) to revise the standards for mailing sharps and other regulated medical waste containers. Our proposal included the following changes:

1. To require container vendors to provide the Postal Service with the names and addresses of their distributors and to provide updates on a quarterly basis.
2. To revise the process for authorizing and suspending authorization for mailing sharps and other regulated medical waste containers to enhance monitoring and control of medical waste in the mail.
3. To revise container standards and container testing standards to ensure that container testing is performed on a consistent basis for all sharps and other regulated medical waste containers.

## Comments Received

We received comments from four authorized sharps container vendors and one potential vendor. All commenters supported the concept of revising the rules to promote uniform testing methods and to ensure the integrity of mail pieces containing sharps and other medical waste.

## Documentation Requirements

Three commenters objected to the requirement that vendors provide a list of distributors to the Postal Service. All three commenters argued that requiring vendors to provide a quarterly list of distributors could lead to disclosure of sensitive proprietary vendor information. We agree that the Postal Service can identify a vendor's distributors, if needed, by requiring vendors to provide this information on request. Therefore, the final rule requires vendors to provide the names, addresses, and telephone numbers of their distributors to the Postal Service only on request.

## Packaging

One commenter objected to a minimum size limit for the BIOHAZARD symbol placed on the outer shipping container. The commenter stated that requiring a 3 inch by 4 inch symbol would be excessively large on a small mail piece. The Postal Service notes that currently no approved medical waste mail pieces are so small as to not easily accommodate a 3 inch by 4 inch BIOHAZARD symbol. The new standard will clarify that the 3 inch by 4 inch label requirement applies to the outer shipping container. For safety reasons, medical waste containers must be easily identified as containing BIOHAZARDous materials. Therefore, this final rule adopts the standard as published in the proposal.

Three commenters did not want the Postal Service to eliminate the use of outer shipping containers with interlocking bottoms. All three commenters stated that current requirements that allow for the use of shipping containers with interlocking bottom flaps reinforced with tape are more than adequate, especially considering the overall rigorous testing mandates. After further consultation with package testing professionals, we conclude that interlocking bottom flaps sufficiently contain the primary receptacle, particularly when reinforced with tape. Therefore, we will maintain our current standards that allow interlocking bottoms when they are reinforced with water-resistant tape.

Two commenters requested clarification of the proposed changes to the secondary container requirements. The commenters stated that increasing the plastic bag thickness requirement from 3 mil to 4 mil was not necessary. In addition, they stated that it was not advantageous to require the plastic bag to be placed around the secondary box. We believe that increasing the thickness of the plastic bag will help maintain the contents of the primary container should it break. Therefore, we will require plastic bags to be 4 mil thick. However, we will not require the plastic bag to be placed outside the secondary box.

Two commenters requested clarification of the proposed standards in section 601.10.17.7b4 of Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM). We revised this section to clarify that the absorbent material must be placed in the primary receptacle. Item e10 will serve as the required test to ensure that the secondary system is watertight. One commenter suggested that the Postal Service

require screw caps for primary containers. Historical data on safely mailing these mail pieces does not indicate a need to require screw caps. Therefore, this final rule adopts the standard as published in the proposal.

#### Mail piece Testing

One commenter objected to the requirement that mail pieces be tested at the vendor's identified maximum weight and that the container's maximum allowable weight be printed on the outer shipping container. The commenter stated that it was impossible to predict the maximum weight of the materials that might be placed into a container and that end users would not have scales to weigh the mail piece. We believe, in the interest of safety, that these mail pieces should be tested at the highest possible weight determined by the vendor, not to exceed 25 pounds, to ensure that the mail piece can safely contain the maximum weight. Therefore, this final rule adopts the requirements as published in the proposal.

One commenter suggested that the Postal Service require accreditation of package testing facilities. Section 601.10.17.7d of the proposed rule states "the Postal Service may require proof of accreditation or other documentation to support the credentials of an independent testing facility." We believe that this standard provides the authority to require proof of credentials as necessary. Therefore, this final rule adopts the standard as published in the proposal.

One commenter questioned the need for a reference to 49 CFR 178.604, Leak-proof test. The commenter stated that we should not refer to the test because our pass/fail criteria were not the same as the criteria in 49 CFR. The test in 49 CFR 178.604 requires that the primary container hold 20 kPa without leakage. Our criteria allow for air leakage around the opening of the primary container as long as there is no air leakage anywhere else and no leakage of water. We agree that it would be clearer, in this case, to eliminate the reference and to provide only the USPS test procedure and pass/fail criteria.

One commenter requested clarification on the height of the required drop tests. Our proposed rule requires 30-foot drops for the wet and cold tests as identified in 49 CFR 178.609e and f. The impact test requires a drop of 3 feet as identified in 49 CFR 178.609h. While we understand that the test identified in 49 CFR consists of requirements for packaging infectious substances, we believe that the Postal Service's handling and transportation systems are different from those of commercial carriers and require more stringent acceptance criteria. Therefore, this final rule adopts the standard as published in the proposal.

One commenter suggested that testing material should be simulated medical waste. We disagree. The testing material should consist of sharps or other regulated medical waste as defined in DMM 601.10.17.2e and g. Vendors are on notice that contaminated medical waste will not be used for testing purposes. Therefore, this final rule adopts the standard as published in the proposal.

#### Mail piece Acceptance

One commenter objected to requirements that vendors retrieve improperly labeled containers when identified and held at plants. The commenter suggested that the Postal Service should confirm the mail piece was properly marked and labeled before accepting it. While we continually educate employees on acceptance criteria, the mailer remains responsible for properly labeling the mail piece.

Therefore, this final rule adopts the requirement as published in the proposal. This final rule will be effective on November 9, 2006. Sharps and other regulated medical waste containers that are currently approved for mailing can maintain their authorization until it expires (24 months from the most recent approval). Containers must meet the new standards if they are submitted for authorization (or renewal of authorization) on or after November 9.

We adopt the following amendments to Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM), incorporated by reference in the Code of Federal Regulations. See 39 CFR 111.1.

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

Accordingly, 39 CFR part 111 is amended as follows:

PART 111--[AMENDED]

1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 414, 416, 3001-3011, 3201-3219, 3403-3406, 3621, 3626, 5001.

2. Revise the following sections of Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM), as follows:

600 Basic Standards for All Mailing Services

601 Mailability

\* \* \* \* \*

10.0 Hazardous Materials

\* \* \* \* \*

10.17 Infectious Substances (Hazard Class 6, Division 6.2)

\* \* \* \* \*

[Revise title of 10.17.7 as follows:]

10.17.7 Sharps Medical Waste and Regulated Medical Waste Containers

[Replace “distributor or manufacturer” with “vendor” throughout

10.17.7.]

\* \* \* \* \*

[Add new authorization information to the end of item a1 as follows:]

1. \* \* \* Vendors that market their containers to distributors are responsible for disposal and cleanup costs attributed to those containers. In addition, vendors must provide a list of distributors, including firm names, addresses, and telephone numbers, to the Postal Service on request.



\* \* \* \* \*

[Revise item a3 to add “name” and “phone number” as follows:]

3. Name, address, and phone number of each storage and disposal site.

\* \* \* \* \*

[Add text at the end of item a8 as follows:]

8. \* \* \* and verification that the merchandise return service (MRS) permit fee and accounting fee have been paid.

[Add new item a9 as follows:]

9. Address of the post office or postage due unit where the containers are delivered.

\* \* \* \* \*

[Revise the package testing information in item b1 by replacing the last sentence as follows:]

[[Page 64120]]

1. \* \* \* Package testing results must show that the contents of the primary container did not penetrate through the primary container during package testing and that the primary container can maintain its integrity at temperatures as low as 0[deg]F and as high as 120[deg]F.

[Revise the third sentence of item b2 to read “4 mil” as follows:]

2. \* \* \* If one of the components is a plastic bag, the bag must be at least 4 mil in thickness and must be used in conjunction with a fiberboard box. \* \* \*

\* \* \* \* \*

[Revise item b4 by replacing “a watertight barrier” with “the primary receptacle” as follows:]

4. There must be enough material within the primary receptacle \* \* \*

[Revise item b5 as follows:]

5. Each mail piece must not weigh more than 25 pounds. The container’s maximum allowable weight must be printed on the outside of the box and on the assembly and closure instructions included with each mail piece. The mail piece must be tested at the maximum allowable weight identified by the vendor.

\* \* \* \* \*

[Add a new sentence at the end of item c1 as follows:]

1. \* \* \* Place the label on the top or on a side of the container. [Add a new sentence at the end of item c2 as follows:]
2. \* \* \* The symbol on the outer shipping container must be at least 3 inches high and 4 inches wide.

\* \* \* \* \*

[Add new item c7 as follows:]

7. Vendors must retrieve mail pieces held at processing facilities due to improper labeling such as no return address or due to improperly completed shipping papers.

\* \* \* \* \*

[Revise item days as follows:]

days. Package Testing. Vendors must submit to the manager, Mailing Standards (see 608.8 for address), package testing results from an independent testing facility for each package for which the vendor is requesting authorization. In addition, vendors must submit package testing results from an independent testing facility when the design of a container system changes or every 24 months, whichever occurs first. The test results must show that if every mail piece prepared for mailing were subject to the environmental and test conditions in 49 CFR and the additional test requirements in 10.17.7e, no contents would be released into the environment and the effectiveness of the packaging would not be significantly reduced. The Postal Service may require proof of accreditation or other documentation to support the credentials of an independent testing facility.

[Add new item e as follows:]

- e. Testing Criteria. Each mail piece must pass each of the tests described below:
  1. Leak-proof test. The test must be conducted on one primary receptacle with the lid in place, without the secondary and outer packaging. The test duration must be at least 5 minutes and must be conducted at 20 kPa (3 psi). The pass/fail criterion is: No air leakage from anywhere other than the closure of the primary receptacle. Air leakage at the closure is not considered a failure if the primary receptacle passes the test for watertightness as determined by placing 50 ml of deionized water into the primary receptacle, securing the closure, and then turning the container on its side and observing for any evidence of leakage. Any evidence of water leaking from the primary receptacle is a failure.
  2. Stacking test. One mail piece must withstand the test in 49 CFR 178.606. The dynamic compression test must be conducted on the empty, unsealed mail piece assembled for mailing, without the primary receptacle(s). The test mass is the vendor-identified maximum weight, not to exceed 25 pounds, as indicated on the outer shipping container and on the assembly and closing instructions. A compensation factor of 1.5 must be used to compute the test load, based on the vendor-identified weight. The pass/fail criteria are: No buckling of the side walls sufficient to cause damage to the contents in the primary container, and in no case does the deflection exceed 1 inch.
  3. Vibration test. One mail piece filled with sharps or other regulated medical waste must withstand the test in 49 CFR 178.608. The test mail piece is filled with sharps or other regulated medical waste to the vendor-identified maximum weight, not to exceed 25 pounds, as indicated on the outer shipping container and on the assembly and closing instructions. The test sample is prepared as it would be for mailing. The pass/fail criterion is: No rupture, cracking, or splitting of any primary receptacle.
  4. Wet drop test. Five mail pieces filled with sharps or other regulated medical waste must withstand the test in 49 CFR 178.609e. Each test mail piece is filled with sharps or other regulated medical waste to the vendor-identified maximum weight, not to exceed 25 pounds, as indicated on the outer

shipping container and on the assembly and closing instructions included with each mail piece. Each mail piece is prepared as it would be for mailing and subjected to the water spray as described in the test. A separate, untested mail piece is used for each drop orientation: Top, longest side, shortest side, and corner. The pass/fail criteria are: No rupture, cracking, or splitting of any primary receptacle, and no contents may penetrate into or through the body or lid of any primary receptacle.

5. Cold drop test. Five mail pieces filled with sharps or other regulated medical waste must withstand the test in 49 CFR 178.609f. Each test mail piece is filled with sharps or other regulated medical waste to the vendor-identified maximum weight, not to exceed 25 pounds, as indicated on the outer shipping container and on the assembly and closing instructions included with each mail piece. Each mail piece is prepared as it would be for mailing and chilled as described in the test. A separate, untested mail piece is used for each drop orientation: Top, longest side, shortest side, and corner. The pass/fail criteria are: No rupture, cracking, or splitting of any primary receptacle, and no contents may penetrate into or through the body or lid of any primary receptacle.
6. Impact test. One mail piece filled with sharps or other regulated medical waste must withstand the test in 49 CFR 178.609h. The test mail piece is filled with sharps or other regulated medical waste to the vendor-identified maximum weight, not to exceed 25 pounds, as indicated on the outer shipping container and on the assembly and closing instructions included with each mail piece. The mail piece is prepared as it would be for mailing. The pass/fail criteria are: No rupture, cracking, or splitting of any primary receptacle, and no contents may penetrate into or through the body or lid of any primary receptacle.
7. Puncture-resistant test. Package testing results must show that during all of the previous tests, the contents did not penetrate through the primary container.
8. Temperature test. Package testing results must show that each primary receptacle maintained its integrity when exposed to temperatures as low as 0[deg]F and as high as 120[deg]F.
9. Absorbency test. Package testing results must show that the primary receptacle(s) contain enough absorbent material to absorb three times the total liquid allowed within the primary receptacle in case of leakage. Absorbency is determined by pouring 150 ml of deionized water into the primary receptacle(s), then turning the receptacle(s) upside down and observing for any evidence of free liquid not absorbed on contact. Any evidence of free liquid is a failure.
10. Watertight test. Package testing results must show that no leakage occurred when 50 ml of deionized water was placed into the secondary containment system and the entire system turned upside down for 5 minutes.

[Add new item f as follows:]

- f. Suspension of Authorization.
  1. The Postal Service may suspend a vendor's authorization based on information that a mail piece no longer meets the standards for mailing sharps medical waste and regulated medical waste containers, or that the mail piece poses an unreasonable safety risk to Postal Service employees or the public. The suspension can be made immediately, making the mail piece nonmailable immediately. The vendor may contest a decision to suspend authorization by writing to the manager, Mailing Standards (see 608.8 for address), within 7 days from the date of the letter of suspension.

The appeal should provide evidence demonstrating why the decision should be reconsidered. Any order suspending authorization remains in effect during an appeal or other challenge.

2. When a vendor is notified that its authorization to mail sharps or other regulated medical waste containers has been suspended, the vendor must immediately: (1) Recall all identified containers. (2) Notify all customers that they cannot mail the identified containers. (3) Suspend sales and distribution of all identified containers. (4) Collect the identified containers from distributors, consumers, and the Postal Service without using the mail and in accordance with all Federal and State regulations.

\* \* \* \* \*

Neva R. Watson,

Attorney, Legislative.

[FR Doc. E6-18063 Filed 10-31-06; 8:45 am]

BILLING CODE 7710-12-P **10.0**      **Hazardous Materials**

#### 10.17 Definitions

The following definitions apply:

- a. Hazardous material is any article or substance designated by the U.S. Department of Transportation (DOT) as being capable of posing an unreasonable risk to health, safety, and property during transportation. In international commerce, hazardous materials are known as “dangerous goods.”
- b. Limited quantity is the maximum amount of a specific hazardous material that is exempted from the labeling or packaging requirements in 49 CFR. Not every hazardous material is eligible to be shipped as a limited quantity. Almost all limited quantity materials are nonmailable.
- c. ORM-D (Other Regulated Material) material is a limited quantity of a hazardous material that presents a limited hazard during transportation due to its form, quantity, and packaging. In almost all instances, the proper shipping name for an ORM-D material is consumer commodity. Not all hazardous material permitted to be shipped as a limited quantity can qualify as an ORM-D material. ORM-D materials having the proper shipping name of “consumer commodity” are mailable subject to USPS quantity and packaging standards.
- d. Consumer commodity is a hazardous material that is packaged and distributed in a quantity and form intended or suitable for retail sale and designed for consumption by individuals for their personal care or household use purposes. This term can also include certain drugs or medicines. Not all hazardous material permitted to be shipped as a limited quantity can qualify as a consumer commodity.
- e. Air transportation requirements, for the purposes of 10.0 only, apply to all mailable hazardous materials sent at the First-Class Mail, Priority Mail, or Express Mail rates. All mailable hazardous materials sent at those rates must meet the requirements that apply to air transportation. Mailable hazardous materials sent at any of those rates may or may not be transported via air depending on the distance between the point of origination and the point of destination, and the ability of the USPS to obtain an air carrier between those points.
- f. Surface transportation requirements, for the purposes of 10.0 only, apply to all mailable hazardous materials sent at the Standard Mail or Package Services rates. All mailable hazardous materials sent at the Standard Mail or Package Services rates must meet the requirements that apply to surface transportation.
- g. Primary receptacle is the container (e.g., tube, vial, bottle) that holds the hazardous material.
- h. Secondary container is the packaging component into which the primary receptacle(s) and any required absorbent and cushioning material is securely placed. The packaging of certain mailable hazardous materials does not require the use of a secondary container.
- i. Outer shipping container is the exterior packaging component into which a primary receptacle, along with any required absorbent and cushioning material, and the secondary container (if required) are securely placed. The outer shipping container bears the addressing information along with all required markings.

## 10.2 U.S. Department of Transportation Regulations of Hazardous Material

The U.S. Department of Transportation (DOT) regulates the surface and air carriage of hazardous materials within the United States via any means of transportation. The DOT regulations for the transport of hazardous materials are codified in Title 49, Code of Federal Regulations (49 CFR) 100-185. USPS mailing standards for hazardous materials generally adhere to 49 CFR, but also include many additional limitations and prohibitions.

## 10.3 USPS Standards for Hazardous Material

The USPS standards generally restrict the mailing of hazardous materials to ORM-D materials with the proper shipping name of “consumer commodity” that meet USPS quantity limitations and packaging requirements. The few non-ORM-D materials permitted to be mailed are subject to the standards in 10.0. Detailed information on the mailability of specific hazardous materials is contained in Publication 52, Hazardous, Restricted, and Perishable Mail.

## 10.4 Hazard Class

Every hazardous material is assigned to one of nine hazard classes identified in 49 CFR 172.101 and 173. Some hazard classes are further separated into divisions based on their physical or chemical properties. For postal purposes, Exhibit 10.4 generally summarizes the mailability of hazardous materials by hazard class.

Exhibit 10.4 DOT Hazard Classes and Mailability Summary

Class	Hazard Class Name and Division	TRANSPORTATION METHOD		
		Domestic Mail Air Transportation	Domestic Mail Surface Transportation	International Mail
<b>1</b>	<b>Explosives</b> Division - 1.1 Mass Explosive Hazard 1.2 Projection Hazard 1.3 Fire Hazard and/or Minor Blast/Minor Projection Hazard 1.4 Minor Blast Hazard 1.5 Very Insensitive With Mass Explosion Hazard 1.6 Extremely Insensitive With No Mass Explosion Hazard	Prohibited	Prohibited except with written permission as allowed in 10.11.2	Prohibited
<b>2</b>	<b>Gases</b> Division - 2.1 Flammable Gases 2.2 Nonflammable, Nontoxic Gases 2.3 Toxic Gases	<i>Division 2.1 and 2.3: Prohibited.</i> <i>Division 2.2: Only ORM-D material per 10.12.2</i>	<i>Divisions 2.1 and 2.2: Only ORM-D material per 10.12.2.</i> <i>Division 2.3: Prohibited</i>	Prohibited

Class	Hazard Class Name and Division	TRANSPORTATION METHOD		
		Domestic Mail Air Transportation	Domestic Mail Surface Transportation	International Mail
3	<b>Flammable and Combustible Liquids</b>	<i>Flammable liquids:</i> Prohibited.  <i>Combustibles:</i> Only ORM-D material per 10.13.3	<i>Flammable liquids:</i> Only ORM-D material per 10.13.2.  <i>Combustibles:</i> Only ORM-D material per 10.13.3	Prohibited
4	<b>Flammable Solids</b>  Division - 4.1 Flammable Solids 4.2 Spontaneously Combustible 4.3 Dangerous When Wet	Prohibited	Only ORM-D material per 10.14.2	Prohibited
5	<b>Oxidizing Substances, Organic Peroxides</b>  Division - 5.1 Oxidizing Substances 5.2 Organic Peroxides	Only ORM-D material per 10.15.2	Only ORM-D material per 10.15.2	Prohibited
6	<b>Toxic Substances and Infectious Substances</b>  Division - 6.1 Toxic Substances 6.2 Infectious Substances	<i>Division 6.1:</i> Only ORM-D material per 10.16.2.  <i>Division 6.2:</i> Only per 10.17	<i>Division 6.1:</i> Only ORM-D material per 10.16.2.  <i>Division 6.2:</i> Only per 10.17	<i>Division 6.1:</i> Prohibited.  <i>Division 6.2:</i> Only mailable per IMM 135
7	<b>Radioactive Materials</b>	Prohibited	Only in limits per 9.0 and Publication 52	Only mailable in limits per IMM 135
8	<b>Corrosives</b>	Only ORM-D material per 10.19.2	Only ORM-D material per 10.19.2	Prohibited
9	<b>Miscellaneous Hazardous Materials</b>	Only ORM-D material per 10.20	Only ORM-D material per 10.20	Prohibited, except magnetized materials per IMM 136

#### 10.5 Mailer Responsibility for Mailing Hazardous Materials

Full responsibility rests with the mailer to comply with all postal and nonpostal laws and regulations regarding the mailing of hazardous materials. Anyone who mails, or causes to be mailed, a nonmailable or improperly packaged hazardous material can be subject to legal penalties, including but not limited to those specified in 18 USC.

### 10.6 Mailability Rulings for Hazardous Materials

Generally, the acceptability for mailing chemicals and other types of hazardous materials depends on container fluid/vapor capacities, the ability of the complete mail piece to contain the material, and the method of absorbing and containing the product in case of accidental leakage of the primary receptacle. To determine mailability of a specific material, a mailer must submit a material safety data sheet (MSDS) and the following information to the Pricing and Classification Service Center (PCSC):

- a. Name of material, hazard class, and assigned United Nations (UN) or North America (NA) identification number.
- b. Chemical composition by percentage of ingredient.
- c. Flash point.
- d. Toxic properties.
- e. Irritant action when inhaled, swallowed, or contacted by eyes or skin.
- f. Special precautions necessary to permit handling without harm to USPS employees or damage to property or other mail.
- g. Explanation of warning labels and shipping papers required by state or federal regulations.
- h. Proposed packaging method, including the addressing and required markings.
- i. Proposed number of pieces to be mailed, class of mail, and post office(s) of mailing.

### 10.7 Warning Labels for Hazardous Materials

With few exceptions as noted in these standards, most hazardous materials acceptable for mailing fall within the Other Regulated Materials (ORM-D) regulations of CFR 49 173.144, which do not require DOT hazard class warning labels. Except for Division 6.2 materials under 10.17.4 and dry ice under 10.20.4, any hazardous material bearing or required to bear a DOT hazard class warning label under the requirements in 49 CFR is prohibited from mailing. Mailable ORM-D material must be marked as required in 10.8. Mailable hazardous material must bear DOT handling labels (e.g., orientation arrows, magnetized materials) when applicable.

### 10.8 Package Markings for Hazardous Materials

Each mail piece containing a mailable hazardous material must be plainly and durably marked on the address side with the required shipping name and UN identification number. The UN identification number is not required on a mail piece that contains an ORM-D material. A mailable ORM-D material must be marked on the address side with "ORM-D" or "ORM-D AIR," as applicable, immediately following or below the proper shipping name. The proper shipping name for a mailable ORM-D material is "consumer commodity." The designation "ORM-D" or "ORM-D AIR," as required, must be placed within a rectangle that is approximately 6.3 mm (1/4 inch) larger on each side than the designation. Mailable ORM-D materials sent as Standard Mail or Package Services must also be marked on the address side as "Surface Only" or "Surface Mail Only."

### 10.9 Shipping Papers for Hazardous Materials

A shipper's declaration for dangerous goods (shipping paper) prepared under 49 CFR 172.200 through 172.205 is required for certain types of hazardous materials when mailed. The shipping paper must be completed and signed in triplicate by the mailer. It must be affixed to the outside of the mail piece within an envelope or similar carrier that can be easily opened and resealed to allow viewing of the document. Shipping papers are required as follows:

- a. Air transportation requirements. Except for nonregulated materials sent under 10.17.3 or 10.17.8 and biological substance, Category Bs sent under 10.17.5, mail pieces containing mailable hazardous materials sent at the First-Class Mail, Priority Mail, or Express Mail rates must include a shipping paper.
- b. Surface transportation requirements. Except for nonregulated materials sent under 10.17.3 or 10.17.8 and mailable ORM-D materials, mail pieces containing mailable hazardous materials sent at the Standard Mail or Package Services rates must include a shipping paper.

## 10.10 Air Transportation Prohibitions for Hazardous Materials

All mailable hazardous materials sent at the First-Class Mail, Priority Mail, or Express Mail rates must meet the requirements for air transportation. The following types of hazardous materials that are prohibited from carriage on air transportation must not be sent at the First-Class Mail, Priority Mail, or Express Mail rates:

- a. Anything susceptible to damage or that can become harmful because of changes in temperature or atmospheric pressures unless protected against the effects of such changes.
- b. Magnetic materials that have a field strength sufficient to cause a compass deviation at a distance of 15 feet (4.6 meters) or more from any point on the outer packaging.
- c. Flammable materials (gases, liquids, and solids).
- d. Radioactive materials.
- e. Materials excluded from air shipment by DOT regulations (49 CFR 100-185) or of the applicable state (country) or air carrier operator variations. Certain restricted articles, as described in 49 CFR 100-185 and the operator variations of the air carriers, may be accepted for air transportation if properly packaged. These articles must be labeled and bear a shipper's declaration in triplicate, as required by 49 CFR 172.204, or must be marked according to the air carrier's operator variations. Refer to the technical instruction of the International Civil Aviation Organization (ICAO) for air carrier operator variations.

## 10.11 Explosives (Hazard Class 1)

### 10.11.1 Definition

An explosive is any substance, article, or device that is designed to function by explosion (i.e., an extremely rapid release of gas and heat) or that, by chemical reaction within itself, is able to function in a similar manner even if not designed to function by explosion, unless the substance or article is otherwise classed under the provisions in 49 CFR. Hazard class 1 has six divisions as shown in Exhibit 10.4. No further explanation of the six divisions is provided in these standards because explosives are prohibited in the mail except as permitted in 10.11.2.

### 10.11.2 Mailability

Explosives are prohibited in international mail. Explosives are prohibited in the domestic mail via air transportation. For domestic surface transportation, explosives are prohibited except for certain Division 1.4S toy propellant devices and safety fuses specifically approved by the manager of Mailing Standards (see 608.8.0 for address) before mailing. A mailable explosive must meet the packaging and marking requirements provided with the manager's approval. A shipping paper is required.

## 10.12 Gases (Hazard Class 2)

### 10.12.1 Definition

Hazard class 2 consists of three divisions:

- a. Division 2.1, Flammable Gases. A material that is a gas at 68°F (20°C) or less and 14.7 psi (101.3 kPa) of pressure. Flammable gases also include materials that have a boiling point of 68°F (20°C) or less at 14.7 psi (101.3 kPa) and that are ignitable at 14.7 psi (101.3 kPa) when in a mixture of 13% or less by volume with air or that have a flammable range at 14.7 psi (101.3 kPa) with air of at least 12% regardless of the lower limit. These conditions must be established in accordance with ASTM E681-85, Standard Test Method for Concentration Limits of Flammability of Chemicals, or other approved equivalent method. The flammability of aerosols must be determined using the tests specified in 49 CFR 173.306(i).
- b. Division 2.2, Nonflammable, Nontoxic Gases. A material that does not meet the definition of Division 2.1 or 2.3 and exerts in its packaging an absolute pressure of 40.6 psi (280 kPa) or greater at 68°F (20°C).
- c. Division 2.3, Toxic Gases. A material that is poisonous by inhalation and is a gas at 68°F (20°C) or less and a pressure of 14.7 psi (101.3 kPa) or a material that has a boiling point of 68°F (20°C) or less at 14.7 psi (101.3 kPa).

### 10.12.2 Mailability

Gases are prohibited in international mail. Toxic gases in Division 2.3 are prohibited in domestic mail. Flammable gases in Division 2.1 are prohibited in domestic mail via air transportation, but are permitted via surface transportation if



the material can qualify as an ORM-D material and meet the standards in 10.12.3 and 10.12.4. Nonflammable gases in Division 2.2 are generally permitted in the domestic mail via air or surface transportation if the material can qualify as an ORM-D material and meet the standards in 10.12.3 and 10.12.4.

### 10.12.3 Container

An other-than-metal primary receptacle containing a mailable gas may be acceptable if the water capacity of the primary receptacle is 4 fluid ounces (7.22 cubic inches) or less per mail piece and the primary receptacle meets 49 CFR requirements. Mailable nonflammable and flammable compressed gases are acceptable in metal primary receptacles that have a water capacity up to 33.8 fluid ounces (1 liter or 61.0 cubic inches), depending on their internal pressure. A DOT 2P container must be used as the primary receptacle if the internal pressure is from 140 to 160 psi at 130°F (55°C). A DOT 2Q container must be used as the primary receptacle if the pressure is from 161 to 180 psi at 130°F (55°C). A container with an internal pressure over 180 psi at 130°F (55°C) is prohibited from mailing. Mailable flammable compressed gases are restricted to 33.8 fluid ounces (1 liter) per mail piece. Mailable nonflammable compressed gases are permitted in individual 33.8 fluid ounce (1 liter) containers that must be securely packed within an outer shipping container. Each mail piece must not exceed a total weight of 25 pounds.

### 10.12.4 Marking

For surface transportation, packages of mailable gases must be clearly marked on the address side with “Surface Only” or “Surface Mail Only” and “ORM-D” immediately following or below the proper shipping name (consumer commodity). For air transportation, packages must be plainly and durably marked on the address side with “ORM-D AIR” immediately following or below the proper shipping name and must also bear a shipper’s declaration for dangerous goods.

## 10.13 Flammable and Combustible Liquids (Hazard Class 3)

### 10.13.1 Definitions

The terms used in the standards that apply to hazard class 3 are defined as follows:

- a. Flammable liquid means a liquid that has a flash point of not more than 141°F (60.5°C), or any material in a liquid phase that has a flash point at or above 100°F (38°C).
- b. Combustible liquid means any liquid that does not meet the definition of any other hazard class and has a flash point above 141°F (60.5°C) and below 200°F (93°C). Note: A flammable liquid with a flash point at or above 100°F (38°C) that does not meet the definition of any other hazard class may be reclassified as a combustible liquid per 49 CFR 173.120(b).

### 10.13.2 Flammable Liquid Mailability

Flammable liquid is prohibited in international mail. Flammable liquid with a flash point of 20°F (-7°C) or below is prohibited in domestic mail. Other flammable liquid is prohibited in domestic mail via air transportation but is permitted via surface transportation if the material can qualify as an ORM-D material and meet the following conditions as applicable:

- a. The flash point is above 20°F (-7°C) but no more than 73°F (23°C); the liquid is in a metal primary receptacle not exceeding 1 quart, or in another type of primary receptacle not exceeding 1 pint, per mail piece; enough cushioning surrounds the primary receptacle to absorb all potential leakage; the cushioning and primary receptacle are packed within a securely sealed secondary container that is placed within a strong outer shipping container; and each mail piece is plainly and durably marked on the address side with “Surface Only” or “Surface Mail Only” and “ORM-D” immediately following or below the proper shipping name.
- b. The flash point is above 73°F (23°C) but less than 100°F (38°C); the liquid is in a metal primary receptacle not exceeding 1 gallon, or in another type of primary receptacle not exceeding 1 quart, per mail piece; enough cushioning surrounds the primary receptacle to absorb all potential leakage; the cushioning and primary receptacle are placed within a securely sealed secondary container that is placed within a strong outer shipping container; and each mail piece is plainly and durably marked on the address side with “Surface Only” or “Surface Mail Only” and “ORM-D” immediately following or below the proper shipping name.

### 10.13.3 Combustible Liquid Mailability

Combustible liquid is prohibited in international mail. Combustible liquid is permitted in domestic mail if the material can qualify as an ORM-D material and meet the following conditions as applicable:

- a. For surface transportation, if the flash point is 100°F (38°C) but no more than 141°F (60.5°C); the liquid is in a metal primary receptacle not exceeding 1 gallon, or in another type of primary receptacle not exceeding 1 quart, per mail piece; enough cushioning surrounds the primary receptacle to absorb all potential leakage; the cushioning and primary receptacle are packed in a securely sealed secondary container that is placed within a strong outer shipping container; and each mail piece is plainly and durably marked on the address side with “Surface Only” or “Surface Mail Only” and “ORM-D” immediately following or below the proper shipping name.
- b. For surface or air transportation, if the flash point is above 141°F (60.5°C) but no more than 200°F (93°C); the liquid is in a primary receptacle not exceeding 1 gallon per mail piece; enough cushioning surrounds the primary receptacle to absorb all potential leakage; the cushioning and primary receptacle are packed in a securely sealed secondary container that is placed within a strong outer shipping container; and each mail piece is plainly and durably marked on the address side with “ORM-D” or “ORM-D AIR,” as applicable, immediately following or below the proper shipping name. Mailable material sent via surface transportation must be marked on the address side as “Surface Only” or “Surface Mail Only.” For air transportation, each mail piece must bear a shipper’s declaration for dangerous goods.
- c. For air or surface transportation, if the flash point is above 200°F (93°C) the material is not regulated as a hazardous material. Such nonregulated materials must be properly and securely packaged to prevent leakage under the general packaging requirements in 2.0, Packaging.

### 10.13.4 Cigarette Lighters

A cigarette lighter equipped with an ignition element and containing fuel is a Class 3 flammable liquid. A cigarette lighter that contains a flammable gas is classed as a Division 2.1 flammable gas. A cigarette lighter containing either flammable liquid or flammable gas is permitted only in domestic mail via surface transportation when all of the following conditions are met:

- a. The design of the lighter and its packaging are approved by the DOT Associate Administrator for Hazardous Material Safety, per 49 CFR 173.21(i) and 173.308; and a DOT Approval Number (T-Number) is issued.
- b. The prospective mailer of the lighter submits to the PCSC manager a written request for authorization to mail the lighter, accompanied by a legible photocopy of the official DOT notice conveying the approval described in 10.13.4a and a specimen of the actual lighter, the packaging materials in which each lighter is to be mailed, the number of mail pieces and mailing location; and the mailer receives from the PCSC manager a letter approving the requested authorization for mailing.
- c. When presented for mailing, the address side of the mail piece containing the lighter prominently displays the T-Number, the proper shipping name “Lighter(s)” or “Lighter(s) for Cigarette,” and the marking “Surface Only” or “Surface Mail Only”; all preparation and packaging requirements in the PCSC manager’s approval letter are met; and a legible photocopy of the PCSC manager’s approval letter accompanies the mailing.

### 10.13.5 Special Permit Authorization DOT-SP 9275

[9-13-07] Manufacturers and distributors seeking to mail parcels via air transportation in accordance with Department of Transportation Special Permit 9275 must submit a written request for approval to the manager, Mailing Standards (see 608.8.0 for address). Approval to mail parcels using DOT-SP 9275 allows the mailer to use First-Class Mail, Priority Mail, or Parcel Select services for shipping in compliance with all DOT regulations in DOT-SP 9275 and the following mailing requirements:

- a. Mailers must present a current copy of their DOT Special Permit Authorization letter with a written request for approval to the manager, Mailing Standards.
- b. Once approved, mailers must present a copy of their approval letter from the manager, Mailing Standards (to be kept on file at the office of mailing) at the time of their first mailing at any given postal facility, along with a copy of their current DOT Special Permit Authorization letter. It is the mailers responsibility to provide the office of mailing with updated DOT Special Permit approval letters. The Postal Service may refuse mailings not supported by a current DOT authorization letter.

- c. Mailers must enter parcels using First-Class Mail, Priority Mail, or Parcel Select service via a USPS-authorized manifest mailing system (MMS) (see 705.2.0).
- d. Mailers must label each parcel on the address side with “USPS Approved DOT-SP 9275” using at least 14-point type.
- e. Parcels must weigh 10 pounds or less. Each inner package (receptacle) may not exceed 16 ounces of flammable liquid or 1 pound of solids containing flammable liquid.
- f. Mailers must ensure that all addressees are notified that they are not authorized to remail the contents of the parcel via the Postal Service under DOT-SP 9275. Mailers must include the following notice: “Flammable substances contained in these packages may be mailed only by consumers (the addressee) via surface transportation in accordance with 10.13. Full responsibility rests with the mailer to comply with all postal and nonpostal statutes and regulations regarding mail. Information regarding postal statutes, regulations, and mailing requirements is available from your local Postmaster or Postal Service Business Mail Entry Manager, and at the Postal Service’s mailing standards Web site at [pe.usps.com](http://pe.usps.com).”
- g. Mailers must comply with the warning and labeling requirements in 21 CFR Part 700 (740.1 and 701.3) when mailing each parcel.

#### 10.14 Flammable Solids (Hazard Class 4)

##### 10.14.1 Definitions

Hazard class 4 consists of three divisions:

- a. Division 4.1, Flammable Solids. Any solid material other than one classed as an explosive that, under conditions normally incident to transportation, is likely to cause fires through friction or retained heat from manufacturing or processing, or that can be ignited readily and, when ignited, burns so vigorously and persistently as to create a serious transportation hazard.
- b. Division 4.2, Spontaneously Combustible. A liquid or solid pyrophoric material that even in small amounts and without an external ignition source can ignite within 5 minutes after coming in contact with air, or a self-heating material that, when in contact with air and without an energy supply, is liable to self-heat.
- c. Division 4.3, Dangerous When Wet. A material that, by contact with water, is likely to become spontaneously flammable or to give off flammable or toxic gas at a rate greater than 1 liter per kilogram of the material per hour.

##### 10.14.2 Mailability

Flammable solids are prohibited in international mail. Flammable solids are prohibited in domestic mail via air transportation. A flammable solid that can qualify as an ORM-D material is permitted in domestic mail via surface transportation if the material is contained in a secure primary receptacle having a weight of 1 pound or less; the primary receptacle(s) is packed in a strong outer shipping container with a total weight of 25 pounds or less per mail piece; and each mail piece is plainly and durably marked on the address side with “Surface Only” or “Surface Mail Only” and “ORM-D” immediately following or below the proper shipping name.

##### 10.14.3 Matches

Matches are classified as flammable solids. Strike-anywhere matches are prohibited in international and domestic mail. Safety matches (book, card, or strike-on-box) are prohibited in international mail, and in domestic mail via air transportation, but are permitted in domestic mail via surface transportation if:

- a. They do not ignite spontaneously under conditions normally incident to transportation or when subjected for 8 consecutive hours to a temperature of 200°F (93°C).
- b. They cannot be readily ignited by friction unless struck on their own or a similar box, card, or book.
- c. They are tightly packed in a securely sealed primary receptacle to prevent any shifting or movement that could cause accidental ignition by rubbing against adjoining items. The primary receptacle(s) is placed securely within an outer shipping container made of fiberboard, wood, or other equivalent material. Multiple primary receptacles may be placed in a single outer shipping container. The address side of the mail piece must be marked “Surface Only” or “Surface Mail Only” and “Book Matches,” “Strike-on-Card Matches,” or “Card Matches,” as appropriate. A shipping paper is not required.

- d. The gross weight of each mail piece is not more than 25 pounds.

## 10.15 Oxidizing Substances, Organic Peroxides (Hazard Class 5)

### 10.15.1 Definition

Hazard class 5 consists of two divisions:

- a. Division 5.1, Oxidizing Substances. A material that may, generally by yielding oxygen, cause or enhance the combustion of other materials.
- b. Division 5.2, Organic Peroxides. Any organic compound that contains oxygen in the bivalent structure and that may be considered a derivative of hydrogen peroxide, where one or more of the hydrogen atoms have been replaced by organic radicals.

### 10.15.2 Mailability

Oxidizing substances and organic peroxides are prohibited in international mail. For domestic mail, a material that can qualify as an ORM-D material is permitted via air or surface transportation. Liquid materials must be enclosed within a primary receptacle having a capacity of 1 pint or less; the primary receptacle(s) must be surrounded by absorbent cushioning material and held within a leak-resistant secondary container that is packed within a strong outer shipping container. Solid materials must be contained within a primary receptacle having a weight capacity of 1 pound or less; the primary receptacle(s) must be surrounded with cushioning material and packed within a strong outer shipping container. Each mail piece may not exceed a total weight of 25 pounds. The address side of each mail piece must be plainly and durably marked with "ORM-D AIR" or "ORM-D," as applicable, immediately following or below the proper shipping name. A mailable Class 5 material sent via surface transportation must be marked "Surface Mail" or "Surface Mail Only" on the address side. A mailable material sent via air transportation must bear a shipper's declaration for dangerous goods.

## 10.16 Toxic Substances (Hazard Class 6, Division 6.1)

### 10.16.1 Definitions

The terms used in the standards for Division 6.1 material are:

- a. Toxic substance is a poisonous material, other than a gas, that is known to be so toxic to humans as to cause death, injury, or harm to human health if swallowed, inhaled, or contacted by the skin.
- b. Oral toxicity applies to a liquid with a lethal dose (LD50) for acute oral toxicity of not more than 500 mg/kg or a solid with an LD50 for acute oral toxicity of not more than 200 mg/kg that when administered by mouth is likely to cause death within 14 days in half of the test animals.
- c. Dermal toxicity applies to a material with an LD50 for acute dermal toxicity of not more than 1,000 mg/kg that when administered by continuous contact with bare skin is likely to cause death within 14 days in half of the test animals.
- d. Inhalation toxicity applies to a dust or mist with a lethal concentration (LC50) for acute inhalation toxicity of not more than 10 mg/L; or a saturated vapor concentration in air at 68°F (20°C) of more than one-fifth of the LC50 for acute toxicity on inhalation of vapors and with an LC50 for acute inhalation toxicity of vapors of not more than 5,000 ml/m<sup>3</sup>; that when administered by continuous inhalation for 1 hour is likely to cause death within 14 days in half of the test animals.
- e. Irritating material is any liquid or solid substance (e.g., tear gas) that gives off intense fumes and causes extreme irritation and impairment to a person's ability to function.

### 10.16.2 Mailability

Toxic substances or poisons are prohibited in international mail. For domestic mail, a Division 6.1 toxic substance or poison that can qualify as an ORM-D material is permitted when packaged under the applicable requirements in 10.16.4. Certain other poisonous materials are permitted to be mailed only between the authorized parties and under the conditions in 10.16.3.

### 10.16.3 Authorized Parties

A Division 6.1 toxic substance having an LD50 for oral toxicity of greater than 5mg/kg but less than or equal to 50 mg/kg is mailable only if packaged under the applicable requirements in 10.16.4 and when sent between authorized parties and under specified conditions, as follows:

- a. Toxic substances for scientific use (not outwardly or of their own force dangerous or injurious to life, health, or property) may be sent only between manufacturers, dealers, bona fide research or experimental scientific laboratories, and employees of federal, state, or local governments who have official use for such poisons and are designated by the agency head to receive or send such poisons. For air transportation, a shipper's declaration for dangerous goods is required.
- b. Poisonous drugs and medicines may be sent only from the manufacturer or dealer of the drugs and medicines to licensed physicians, surgeons, dentists, pharmacists, druggists, cosmetologists, barbers, and veterinarians (18 USC 1716). In limited circumstances, when the mailing is initiated by a drug manufacturer or the drug manufacturer's registered agent, customers may return prescription drugs to the manufacturer or its registered agent as indicated in 11.11.4 and 11.11.5.

### 10.16.4 Packaging and Marking

The following requirements must be met, as applicable:

- a. A toxic substance that can qualify as an ORM-D material and does not exceed a total capacity of 8 ounces per mail piece is permitted if: the material is held in a primary receptacle(s); enough cushioning material surrounds the primary receptacle to absorb all potential leakage; the cushioning and primary receptacle(s) are packed in another securely sealed secondary container that is placed within a strong outer shipping container. Each mail piece must be plainly and durably marked on the address side with "ORM-D" or "ORM-D AIR," as applicable, immediately following or below the proper shipping name. Mailable material sent via surface transportation must be marked on the address side as "Surface Only" or "Surface Mail Only."
- b. Other toxic substances and poisons are permitted to be sent between the authorized parties and under the conditions in 10.16.3 when they do not exceed 8 ounces per mail piece and if: the material is held in a leak-resistant primary receptacle(s); sufficient absorbent and cushioning material completely surround each primary receptacle; the primary receptacle(s) and the absorbent and cushioning materials are firmly held within a leakproof (for liquids) or siftproof (for solids) secondary container; the secondary container is firmly and securely held within a strong outer shipping container of 200-pound grade corrugated fiberboard or equivalent strength. The address side of each mail piece must be marked with the proper shipping name and UN (or NA) identification number of the material (unless exempted by 11.11.6). Mailable materials sent via surface transportation must be marked on the address side as "Surface Only" or "Surface Mail Only." Each mail piece must bear a shipping paper.

### 10.16.5 Irritants

Irritants are prohibited in international mail and domestic mail.

## 10.17 Infectious Substances (Hazard Class 6, Division 6.2)

### 10.17.1 General

Division 6.2 materials include infectious substances, biological products, regulated medical waste, sharps medical waste, used health care products, and forensic materials. Division 6.2 materials are not permitted in international mail or domestic mail, except when they are intended for medical or veterinary use, research, or laboratory certification related to the public health; and only when such materials are properly prepared for mailing to withstand shocks, pressure changes, and other conditions related to ordinary handling in transit. Mailable Division 6.2 materials sent as international mail must meet the standards in the International Mail Manual. For domestic mail, mailable Division 6.2 materials must meet the applicable standards in 10.17. Unless otherwise noted, all mailable Division 6.2 materials must meet the mail preparation requirements for air transportation.

### 10.17.2 Definitions

The terms used in the standards for Division 6.2 materials are defined as follows:

- c. Infectious substance means a material known or reasonably expected to contain a pathogen. A pathogen is a microorganism that can cause disease in humans or animals. Examples of pathogens include bacteria, viruses, fungi, and other infectious agents. An infectious substance must be assigned to one of the following two categories:
  3. Category A: An infectious substance transported in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure occurs. Category A infectious substances are not mailable. A Category A infectious substance is assigned the identification number UN 2814 or UN 2900, based on the known medical history or symptoms of the source patient or animal, endemic local conditions, or professional judgment concerning the individual circumstances of the source human or animal.
  4. Category B: An infectious substance that does not meet the criteria for inclusion in Category A. A mail piece known or suspected to contain a Category B infectious substance must bear the proper shipping name "Biological substance, Category B" on the address side of the mail piece and must be assigned to and marked with identification number UN 3373 or, for regulated medical waste and sharps medical waste, identification number UN 3291.
- d. Biological product means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product or arsphenamine or derivative of arsphenamine (or any other trivalent arsenic compound) intended to prevent, treat, or cure a disease or condition of humans or animals. A biological product includes a material subject to regulation under 42 U.S.C. 262 or 21 U.S.C. 151-159. Unless otherwise excepted, mark these mail pieces with identification number UN 3373 when they contain a biological product known or reasonably expected to contain a pathogen that meets the definition of a Category B infectious substance.
- e. Cultures are infectious substances that result from a process by which pathogens are intentionally propagated. This definition does not include a human or animal patient specimen as defined in 10.17.2e.
- f. Exempt human or animal specimen means a human or animal sample (including, but not limited to, secretions, excretions, blood and its components, tissue and tissue fluids, and body parts) transported for routine testing not related to the diagnosis of an infectious disease. Typically, exempt human specimens are specimens for which there is a low probability that the sample is infectious, such as specimens for drug or alcohol testing; cholesterol testing; blood glucose level testing; prostate-specific antigens (PSA) testing; testing to monitor heart, kidney, or liver function; pregnancy testing; and testing for diagnosis of noninfectious diseases such as cancer biopsies. Exempt human or animal specimens are not subject to regulation as hazardous materials but must be packaged according to 10.17.9.
- g. Patient specimen means material that is collected directly from humans or animals and transported for purposes such as diagnosis and research. Patient specimens include excretions, secretions, blood and its components, tissue and tissue swabs, body parts, and specimens in transport media (such as transwabs, culture media, and blood culture bottles).
- h. Regulated medical waste, for USPS purposes, means a soft waste material (other than a sharp) derived from the medical treatment, diagnosis, immunization, or biomedical research of a human or animal. Soft medical waste includes items such as used rubber gloves, swabs, gauze, tongue depressors, and other similar material. Mark these mail pieces with identification number UN 3291.
- i. Sharps medical waste, for USPS purposes, means a medical waste object that is capable of cutting or penetrating skin or packaging material and that is contaminated with a pathogen or may become contaminated with a pathogen derived from the medical treatment, diagnosis, immunization, or biomedical research of a human or animal. Sharps include used medical waste such as needles, syringes, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, and exposed ends of dental wires. Mark these mail pieces with identification number UN 3291.
- j. Toxin means a Division 6.1 material from a plant, animal, or bacterial source. A toxin containing an infectious substance or a toxin contained in an infectious substance must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814, UN 2900, or UN 3373, as appropriate. A toxin known or suspected to contain a Category A infectious substance is not mailable. A toxin known or suspected to contain a Category B infectious substance must be marked UN 3373 and packaged under 10.17.5. Toxins from plant, animal, or bacterial sources that do not contain an infectious substance, and are not contained in an infectious substance, may be considered for classification as Division 6.1 toxic substances under 10.16.

- k. Used health care product means a medical, diagnostic, or research device or piece of equipment, or a personal care product used by consumers, medical professionals, or pharmaceutical providers that does not meet the definition of a biological substance, Category B, biological product, regulated medical waste, or sharps waste, is contaminated with potentially infectious body fluids or materials, and is not decontaminated or disinfected to remove or mitigate the infectious hazard prior to transport.

### 10.17.3 Nonregulated Materials

The following materials are not subject to regulation as Division 6.2 hazardous materials and are mailable when the packaging requirements in 10.17.8 are met:

- a. A biological product, including an experimental or investigational product or component of a product, subject to Federal approval, permit, review, or licensing requirements, such as those required by the Food and Drug Administration of the U.S. Department of Health and Human Services or the U.S. Department of Agriculture. A biological product known or suspected to contain a Category B infectious substance must be marked UN 3373 and packaged under 10.17.4. A biological product known or suspected to contain a Category A infectious substance is not mailable.
- b. Blood collected for the purpose of blood transfusion or the preparation of blood products; blood products; plasma; plasma derivatives; blood components; tissues or organs intended for use in transplant operations; and human cell, tissues, and cellular and tissue-based products regulated under the Public Health Service Act (42 U.S.C. 264-272) or the Food, Drug, and Cosmetic Act (21 U.S.C. 332 et seq.).
- c. Blood, blood plasma, and blood components collected for the purpose of blood transfusion or the preparation of blood products and sent for testing as part of the collection process, except where the person collecting the blood has reason to believe it contains a Category B infectious substance, in which case the test sample must be shipped as a Category B infectious substance. Materials known or suspected to contain a Category A infectious substance are not mailable.
- d. Dried blood spots, collected by applying a drop of blood to absorbent material, or dried specimens for fecal occult blood detection. (These materials are not classified as exempt human or animal specimens.)
- e. Forensic material containing a biological material, such as tissue, body fluid, excreta, or secretions, not expected to contain a Category A or Category B infectious substance and transported on behalf of a U.S. Government agency or a state, local, or Indian tribal government agency. A forensic material known or suspected to contain a Category B infectious substance must be shipped as a Category B infectious substance. A forensic material known or suspected to contain a Category A infectious substance is not mailable. Packaging—General

All materials mailable under the provisions in 10.17 must be properly packaged. Exhibit 10.17.3 lists the specific reference in 10.17 under which each type of mailable material must be packaged.

Exhibit 10.17.3 Packaging Standards for Division 6.2 Infectious Substances

Material Being Mailed	Packaging Standards		
	Nonregulated	Category A	Category B
Blood for Transfusion	10.17.8	nm	10.17.4
Biological Product	10.17.8	nm	10.17.4
Culture or Stock	10.17.8	nm	10.17.4
Patient Specimen	n/a	nm	10.17.4
Exempt Human or Animal Specimen	10.17.9	n/a	n/a
Forensic Material	10.17.8	nm	10.17.4
Regulated Medical Waste	10.17.5	nm	10.17.5
Sharps Waste	10.17.5	nm	10.17.5
Toxin	10.16.4	nm	10.17.4
Treated Medical Waste	10.17.8	n/a	n/a
Used Health Care Product	10.17.6	nm	10.17.6

nm = Not mailable.

n/a = Not applicable.

\* Toxin means a Division 6.1 material from a plant, animal, or bacterial source. A toxin containing an infectious substance or a toxin contained in an infectious substance must be classified as Division 6.2; described as an infectious substance; and assigned to UN 2814, UN 2900, or UN 3373, as appropriate. A Division 6.1 toxin that can qualify as an ORM-D material is permitted when packaged under 10.16.3 or 10.16.4.

#### 10.17.4 Packaging Category B Infectious Substances

A material that is classified as a Category B infectious substance and that meets the definition in 10.17.2a2 must be triple-packaged, meeting the packaging requirements in 49 CFR 173.199, and sent as First-Class Mail, Priority Mail, or Express Mail. Each primary receptacle containing a liquid must be leakproof and surrounded by absorbent material sufficient to protect the primary receptacle and absorb the total amount of liquid should the primary receptacle leak or break. Each primary receptacle containing a solid must be siftproof. Secondary containers for liquids must be leakproof. Secondary containers for solids must be siftproof. The primary and secondary packaging must be enclosed in a rigid outer shipping container. A single primary receptacle must not contain more than 1 liter (34 ounces) of a liquid specimen or 4 kg (8.8 pounds) of a solid specimen. Two or more primary receptacles whose combined volume does not exceed 4 liters (1 gallon) for liquids or 4 kg (8.8 pounds) for solids may be enclosed in a single secondary container. In addition:

- a. The secondary container must be marked with the international BIOHAZARD symbol shown in Exhibit 10.17.5d3.
- b. The primary receptacle or secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi) in the range of -40° C to 55° C (-40° F to 130° F).
- c. All mail pieces sent under 10.17.4 must be marked on the address side with the shipping name “Biological substance, Category B” and “UN 3373” as outlined in 49 CFR 173.199 (a)(5). Regulated medical waste and sharps medical waste as defined in 10.17.2f and 10.17.2g must be marked UN 3291. See 10.17.5.
- d. Orientation arrows are not required on these mail pieces but may be used.
- e. The outer packaging must show the name and telephone number of a person who is knowledgeable about the material shipped and has comprehensive emergency response and incident mitigation information, or of someone who has immediate access to the person with such knowledge and information.

#### 10.17.5 Sharps Waste and Other Mailable Regulated Medical Waste

Regulated medical waste and sharps medical waste known or suspected to contain a Category A infectious substance is not mailable. Regulated medical waste and sharps medical waste as defined in 10.17.2f and 10.17.2g, and containing materials classified as Category B infectious substances, must be marked UN 3291 and are permitted for mailing only using merchandise return service (see 507.10.0) with First-Class Mail or Priority Mail service, subject to the following requirements:

- a. Authorization. Each vendor of a complete regulated medical waste or sharps waste mailing container system (including all component parts required to safely mail such waste to a storage or disposal facility) must obtain authorization from the USPS prior to mailing. Before applying for authorization, each type of mailing container system must be tested and certified under the standards in 10.17.5e by an independent testing facility. The vendor in whose name the authorization is being sought must submit a written request to the manager, Mailing Standards, USPS Headquarters (see 608.8.0, USPS Contact Information, for address). The request for authorization must contain the following:
  1. An irrevocable \$50,000 surety bond or letter of credit as proof of sufficient financial responsibility to cover disposal costs if the vendor ceases doing business before all its waste container systems are disposed of or to cover cleanup costs if spills occur while the containers are in USPS possession. The surety bond or letter of credit must be issued in the name of the vendor seeking the authorization and must name the USPS as the beneficiary or obligee. Vendors that market their containers to distributors are responsible for disposal and cleanup costs attributed to those containers. In addition, vendors must provide a list of distributors, including firm names, addresses, and telephone numbers, to the Postal Service on request.
  2. Address of the headquarters or general business office of the vendor seeking the authorization.
  3. Name, address, and phone number of each storage and disposal site.

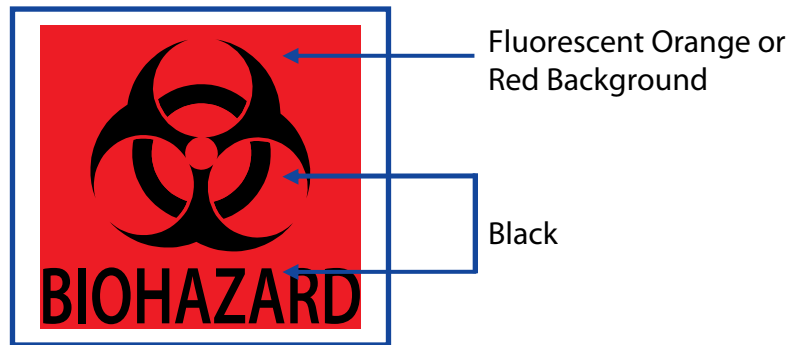


4. List of all types of mailing container systems to be covered by the request, a complete sample of each mailing container system, and proof of package testing certifications performed by the independent testing facility that subjected the packaging materials to the testing requirements in 10.17.5e.
  5. Copy of the proposed waste shipping paper to be used with each mailing container system.
  6. 24-hour toll free telephone number for emergencies.
  7. List of the types of waste to be mailed for disposal in each mailing container system.
  8. Copy of the merchandise return service label to be used with each mailing container system and verification that the merchandise return service permit fee and accounting fee have been paid.
  9. Address of the post office or postage due unit where the containers are delivered.
- b. Packaging. Regulated medical waste and sharps medical waste that also meets the definition of a Category A infectious substance is not mailable. A medical waste material treated by steam sterilization, chemical disinfections, or other appropriate method so that it no longer contains a Category A or Category B infectious substance must be packaged under 10.17.8. The packaging for regulated medical waste and sharps medical waste containing or suspected of containing a Category B infectious substance is subject to these standards:
1. Sharps medical waste and regulated medical waste meeting the definitions in 10.17.2e and 10.17.2g must be collected in a rigid, securely sealed, and leakproof primary receptacle. For sharps waste, the primary receptacle must also be puncture-resistant and may not have a maximum capacity that exceeds 3 gallons in volume. For regulated medical waste, the primary receptacle may not have a maximum capacity that exceeds 5 gallons in volume. Each primary receptacle may not contain more than 50 ml (1.66 ounces) of residual waste liquid. Each primary receptacle must display the international BIOHAZARD symbol shown in Exhibit 10.17.5d3. Package testing results must show that the contents did not penetrate through the primary container during package testing and that the primary container can maintain its integrity at temperatures as low as 0°F and as high as 120°F.
  2. The primary receptacle must be packaged within a watertight secondary container or containment system. The secondary container may consist of more than one component. If one of the components is a plastic bag, the bag must be at least 4 mil in thickness and must be used in conjunction with a fiberboard box. A plastic bag by itself does not meet the requirement for a secondary container. Several primary receptacles may be enclosed in a secondary container. The primary receptacle(s) must fit securely and snugly within the secondary container to prevent breakage during ordinary processing.
  3. The secondary container must be enclosed in a strong outer shipping container constructed of 200-pound grade corrugated fiberboard. The joints and flaps of the outer shipping container must be securely taped, glued, or stitched to maintain the integrity of the container. When tape or glue is used to secure an outer shipping container, the material must be water-resistant. Fiberboard boxes with interlock bottom flaps (i.e., easy-fold) are not permitted as outer shipping containers unless reinforced with water-resistant tape. The secondary container must fit securely and snugly within the outer shipping container to prevent breakage during ordinary processing.
  4. There must be enough material within the primary receptacle to absorb and retain three times the total liquid allowed within the primary receptacle (150 ml per primary receptacle) in case of leakage.
  5. Each mail piece must not weigh more than 25 pounds. Medical Professional Packages as identified in 10.17.5c, may not weigh more than 35 pounds. The container's maximum allowable weight must be printed on the outside of the box and on the assembly and closure instructions included with each mail piece. The mail piece must be tested at the maximum allowable weight identified by the vendor.
  6. In each mailing container system, the authorized vendor must include a step-by-step instruction sheet that clearly details the proper sequence and method of container system assembly prior to mailing to prevent package failure during transport due to improper assembly. The instruction sheet must also include a customer service telephone number, or provide specific information on where such a telephone number is located elsewhere on the container system, for third-party end users to contact if they have assembly questions or find a component part is missing.
- c. Medical Professional Packages. Medical Professional Packages, while intended for use by small medical offices, is not limited to use by medical offices only. One primary receptacle larger than 5 gallons in volume may be used for

mailing pre-primary sharps receptacles (sharps receptacles normally used in doctors' offices) and other regulated medical waste under the following conditions:

1. The mail piece must meet all the requirements in 10.17.5 except for the primary receptacle capacity limits of 10.17.5b1.
  2. Only rigid, securely closed, puncture and leak-resistant pre-primary sharps receptacles that meet or exceed Occupational Safety and Health Administration standards as identified in 29 CFR 1910.1030, may be placed inside the primary receptacle. Each pre-primary sharps container may contain no more than 50 ml (1.66 ounces) of residual waste liquid. Several pre-primary sharps receptacles may be enclosed in the single primary receptacle.
  3. Multiple tie-closed plastic bags of regulated medical waste may be placed inside the single primary receptacle.
  4. The primary receptacle must be lined with a plastic bag at least 4 mil in thickness and must include sufficient absorbent material within the liner to absorb all residual liquid in the primary receptacle.
  5. The mail piece must not weigh more than 35 pounds.
- d. Mail piece Labeling, Marking, and Documentation. Regulated medical waste and sharps waste must meet the following requirements:
1. For Medical Professional Packages, the additional marking "Medical Professional Packaging" must be clearly printed in lettering at least 2 inches high on the address side of the outer shipping container.
  2. Each primary receptacle and outer shipping container must bear a label, which cannot be detached intact, showing: (a) the company name of the vendor to which the mailing authorization is issued; (b) the USPS Authorization Number, and; (c) the container ID number (or unique model number) signifying that the packaging material is certified and that the vendor obtained the authorization required by 10.17.5a. Place the label on the top or on a side of the container.
  3. The primary receptacle(s) and the outer shipping container must bear the international BIOHAZARD symbol in black with either a fluorescent orange or fluorescent red background as shown in Exhibit 10.17.5d3. The symbol on the outer shipping container must be at least 3 inches high and 4 inches wide.

Exhibit 10.17.5d3 International BIOHAZARD Symbol



4. Each mail piece must have a four-part waste shipping paper. The shipping paper must be affixed to the outside of the mail piece in an envelope or similar carrier that can be easily opened and resealed to allow review of the document. The shipping paper must comply with all applicable requirements imposed by the laws of the state from which the container system is mailed. At a minimum, the information in Exhibit 10.17.5d4 must be on the shipping paper.

## Exhibit 10.17.5d4 Shipping Paper for Regulated Medical Waste and Sharps Waste Containers

Section	Information Required
1. Generator (Mailer)	<p>a. Name.</p> <p>b. Complete address (not a Post Office box).</p> <p>c. Telephone number.</p> <p>d. Description of contents of mailing container. "Regulated Medical Waste" or "Regulated Medical Waste-Sharps" is required as appropriate.</p> <p>e. Date container was mailed.</p> <p>f. State permit number of approved facility in which contents are to be disposed of.</p>
2. Destination Facility (Disposal Site)	Complete address (not a Post Office box)
3. Generator's (Mailer's) Certification	<p>The following certification statement must be printed on the shipping paper:</p> <p>"I certify that this container has been approved for the mailing of [insert either "regulated medical waste" or "sharps waste," as appropriate], has been prepared for mailing in accordance with the directions for that purpose, and does not contain excess liquid or nonmailable material in violation of the applicable Postal Service regulations. I AM AWARE THAT FULL RESPONSIBILITY RESTS WITH THE GENERATOR (MAILER) FOR ANY VIOLATION OF 18 USC 1716 WHICH MAY RESULT FROM PLACING IMPROPERLY PACKAGED ITEMS IN THE MAIL. I also certify that the contents of this consignment are fully and accurately described above by proper shipping name and are classified, packed, marked, and labeled, and in proper condition for carriage by air according to the national governmental regulations."</p> <p>This statement must be followed by printed or typewritten name of generator (mailer), signature of generator, and date signed.</p>
4. Destination Facility (Storage or Disposal Site)	<p>The following certification statement of receipt, treatment, and disposal must be printed on the shipping paper:</p> <p>"I certify that the contents of this container have been received, treated, and disposed of in accordance with all local, state, and federal regulations."</p> <p>This statement must be followed by printed or typewritten name of an authorized recipient at destination facility, signature of authorized recipient, and date signed.</p>
5. Transporter Intermediate Handler Other Than the Postal Service (If Different From Destination Facility)	<p>a. Name.</p> <p>b. Complete address (not a Post Office box).</p> <p>c. Printed or typewritten name of transporter or intermediate handler.</p> <p>d. Signature of transporter or intermediate handler and date signed.</p>
6. Serialized Waste	<p>Shipping Papers</p> <p>Each waste shipping paper or mail disposal service shipping record must be serialized using a unique numbering system for identification purposes.</p>
7. Comment Area	Each shipping paper must contain an area designated for entering comments or noting discrepancies.

Section	Information Required
8. Completion and Distribution of Waste Shipping Paper	<p>Each shipping paper must contain instructions for properly completing the four-part form.</p> <p>Copies of the form must be distributed as follows:</p> <ol style="list-style-type: none"> <li>One copy must be kept by generator (mailer).</li> <li>One copy must be kept by transporter or intermediate handler for 90 days.</li> <li>One copy must be kept by destination facility for 90 days.</li> <li>One copy must be mailed to generator by destination facility.</li> </ol>
9. Emergency Telephone Number	<p>Each shipping paper must bear the following statement with appropriate information:</p> <p>“IN CASE OF EMERGENCY, OR THE DISCOVERY OF DAMAGE OR LEAKAGE, CALL 1 (800) ###-####.”</p>

- The outer shipping container must bear a properly prepared merchandise return service label (see 507.10.0). The merchandise return service permit must be held in the same name as that of the authorized medical waste vendor.
- The outer shipping container must be marked on two opposite side walls with the package orientation marking in 49 CFR 173.312 to identify the proper upright position of the mail piece during handling.
- Mail pieces containing regulated medical waste or sharps waste must be marked on the address side with the correct UN number and proper shipping name (e.g., “Regulated Medical Waste, UN 3291” or “Regulated Medical Waste-Sharps, UN 3291”).
- Vendors must retrieve mail pieces held at processing facilities due to improper labeling such as no return address or due to improperly completed shipping papers.
- Package Testing. Vendors must submit to the manager, Mailing Standards (see 608.8.0 for address), package testing results from an independent testing facility for each package for which the vendor is requesting authorization. In addition, vendors must submit package testing results from an independent testing facility when the design of a container system changes or every 24 months, whichever occurs first. The test results must show that if every mail piece prepared for mailing were subject to the environmental and test conditions in 49 CFR and the additional test requirements in 10.17.5f, no contents would be released into the environment and the effectiveness of the packaging would not be significantly reduced. The Postal Service may require proof of accreditation or other documentation to support the credentials of an independent testing facility.
- Testing Criteria. Packages tested for approval as Medical Professional Packages may not be tested using pre-primary containers that are currently, or have previously been, approved as USPS primary containers. Test reports must identify by brand name the pre-primary containers used during testing. Each mail piece must pass each of the tests described below:
  - Leak-proof test. The test must be conducted on one primary receptacle with the lid in place, without the secondary and outer packaging. The test duration must be at least 5 minutes and must be conducted at 20 kPa (3 psi). The pass/fail criterion is: no air leakage from anywhere other than the closure of the primary receptacle. Air leakage at the closure is not considered a failure if the primary receptacle passes the test for watertightness as determined by placing 50 ml of deionized water into the primary receptacle, securing the closure, and then turning the container on its side and observing for any evidence of leakage. Any evidence of water leaking from the primary receptacle is a failure.
  - Stacking test. One mail piece must withstand the test in 49 CFR 178.606. The dynamic compression test must be conducted on the empty, unsealed mail piece assembled for mailing, without the primary receptacle(s). The test mass is the vendor-identified maximum weight, not to exceed 25 pounds, as indicated on the outer shipping container and on the assembly and closing instructions. A compensation factor of 1.5 must be used to compute the test load, based on the vendor-identified weight. The pass/fail criteria are: no buckling of the sidewalls sufficient to cause damage to the contents in the primary receptacle, and in no case does the deflection exceed 1 inch.

3. Vibration test. One mail piece filled with sharps or other regulated medical waste must withstand the test in 49 CFR 178.608. The test mail piece is filled with sharps or other regulated medical waste to the vendor-identified maximum weight, not to exceed 25 pounds, as indicated on the outer shipping container and on the assembly and closing instructions. The test sample is prepared as it would be for mailing. The pass/fail criterion is: no rupture, cracking, or splitting of any primary receptacle.
  4. Wet drop test. Five mail pieces filled with sharps or other regulated medical waste must withstand the test in 49 CFR 178.609e. Each test mail piece is filled with sharps or other regulated medical waste to the vendor-identified maximum weight, not to exceed 25 pounds, as indicated on the outer shipping container and on the assembly and closing instructions included with each mail piece. Each mail piece is prepared as it would be for mailing and subjected to a water spray as described in the test. A separate, untested mail piece is used for each drop orientation: top, longest side, shortest side, and corner. The pass/fail criteria are: no rupture, cracking, or splitting of any primary receptacle, and no contents may penetrate into or through the body or lid of any primary receptacle.
  5. Cold drop test. Five mail pieces filled with sharps or other regulated medical waste must withstand the test in 49 CFR 178.609f. Each test mail piece is filled with sharps or other regulated medical waste to the vendor-identified maximum weight, not to exceed 25 pounds, as indicated on the outer shipping container and on the assembly and closing instructions included with each mail piece. Each mail piece is prepared as it would be for mailing and chilled as described in the test. A separate, untested mail piece is used for each drop orientation: top, longest side, shortest side, and corner. The pass/fail criteria are: no rupture, cracking, or splitting of any primary receptacle, and no contents may penetrate into or through the body or lid of any primary receptacle.
  6. Impact test. One mail piece filled with sharps or other regulated medical waste must withstand the test in 49 CFR 178.609h. The test mail piece is filled with sharps or other regulated medical waste to the vendor-identified maximum weight, not to exceed 25 pounds, as indicated on the outer shipping container and on the assembly and closing instructions included with each mail piece. The mail piece is prepared as it would be for mailing. The pass/fail criteria are: no rupture, cracking, or splitting of any primary receptacle, and no contents may penetrate into or through the body or lid of any primary receptacle.
  7. Puncture-resistant test. Package testing results must show that during all of the previous tests, the contents did not penetrate through the primary receptacle.
  8. Temperature test. Package testing results must show that each primary receptacle maintained its integrity when exposed to temperatures as low as 0°F and as high as 120°F.
  9. Absorbency test. Package testing results must show that the primary receptacle(s) contain enough absorbent material to absorb three times the total liquid allowed within the primary receptacle in case of leakage. Absorbency is determined by pouring 150 ml of deionized water into the primary receptacle(s), then turning the receptacle(s) upside down and observing for any evidence of free liquid not absorbed on contact. Any evidence of free liquid is a failure.
  10. Watertight test. Package testing results must show that no leakage occurred when 50 ml of deionized water was placed into the secondary containment system and the entire system turned upside down for 5 minutes.
- g. Suspension of Authorization. The Postal Service may suspend a vendor's authorization based on information that a mail piece no longer meets the standards for mailing sharps medical waste and regulated medical waste containers, or that the mail piece poses an unreasonable safety risk to Postal Service employees or the public. The suspension can be made immediately, making the mail piece nonmailable immediately. The vendor may contest a decision to suspend authorization by writing to the manager, Mailing Standards (see 608.8.0 for address), within 7 days from the date of the letter of suspension. The appeal should provide evidence demonstrating why the decision should be reconsidered. Any order suspending authorization remains in effect during an appeal or other challenge. When a vendor is notified that its authorization to mail sharps or other regulated medical waste containers has been suspended, the vendor must immediately:
1. Recall all identified containers.
  2. Notify all customers that they cannot mail the identified containers.
  3. Suspend sales and distribution of all identified containers.

4. Collect the identified containers from distributors, consumers, and the Postal Service without using the mail and in accordance with all federal and state regulations.

#### 10.17.6 Packaging Used Health Care Products

A used health care product known or reasonably suspected to contain a Category A material is not mailable. A used health care product not suspected to contain an infectious material, or that is known or suspected to contain a Category B infectious substance, and is being returned to the manufacturer or manufacturer's designee is mailable as First-Class Mail, Priority Mail, or Express Mail subject to the following packaging requirements:

- a. Each used health care product must be drained of liquid to the extent possible and placed in a watertight primary receptacle designed and constructed to ensure that it remains intact under normal conditions of transport. For a used health care product capable of cutting or penetrating skin or packaging material, the primary receptacle must be capable of retaining the product without puncture of the packaging under normal conditions of transport. The primary receptacle must be marked with the international BIOHAZARD symbol as shown in Exhibit 10.17.5d3.
- b. Each primary receptacle must be placed inside a watertight secondary container designed and constructed to ensure that it remains intact under normal conditions of transport. The secondary container must also be marked with the international BIOHAZARD symbol as shown in Exhibit 10.17.5d3.
- c. The secondary container must be placed inside an outer shipping container with sufficient cushioning material to prevent movement between the secondary container and the outer shipping container. An itemized list of the contents of the primary receptacle and information concerning possible contamination with a Division 6.2 material, including its possible location on the product, must be placed between the secondary container and the outer shipping container. A shipping paper and a content marking on the outer shipping container are not required.

#### 10.17.7 Packaging Forensic Material

Forensic material containing a biological material, such as tissue, body fluid, excreta, or secretions, and sent on behalf of a U.S. Government agency or a state, local, or Indian tribal government agency must be packaged under 10.17.8 when it is not known or suspected to contain a Category A or Category B infectious substance. Forensic material known or suspected to contain a Category A infectious substance is not mailable. Forensic material known or suspected to contain a Category B infectious substance as identified in 10.17.4 is mailable as First-Class Mail, Priority Mail, or Express Mail when triple-packaged in a primary receptacle, secondary container, and a rigid outer shipping container as follows:

- a. The forensic material must be held within a securely sealed primary receptacle. The primary receptacle must be surrounded by sufficient absorbent material (for liquids) and cushioning material to protect the primary container from breakage. The absorbent material must be capable of taking up the entire liquid contents of the primary receptacle in case of leakage. The primary receptacle must be marked with the international BIOHAZARD symbol as shown in Exhibit 10.17.5d3.
- b. The primary receptacle and the absorbent and cushioning material must be enclosed in a watertight and securely sealed secondary container. The secondary container must also display the international BIOHAZARD symbol as shown in Exhibit 10.17.5d3.
- c. The secondary container must be firmly and snugly packed within a strong outer shipping container that is securely sealed. A shipping paper and a content marking on the outer shipping container are not required.

#### 10.17.8 Packaging Nonregulated Materials

Nonregulated materials as defined in 10.17.3 are not subject to regulation as hazardous materials but must be properly packaged when presented for mailing. Regulated medical waste, sharps medical waste, and used health care products must be packaged and mailed under 10.17.5 and 10.17.6. Exempt human and animal specimens must be packaged under 10.17.9. Nonregulated materials are mailable as First-Class Mail, Priority Mail, Express Mail, or Package Services mail. Such materials must be held within a securely sealed primary receptacle. The primary receptacle must be surrounded by sufficient absorbent material (for liquids) and cushioning material to protect the primary receptacle from breakage. The absorbent material must be capable of taking up the entire liquid contents of the primary receptacle in case of leakage. Either the primary receptacle or the inner packaging must be marked with the international BIOHAZARD symbol shown in Exhibit 10.17.5d3. The primary receptacle and the absorbent and cushioning material must be snugly enclosed in a rigid outer shipping container that is securely sealed. A shipping paper and a content marking on the outer shipping

container are not required. Nonregulated material specimens and biological products are subject to the following packaging standards:

- a. **Liquid Patient Specimens and Biological Products.** Mailers must package a liquid nonregulated patient specimen, a forensic specimen, or a biological product (such as polio vaccine) as follows:
  1. Not exceeding 50 ml. A patient specimen or biological product consisting of 50 ml or less per mail piece must be packaged in a securely sealed primary receptacle. Two or more primary receptacles whose combined volume does not exceed 50 ml may be enclosed within a single mail piece. Sufficient absorbent material and cushioning material to withstand shock and pressure changes must surround the primary receptacle(s), or be otherwise configured to take up the entire liquid contents in case of leakage. The primary receptacle(s) and the absorbent cushioning must be enclosed in a secondary container with a leakproof barrier that can prevent failure of the secondary container if the primary receptacle(s) should leak during transport. The secondary container must be securely sealed, and it may serve as the outer shipping container if it has sufficient strength to withstand ordinary postal processing. The secondary container must be marked with the international BIOHAZARD symbol shown in Exhibit 10.17.5d3, except when the secondary container also serves as the outer shipping container. In that case, the BIOHAZARD symbol must appear on the inner packaging or on the primary container. A shipping paper and a content marking on the outer shipping container are not required.
  2. Exceeding 50 ml. A liquid patient specimen, forensic material, or biological product that exceeds 50 ml must be packaged in a securely sealed primary receptacle. A single primary receptacle must not contain more than 500 ml of specimen. Two or more primary receptacles whose combined volume does not exceed 500 ml may be enclosed in a single secondary container. Sufficient absorbent material and cushioning material to withstand shock and pressure changes must surround the primary receptacle(s), or be otherwise configured to take up the entire liquid contents in case of leakage. The primary receptacle(s) and the absorbent cushioning must be enclosed in a secondary container with a leakproof barrier that can prevent failure of the secondary container if the primary receptacle(s) should leak during transport. The secondary container cannot serve as the outer shipping container. The secondary container must be marked with the international BIOHAZARD symbol shown in Exhibit 10.17.5d3. The secondary container must be securely and snugly enclosed in a fiberboard box or container of equivalent strength that serves as the outer shipping container. A shipping paper and a content marking on the outer shipping container are not required.
- b. **Solid (or Dry) Specimen.** A solid or dry specimen, such as a saliva swab, blood spot, fecal smear, culture or stock, or forensic material, must be completely dried before packaging in a mailing container or envelope. Cushioning material to withstand shock and pressure changes is required only if the dry specimen is placed in a breakable primary receptacle. When required, the cushioning material must surround the primary receptacle. The primary receptacle (and cushioning material, if required) must be enclosed in a secondary container with a siftproof barrier that can prevent failure of the secondary container if the primary receptacle breaks during shipment. The secondary container must be securely sealed, and it may serve as the outer shipping container if it has sufficient strength to withstand ordinary postal processing. The secondary container must be marked with the international BIOHAZARD symbol shown in Exhibit 10.17.5d3, except when the secondary container also serves as the outer shipping container. In that case, the BIOHAZARD symbol must appear either on the inner packaging or on the primary receptacle. A shipping paper and a content marking on the outer shipping container are not required.

#### 10.17.9 Packaging Exempt Human or Animal Specimens

Exempt human or animal specimens as defined in 10.17.2d are not subject to regulation as hazardous materials but when presented for mailing must be triple-packaged in leakproof (for liquids) or siftproof (for solids) primary receptacles. Sufficient cushioning and absorbent materials must surround each primary receptacle containing liquid. Secondary containers for liquids must be leakproof. Secondary containers for solids must be siftproof. The primary and secondary packaging must be enclosed in a rigid outer shipping container. A single primary receptacle must not contain more than 500 ml of a liquid specimen or 500 grams of a solid specimen. Two or more primary receptacles whose combined volume does not exceed 500 ml (for liquids) or 500 grams (for solids) may be enclosed in a single secondary container. The secondary container cannot serve as the outer shipping container. The secondary container must be marked with the international BIOHAZARD symbol shown in Exhibit 10.17.5d3. The secondary container must be securely and snugly enclosed in a fiberboard box or container of equivalent strength that serves as the outer shipping

## APPENDIX F

container. A shipping paper is not required. The outer shipping container must be marked on the address side with the words “Exempt human specimen” or “Exempt animal specimen,” as appropriate. In addition, at least one surface of the outer packaging must have a minimum dimension of 3.9 inches x 3.9 inches (100 mm x 100 mm). Exempt human and animal specimens are mailable as First-Class Mail, Priority Mail, Express Mail, or Package Services mail.



**APPENDIX G**  
**Special Waste Treatment  
and Disposal**



## Order Form for EPA Brochures

Please send me \_\_\_\_\_ copies of the healthcare professional brochure *Disposal Tips for Home Healthcare: Educating Your Patients*  
(EPA/530-SW-90-014A)

Please send me \_\_\_\_\_ copies of the patient flyer *Disposal Tips for Home Healthcare*  
(EPA/530-SW-90-014B)

Name \_\_\_\_\_

Address \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip \_\_\_\_\_

Return Address

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

RCRA Docket (OS-305)  
U.S. Environmental Protection Agency  
401 M Street, S.W.  
Washington, DC 20460



**Table 24: Treatment, Decontamination, and Disposal of Special Waste from Healthcare Related Facilities**

After treatment all medical waste shall be disposed of in a sanitary landfill unless incinerated or discharged to the sanitary sewer.

Type of Special Waste	Grinding and/or Flushing into a Sanitary Sewer	Steam Sterilization	Steam Sterilization/ Grinding & Discharge to Sanitary Sewer	Incineration	Thermal Inactivation	Thermal Inactivation/ Grinding & Discharge to a Sanitary Sewer	Chemical Disinfection	Chemical Disinfection/ Grinding & Discharge to a Sanitary Sewer	Moist Heat Disinfection/ Microwaving & Radio Wave	Chlorine Disinfection/ Maceration	Approved Alternate Treatment Process
1. Animal waste											
a. Carcasses		X3	X	X3					X3	X3	X3
b. Body Parts		X3	X	X3					X3	X3	X3
c. Bulk whole blood, serum, plasma, or other blood components		X3	X	X3	X3	X	X3	X	X3	X3	X3
d. Animal bedding		X3		X3					X3	X3	X3
2. Bulk human bloods & body fluids	X	X3		X3	X3	X	X3	X	X3	X3	X3
3. Microbiological waste		X3		X3	X3	X3	X3		X3	X3	X3
4. Pathological waste											
a. Human											
i. Body Parts <sup>1</sup>		X2		X3					X3,6		
ii. Tissues, fetuses, organs <sup>1</sup>	X	X2		X3					X3	X3,6	X3,6
iii. Bulk blood and body fluids	X	X3		X3	X3	X	X3	X	X3	X3	X3,6
a. Products of human abortion <sup>1</sup>		X3								X3	X3,6
i. Body Parts <sup>1</sup>	X	X3		X3					X3		
ii. Bulk blood and body fluids	X	X3		X3	X	X3	X3	X	X3	X3	X3,6
c. Lab specimens of blood or tissue	X	X3	X	X3					X3	X3	X3,6
d. Anatomical remains <sup>1</sup>		X3		X2				X	X	x	X3,6
5. Sharps											
a. Needles, blades, and razors <sup>5</sup>		X4		X4			X4		X4	X4	X3,6
b. Pipettes and broken glass <sup>5</sup>		X4		X4			X4		X3	X3	

<sup>1</sup>Interment


<sup>2</sup>Work must be interred after Rx

<sup>3</sup>Followed by deposition in a sanitary landfill

<sup>4</sup>In puncture-resistant container then to sanitary landfill

<sup>5</sup>Encapsulation in a matrix is an acceptable means of treatment <sup>6</sup>Provided item is rendered unrecognizable

Figure 5: Home disposal for sharps



United States Environmental Protection Agency  
Solid Waste and Emergency Response (5305)

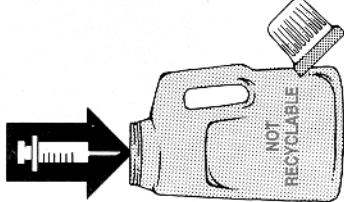
EPA530-F-93-027B  
November 1993

## Disposal Tips for Home Health Care

**You** can help prevent injury, illness, and pollution by following some simple steps when you dispose of the sharp objects and contaminated materials you use in administering health care in your home. You should place:

- **Needles,**
- **Syringes,**
- **Lancets, and**
- **Other sharp objects**

*in a hard-plastic or metal container with a screw-on or tightly secured lid.*

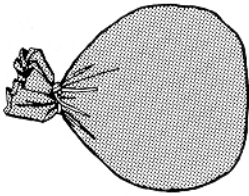


Many containers found in the household will do, or you may purchase containers specifically designed for the disposal of medical waste sharps. Before discarding a container, be sure to reinforce the lid with heavy-duty tape. **Do not put sharp objects in any container you plan to recycle or return to a store, and do not use glass or clear plastic containers** (see additional information below). Finally, make sure that you keep all containers with sharp objects out of the reach of children and pets.

We also recommend that:

- **Soiled bandages,**
- **Disposable sheets, and**
- **Medical gloves**

*be placed in securely fastened plastic bags before you put them in the garbage can with your other trash.*



<http://www.safeneededdisposal.org>  
<http://www.epa.gov/epaoswer/other/medical>  
<http://www.earth911.org>


## Preventing Injury and Pollution

**Containers with sharps are not recyclable**


EPA promotes all recycling activities, and therefore encourages you to discard medical waste, sharps in sturdy, nonrecyclable containers, when possible. If a recyclable container is used to dispose of medical waste sharps, make sure that you don't mix the container with other materials to be recycled. Since the sharps impair a container's recyclability, a container holding your medical waste sharps properly belongs with the regular household trash. You may even want to label the container, "**NOT FOR RECYCLING.**" These steps go a long way toward protecting workers and others from possible injury. (Although disposing of recyclable containers removes them from the recycling stream, the expected impact is minimal.)

**Local Programs**

Your state or community environmental programs may have other requirements or suggestions for disposing of your medical waste. You should contact them for any information you may need.



For additional copies of these disposal tips, please call the RCRA Hotline Monday through Friday, 8:30 a.m. to 7:30 p.m. EST. The national toll-free number is (800) 424-9346; for the hearing impaired, it is TDD (800) 553-7672.

  
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\*U.S. GOVERNMENT PRINTING OFFICE: 1993-0-718-943

# Appendix H

# **Bibliography**





# Bibliography

Bennett JV, Brachman PS. *Hospital Infections*. Little, Brown and Co, Boston/Toronto, 1986.

CDC's Division of Healthcare Quality Promotion. CDC workbook for designing, implementing and evaluating as sharps injury prevention program. Retrieved February 12, 2004. <http://www.cdc.gov/sharpssafety/>

Centers for Disease Control and Prevention. Notice to Readers. *MMWR*; 46 (26): 603–6. Centers for Disease Control and Prevention. Guidelines for preventing the transmission of tuberculosis in healthcare settings, with special focus on HIV-related issues. *MMWR* 1990; 39 (RR-17).

Centers for Disease Control and Prevention. Public health service guidelines for the management of healthcare worker exposures to HIV and recommendations for postexposure prophylaxis. *MMWR* 47 (RR-7):7–33; May 15, 1998

Centers for Disease Control and Prevention. Updated U.S. public health service guidelines for the management of occupational exposures to HBV, HCV, and HIV and recommendations for postexposure prophylaxis. *MMWR* 50 (RR-11); 1–42 (2001, June 29) Updates and consolidates recommendations for the management of healthcare personnel (HCD). <http://www.osha.gov/SLTC/bloodborne pathogens/postexposure.html>

Centers for Disease Control and Prevention. Updated U.S. public health service guidelines for the management of occupational exposures to HIV and Recommendations for postexposure prophylaxis *MMWR* 54(RR09); 1-17 (2005, September 30) Updates US Public Health Service Recommendations for the management of occupational exposures to blood and other fluids that might contain human immunodeficiency virus (HIV). <http://www.osha.gov/SLTC/bloodborne pathogens/postexposure.html>

Centers for Disease Control and Prevention of viral hepatitis. *MMWR* 1990; 39 (RR-2).

Centers for Disease Control and Prevention. Hepatitis B Virus: A comprehensive strategy for eliminating transmission in the United States through universal childhood vaccination. *MMWR* 1991; 40 (RR-13).

Centers for Disease Control and Prevention. Recommendations for prevention of HIV transmission in healthcare settings. *MMWR* 1987; 36 (S2:1S–18S).

Centers for Disease Control and Prevention. Update: universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other blood-borne pathogens in healthcare settings. *MMWR* 1988;37:377–382, 387–388.

- Garner, Julia S. Hospital Infection Control Practices Advisory Committee Department of Health and Human Services Center for Disease Control and Prevention, Guideline for isolation precautions in hospitals. *Infection Control Hosp Epidemiology* 1996; 24:24–52.  
[http://www.cdc.gov/ncidod/dhqp/gl\\_isolation\\_tableII.html](http://www.cdc.gov/ncidod/dhqp/gl_isolation_tableII.html)
- Centers for Disease Control and Prevention. Vaccine management. recommendations for handling and storage of selected biologicals. March 1991.
- Department of Labor/Department of Health and Human Services. Joint advisory notice. protection against occupational exposure to hepatitis B virus (HBV) and human immunodeficiency virus (HIV). October 1987.
- Emergency Care Research Institute. Needlestick prevention devices. *Health devices* 1991; 20 (5):154–80.
- Environmental Protection Agency. Registered sterilants, list A. registered hospital disinfectants which are also mycobactericidal and virucidal, list B. October 1996.
- Favero MS, Bond WW. Sterilization, Disinfection and antisepsis in the hospital. In: *Manual of clinical microbiology*, 6th Edition. Washington, DC: American Society for Microbiology, 1991: 183–200.
- Garner JS, Favero MS. Guideline for handwashing and hospital environmental control. HHS publication no. 99–1117. Atlanta: Centers for Disease Control and Prevention, 1985.
- Guidelines for preventing the transmission of mycobacterium tuberculosis in healthcare settings, 2005 *MMWR Recommendations and Reports* December 30, 2005/ Vol. 54/ No. RR-17.
- Mayhall CG, ed. *Hospital epidemiology and infection control*. Baltimore, MD: Williams & Wilkins: 1996.
- Occupational Safety and Health Administration, Department of Labor. 29 CFR 1910.1030, Occupational exposures to bloodborne pathogens; final rule. *Federal Register* 1991; 56:64004–182.
- Occupational Safety and Health Administration, Department of Labor, 29 CFR Part 1910 Occupational exposure to bloodborne pathogens; needlesticks and other sharps injuries; final rule. *Federal Register*/ Vol. 66, No. 12/ January 18, 2001/ Rules and Regulations
- Occupational Safety and Health Administration, Department of Labor. Enforcement procedures for occupational exposure to hepatitis B virus (HBV) and human immunodeficiency virus (HIV). *OSHA Instruction CPL 2-2.44C*, March 1992.
- Occupational Safety and Health Administration, Department of Labor. Part 1910. Occupational safety and health standards, subpart C, general safety and health provisions. 1910.20, *Access to Employee Exposure and Medical Records*.
- Public Health Service. Principles of UV Air Disinfection. Publication No. 00-2215 (H-5.)
- Rutala WA. Disinfection, sterilization and waste disposal, in: prevention and control of nosocomial infections, Wenzel RP, ed. Baltimore, MD: Williams & Wilkins, 1987: 257–82.

- Rutala WA, Weber DJ. Healthcare Infection Control Advisory Practices Advisory Committee (HICPAC), CDC, US Department of Health and Human Services. Guideline for disinfection and sterilization in healthcare facilities, 2008. [http://www.cdc.gov/ncidod/dhpq/pdf/guidelines/Disinfection\\_Nov\\_2008.pdf](http://www.cdc.gov/ncidod/dhpq/pdf/guidelines/Disinfection_Nov_2008.pdf)
- Schuster, Lynne et al. Guidelines for environmental infection control healthcare facilities. recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). *MMWR Recommendations and Reports* June 6, 2003/ 52(RR10); 1–42. <http://www.cdc.gov/MMWR/preview/MMWRhtml/rr5210a1.htm>
- Siegal, Jane, et al. 2007 Guidelines for isolation precautions: preventing transmission of infections agents in healthcare settings, HICPAC, CDC, and United States Department of Health and Human Services
- Texas Department of Health. Bureau of Laboratories. Revised guidelines for submission of laboratory specimens, 23 October 1991.
- Texas Department of State Health Services Bureau of Laboratories. Revised guidelines for submission of laboratory specimens, 31 March 2006.
- Texas Department of Health. Rules & regulations for the control of communicable and sexually transmitted disease & reporting of occupational disease, 25 TAC 97. Revised February, 1994.
- Texas Department of State Health Services TAC Chapter 96 Bloodborne pathogen rules revised effective July 2006: Blood/body fluid exposure management and clinicians's post exposure prophylaxis hotline; Reporting of sharps injuries, Bloodborne pathogen exposure control plan. [http://www.dshs.state.tx.us/idcu/health/bloodborne\\_pathogens/reporting](http://www.dshs.state.tx.us/idcu/health/bloodborne_pathogens/reporting)
- Texas Department of State Health Services Infectious Disease Control Unit: <http://www.dshs.state.tx.us/idcu/default.asp>
- Texas Department of State Health Services TAC Title 25 Part 1 Chapter 1 Subchapter K Definition, treatment, and disposition of special waste from healthcare-related facilities, amended effective December 1994.
- Texas Commission on Environmental Quality TAC Title 30, Part 1, Chapter 330, Subchapter Y Medical waste management effective March 27, 2006
- U.S. Food and Drug Administration Center for Device and Radiological Health, Device Evaluation Information, FDA-Cleared sterilants and high level disinfectants with general claims for processing reusable medical and dental devices September 28, 2006 <http://www.fda.gov/cdrh/ode/germlab.html>
- U.S. Department of Labor Occupational Safety & Health Administration Housekeeping/Utility Module <http://www.osha.gov/SLTC/etools/hospital/housekeeping/housekeeping.html>





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