Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition

Based on U.S. regulations, this document provides guidance on the risk of transmission of infectious agents by aerosols, droplets, blood, and body substances in a laboratory setting; specific precautions for preventing the laboratory transmission of microbial infection from laboratory instruments and materials; and recommendations for the management of exposure to infectious agents.

A guideline for national application developed through the Clinical and Laboratory Standards Institute consensus process.
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- the authorization of a project
- the development and open review of documents
- the revision of documents in response to comments by users
- the acceptance of a document as a consensus standard or guideline.

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Abstract

Clinical and Laboratory Standards Institute document M29-A3, Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition is intended to be a practical tool for laboratory and healthcare workers. It promotes the essence of good laboratory practice to protect workers from infectious diseases encountered in the workplace. A few of the many laboratory practices that reduce the risk of infection include: standard precautions, safety devices, personal protective equipment, and appropriate decontamination and disposal of biological hazards. New information is included on packaging and shipping infectious substances, prions, agents of Creutzfeldt-Jakob disease, airborne transmission of emerging pathogens, and organisms resistant to multiple antimicrobial agents.

This guideline contains detailed recommendations for the protection of workers from disease agents transmitted by aerosols, droplets, blood, and body substances; it focuses on hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV), because they pose a risk that is both common and grave. Other blood-borne viruses of concern to laboratory workers include hepatitis D virus (HDV); hepatitis E (HEV); hepatitis G (HGV); other possible parenterally transmitted non-A, non-B hepatitis viruses (NANB); human T cell lymphotropic virus I and II (HTLV-I/II); and other HTLVs. Other viruses, which may be found in blood, include hepatitis A virus (HAV); equine encephalomyelitis viruses; herpes viruses; poliovirus; rabies virus; lymphocytic choriomeningitis virus; influenza virus; poxviruses; vesicular stomatitis virus; and B-virus. It is felt that precautions recommended for HBV are sufficient for these viruses. In addition, safety recommendations are provided for two emerging viruses, SARS-CoV and West Nile virus.

Bacteria that are transmitted by airborne droplets or aerosols pose a real risk to laboratory and other healthcare workers and include Mycobacterium tuberculosis, Bacillus anthracis, Brucella spp., Francisella tularensis, Neisseria meningitidis, Burkholderia mallei, and Burkholderia pseudomallei. Other bacterial, fungal, and parasitic agents are not specifically discussed, but the protective measures described are useful to prevent their transmission.

The information in this guideline should alleviate much of the confusion and uneasiness currently felt by the laboratory community about the infectious risk of laboratory practices and the protective measures appropriate to that risk.

While this document will serve as a useful resource for a wider audience, it is based on U.S. regulations and is intended for use primarily in the United States.

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Foreword

Globalization is impacting the rapid transmission of infectious agents worldwide through the free movement of goods and people across national borders. The worldwide transmission of infectious agents increases the risk for workers in the medical community for occupationally acquired infections from their exposure to blood, tissue, and other potentially infectious material from infected patients. The recognition of new infectious agents; the worldwide emergence of antimicrobial resistance; the introduction of new diagnostic and treatment methods; and the potential for acts of bioterrorism have focused attention on the risk of infection to healthcare workers. The risk to these workers increases with expanded exposure to these potentially infectious materials and is present in the three phases of laboratory workflow. In the preanalytic phase, there is increased risk of percutaneous injury during collection of blood specimens, exposure to patients in isolation precautions, and contact exposure during transport of specimens. In the analytic phase, specimen and culture manipulations expose the laboratory worker to numerous risks. Waste management is the primary risk associated with the postanalytic phase. Laboratory workers, who are routinely exposed to potentially infectious material, have long been recognized as a high-risk group for occupationally related infections. Experience has shown that implementing practices that decrease the exposure of the worker to potentially infectious material can minimize the risk of infection. These practices include the use of standard precautions, personal protective equipment, and safety devices, as well as appropriate handling and disposal of biohazardous waste.

The working group has updated the document from the previous edition. The scope of the guideline was expanded again to include not only blood-borne pathogens but also other agents associated with laboratory-acquired infections, antimicrobial resistance, acts of bioterrorism, and emerging infections such as SARS-CoV and West Nile virus. Also, laboratories wishing to retain wild poliovirus materials must provide documentation of BSL3/poliovirus containment facilities and be listed on the U.S. National Inventory maintained by CDC within one year after the detection of the last wild poliovirus. These updates were necessitated by the potential for exposure to many different agents due to increased worldwide travel and trade. Other updates reflect the advances made in the diagnosis, treatment, and prevention of infections; adaptation of new technologies and instrumentation related to health care; and the promulgation of new regulations and recommendations. Appendixes are provided for in-depth information on criteria for BSL2 practices and procedures, biological safety cabinets, prions, and the regulation of antimicrobial chemicals. This guideline is published to inform the reader, but equally important are the comments that the reader makes concerning the recommendations contained herein, especially in light of all the changes to the document. We urge readers to submit comments to the CLSI Executive Offices. We would deeply appreciate receiving specific comments on the contents, as well as any additional information that was not available to the working group. Each comment will be evaluated and addressed in the next edition of the guideline.

CLSI believes that a single source of authoritative, current, complete, and practical recommendations which addresses all areas of the healthcare facility laboratory (clinical, anatomical pathology, point-of-care testing, and medical clinics and offices) offers a useful guide to the current best practices for the protection of laboratory workers. This guideline is intended to be a bench document for those workers who are potentially exposed to infectious materials. Source material is included as appendixes so that the reader can easily access the reference material. The references are not comprehensive but include U.S. and other international standards on laboratory safety1-4 and the most important documents that were used by the working group. Although this document draws heavily from the recommended and mandated guidelines and regulations applicable in the United States, the material contained in this document is useful for improving laboratory safety throughout the world. Changes in regulations and recommendations occur rapidly, and the reader is advised to consult authoritative publications and websites for the most current information.

The recommendations in this guideline are based on current knowledge and will be updated as necessary. This guideline is provided to assist in establishing local institutional policy, but each institution must follow the laws and regulations applicable to its location. Throughout this guideline certain terms are used
Foreword (Continued)

which should be interpreted unambiguously. A guideline is a set of instructions that are offered for the consideration of the user. A recommendation is a suggestion, the adoption of which is left to the user’s option. The word “should” implies a strong recommendation, but leaves the final adoption of the instruction to the user. In rare instances, the word “must” is used to indicate the lack of choice on the part of the user. In the United States, OSHA documents use the words “shall” and “must” to remove any freedom of choice on the part of the user.

Consideration has been given to the issues of cost versus benefits of the recommendations contained herein in relation to the prevalence of an infectious disease in the population served by a given institution.

The working group believes that, whereas the full set of precautions recommended in this guideline is appropriate based only on the known risk posed by HBV, it is an item of local option to reduce or modify these recommendations in situations where the prevalence of HIV, HBV, HCV, and other infectious agents is known to be very low in the patient population. However, the user in the United States must realize that any modification of the OSHA regulations will be a violation.

CLSI consensus documents are developed through an open process that ensures wide review and broad application. This unique approach leads to standards and guidelines for medical testing and healthcare services that address identified needs of both its global and national constituents. Most CLSI consensus documents are intended for global application. Under certain circumstances, however, a CLSI standard or guideline may be intended for primary use in a specific country or region.

CLSI document M29-A3—Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition is one such consensus document. While M29-A3 is a useful resource for a wider audience, it is intended primarily to help the U.S. user navigate through stringent U.S. regulations. Since occupational exposure practices are heavily regulated and widely “country-specific,” the Area Committee on Microbiology determined that it would not be feasible to develop a comparable guideline intended for global application at this time. We hope that development of such a guideline may be possible in the future, as part of a long-term effort to harmonize regulations and practices.

The imprint of the flag and the unique tagline on the cover call attention to its national focus, and differentiate M29-A3 from our global consensus documents.

Acknowledgment

The Area Committee on Microbiology and the Working Group on Protection of Laboratory Workers wish to acknowledge the following individuals for their valuable contributions in preparing the approved-level, third edition of this guideline: Kay M. Creed, BS MT(ASCP), Bon Secours Richmond, Richmond, VA.; Diane O. Fleming, PhD, RBP, CBSP (ABSA) Biosafety Consultant, Bowie, MD.; William E. Homovec, MPH, Labcorp, Burlington, NC; and Maxie Prinsloo, Canterbury Health Laboratories, Christchurch, New Zealand.

Key Words

Aerosols, airborne transmission, biological safety cabinet, blood-borne pathogens, exposure control, infectious disease, instrument biohazards, laboratory workers, medical waste, personal protective equipment (barrier protection), standard precautions, universal precautions
Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition

1 Scope

This guideline is intended to be a practical tool for the healthcare facility laboratory worker, and to promote the essence of good laboratory practice for the protection of laboratory workers from major infectious pathogens. M29-A3 has expanded its scope to include not only those agents that pose a risk that is both common and grave, such as HBV, HCV, and HIV, but also other agents that may be associated with laboratory-acquired infections involving aerosols, droplets, or other potentially infectious materials.

This guideline deals not only with issues concerning clinical laboratories; it also includes detailed discussion of common functions and practices that may affect many other healthcare workplaces or research and animal facilities. Although this document does not specifically address these areas, information may be extracted from this guideline for use in other areas that handle potentially infectious material.

2 Introduction

Clinical laboratory workers are a high-risk group for job-related exposure to blood-borne pathogens including HBV, HCV, and HIV, as are pathologists and other workers who handle tissue and body substances from infected patients. Exposures occur through needlesticks, cuts from sharp instruments, or contact of the eye, nose, mouth, and skin with infected patients’ blood, body substances, or other potentially infectious materials. And though most exposures do not result in infection, the risk of healthcare workers acquiring HBV, HCV, or HIV following needlesticks or cuts via percutaneous exposure (the most frequently cited mode of transmission) is estimated to be 6 to 30%, 1.8%, and 0.3%, respectively. Transmission of at least 20 different pathogens by needlestick and sharps injuries has been reported. During the past decade, an estimated 100 to 200 U.S. healthcare personnel have died each year from occupationally acquired HBV infection. From 1978 through December 2002, 57 healthcare workers have acquired HIV through occupational exposure, with 139 additional cases of undocumented, but possible, occupationally acquired HIV infection among healthcare workers in the United States (see Table 1). With the publication of the approved revision of CLSI guideline M29-A3, CLSI has consolidated the available information on the subject for the United States. Worldwide data are not currently available.
### Table 1. Epidemiologic Statistics for Healthcare Workers and General U.S. Population

(Adapted from CDC, Guidelines for Infection Control in Health Care Personnel; 1998, and CDC, NCID Division of Viral and Rickettsial Diseases; 2000.)

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<th>HCV</th>
<th>HIV</th>
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<tr>
<td><strong>Healthcare Workers</strong> (8 - 9 million)</td>
<td>New cases per year*</td>
<td>800 - 1000†</td>
<td>500 – 1000‡</td>
<td>57 in 23 yrs (since 1978)**</td>
</tr>
<tr>
<td></td>
<td>Deaths per year*</td>
<td>100-200†</td>
<td>Unknown</td>
<td>Unknown</td>
</tr>
<tr>
<td></td>
<td>Total infected*</td>
<td>Unknown</td>
<td>80 000 – 180 000§</td>
<td>57 documented cases 139 possible cases</td>
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<tr>
<td><strong>U.S. Population in General</strong> (250 – 300 million)</td>
<td>New cases per year</td>
<td>78 000#</td>
<td>25 000‖</td>
<td>42 651††</td>
</tr>
<tr>
<td></td>
<td>Deaths per year</td>
<td>5000#</td>
<td>8000 – 10 000§</td>
<td>16 371‡‡</td>
</tr>
<tr>
<td></td>
<td>Total infected</td>
<td>1.25 million#</td>
<td>2.7 million#</td>
<td>830 274††</td>
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* Occupationally acquired.  
§ Seroprevalence studies conducted between 1992 and 1995 estimated the HCV incidence among all healthcare workers (8 to 9 million) was between 1% to 2% in the US. CDC guidelines for infection control in health care personnel, 1998. *Am J Infect Control*. 1998;26:304.  
# CDC. NCID Division of Viral and Rickettsial Diseases; Viral Hepatitis Surveillance (www.cdc.gov/ncidod/diseases/hepatitis)  

### 3 Definitions

**aerosol** – a system of respirable particles dispersed in a dust, gas, smoke, vapor, or fog that can be retained in the lungs (modified from ISO 15190)¹; **NOTE 1**: Aerosol particles generally are ≤5 µm in size; **NOTE 2**: See droplet nuclei.

**airborne precautions** – applies to patients known or suspected to have serious illnesses transmitted by airborne droplet nuclei.

**airborne transmission** – the spread of infection by inhalation of droplet nuclei or dust particles containing infectious agents.⁸

**antiseptic** – chemical germicide formulated to be used on skin or tissue (ISO 15190)¹; **NOTE 1**: Antiseptics should not be used as disinfectants; **NOTE 2**: The FDA has regulatory authority over antiseptic compounds.

**blood-borne pathogens** – pathogenic microorganisms that are present in human blood, blood products, or other potentially infectious material contaminated with blood, and can cause disease in humans.

**contact precautions** – applies to patients known or suspected to have serious illnesses easily transmitted by direct patient contact or by contact with items in the patient’s environment.

**contact transmission** – the spread of infectious agents through direct transfer of microorganisms from one person to another or indirect transfer of microorganisms from a contaminated object or person.⁸

**contaminant** – a microorganism, chemical, or other material that makes something impure by contact or mixture with it.

**contaminated** – presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.
contaminated sharps – any contaminated object that may inflict a puncture or laceration of the skin including, but not limited to, needles, scalpels, broken glass, lancets, and broken capillary tubes.

decontamination – procedure that eliminates or reduces microbial or toxic agents to a safe level with respect to the transmission of infection or other adverse effects (ISO 15190)\textsuperscript{1}; \textbf{NOTE}: Some disinfectants can be used for decontamination. These are intermediate or low-level disinfectants and in the U.S., are regulated by the EPA for use on inanimate surfaces. They should not be used on medical devices used on patients. Likewise, liquid chemical germicides formulated as sterilants or high-level disinfectants ordinarily are not to be used for purposes of decontamination because of the risk to personnel.

disinfectant – an agent capable of disinfecting inanimate surfaces (e.g., work surfaces or medical devices (modified from ISO 15190)\textsuperscript{1}; \textbf{NOTE 1}: Most disinfectants are not effective sterilizers; \textbf{NOTE 2}: See disinfection.

disinfection – a process to eliminate most pathogenic microorganisms without necessarily killing or removing all organisms (e.g., bacterial spores) (modified from ISO 15190)\textsuperscript{1,8}; \textbf{NOTE 1}: Chemical germicides that are formulated as disinfectants are used on inanimate surfaces (medical devices, etc.) and should not be used on skin or tissues; \textbf{NOTE 2}: See disinfectant.

droplets – particles of moisture produced by aerosolization that may carry an infectious agent; \textbf{NOTE 1}: Droplets larger than 150 µm generally fall to a surface; \textbf{NOTE 2}: Droplets smaller than 150 µm generally evaporate and may remain suspended in air.

droplet nuclei – the small residues that result from evaporation of fluid from droplets emitted by an infectious host, or created by an atomizing device, or accidentally in microbiology laboratories, autopsy rooms, etc; \textbf{NOTE}: Droplet nuclei are generally ≤5 µm in size and can remain suspended in air for extended periods of time.

droplet precautions – applies to patients with known or suspected to have serious illnesses transmitted by large particle droplets (>5 µm in size).

engineering controls – controls (e.g., biological safety cabinets, centrifuge safety cups, 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 hazard from exposure in the workplace.

equipment – the articles or implements used or needed for a specific purpose or activity.

ergicide – a general term that indicates an agent that kills pathogenic microorganisms on inanimate surfaces.

hazard – potential source of harm (IEC 61010-1.2001).\textsuperscript{9}

hazardous waste – any waste that is potentially flammable, combustible, ignitable, corrosive, toxic, reactive, or injurious to people or the environment (ISO 15190).\textsuperscript{1}

hospital disinfectant – a U.S. EPA-registered agent with demonstrated effectiveness against Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa and may also be effective against specifically named organisms such as Mycobacterium tuberculosis, pathogenic fungi, or certain viruses.

infectious waste – waste containing or assumed to contain pathogens of sufficient virulence and quantity, so that exposure (e.g., inhalation or percutaneous injury) to the waste by a susceptible host could result in a communicable disease.
**instrument** – a device that will give analytical answers as a result of electrical or mechanical measurements on an element, compound, solution, etc.

**laboratory worker** – employee who draws blood and/or performs diagnostic or other screening procedures on blood or other potentially infectious material; **NOTE**: This includes healthcare workers who perform point-of-care testing in areas outside of the laboratory.

**medical waste** – that portion of the infectious waste stream regulated by the authority having jurisdiction and may require some decontamination treatment.

**microbial aerosol** – suspensions of particles in air consisting partially or wholly of microorganisms that may remain suspended in air for extended periods of time; **NOTE 1**: Some particles (1 to 5 µm) are easily drawn into the alveoli of the lungs and may be retained there; **NOTE 2**: See *droplet nuclei*.

**microbicide** – a general term that indicates an agent that kills pathogenic microorganisms on inanimate surfaces; **NOTE**: The term is often used in place of germicide.3

**needleless system** – a device that does not use needles for (1) the collection of body 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 blood-borne pathogens due to percutaneous injuries from contaminated sharps.

**occupational exposure** – reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee’s duties.

**other potentially infectious materials (OPIMs)** – human body fluids including semen; vaginal secretions; urine; cerebrospinal fluid; synovial fluid; pleural fluid; pericardial fluid; peritoneal fluid; amniotic fluid; saliva; body fluids which may be contaminated with blood; unfixed tissue; HIV or hepatitis virus containing cell or organ cultures; blood and tissue from infected animals; reagents; infectious waste; and cultures (i.e., nonpatient specimens).

**parenteral** – piercing mucous membranes or the skin through such events as needlesticks, human bites, cuts, and abrasions.

**percutaneous** – parenteral inoculation of infectious material or transfusion of blood or blood products.

**personal protective equipment (PPE)** – material, including clothing, used to prevent contamination of a person by chemical or biological matter (ISO 15190).1

**primary container** – a vessel, including its closure, that contains the specimen.

**prions** – abnormally folded host membrane proteins associated with transmissible spongiform encephalopathies and demonstrate resistance to conventional disinfection and sterilization procedures.

**regulated waste** – liquid or semiliquid blood or OPIMs; contaminated items that would release blood or OPIMs in a liquid or semiliquid state if compressed; items that are caked with dried blood or OPIMs and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or OPIMs.

**risk** – a combination of the probability of occurrence of harm and the severity of that harm (ISO 15190).1

**safety device** – see *sharps with engineered sharps injury protections*. 
secondary container – a vessel, into which the primary container is placed for transport within an institution that will contain a specimen if the primary container breaks or leaks in transit.

sharps container – a container approved for the containment of contaminated sharps for transport.

sharps with engineered sharps injury protections – a non-needle 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.

standard precautions – set of precautions applied to all patients designed to reduce risk of transmission of microorganisms in the healthcare setting; NOTE: All blood, tissue, body fluids, secretions, and excretions (except sweat) are considered potentially infectious.

sterilization – validated process, used to render a product free from micro-organisms (ISO 15190); NOTE: Effectively killing all microbial life on inanimate surfaces, including bacterial spores.

sterilant – an agent intended to destroy all microorganisms (viruses, vegetative bacteria, fungi, and large numbers of highly resistant bacterial endospores) on inanimate surfaces.

universal precautions – set of precautions designed to reduce risk of transmission of HIV, hepatitis B virus, and other blood-borne pathogens in the healthcare setting; NOTE 1: All human blood, other body fluids containing visible blood, semen, vaginal secretions, tissue, and the following fluids (cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic) are considered potentially infectious for HIV, HBV, and other blood-borne pathogens; NOTE 2: Universal precautions do not apply to feces, nasal secretions, saliva (except in a dental setting), sputum, sweat, tears, urine, and vomitus unless they contain visible blood; NOTE 3: “Universal precautions” applies to specific body fluids that are more likely to harbor blood-borne pathogens; this term was used in OSHA documents in the early 1990s and is still used in some OSHA documents.

wipe test – a wipe paper (beta: foam; gamma: paper) used to wipe a potentially radioactive-contaminated surface; NOTE: The presence of a radioisotope on the wipe paper is measured by a beta or gamma counter.

4 Acronyms/Abbreviations

ACIP Advisory Committee on Immunization Practices
ALT alanine aminotransferase
APIC Association for Professionals in Infection Control and Epidemiology
ASHRAE American Society of Heating, Refrigeration, and Air Conditioning Engineers
BSC biological safety cabinet
CDC Centers for Disease Control and Prevention
CJD Creutzfeldt-Jakob disease
CMV cytomegalovirus
DOL U.S. Department of Labor
<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>EIA</td>
<td>enzyme immunoassay</td>
</tr>
<tr>
<td>EPA</td>
<td>U.S. Environmental Protection Agency</td>
</tr>
<tr>
<td>FDA</td>
<td>U.S. Food and Drug Administration</td>
</tr>
<tr>
<td>HAV</td>
<td>hepatitis A virus</td>
</tr>
<tr>
<td>HBIG</td>
<td>hepatitis B virus immune globulin</td>
</tr>
<tr>
<td>HBV</td>
<td>hepatitis B virus</td>
</tr>
<tr>
<td>HBsAg</td>
<td>hepatitis B surface antigen</td>
</tr>
<tr>
<td>HCV</td>
<td>hepatitis C virus</td>
</tr>
<tr>
<td>HCW</td>
<td>healthcare worker</td>
</tr>
<tr>
<td>HDCV</td>
<td>human diploid cell rabies vaccine</td>
</tr>
<tr>
<td>HDV</td>
<td>hepatitis D virus</td>
</tr>
<tr>
<td>HEPA filtration</td>
<td>high-efficiency particulate air filtration</td>
</tr>
<tr>
<td>HEV</td>
<td>hepatitis E virus</td>
</tr>
<tr>
<td>HGV</td>
<td>hepatitis G virus</td>
</tr>
<tr>
<td>HHS</td>
<td>U.S. Department of Health and Human Services</td>
</tr>
<tr>
<td>HICPAC</td>
<td>Healthcare Infection Control Practices Advisory Committee</td>
</tr>
<tr>
<td>HIV</td>
<td>human immunodeficiency virus</td>
</tr>
<tr>
<td>HTLV</td>
<td>human T cell lymphotrophic virus</td>
</tr>
<tr>
<td>IATA</td>
<td>International Air Transport Organization</td>
</tr>
<tr>
<td>ICAO</td>
<td>International Civil Aviation Organization</td>
</tr>
<tr>
<td>ID</td>
<td>intradermally</td>
</tr>
<tr>
<td>IDSA</td>
<td>Infectious Diseases Society of America</td>
</tr>
<tr>
<td>IM</td>
<td>intramuscularly</td>
</tr>
<tr>
<td>IPV</td>
<td>inactivated poliovirus vaccine</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organization for Standardization</td>
</tr>
<tr>
<td>JCAHO</td>
<td>Joint Commission on the Accreditation of Healthcare Organizations</td>
</tr>
</tbody>
</table>
NANB  non-A, non-B hepatitis virus
NIOSH  National Institute for Occupational Safety and Health
NSF  National Sanitation Foundation International
OPIM  other potentially infectious material
OPV  oral poliovirus vaccine
OSHA  Occupational Safety and Health Administration
PEP  postexposure prophylaxis
PPE  personal protective equipment
RVA  rabies vaccine absorbed
SARS  Severe acute respiratory syndrome
SARS Co-V  SARS coronavirus
SC  subcutaneously
SHEA  Society for Healthcare Epidemiology of America
SOP  standard operating procedure
TB  tuberculosis
TSE  Transmissible spongiform encephalopathy
WHO  World Health Organization

5   General Considerations

5.1   Epidemiology

The major factors that influence the risk of acquiring a blood-borne infection depends on the amount of blood involved in the exposure, the amount of virus in the patient’s blood at the time of exposure, and whether postexposure treatment was administered. The experience with accidental parenteral inoculation of medical personnel with HIV-infected blood has partially recapitulated the experience with HBV. Whereas many healthcare workers have been occupationally infected with HBV (≈12,000 cases/year prior to the licensure of hepatitis B vaccine in 1982 to ≈800 cases/year in 1996), only a small number have been infected with HIV (57 cases, as of December 2002). Notwithstanding, among U.S. healthcare workers with documented occupational HIV seroconversion, 88% (50/57) were associated with percutaneous exposure, e.g., needlestick (see Table 2). It is estimated that within the average hospital, workers incur approximately 30 needlestick injuries per 100 beds per year. Indeed, following workplace exposure to HIV-infected materials, healthcare workers have seroconverted and developed the acute retroviral syndrome in which 45% have developed AIDS (26/57).
Table 2. Healthcare Workers with Documented Occupationally Acquired AIDS/HIV Infection by Type of Occupational Exposure and Type of Fluid Involved, Reported from 1978 through December 2002, United States (CDC. Issues in Healthcare Settings. Surveillance of Healthcare Personnel with HIV/AIDS, as of December 2002 [See www.cdc.gov/ncidod/hip/BLOOD/hivpersonnel.htm]).

<table>
<thead>
<tr>
<th>Type of Occupational Exposure</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percutaneous (needlestick or cuts)</td>
<td>48</td>
</tr>
<tr>
<td>Mucocutaneous (eye, nose, mouth, or skin)</td>
<td>5</td>
</tr>
<tr>
<td>Both (above)</td>
<td>2</td>
</tr>
<tr>
<td>Undetermined</td>
<td>2</td>
</tr>
<tr>
<td>TOTAL</td>
<td>57</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Type of Fluid Involved in Exposure</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood</td>
<td>49</td>
</tr>
<tr>
<td>Concentrated virus in laboratory</td>
<td>3</td>
</tr>
<tr>
<td>Visibly bloody fluid</td>
<td>1</td>
</tr>
<tr>
<td>Unspecified fluid</td>
<td>4</td>
</tr>
<tr>
<td>TOTAL</td>
<td>57</td>
</tr>
</tbody>
</table>

Currently, the number of healthcare workers infected with HCV through occupational exposure is unknown. But, studies have shown that 1% of hospital healthcare workers have evidence of HCV infection suggesting that 500 to 1000 cases occur each year, with 1.8% of the U.S. population having evidence of infection.\(^{5}\) Hepatitis C virus infection is the most common chronic blood-borne infection in the United States. During the 1980s, CDC estimates that 240 000 new infections occurred each year. After 1989, however, infections began to steadily decline and by 2001 a reduction in the infection rate of \(>89\%\) was observed, with approximately 25 000 cases/year. To date, at least 3.9 million Americans are thought to be infected with HCV, of whom 2.7 million are chronically infected.\(^{12,13}\)

5.2 Laboratory Transmission of Human Hepatitis Viruses and Retroviruses

HBV, HCV, HEV, HDV, HGV, HAV, HIV-1, HIV-2, and HTLV I/II can be transmitted in a variety of epidemiological settings including laboratories. Laboratory modes of transmission are listed below in the probable order of efficiency of agent transmission (see Sections 5.2.1 to 5.2.5).

HBV can be present in extraordinary concentrations in blood (\(10^8\) to \(10^9\) infectious particles per mL). In contrast, HIV-1 is usually found in concentrations of \(10^0\) to \(10^4\) infectious particles/mL. Consequently, the likelihood of being infected with HBV is 300 times greater than HIV. Precautions based on the HBV model are considered to be conservative with respect to HIV transmission. With the introduction of the Hepatitis B vaccine in 1982, followed in 1986 by the Department of Labor-Health and Human Services statement requiring employers to provide vaccination at no cost, the incidence of HBV infections among healthcare workers decreased more than 95% (386 per 100 000 to 9.1 per 100 000). During this same period (1983 to 1995) the incidence within the general population also showed a decline from 122 per 100 000 to 50 per 100 000.\(^{14}\) Overall, the incidence among healthcare workers changed significantly, i.e., threefold higher than the general population in 1983 to fivefold lower in 1995.

HBsAg has been found in blood, bile, breast milk, cerebrospinal fluid, feces, nasopharyngeal washings, saliva, semen, sweat, synovial fluid, urine, peritoneal fluid, tissue, and blood products that have not been rendered virus-free. All of these sources, if they contain blood or blood components, may be potential vehicles in the laboratory transmission of HBV. The average volume of blood inoculated during a needlestick injury with a 22-gauge needle is approximately 1 \(\mu\)L,\(^{15}\) a quantity sufficient to contain up to 100 infectious doses of HBV.\(^{16}\) The risk of transmission after a needlestick exposure to a nonimmune person can be as high as 30% if the source patient is HBeAg positive, but is less than 6% if the patient is...
HBeAg negative (see Table 3). The primary modes of HBV transmission in the healthcare setting are a) direct inoculation of blood/body substances via a needlestick or sharp injury; b) direct inoculation of blood/body substances onto mucous membranes, abrasions, and scratches; and c) indirect inoculation from environmental surfaces contaminated with blood/body substances onto mucous membranes, abrasions, and scratches.

HCV has been found in blood and is believed to have the same distribution and to share routes of infection with HBV. HCV has been reported in concentrations in human blood of $10^2$ to $10^3$ particles/mL. The prevalence of HCV infection among healthcare workers, including orthopedic, general, and oral surgeons, is no greater than the general population, averaging 1% to 2%, and is ten times lower than that for HBV infection. Transmission of HCV occurs primarily through large or repeated direct percutaneous exposures to blood, including injection-drug use which currently accounts for 60% of HCV transmission in the United States, followed by sexual exposure, health-related work, and transfusion. At least 75% to 85% of individuals that seroconvert from HCV exposure become chronically infected; 70% of whom develop active liver disease. Of the patients with active liver disease, 10% to 20% develop cirrhosis, and 1% to 5% develop cancer. The HBV model for developing safety strategies is thought to be adequate with regard to HCV.

Table 3. Percent (%) Risk of Infection Following Occupational Exposure to Infected Blood Among Healthcare Workers

<table>
<thead>
<tr>
<th>Type of Exposure</th>
<th>HBV</th>
<th>HCV</th>
<th>HIV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percutaneous</td>
<td>18% (6% - 30%)</td>
<td>1.8% (0% - 7%)</td>
<td>0.3% (0.2% - 0.5%)</td>
</tr>
<tr>
<td>Mucous membrane (Eye, nose, mouth)</td>
<td>Unknown</td>
<td>— *</td>
<td>0.09% (0.006% - 0.5%)</td>
</tr>
<tr>
<td>Nonintact skin</td>
<td>Unknown</td>
<td>— *</td>
<td>&lt;0.09%</td>
</tr>
<tr>
<td>Concentration in blood (Particles per mL)</td>
<td>$10^8$ to $10^9$</td>
<td>$10^2$ to $10^3$</td>
<td>$10^0$ to $10^4$</td>
</tr>
</tbody>
</table>

* Although no incidence studies have documented transmission associated with mucous membrane or nonintact skin exposures, transmission of HCV from blood splashes to the eye have been described.

Blood-borne transmission of HAV in laboratory personnel has been reported, but contact with blood is not the major route of transmission for HAV.

HIV has been isolated from blood, semen, vaginal secretions, saliva, tears, breast milk, cerebrospinal fluid, amniotic fluid, alveolar fluid, and urine. It is likely that HIV is present in other body fluids, secretions, and excretions. However, only blood, body fluid, or concentrated virus solutions have been implicated in the laboratory transmission of HIV to date.

HTLV I/II are found in circulating lymphocytes and require the introduction of infected lymphocytes to produce infection. Therefore, whereas blood is infective, cell-free fluids are not. HTLV I/II are usually transmitted in nature by breast milk, semen, vaginal secretions, or blood. No cases of laboratory transmission of HTLV I/II have been reported.

OSHA defines body fluids as “fluids which have been directly linked to the transmission of HIV and/or HBV and/or to which standard precautions apply: blood, semen, blood products, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, peritoneal fluid, pericardial fluid, amniotic fluid, and concentrated HIV or HBV viruses.”
5.2.1 Direct Contact

Information about HIV infection in healthcare workers through direct contact is shown below in Table 4.

The literature indicates that the risk of seroconversion after accidental skin puncture with a needle contaminated with HIV-infectious blood is on average approximately 0.3% (1 in 333). Various reports have placed the seroconversion rate after skin puncture at ≤0.5%, while mucous membrane exposure approaches 0.1%. The comparable risk of developing HBV infection after accidental needlestick in a susceptible person has been reported to be between 6% and 30%; estimates for the development of any one of the various clinical outcomes following HBV infection are shown in Table 5. The risk of developing HTLV I/II or HGV infection after needlestick is unknown. The risk of HCV infection after needlestick is estimated to be an average of 1.8% (0 to 7 % range), and may be as high as 10% if second generation and PCR test are used.

Table 4. Healthcare Workers with Documented and Possible Occupationally Acquired AIDS/HIV Infection by Occupation, Reported from 1978 through December 2002, United States


<table>
<thead>
<tr>
<th>Occupation</th>
<th>Documented Occupational Transmission†</th>
<th>Possible Occupational Transmission‡</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Number</td>
</tr>
<tr>
<td>Nurse</td>
<td>24</td>
<td>35</td>
</tr>
<tr>
<td>Laboratory worker, clinical</td>
<td>16</td>
<td>17</td>
</tr>
<tr>
<td>Physician, nonsurgical</td>
<td>6</td>
<td>12</td>
</tr>
<tr>
<td>Laboratory technician, nonclinical</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>Housekeeper/maintenance worker</td>
<td>2</td>
<td>13</td>
</tr>
<tr>
<td>Technician, surgical</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Embalmer/morgue technician</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Health aide/attendant</td>
<td>1</td>
<td>15</td>
</tr>
<tr>
<td>Respiratory therapist</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Technician, dialysis</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Dental worker, including dentist</td>
<td>-</td>
<td>6</td>
</tr>
<tr>
<td>Emergency medical technician/paramedic</td>
<td>-</td>
<td>12</td>
</tr>
<tr>
<td>Physician, surgical</td>
<td>-</td>
<td>6</td>
</tr>
<tr>
<td>Other technician/therapist</td>
<td>-</td>
<td>9</td>
</tr>
<tr>
<td>Other healthcare occupation</td>
<td>-</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>57</strong></td>
<td><strong>139</strong></td>
</tr>
</tbody>
</table>
Footnotes to Table 4

* Healthcare workers are defined as those persons, including students and trainees, who have worked in a healthcare, clinical, or HIV laboratory setting at any time since 1978. (See MMWR. 1992;41:823-825.)

† Healthcare workers who had documented HIV seroconversion after occupational exposure or had other laboratory evidence of occupational infection. Twenty-five of these health care workers developed AIDS.

‡ These healthcare workers have been investigated and are without identifiable behavioral or transfusion risks; each reported percutaneous or mucocutaneous occupational exposures to blood or body fluids, or laboratory solutions containing HIV, but HIV seroconversion specifically resulting from an occupational exposure was not documented.

HBV, HCV, and HIV (and presumably HTLV I/II) have been shown to be transmitted in the laboratory directly by the following routes.

5.2.1.1 Percutaneous

Parenteral inoculation of infectious blood, plasma, serum, body substances, or other potentially infectious material occurs by accidental needlesticks, scalpel cuts, etc., and by transfusion of infectious blood or blood products. The importance of preventing percutaneous exposure cannot be overemphasized. Among the 57 healthcare workers with documented occupationally acquired HIV infection, almost 90% resulted from either a needlestick or cut, or both (see Table 2). Twenty-six of them have subsequently developed AIDS. The infection rate after needlestick exposure with HBV-infected blood is between 6% and 30% (average = 18%); for HCV, 0% to 7% (average = 1.8%); and for HIV, 0.2% to 0.5% (average = 0.3%) (see Table 3).

5.2.1.2 Mucous Membranes

Contamination of mucosal surfaces with infectious blood, plasma, serum, body substances, or other potentially infectious materials may occur with mouth pipetting (a prohibited activity), splashing, or spattering of oral or nasal mucosa or conjunctiva. Approximately 12% (7/57) of healthcare workers with documented occupationally acquired HIV resulted from mucous membrane exposure.

5.2.1.3 Nonintact Skin

Transfer of HIV by exposure to infectious blood, plasma, serum, or body substances in the absence of overt puncture of the skin has not been quantified, but is estimated to be less than 0.1%. This estimate includes exposure through the contamination of pre-existing minute cuts, scratches, abrasions, burns, weeping or exudative skin lesions, etc.5

5.2.1.4 Intact Skin

There have been no documented cases of HIV transmission due to exposure through intact skin involving a small amount of blood (see Section 11). Nonetheless, the risk may be higher (for all exposures) if the contact involves a large area of skin, a large volume of blood, a higher concentration of HIV, or prolonged time of exposure.10

5.2.2 Indirect Contact

HBV has been recovered from common environmental surfaces such as telephones, test tubes, laboratory devices, and other surfaces contaminated with infectious blood, plasma, serum, or body fluids and may be potentially transferred to the skin or mucous membranes by hand contact. To date no environmentally mediated transmission of HIV, HBV, or HCV has been documented.
Nail biting, smoking, eating, contact lens manipulation, and other hand-to-nose, hand-to-mouth, and hand-to-eye actions may contribute to indirect transmission and should not be done in the laboratory. Contact lenses (especially soft lenses) should not be worn in areas where hazardous chemicals are manipulated, unless proper eye protection is used (e.g. goggles or a face shield). Please refer to the most current version of CLSI/NCCLS document GP17—Clinical Laboratory Safety for additional information.

Table 5. Estimates of the Percent (%) for HBV Infection Outcome of Annual HBV Infections Among Healthcare Workers Exposed to Blood or Other Potentially Infectious Material (Adapted from OSHA. OSHA Preambles Bloodborne Pathogens (29 CFR 1910.1030). Section V. Quantitative Risk Assessment.)

<table>
<thead>
<tr>
<th>HBV INFECTION OUTCOME</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>No or mild symptoms</td>
<td>65 - 75</td>
</tr>
<tr>
<td>Clinical illness</td>
<td>25 - 33</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>5 - 7</td>
</tr>
<tr>
<td>Chronic HBV carrier</td>
<td>5 - 10</td>
</tr>
<tr>
<td>Death (cirrhosis)</td>
<td>1.7</td>
</tr>
<tr>
<td>Death (liver cancer)</td>
<td>0.4</td>
</tr>
<tr>
<td>Death (fulminant hepatitis)</td>
<td>0.1</td>
</tr>
<tr>
<td>Death (all)</td>
<td>2.2</td>
</tr>
</tbody>
</table>

5.2.3 Fecal-Oral Transmission

The fecal-oral route does not appear to be an efficient mode of transmission of either HBV or HIV. However, stool containing blood may pose a hazard for the transmission of HAV and HEV and for other enterically transmitted NANB virus by parenteral or mucous membrane exposures. The lymphoid cells present in stool may contain HTLV I/II as well as HIV. Standard precautions used in the handling of blood (gloves and hand hygiene) are adequate to prevent transmission of hepatitis and retroviruses from blood-contaminated feces.

5.2.4 Airborne Transmission

Aerosols are particles—generally ≤5 µm in size—that float on air currents. They should not be confused with droplets and/or splashes, since considerable energy is required to generate aerosols, which is not likely to be present in clinical settings. Accordingly, there have been no known instances of blood-borne pathogen transmission by aerosols. However, splashing, spattering, centrifuge accidents, or removal of rubber stoppers from tubes can produce large- or small-droplet transfer into the mouth or eyes, or onto nonintact skin surface. This is not airborne transmission by aerosol, but rather transmission by direct droplet contact.

5.2.5 Survival of HIV in the Laboratory

HIV is fragile with rapid degradation in serum at room temperature. Although HBV is stable in dried blood and blood products at 25 °C for at least seven days, and perhaps much longer, HIV appears to be much less stable in the dried state. Results from HIV survival laboratory studies should not be used to assess specific personal risk of infection acquisition by environmental exposure because of various factors, including little correlation between viral concentrations used in laboratory studies versus those found in clinical specimens; the inability of HIV to survive in the environment; and the lack of any documented case resulting from contact with an environmental surface.

5.2.5.1 Effects of Drying

Laboratory studies indicate that drying HIV causes a rapid (within several hours) 1 to 2 log (90 to 99%) reduction in HIV-infective concentration. This conclusion is based on a study that showed that when
highly concentrated HIV samples \(10^7\) TCID\(_{50}/\text{mL}\) were dried at room temperature (23 to 27 °C) approximately 90% of the HIV population was inactivated every nine hours. In this study, HIV could be detected for one to three days after drying.

High concentrations of cell-free HIV stored in tissue culture fluid at room temperature could be detected for up to 15 days, and when stored at 37 °C for up to 11 days; whereas in tissue culture, cell-associated HIV could be detected for only up to one day. HIV is stable for a long period of time in the frozen or lyophilized state, and for extended periods at 4 °C. The survival of HIV in blood and tissue specimens is expected to parallel the survival data for cell cultures.

**NOTE:** The working group recommends that dried blood found in the laboratory be considered potentially infectious and treated with the same precautions as liquid blood.

### 5.2.5.2 Relation to Healthcare Facilities

The results of the study cited above, when considered in the light of the concentration of HIV usually found in the blood of infected individuals (i.e., \(10^0\) to \(10^4\) infectious virions/mL) and extrapolated to environmental conditions found in healthcare facilities, indicate that no change is required in any of the currently recommended housekeeping, disinfection, or sterilization strategies.

### 5.2.5.3 Relation to Laboratory Environment

In the laboratory, when medical devices are often contaminated with blood or body fluids, existing recommendations include the cleaning of the devices with a detergent solution followed by either disinfection or sterilization, depending on the device. Whether viruses or bacteria are inactivated after drying does not affect cleaning and decontamination strategies. Consequently, in order to deal with HBV and HIV no additional requirements need be added to the published procedures for the cleaning, decontamination, or sterilization of medical devices (see Section 12).

### 5.2.5.4 Cadavers

HIV has been cultured from cadavers stored at 6 °C for up to six days. Precautions appropriate for handling HBV-infected cadavers are appropriate for HIV-infected cadavers. Embalming fluids are similar to the types of chemical germicides (e.g., glutaraldehyde) that have been found to inactivate HIV. Cases of occupationally acquired HIV infection have been reported in a mortician and a pathologist.

### 5.3 Laboratory Transmission of Agents Other Than Hepatitis Viruses and Retroviruses

During the 1950s and 60s, several studies reported that the most frequent causes of accidental laboratory-acquired infections were a) spills, sprays, and spattering, 27%; b) needles and syringes, 25%; c) broken glass and other sharps, 16%; d) animal/ectoparasite bites, 13%; and e) pipetting, 13%. More recently, several procedures have been reported that generate respirable aerosols, such as sonication, homogenization, centrifugation, mixing, pipetting, removing bubbles from syringes, withdrawing needles from stoppered bottles containing organisms, heating inoculating loops, streaking agar plates, and opening lyophilized ampules as well as bone saws and other autopsy procedures. Moreover, since bacteria continue to be considered the most frequently encountered cause of laboratory-acquired infections in today’s clinical laboratory (followed by viral, rickettsial, fungal, and parasitic infections), it becomes essential that safe laboratory practices are employed when handling/manipulating such specimens and cultures to minimize the likelihood of aerosol exposure. This is especially the case when handling cultures of *N. meningitidis*. Such practices should include prohibition of mouth pipetting, utilization of incinerator-type devices to heat contaminated loops, and use of appropriate safety devices for instrumentation (i.e., centrifuges; see Section 12.2.1). When performing procedures with a potential for generating infectious aerosols or splashes (e.g., subculturing blood bottles, mixing, or vortexing), the
procedure should be performed in a biological safety cabinet (BSC) or behind a splashguard. Because the processing and inoculation of specimens for microbiological analysis involve procedures (e.g., removal of caps from transport devices, preparation of smears, inoculation, and streaking media) known to generate splashing and infectious aerosols, these activities should also be performed in a BSC or behind a splashguard.

Pure cultures of agents that are known to be particularly pathogenic to those with an intact immune system should always be transferred within a BSC, although many common bacterial and fungal pathogens may be safely manipulated on the open bench using BSL2 procedures and practices. In addition, laboratory workers with certain medical conditions (e.g., immunosuppression, pulmonary disease, achlorhydria, pregnancy) may have increased risk if exposed to agents not normally pathogenic to others, such as *Legionella pneumophila* and *Listeria monocytogenes*. Finally, examination of molds should be performed in a BSC not only to prevent contamination of the laboratory environment but because of the possibility of systemic fungi such as *Blastomyces dermatitidis*, *Coccidioides immitis*, and *Histoplasma capsulatum*. The following is a partial list of infectious agents that may cause laboratory-acquired infections and is not intended to be inclusive. The reader is advised to periodically consult authoritative publications, websites (http://www.cdc.gov), and regional/local health facilities for the most current information.

5.3.1 Airborne or Droplet Transmission

Agents that can be transmitted by the aerosol route are a risk for laboratory-acquired infections. Several agents transmitted by airborne droplets or aerosols that pose an increased risk to laboratory workers as well as the community include *Mycobacterium tuberculosis*, *Bordetella pertussis*, *Corynebacterium diphtheriae*, *Neisseria meningitidis*, *Bacillus anthracis*, *Yersinia pestis*, and emerging viral agents, such as SARS-CoV. *N. meningitidis* and other bacterial agents (e.g., *Brucella* spp., *Francisella tularensis*, *Burkholderia mallei*, and *Burkholderia pseudomallei*) that are transmitted via an airborne route will be discussed below because of the high mortality seen in laboratory-acquired infections or their potential for use in acts of biological terrorism. Consult *Public Health: Select Agents and Toxins* (CFR §73, 2003) for complete details regarding the Select Agent and Toxin Program or CDC (http://www.cdc.gov/od/sap). The CDC website contains a listing of select agents and a guidance document in the event that a select agent is isolated from a clinical specimen. The laboratory must complete and forward Form CD-1318 to CDC. For the most recent recommendations on emerging infectious diseases, consult the CDC website (http://www.cdc.gov). Procedures for handling agents of bioterrorism are available from CDC (http://www.bt.cdc.gov), American Society for Microbiology (http://www.asm.org), and regional/local health laboratories.

Transmission of airborne agents has been associated with close contact and the performance of certain procedures on infected individuals (e.g., autopsies, bronchoscopy, endotracheal intubation and suctioning, sputum induction, and aerosol treatments that induce coughing). In addition, laboratory workers who process specimens from infected patients can be at risk for infection when aerosols are produced and containment or respiratory protection is inadequate. As discussed in Section 11, the postexposure plan should include medical surveillance for all highly infectious agents.

An effective control program to prevent the transmission of *M. tuberculosis* and other airborne infectious agents requires early identification, isolation, and effective treatment of infected persons. The program should be based on three levels of controls, which include the following measures:

- Administrative measures that are intended to reduce the risk of exposing individuals to infected persons. These steps include:
  - writing policies and protocols to ensure rapid identification, isolation, and treatment of infected persons;
— conducting annual risk assessments of the setting;

— implementing effective work practices among healthcare workers, such as using good biological safety procedures;

— if necessary, wearing adequate respiratory protection;

— annually educating, training, and counseling healthcare workers about occupationally acquired infections; and

— screening healthcare workers for infection.

• Engineering controls to prevent the spread and reduce the concentration of infectious droplet nuclei and other infectious particles. These controls can include direct source control using local exhaust ventilation; directional air control; diluting and removing contaminated air by general ventilation and air cleaning by air filtration; or augmentation of previous controls by use of ultraviolet germicidal irradiation. All engineering controls are on a preventative maintenance schedule.

These two levels of control are meant to minimize the number of areas in the healthcare facility where exposure can occur and to reduce the risk of exposure in those few areas that remain.

• Respiratory protection is the third level of control and includes airborne precautions, i.e., wearing adequate personal respiratory protective equipment when, despite all other control measures, the risk for infection remains relatively high. Additional measures include implementing a respiratory protection program and training in individuals on respiratory protection (see Section 6.2.3). Healthcare workers must be medically cleared and fit-tested to wear N95 respirators. According to CDC and NIOSH recommendations, 20-22 respiratory protective devices used in healthcare settings for protection against *M. tuberculosis* and other airborne infectious agents should meet the defined performance criteria and be NIOSH certified (see Section 6.2.3).

**NEISSERIA MENINGITIDIS**

Meningococcal meningitis is a demonstrated but rare hazard to laboratory workers.

*Laboratory Hazards:* The agent may be present in pharyngeal exudates, cerebrospinal fluid, blood, and saliva. Parenteral inoculation, droplet exposure of mucous membranes, infectious aerosol, and ingestion are the primary hazards to laboratory personnel.

*Recommended Precautions:* Biosafety Level 2 practices, containment equipment, and facilities are recommended for all activities utilizing known or potentially infectious body fluids, tissues, and cultures. Additional primary containment and personnel precautions, such as those described for Biosafety Level 3, may be indicated for activities with a high potential for droplet or aerosol production and for activities involving production quantities or concentrations of infectious materials.

**NOTE:** Vaccines for *N. meningitidis* are available and should be considered for personnel regularly working with infectious materials. The reader is advised to consult the current recommendations of the Advisory Committee on Immunization Practices (ACIP) published in the CDC Morbidity and Mortality Weekly Report (MMWR) for recommendations for vaccination against *N. meningitidis*. **(NOTE:** Laboratorians who are likely to encounter meningococcal isolates from sterile sites may have increased

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a From *Biosafety in Microbiological and Biomedical Laboratories.* U.S. Department of Health and Human Services; Public Health Service, Centers for Disease Control and Prevention; and National Institutes of Health. 4th ed. May 1999 (Stock number: 017-040-00547-4).

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risk of infection and should consider the use of PPEs (e.g., splashguards, masks) or a BSC during manipulation of these isolates and vaccination as an adjunctive measure.\textsuperscript{18} Vaccination does not eliminate the risk of infection.

**Bacillus Anthracis**

Until recently, no laboratory-associated cases of anthrax have been reported in the United States since the late 1950s when human anthrax vaccine was introduced. In 2002, a case of cutaneous anthrax was reported in a laboratory worker manipulating an environmental sample.\textsuperscript{23} Any work with *B. anthracis* requires special security considerations due to its potential use for purposes of biological terrorism. Consult CDC’s website (http://www.cdc.gov/od/sap) for details regarding the Select Agent and Toxin Program’s requirements. Naturally and experimentally infected animals pose a potential risk to laboratory and animal care personnel.

**Laboratory Hazards:** The agent may be present in blood, skin lesion exudates, cerebrospinal fluid, pleural fluid, sputum, and rarely, in urine and feces. Direct and indirect contact of the intact and broken skin with cultures and contaminated laboratory surfaces, accidental parenteral inoculation, and rarely, exposure to infectious aerosols are the primary hazards to laboratory personnel.

**Recommended Precautions:** Biosafety Level 2 practices, containment equipment, and facilities are recommended for activities using clinical materials and diagnostic quantities of infectious cultures. Animal Biosafety Level 2 practices, containment equipment, and facilities are recommended for studies utilizing experimentally infected laboratory rodents. Biosafety Level 3 practices, containment equipment, and facilities are recommended for work involving production quantities or concentrations of cultures, and for activities with a high potential for aerosol production.

**NOTE:** A licensed vaccine is available through the CDC; however, immunization of laboratory personnel is not recommended unless frequent work with clinical specimens or diagnostic cultures is anticipated (e.g., animal disease diagnostic laboratory). In these facilities immunization is recommended for all persons working with the agent, all persons working in the same laboratory room where the cultures are handled, and persons working with infected animals.

**NOTE:** The identification of a U.S. case of inhalation anthrax on October 4, 2001 marked the beginning of an outbreak associated with intentional anthrax release. Laboratory workers collecting environmental samples that place them at risk for exposure to *B. anthracis* should wear protective personal equipment, including a respiratory device (powered air-purifying respirator with a HEPA filter), protective clothing, and gloves. Most routine clinical laboratories are not trained or equipped to handle environmental samples. These materials should be transported to a laboratory that is equipped to process the samples. In the U.S., the Select Agent Transfer Program places additional shipping and handling requirements on laboratory facilities that transfer or receive select agents capable of causing substantial harm to human health.

**Brucella**

Brucellosis continues to be the most commonly reported laboratory-associated bacterial infection. *B. abortus, B. canis, B. melitensis,* and *B. suis* have all caused illness in laboratory personnel. Hypersensitivity to *Brucella* antigens is also a hazard to laboratory personnel. Occasional cases have been attributed to exposure to experimentally and naturally infected animals or their tissues.

**Laboratory Hazards:** The agent may be present in blood, cerebrospinal fluid, semen, and occasionally urine. Most laboratory-associated cases have occurred in research facilities and have involved exposure to *Brucella* organisms grown in large quantities. Cases have also occurred in the clinical laboratory setting from sniffing cultures. Direct skin contact with cultures or with infectious clinical specimens from
animals (e.g., blood, uterine discharges) are commonly implicated in these cases. Aerosols generated during laboratory procedures have caused large outbreaks. Mouth pipetting; accidental parenteral inoculations; and sprays into eyes, nose, and mouth have also resulted in infection.

**Recommended Precautions:** Biosafety Level 2 practices are recommended for activities with clinical specimens of human or animal origin containing or potentially containing pathogenic *Brucella* spp. Biosafety Level 3 and Animal Biosafety Level 3 practices, containment equipment, and facilities are recommended, respectively, for all manipulations of cultures of the pathogenic *Brucella* spp.

**NOTE:** While human *Brucella* vaccines have been developed and tested in other countries with limited success, at the time of this publication no human vaccine is available in the United States. *B. abortus, B. melitensis,* and *B. suis* are listed as Select Agents. Consult CDC’s website (http://www.cdc.gov/od/sap) for details regarding the Select Agent and Toxin Program’s requirements.

### FRANCISELLA TULARENSIS

Tularemia has been a commonly reported laboratory-associated bacterial infection. Almost all cases occurred at facilities involved in tularemia research. Occasional cases have been related to work with naturally or experimentally infected animals or their ectoparasites. Although not reported, cases have occurred in clinical laboratories. Work with cultures of *F. tularensis* requires special security considerations due to their potential use for purposes of biological terrorism.

**Laboratory Hazards:** The agent may be present in lesion exudates, respiratory secretions, cerebrospinal fluid, blood, urine, tissues from infected animals, and fluids from infected arthropods. Direct contact of skin or mucous membranes with infectious materials, accidental parenteral inoculation, ingestion, and exposure to aerosols and infectious droplets has resulted in infection. Infection has been more commonly associated with cultures than with clinical materials and infected animals. The human 25% to 59% infectious dose is approximately ten organisms by the respiratory route.

**Recommended Precautions:** Biosafety Level 2 practices, containment equipment, and facilities are recommended for activities with clinical materials of human or animal origin containing or potentially containing *F. tularensis*. Biosafety Level 3 and Animal Biosafety Level 3 practices, containment equipment, and facilities are recommended, respectively, for all manipulations of cultures and for experimental animal studies.

**NOTE:** Vaccination for *F. tularensis* is available and should be considered for personnel working with infectious materials or infected rodents. Vaccination is recommended for persons working with the agent or infected animals, and for persons working in or entering the laboratory or animal room where cultures or infected animals are maintained. The reader is advised to consult the current recommendations of the Advisory Committee on Immunization Practices (ACIP) published in the CDC Morbidity and Mortality Weekly Report (MMWR) for recommendation for vaccination against *F. tularensis*. *F. tularensis* is listed as a Select Agent. Consult CDC’s website (http://www.cdc.gov/od/sap) for details regarding the Select Agent and Toxin Program’s requirements.

### BURKHOLDERIA MALLEI/PSEUDOMALLEI

Glanders and melioidosis are diseases caused by *B. mallei* and *B. pseudomallei*, respectively. Two laboratory-associated cases of melioidosis have been reported: one associated with a massive aerosol and skin exposure; the second resulting from an aerosol created during the open-flask sonication of a culture presumed to be *B. cepacia*. A case of laboratory-acquired glanders occurred in a research laboratory.24
Laboratory Hazards: The agents may be present in sputum, blood, wound exudates, and various tissues depending on the infection’s site of localization. Direct contact with cultures and infectious materials from humans, animals, or the environment; ingestion; autoinoculation; and exposure to infectious aerosols and droplets are the primary laboratory hazards. The agents have been demonstrated in blood, sputum, and abscess materials, and *B. pseudomallei* may be present in soil and water samples from endemic areas.

Recommended Precautions: Biosafety Level 2 practices, containment equipment, and facilities are recommended for all activities utilizing known or potentially infectious body fluids, tissues, and cultures. Gloves should be worn when handling infected animals, during their necropsy, and when there is the likelihood of direct skin contact with infectious materials. Additional primary containment and personnel precautions, such as those described for Biosafety Level 3, may be indicated for activities with a high potential for aerosol or droplet production, and for activities involving production quantities or concentrations of infectious materials. Vaccines are not currently available for use in humans.

NOTE: *B. mallei* and *B. pseudomallei* are listed as Select Agents. Consult CDC’s website (http://www.cdc.gov/od/sap) for details regarding the Select Agent and Toxin Program’s requirements.

**YERSINIA PESTIS**

*Y. pestis* is a rare cause of laboratory-acquired infection.

Laboratory Hazards: The agent may be present in bubo fluid, blood, sputum, CSF, feces, and urine. The primary hazards to laboratory personnel involve direct contact with infectious material and exposure to aerosols produced by manipulation of cultures.

Recommended Precautions: Biosafety Level 2 practices, containment equipment, and facilities are recommended for handling potentially infectious clinical material, and Biosafety Level 3 practices and facilities for manipulations with a high potential for aerosol or droplet formation. Vaccination is available and recommended for working with infected rodents and other highly infectious material. The reader is advised to consult the current recommendations of the Advisory Committee on Immunization Practices (ACIP) published in the CDC Morbidity and Mortality Weekly Report (MMWR) for recommendation for vaccination against *Y. pestis*.

NOTE: *Y. pestis* is listed as a Select Agent. Consult CDC’s website (http://www.cdc.gov/od/sap) for details regarding the Select Agent and Toxin Program’s requirements.

**MYCOBACTERIUM TUBERCULOSIS**

The CDC guidelines for preventing the transmission of *M. tuberculosis* in healthcare facilities and laboratories are targeted to all aspects of healthcare delivery and primarily to the care of patients who are infected with *M. tuberculosis*. The CLSI guidelines, on the other hand, focus primarily on those aspects that apply to laboratory personnel and their risks of acquiring infection as a result from working in laboratories, with laboratory devices, and from work conducted in other areas of the healthcare facility where infected patients are present.

Tuberculosis has been decreasing in incidence in the United States and other developed countries and reached a low of 5.2 cases per 100,000 in 2002 in the United States (http://www.cdc.gov/nchstp/tb/surv/surv2002/default.htm). The majority of cases are associated with foreign-born individuals from areas of the world that have a high prevalence of TB; homeless persons; medically underserved populations; injection-drug users; the elderly; and especially individuals who are immune-compromised as a result of HIV infection or chronic renal failure, diabetes mellitus, or immunosuppressive therapy. In general, persons who become infected have about a 10% chance of developing active TB during their lifetime.
Individuals who are immune-compromised, such as those who are HIV-infected, have about an 8 to 10% or higher chance per year for developing active TB.

Transmission of *M. tuberculosis* in healthcare facilities is a recognized risk. The magnitude of the risk varies considerably by the type of healthcare facility; the prevalence of TB in the community; the patient population served; the number of patients with TB presenting for care; occupations of those working within the healthcare facility; specific areas within the healthcare facility; and the effectiveness of TB infection control interventions.20

*Laboratory Hazards:* The agent may be present in sputum, cerebrospinal fluid, gastric lavage fluids, urine, and in lesions from a variety of tissues. The greatest risk to laboratory personnel is from exposure to infectious aerosols generated from handling liquid cultures, preparation of frozen sections, and performing autopsies on infected patients. Infrequently, infections can occur from parenteral inoculation.26 The 50% infectious dose for humans is <10 bacilli.

*Recommended Precautions:* Laboratory procedures for culturing *M. tuberculosis* and for examining specimens from infected patients use the biosafety precautions described in the CDC/NIH manual.4 BSL 2 practices and procedures, containment equipment, and facilities are required for nonaerosol-producing manipulations of clinical specimens. All aerosol-producing activities must be conducted in an annually certified BSC. BSL3 practices, containment equipment, and facilities are required for laboratory activities in the propagation and manipulation of cultures for *M. tuberculosis*. Individuals who work in a medium-risk laboratory (where clinical specimens that might contain *M. tuberculosis* are manipulated) should be tested at least annually for *M. tuberculosis* infection.20 If these requirements cannot be met, laboratory work should not be performed.

**SARS-CoV** (CDC, Public Health Guidance for Community-Level Preparedness and Response to Acute Respiratory Syndrome (SARS), 2004).

The SARS-associated coronavirus (SARS-CoV) infected 8098 people worldwide during the 2003 outbreak with an approximate mortality rate of 10%. Two cases (one presumed) of laboratory-acquired SARS-CoV infection occurred in research laboratories and underscore the potential risk of handling infected material. Until more information on the transmission of SARS-CoV in the laboratory is known, precautions should be taken when handling specimens and infected tissue culture material.

*Laboratory Hazards:* SARS-CoV may be present in blood, stool, urine, upper and lower respiratory secretions, tissues from major organs, and pleural fluid. The agent is thought to be transmitted most readily by respiratory droplets, indirect contact with contaminated surfaces, possibly by aerosols, or by other unknown means.

*Recommended Precautions:* As a minimum, standard precautions should be followed when performing routine hematology, urinalysis, chemistry and microbiology diagnostic tests on urine, blood, or serum specimens from potential SARS-CoV cases. Increased precautions should be employed in microbiology and pathology laboratories performing diagnostic tests on stool, respiratory, or tissue specimens. These laboratories should use BSL 2 work practices in a BSC and perform procedures that may generate aerosols in a BSC. Centrifugation of all specimens should be performed in sealed rotors, if available, and unloaded in a BSC. Any procedure that cannot be performed in a BSC should be performed while wearing gloves, gown, eye protection, and respiratory protection. SARS-CoV propagation in cell culture and characterization of viral isolates recovered in cultures of SARS-CoV specimens must be performed in a BSL 3 facility using BSL 3 work practices. A medical surveillance program should be employed for personnel who handle SARS-CoV specimens or cultures.

Because of the emerging nature of SARS-CoV, laboratories working with specimens from potentially infected patients should obtain the most current information available from CDC and/or WHO.
VIRAL AGENTS OF BIOTERRORISM

The potential viral agents of bioterrorism include smallpox, filovirus, arenavirus, alphavirus, and other agents of viral hemorrhagic fever. Some agents may be spread through aerosols or direct contact with contaminated materials. If these agents are suspected, clinical laboratories should contact public health officials before specimen collection. In the event that a specimen containing one of these agents is cultured from a patient with a suspected infection, the laboratory should notify the public health department for instructions on forwarding the viral culture and remaining specimen to the appropriate laboratory. CDC established the Laboratory Response Network (LRN) to respond to acts of bioterrorism, emerging infections, and public health threats and emergencies. LRN laboratories are designated as National, Reference, or Sentinel, where sentinel laboratories represent clinical laboratories that have direct contact with patients (http://www.bt.cdc.gov).

5.3.2 Transmission by Ingestion

Ingestion of microorganisms in the laboratory occurs through splashes, mouth pipetting, or any activity that results in a contaminated article (e.g., contaminated fingers or pencils) being placed in the mouth. Mouth pipetting is not an acceptable practice. Agents transmitted by ingestion include *Salmonella* spp., *Shigella* spp., cytotoxin-producing *E. coli*, *Vibrio* spp., and *Campylobacter* spp. Laboratory workers have become infected from mishandling proficiency samples containing stool pathogens. This is a partial list of infectious agents that may cause laboratory-acquired infections. For a more complete listing of agents, see *Biosafety in Microbiological and Biomedical Laboratories.*

POLIOVIRUS

No laboratory-acquired poliomyelitis has been reported for nearly 30 years in large part due to the availability of highly effective vaccines.

Laboratory Hazards: Poliovirus is present in feces, throat secretions, and lymph nodes, brain tissue, and spinal cord tissue in fatal cases. Ingestion or parenteral inoculation of infectious material poses the greatest risk to nonimmunized laboratorians.

Recommended Precautions: BSL2 work practices and facilities are recommended for handling human specimens. Laboratory personnel must have documented poliovirus vaccination. In anticipation of the eradication of polio, the WHO recommends destruction of all poliovirus stocks not needed for ongoing programs. In the United States laboratories that maintain stocks of wild poliovirus should be listed on the U.S. National Inventory (CDC), and one year after the detection of the last wild poliovirus these laboratories will implement BSL3/polio high containment procedures.

5.3.3 Transmission by Contact

With the emergence of vancomycin-intermediate *Staphylococcus aureus* (VISA) in 1996 and fully resistant strains (VRSA) in 2002 and 2004, the laboratory community faces yet another portentous challenge for the detection of these strains while the patient-care community struggles with heightened containment and expanding surveillance issues. To date, no person-to-person transmission/colonization has been documented; whether among direct patient-care providers, physicians, ancillary staff, family members, or household contacts. Notwithstanding, a strategy for determining the extent of transmission surrounding a laboratory confirmed VISA or VRSA infected/colonized patient can be found at www.cdc.gov/ncidod/hip/ARESIST/visa_vrsa_guide.pdf. The latest laboratory testing algorithm is located at www.cdc.gov/ncidod/hip/Lab/FactSheet/visa_vrsa_algo.htm.

Although no transmission/colonization by VISA/VRSA or other multidrug-resistant organisms has been documented in the laboratory to date, the use of routine safety practices such as decontamination of
laboratory work surfaces, appropriate barrier protection, and proper hand hygiene greatly reduce the potential risk for skin and/or nasal colonization or infection.


There have been 17 reported cases of laboratory-acquired infections with West Nile virus (WNV). One of these infections was attributed to aerosol exposure and two recent infections resulted from percutaneous inoculation during work with infected animals.

*Laboratory Hazards:* WNV is present in blood, serum, tissues, and CSF of infected humans, birds, mammals, and turtles. Parenteral inoculation with contaminated material poses the greatest risk to laboratorians, with contact exposure of broken skin and aerosol-generating procedures a possible risk.

*Recommended Precautions:* BSL2 facilities and work practices are recommended for handling human specimens. Sharps precautions should be strictly enforced. Manipulations of material with a high level of virus (e.g., material from a fatal case) and aerosol-generating procedures should be performed in a BSC. BSL3 facilities and work practices are recommended for all WNV viral cell cultures.

### 6 Protection Techniques

In the United States, OSHA has published a *Final Rule on Occupational Exposure to Bloodborne Pathogens,* and it identifies a hierarchy of work practices for the protection of workers potentially exposed to blood-borne biohazards. These practices include:

- exposure control
  - exposure control plan
  - risk assessment
- methods of compliance
  - universal precautions
  - engineering and work practice controls
  - personal protective equipment
  - housekeeping
- special considerations for HIV, HCV, and HBV research laboratories and production facilities
- hepatitis B vaccination and postexposure evaluation and follow-up
- communication of hazards to employees
- recordkeeping

Protection of employees must occur in all phases (preanalytical, analytical, and postanalytical) of laboratory work, which involve human specimens including specimen procurement, transportation, accessioning, preparation, analysis, and disposal. See **Section 9.8.2** regarding special procedures for microbiology laboratories.
6.1 **Hand Hygiene**

Frequent hand hygiene (as described in universal and standard precautions) is the most important safety precaution, which must be practiced after contact with patients and OPIM. Immediately after accidental skin contact with blood, body substances, or tissues, hands or other skin areas must be decontaminated. If the contact occurs through breaks in gloves, the gloves should immediately be removed, and the hands should be decontaminated. See Section 8.2.1.

6.2 **Barrier Protection**

Institutions should provide their employees with personal protective equipment. This is an OSHA requirement in the U.S.

6.2.1 **Gloves**

Gloves used for healthcare activities must be provided by the employer and in the U.S., must be approved by the FDA for use as a medical glove. These should be of proper size and material and be available at the workstation. Disposable nonsterile latex, nitrile, and vinyl gloves provide adequate barrier protection and are available from healthcare suppliers. Gloves are available in wrist, elbow, and shoulder length. Disposable gloves should be examined for visible defects after donning and before commencing work. Disposal of used gloves, especially consignment to biohazardous waste, should follow local regulatory protocol (see Section 7.1).

Disposable gloves made of thin latex or vinyl are not intended to provide protection from puncture wounds caused by sharp devices. A single disposable glove will protect the hands from contamination with blood and body substances (see Section 6.2.1.4, Double Gloving).

**Disposable gloves should not be washed and reused, since this degrades the protective function of the glove.**

Gloves need not be changed during laboratory activities that routinely result in contaminating the gloves (e.g., wiping the probe of some automated hematology devices). Rather, gloves should be changed when these tasks are completed. Laboratory workers must be diligent in avoiding contamination of a clean area by contact with contaminated gloves.

Laboratory workers should be trained to practice aseptic technique when putting gloves on and removing them. Proper technique will protect the worker from skin contamination from contaminated gloves. Gloves should be worn at the specimen receiving and set-up areas and in TB/virology laboratories, and when hands may contact potentially infectious material, contaminated surfaces, or equipment. Gloves should be removed and hands washed prior to leaving the laboratory environment.

Use general-purpose utility gloves (e.g., rubber household gloves) for housekeeping chores involving potential blood contact and for device cleaning and decontamination procedures. Utility gloves may be decontaminated and reused but should be discarded if they are peeling, cracked, or discolored, or if they have punctures, tears, or other evidence of deterioration.

**NOTE:** In some instances, prolonged glove use can lead to hand irritation and other problems. Extended periods of glove use should be interrupted. Use of moisturizers may help avoid or reduce hand skin irritation and other problems. Some nonpetroleum-based hand creams may affect glove integrity (see Section 8.2.1).
6.2.1.1 Latex Hypersensitivity

Although the majority of healthcare workers can use latex gloves, prevalence studies indicate that from 6% to 17% of the exposed healthcare workforce is allergic to latex. The two types of allergic reactions associated with glove use are allergic contact dermatitis (Type IV delayed hypersensitivity) and the potentially more serious IgE/histamine-mediated allergy (immediate or Type I hypersensitivity). Allergic contact dermatitis appears due to the chemicals used in processing latex or other glove materials. Use of glove liners (e.g., cotton) or alternative glove material without the sensitizing chemical can usually prevent allergic contact dermatitis. IgE/histamine-mediated allergy is due to latex proteins. This type of allergic reaction can involve local symptoms (e.g., hives) or more generalized symptoms, including allergic rhinoconjunctivitis or asthma. In rare cases, an individual may experience anaphylaxis. Type I hypersensitivity can be triggered by either touching items containing the allergen or inhaling the allergen (e.g., glove powder to which latex proteins have adsorbed).

Primary prevention involves reducing unnecessary exposure to latex proteins by selecting:

- gloves with a lower protein content;
- powder-free gloves; or
- alternative gloves prepared from nitrile, polyethylene, or other material.

ASTM International recommends that latex gloves contain no more than 200 micrograms/decimeter squared of water-extractable protein in order to be considered low protein. Because the use of powder-free gloves reduces the dissemination of latex proteins into the environment, powdered latex gloves should be strongly discouraged, at a minimum, as they represent an important risk factor for the induction of latex allergic reactions in healthcare workers due to occupational exposure. Many facilities have designated their workplaces as latex-free zones.

6.2.1.2 General Recommendations

Disposable gloves should be worn by:

- all healthcare providers procuring specimens. Healthcare providers should change disposable gloves as soon as possible if the gloves become visibly contaminated with blood or show evidence of perforation, tears, or leaks. Disposable gloves worn by phlebotomists and other healthcare providers should be changed between each patient contact (see Section 8.2.1).

- all healthcare providers who anticipate contact with tissues; blood; serum; plasma; cerebrospinal fluid; vaginal secretions; semen; bronchopulmonary washings; synovial, pleural, peritoneal, amniotic, and pericardial fluids; breast milk; or other bodily substances possibly contaminated with blood. (See Section 8.2.2 for further details)

- all personnel when handling biohazardous bagged material and visibly contaminated items or linen.

6.2.1.3 Other Considerations

Gloves should be removed before handling telephones, uncontaminated laboratory equipment, doorknobs, etc. Alternatively, specific devices, such as computer keyboards and telephones, may be specially labeled as a biohazard and used only with gloved hands. Care must be taken not to use these marked devices with ungloved hands. Transfer of HBV, HIV, HCV, and HTLV I/II by fomites has not been documented.

Gloves and all other personal protective equipment should be removed before leaving the laboratory.
6.2.1.4 Double Gloving

Wearing two pairs of disposable gloves is recommended during autopsies, dissection of unfixed tissue, and in other situations where gross contamination of gloves with blood or body substances is anticipated, such as in the emergency room. It has been demonstrated that less skin contamination is observed when using double gloves than when using single gloves.

Additionally, it has been reported that when surgeons wear double gloves the rate of puncture of the inner glove is less than the rate of puncture of a single glove.

NOTE: Double gloving is not intended to provide physical protection from accidental puncture. If physical protection is desired, see the recommendations for autopsy in Section 10.1.5.

6.2.2 Facial Protection

Facial barrier protection should be used if there is a reasonably anticipated potential for spattering or splashing blood or body substances. Spattering is usually accidental, and it may be unavoidable under some circumstances. A plastic face shield best provides facial protection. Splashguards may serve as an acceptable alternative to plastic face shields. Facial barrier protection (e.g., face shields, goggles, surgical masks) do not protect against aerosols that may be generated by laboratory procedures (see Section 5.3).

Full-face shields made of lightweight transparent plastic (shaped like those worn by welders) are the preferred means of facial protection, since they offer excellent protection of the entire face and neck region. They are easily decontaminated and are very comfortable to wear for long periods of time, such as during an autopsy.

Disposable face shields are available. Some disposable shields have a plastic cover for the eyes and an integral surgical mask to cover the nose and mouth. If face shields are not used, a fluid-resistant mask and eye protection should be used.

Ordinary prescription glasses are not adequate eye protection. Better protection is afforded by plastic, wraparound safety glasses that fit over regular glasses. If there is a reasonably anticipated hazard of spattering, full-face shields or goggles with a plastic cushion seal should be used.

6.2.3 Respiratory Protection

Respiratory protection devices (e.g., personal particulate respirators) should be able to filter airborne particles that are <5 µm in size. These particles include droplet nuclei, dust that contains infectious agents, and fungal conidia and spores. Particulate respirators do not protect against vapors or gases. Respirators that filter out at least 95% of airborne particles during “worst case” testing using a “most penetrating” sized particle are given a 95 rating, those that filter at least 99% receive a 99 rating, and those that filter at least 99.7% receive a 100 rating (www.cdc.gov/niosh/npptl/topics/respirators/factsheets/respsars.html). The N-95 disposable particulate respirator is the type most commonly used by HCW, but other respirators (e.g., N-99, N-100, powered air-purifying respirators [PAPR], nonpowered full-facepiece elastomeric negative pressure) are also available and are regulated under the general industry standard for respiratory protection, http://www.osha.gov/STLC/respiratoryprotection/index.html.) All respirators used in healthcare settings must be certified and approved by NIOSH. A list of NIOSH-approved respirators can be found at www.cdc.gov/niosh/npptl/respirators/disp_part/particlist.html. OSHA (www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=24895) requires that respirators be used as part of a respiratory protection plan that includes medical evaluations, fit-testing, proper selection of respirators, annual training, and respirator maintenance.
6.2.4 Protective Body Clothing

When working in the laboratory, protective clothing appropriate to the task undertaken should be worn at all times.

- **Potential for soiling clothes** — Wear gowns, laboratory coats, aprons, or similar clothing (e.g., cloth laboratory coat or disposable clothing). If aprons are used, sleeve protectors may be used to protect the forearms.

- **Potential for splashing or spraying** — Wear FLUID-RESISTANT clothing (e.g., nonwoven gowns or laboratory coats with high resistance to fluid penetration).

- **Potential for soaking clothing** — Wear FLUID-PROOF clothing (e.g., plastic or plastic-lined surgeon’s gown). Disposable plastic aprons worn over laboratory coats should cover the entire torso and thighs. Long-sleeved aprons and plastic gowns that also cover the arms are available. At the completion of the task being performed, the apron or gown should be discarded according to institutional policy. Reusable plastic aprons should be decontaminated after use as suggested in Section 10.1.7.

- **Potential for splashing, splattering, or spraying head** — Wear surgical cap or hood.

- **Potential for contaminating and/or soaking shoes** — Wear FLUID-PROOF shoe covers. Shoes should be comfortable, rubber-soled, and cover the entire foot. Disposable, fluid-resistant shoe covers can be worn for jobs where splashing is expected. Because canvas shoes will absorb chemicals or infectious fluids, they are not recommended (if worn, they should be covered with disposable, fluid-resistant shoe covers). Leather or a synthetic, fluid-impermeable material is suggested. See the current edition of CLSI/NCCLS document GP17—Clinical Laboratory Safety.

While in the laboratory, all laboratory workers should wear long-sleeved gowns with closed fronts or long-sleeved laboratory coats that are buttoned closed. Reusable cloth or disposable gowns/coats may be used. Laboratory workers whose duties take them out of the laboratory should NOT wear laboratory coats or gowns out of the laboratory. Gowns and coats used in the laboratory should be removed when the worker leaves. If the personnel desire to wear coats out of the laboratory, it is desirable to have laboratory coats of a different color — one color coat to be worn in the laboratory (considered contaminated) and one color coat (kept uncontaminated) to be worn out of the laboratory. If a laboratory coat is contaminated outside of the laboratory, the coat should be changed.

Protective clothing, if visibly contaminated with blood or body substances, should be changed immediately to prevent blood seeping through and contaminating garments or skin. To ensure cleanliness, protective clothing should be changed at appropriate intervals. Contaminated gowns and laboratory coats should be disposed of or laundered according to institutional policy for infectious waste or contaminated linen. Laboratory protective garments should not be taken home to be washed, but should be laundered by the institution at no cost to the employee.

6.2.5 Occlusive Dressings

All nonintact skin (e.g., exudative lesions, dermatitis, cuts, or abrasions) located on parts of the body exposed to blood or body fluid should be covered with a water-impermeable occlusive bandage. This includes defects on the arms, face, and neck. The fingers and hands are best protected with gloves.
6.3 Biological Safety Cabinet

When the risk of substantial spatter or aerosolization is present, the manipulation should be performed in a Class II Type A1 or Type A2 biological safety cabinet. All manipulation of micro-organisms for which Biosafety Level 3 practices, containment equipment, and facilities are recommended should be performed in a BSC. (See Appendix B for information concerning biological safety cabinets.)

6.4 Sterilization, Disinfection, and Decontamination

6.4.1 The Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA)

6.4.1.1 Disinfectants and Sterilants

The FDA and EPA share responsibility for the regulation of disinfectants and sterilants. The FDA regulates chemical germicides formulated as antiseptics, preservatives, or drugs that are used on or in the human body, and sterilants and high-level disinfectants for processing reusable medical and dental devices. The EPA regulates the other disinfectants used for laboratory disinfections and housekeeping purposes. A complete discussion of this topic and a list of helpful websites are found in Appendix C.

6.4.1.1.1 Sodium Hypochlorite

Liquid household or reagent grade bleach is often used as an intermediate-level disinfectant. Aluminum and stainless steel are corroded by sodium hypochlorite, and, therefore, other intermediate-level disinfectants that have a tuberculocidal claim may be preferred. Sodium hypochlorite should not be mixed with other laboratory reagents or household chemicals (e.g., toilet bowl cleaners, rust removers, vinegar, acids, or ammonia-containing products), because it may produce hazardous gases, such as chlorine and other chlorinated species. The commercial bleach product is usually a 5.25% solution of sodium hypochlorite (50 000 mg/L of free available chlorine) but can range from 5.0 to 6.15%. The EPA encourages the use of registered bleach products for use as surface disinfectants, because the products have been tested for safety and performance when used according to the label instructions. The concentration of disinfectant used depends on the nature of the spill and of the contaminated surface. For example, if the surface is porous and cannot adequately be cleaned before disinfection, a 1:10 dilution of commercial liquid household bleach (0.5% sodium hypochlorite equal to 5000 mg/L of free available chlorine) may be needed. If the surface is hard and smooth and has been adequately cleaned, a 1:100 dilution of bleach (0.05% sodium hypochlorite equal to 500 mg/L of free available chlorine) may be sufficient. Both of these dilutions are sufficiently powerful to kill mycobacteria (i.e., they are “tuberculocidal”).

The time of exposure to the diluted bleach solution may be brief: a 500 mg/L solution (1:100 dilution) inactivates HBV within ten minutes, and HIV in two minutes. If the spill has been adequately cleansed before decontamination, the diluted bleach may be blotted up with disposable absorbent towels shortly (two to three minutes) after the spill area has been soaked with bleach.

NOTE: All dilutions should be made weekly with tap water to prevent the loss of germicidal action during storage. The concentration of disinfectant used depends on the nature of the spill and of the contaminated surface. For example, if the surface is porous and cannot adequately be cleaned before disinfection, a 1:10 dilution of commercial liquid household bleach (0.5% sodium hypochlorite equal to 5000 mg/L of free available chlorine) may be needed. If the surface is hard and smooth and has been adequately cleaned, a 1:100 dilution of bleach (0.05% sodium hypochlorite equal to 500 mg/L of free available chlorine) may be sufficient. Both of these dilutions are sufficiently powerful to kill mycobacteria (i.e., they are “tuberculocidal”).

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## Table 6. Dilutions of Household Bleach

<table>
<thead>
<tr>
<th>Volume of Bleach</th>
<th>Volume of Water</th>
<th>Dilution Ratio</th>
<th>Sodium Hypochlorite (%)</th>
<th>Available Chlorine (mg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Undiluted</td>
<td>0</td>
<td>1</td>
<td>5.25</td>
<td>50 000</td>
</tr>
<tr>
<td>1</td>
<td>9</td>
<td>1:10</td>
<td>0.5</td>
<td>5000</td>
</tr>
<tr>
<td>1</td>
<td>99</td>
<td>1:100</td>
<td>0.05</td>
<td>500</td>
</tr>
</tbody>
</table>

Remove all visible traces of dried blood or body fluid from a surface or medical device before decontamination. The dried blood should be wetted and softened with diluted bleach or detergent disinfectant. If the material cannot be removed by wiping, repeat the application and allow to stand for a longer period of time until the material can be wiped off. After removal of the dried blood or body fluid, disinfect or sterilize as appropriate (i.e., depending on the intended use of the surface or device).

For large spills of cultured or concentrated infectious agents, the spill should first be covered with an absorbent material, flooded or mixed with an EPA-approved hospital disinfectant that is at least tuberculocidal or a 1:10 dilution of sodium hypochlorite, and then allowed to stand (20 to 30 minutes may be necessary).

6.4.1.1.2 Hospital Disinfectants

Hospital disinfectants that are tuberculocidal may be used for decontamination as required in the U.S.

Examples of effective product classes are:

- phenolic disinfectants;
- chlorine-containing agents; and
- tinctures of quaternary ammonium compounds with appropriate label designation as “tuberculocidal.”

- In other regions of the world, accelerated hydrogen peroxide is widely used as an alternative to bleach for environmental disinfection of blood and other body fluid spills.

6.4.1.1.3 Sterilants and High-Level Disinfectants for Processing Reusable Medical and Dental Devices

The products listed below should not be used for environmental decontamination; they should only be used according to the manufacturer’s instructions for instrument or device decontamination.

- glutaraldehyde (2.4% to 3.4%);
- peroxyacetic acid (0.08%) and hydrogen peroxide (1%);
- ortho-phthalaldehyde (0.55%); and
- hydrogen peroxide (7.5%).

A list of commercial disinfectants and sterilants is available on websites listed in Appendix C.

The choice of specific disinfectants in association with protocols for cleaning is a decision made broadly and at various levels of hospital and other healthcare facilities. No single chemical germicide procedure is adequate for all disinfection or sterilization purposes, and the realistic use of chemical germicides depends on a number of factors, which should be considered in selecting among the available procedures.
These include the degree of microbial killing required; the nature and composition of the surface item or device to be treated; and the cost, safety, and ease of use of the available agents.

6.4.2 Procedures and Products

Sterilization and disinfection procedures generally used in healthcare facilities are able to sterilize or disinfect medical devices, and decontaminate and sanitize surfaces. Germicidal activity is classified as high-level, intermediate-level, or low-level. See Table 7. Critical medical devices that penetrate tissues, thereby making contact with normally sterile areas of the body, or through which blood flows should be sterilized before use (e.g., bone-marrow needles). Semicritical medical devices that come into contact with mucous membranes should be sterilized or receive high-level disinfection before use. Blood-borne pathogens, such as HBV, HCV, and HIV, are usually inactivated by all levels of disinfectants. However, OSHA requires the use of EPA-registered disinfectants that are tuberculocidal or effective against HIV-1 and HBV.

Several commercial, quaternary, ammonium-based, housekeeping products have recently been approved by EPA to make claims of activity against HIV and HBV. However, if the user is processing samples other than blood or serum, it is recommended to use a tuberculocidal disinfectant to handle other types of organisms, such as enteroviruses. Refer to the manufacturer’s instructions for exposure times and conditions and a list of microorganisms inactivated by the product.


<table>
<thead>
<tr>
<th>Procedure/Product</th>
<th>Aqueous Concentration †</th>
<th>Activity Level</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sterilization</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glutaraldehyde</td>
<td>Variable</td>
<td>N/A</td>
</tr>
<tr>
<td>Hydrogen peroxide</td>
<td>6 – 30%</td>
<td>N/A</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>6 – 8%</td>
<td>N/A</td>
</tr>
<tr>
<td>Chlorine dioxide</td>
<td>Variable</td>
<td>N/A</td>
</tr>
<tr>
<td>Peracetic acid</td>
<td>Variable</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Disinfection</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glutaraldehyde</td>
<td>Variable</td>
<td>High to intermediate</td>
</tr>
<tr>
<td>Ortho-phthalaldehyde</td>
<td>Variable</td>
<td>High</td>
</tr>
<tr>
<td>Hydrogen peroxide</td>
<td>3 – 6%</td>
<td>High to intermediate</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>1 – 8%</td>
<td>High to low</td>
</tr>
<tr>
<td>Chlorine dioxide</td>
<td>Variable</td>
<td>High</td>
</tr>
<tr>
<td>Peracetic acid</td>
<td>Variable</td>
<td>High</td>
</tr>
<tr>
<td>Chlorine compounds#</td>
<td>500 to 5000 mg/L</td>
<td>Intermediate</td>
</tr>
<tr>
<td></td>
<td>Free/available chlorine</td>
<td></td>
</tr>
<tr>
<td>Alcohols (ethyl, isopropyl)**</td>
<td>70%</td>
<td>Intermediate</td>
</tr>
<tr>
<td>Phenolic compounds</td>
<td>0.5 – 3%</td>
<td>Intermediate to low</td>
</tr>
<tr>
<td>Iodophor compounds††</td>
<td>40 – 50 mg/L free iodine; up to 10 000 mg/L available iodine</td>
<td>Intermediate to low</td>
</tr>
<tr>
<td>Quaternary ammonium compounds</td>
<td>0.1 – 0.2%</td>
<td>Low</td>
</tr>
</tbody>
</table>

**NOTE:** A recent memorandum of understanding (MOU) between FDA and EPA places the *sole* regulatory responsibility for chemical sterilant/high-level disinfectants with FDA. The MOU also placed the regulatory responsibility for environmental (housekeeping) germicides solely with EPA.
Footnotes to Table 7

* This list of chemical germicides centers on generic formulations. A large number of commercial products based on these generic components can be considered for use. Users should ensure that commercial formulations are registered with the EPA and, if used on medical instruments or devices, listed with the FDA. Adequate precleaning of surfaces is the first prerequisite for any sterilizing or disinfecting procedure. Manufacturers’ generally recommended exposure times may not be adequate to disinfect certain instruments or devices, especially those that are difficult to clean because of narrow channels or other areas that may harbor organic material as well as microorganisms; this is of particular importance when high-level disinfection is to be achieved.

† For sterilization or disinfection, refer to the manufacturers’ instructions for exposure times and conditions, as well as recommendations for rinsing and subsequent handling of processed items.

‡ It is imperative that the user of those products closely follows instructions of the manufacturer regarding use as a sterilant or disinfectant; some manufacturers supply test kits to aid in monitoring glutaraldehyde concentrations during the use-life of the product.

§ Because of the ongoing controversy of the role of formaldehyde as a potential occupational carcinogen, the use of formaldehyde is limited to certain specific circumstances under carefully controlled conditions, e.g., for the disinfection of certain hemodialysis equipment. There are no EPA-registered products designed for liquid chemical sterilizing or disinfecting that contain formaldehyde.

¶ Among this registration listing are formulations composed of a single category of active ingredient (e.g., glutaraldehyde, phenolic, or iodophor), but others may contain such an array of “active” chemical agents that the user may have difficulty in attempting to define a generic classification. For this reason among others, the user is urged to pay particular attention to the information on the product label and accompanying package literature (spectrum of activity, approved use patterns, directions for use, safety precautions, etc.).

# Generic disinfectants containing chlorine are available in liquid or solid form, (e.g., sodium or calcium hypochlorite). Although the indicated concentrations are rapid acting and broad spectrum (tuberculocidal, bactericidal, fungicidal, and virucidal), no proprietary hypochlorite formulations are formally registered with the EPA as such (common household bleach is an excellent and inexpensive source of sodium hypochlorite). Concentrations between 500 and 1000 mg/L chlorine are appropriate for the vast majority of uses requiring an intermediate level of germicidal activity; higher concentrations are extremely corrosive as well as irritating to personnel, and their use should be limited to situations in which organic material is difficult to cleanse (e.g., porous surfaces) or contains unusually high concentrations of microorganisms (e.g., spills of cultured material in the laboratory).

** The effectiveness of alcohols as intermediate-level germicides is limited, because they evaporate rapidly, resulting in very short contact times, and because they lack the ability to penetrate residual organic material. They are rapidly tuberculocidal; bactericidal; fungicidal; may vary in spectrum of virucidal activity; and are not sporicidal. Items to be disinfected with alcohols should be carefully precleansed and then totally submerged for an appropriate exposure time (e.g., 10 minutes).

†† Only those iodophors registered with EPA as hard-surface disinfectants should be used, and the instructions of the manufacturer regarding proper dilution and product stability should be closely followed. Antiseptic iodophors are not suitable for disinfecting medical instruments or devices or environmental surfaces.

6.4.3 Spill Clean-Up Procedure

The following procedure is recommended for decontaminating spills of blood, body fluids, or other infectious materials (including culture materials) that occur in the clinical laboratory. Spills in other sites may require modification of these procedures. For biological spills involving BSL3 agents that occur outside the BSC, the occupants should leave the area immediately, and not re-enter for at least 60 minutes to allow bioaerosols to be exhausted and heavier particles to settle. The factors that influence decontamination procedures are: volume of spill; type of body fluid spilled; protein content; infectious agent present; concentration of infectious agent; and nature of the surface (porous vs water-resistant).
(1) Wear gloves, gown, and facial protection. Heavyweight, puncture-resistant utility gloves such as those used for house cleaning and dishwashing are recommended.

- If the spill contains broken glass or other objects, these should be removed and discarded without contact with the hands. Rigid sheets of cardboard or a disposable plastic scoop with a pusher component used as a “pusher” and “receiver” may be used to handle such objects (tongs, forceps, and hemostats), and may be discarded with the objects into an appropriate puncture-resistant biohazard container.

- If the spill is large and/or there is potential of contaminating the worker's shoes, water-impermeable shoe covers should be worn.

- With spills of culture media and materials, the site should be sequestered with absorbent material and a concentrated disinfectant applied. After a period of ten minutes the clean up as described below should be initiated.

- If droplet formation is likely to have occurred (e.g., breakage within a centrifuge), the equipment must remain closed for at least a half hour to allow blood/body fluid droplets to settle before decontamination begins (see Section 12.2.1.4).

(2) Absorb the spill.

- Since most disinfectants are less active, or even ineffective, in the presence of high concentrations of protein as are found in blood and serum, the bulk of the spilled liquid should be absorbed prior to decontamination.

- Absorb the spilled material with disposable absorbent material (e.g., paper towels, gauze pads, or tissue paper wipes). If the spill is large, granular absorbent material such as that used to absorb caustic chemical spills may be used to absorb the liquid. Finely granulated silica gels are available which, when sprinkled on a spill, congeal the liquid immediately. The gelatinous mass may then be scraped up rather than blotted. Absorbent granular material and silica gels containing a chemical that releases chlorine upon wetting are available. The efficacy of such materials in decontamination is not known; therefore, they should not be relied upon to decontaminate a spill. After absorption of the liquid, all contaminated materials should be discarded in the biohazardous waste container.

(3) Clean the spill site of all visible spilled material using an aqueous detergent solution. Any household detergent may be used or a 1:10 dilution of household bleach. The intent is to dilute the spilled material, lyse the red blood cells, and further remove proteins from the contaminated area. Absorb the liquid prior to decontamination to prevent dilution of the disinfectant. The use of a disinfectant detergent is not necessary.

(4) Decontaminate the spill site using an appropriate intermediate hospital disinfectant, such as a dilution of household bleach (see Table 6). Flood the spill site or wipe down the spill site with disposable towels soaked in disinfectant to make the site “glistening wet,” and then allow to dry.

**NOTE:** Do not use low-level disinfectants, such as quaternary ammonium compounds. Phenolic disinfectants are not recommended for use on contaminated medical devices which come into contact with unprotected patients or laboratory workers, but may be used on laboratory devices, floors, and counter tops.

(5) Absorb the disinfectant solution with disposable material. Alternatively, the disinfectant may be permitted to dry.
(6) Rinse the spill site with water to remove any noxious chemicals or odors.

(7) Dry the spill site to prevent slipping.

(8) Place all disposable materials used to decontaminate the spill into a biohazard container. Handle the material in the same manner as other infectious waste (see Section 7). Any reusable materials should be decontaminated prior to storage (see Section 6.4).

A “biohazard spill kit” containing all the materials and protective equipment needed should be prepared and made readily available in all areas where spills are likely to occur. A portable “biohazard spill cart” should be available for transport to areas remote from the laboratory (e.g., the patient’s bedside in case a spill occurs during phlebotomy).

7 Medical Waste Management

The procedures for managing laboratory-generated medical wastes should be integrated into the overall institutional medical waste management plan. This institutional plan is generally developed by the infection control and/or environmental health and safety group and will comply with the requirements defined by OSHA, state and local regulations, and facility-specific policies. While the details of such plans will vary significantly from facility to facility, most plans will include provisions to address the following key elements:

- designation of wastes requiring special handling;
- waste segregation;
- packaging;
- storage;
- transportation;
- tracking (some jurisdictions);
- treatment and disposal; and
- waste reduction.

The following information will focus on the “in-laboratory” provisions of a medical waste management plan, highlighting the issues of greatest concern to the laboratorian. The most current edition of CLSI/NCCLS document GP5—Clinical Laboratory Waste Management should be consulted for additional detailed information.

7.1 Designation of Wastes Requiring Special Handling

No universally accepted, specific definition of medical wastes requiring special handling has been developed. However, there are several categories of wastes that are “generally accepted” as requiring special management, namely: contaminated sharps, blood and body substances, cultures and stocks of etiological agents, and pathological wastes. OSHA included its definition for “regulated waste” in its Final Rule on Occupational Exposure to Bloodborne Pathogens.
The infection control committee and/or safety committee for each facility is typically responsible for interpreting the applicability of these varied definitions and designating the categories of medical wastes specific to that institution, which are consistent with the applicable laws and regulations.

### 7.2 Segregation

Implementation of the waste management plan depends on segregation of the waste into the designated categories to allow for the safest, most efficient and cost-effective treatment and/or disposal. Segregation of the waste might best be performed at the point of generation by personnel knowledgeable in the origin and hazards of the waste. Packaging requirements may vary for different categories of medical waste, and it is essential that appropriate containers are readily available for segregating the various wastes.

### 7.3 Packaging

Designated waste must be packaged in a manner that protects patients, healthcare workers, sanitation or waste management workers, and the general public from possible exposures. The container should be designed to maintain its integrity throughout handling, storage, transportation, and treatment. Selection of the packaging materials should take into account the type and volume of waste, moisture, transportation and handling, treatment technique, and labeling requirements.

OSHA has mandated the following requirements for packaging regulated wastes:

- **Sharps** — Sharps shall be discarded immediately or as soon as feasible into containers that are:
  - closable;
  - puncture-resistant;
  - leakproof on sides and bottom;
  - labeled or color-coded as a biohazard;
  - easily accessible;
  - maintained upright throughout use; and
  - replaced routinely and not allowed to overfill.

- **Other Regulated Wastes** — Other regulated wastes shall be placed in containers that are:
  - closable;
  - constructed to contain all contents and prevent leakage of substances during handling, storage, transport, or shipping;
  - labeled or color-coded as a biohazard; and
  - closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

### 7.4 Storage

Storage areas can be temporary or long-term. The waste should be stored for as brief a time as possible. Temporary storage areas should be properly identified with a biohazard sign, have restricted access, protect the integrity of the stored material, and be located near the site of generation. Long-term storage areas should meet the above conditions and be as close as possible to the site of treatment or loading dock for off-site shipment. Storage temperature and duration should not allow putrefaction.
7.5 Transport

Regulated medical waste is a hazardous material regulated by the U.S. DOT and should be transported to off-site treatment facilities in clearly labeled, dedicated, leak proof containers or carts that meet the U.S. DOT requirements. Specific state/local/regional regulations may also need to be addressed.

7.6 Tracking

In some jurisdictions, the waste generator is responsible for developing a waste tracking program. The program consists of procedures for recording the movement and disposal of hazardous wastes and includes:

- completion of a dangerous goods declaration for all waste leaving the premises;
- documentation of the disposal of the waste; and
- storage of waste tracking records for ten years.

7.7 Treatment and Disposal

Disposal of medical waste should be by licensed organizations that will ensure that no environmental contamination with potentially infectious or aesthetically displeasing materials will result.

In the U.S., treatment and disposal of medical waste must comply with all local ordinances, state and federal EPA regulations, and state and federal OSHA regulations. Regulations may be different in other countries.

7.8 Radioactive Biohazards

Radioactive, biohazardous waste that is properly contained should be disposed of according to institutional policy, including sterilization by autoclaving or chemical sterilization. A dedicated autoclave for radioactive materials is recommended. If this is not possible, users should perform a “wipe test” immediately after using the autoclave.

8 Standard Precautions

The term “standard precautions” refers to the concept that all patients and all laboratory specimens should be handled as if they were infectious and capable of transmitting disease. Accordingly, standard precautions apply to all patients and their specimens regardless of their diagnosis or presumed infection status. Although the term first appeared in the 1996 HICPAC Guidelines for Isolation Precautions in Hospitals, the concept had emerged and grown during the 1980s under the labels “Blood and Body Fluid Precautions,” “Universal Precautions,” and “Body Substance Isolation.” The concept derived from the observation that patients and specimens capable of transmitting certain infectious agents frequently go unrecognized in hospitals and laboratories; hence, the impetus to treat all patients and their specimens as if they were infectious. “Universal precautions” applies to specific body fluids that are more likely to harbor blood-borne pathogens. This term was used in OSHA documents published in the early 1990s and is still used in some OSHA documents.

The 1991 Occupational Safety and Health Administration (OSHA) Occupational Exposure to Bloodborne Pathogens Standard incorporated the basic concepts of standard precautions. The 1999 and 2001 OSHA Instructions provided clarification and additional interpretations of the standard. These OSHA documents target a relatively narrow range of blood-borne pathogens: HIV, hepatitis viruses,
leptospirosis, etc. They stress employer responsibilities for educating workers and providing all necessary supplies to ensure worker safety. In contrast, the HICPAC guidelines address all infectious agents, emphasizing prevention of nosocomial infections as well as worker safety. In the HICPAC guidelines, standard precautions represent the first and most important tier of protection measures, and they apply to a wide range of pathogens. When appropriate, they are coupled with transmission-based precautions (airborne, droplet, and contact) to manage all infectious threats in the hospital. In keeping with their different perspectives, the HICPAC guidelines for standard precautions are more general and universal in scope, whereas the OSHA regulations are more specific and detailed. This section draws material related to laboratory safety from both sources. Additionally, this section adapts material from new guidelines for hand hygiene in healthcare settings, which were published jointly by HICPAC, SHEA, APIC, IDSA and the CDC in 2002.40

Because the concept of standard precautions and safe work practices4 is so fundamental to safety in the healthcare environment, new employees in the laboratory require orientation to their basic principles and dictates. Even seasoned employees need periodic training to reinforce knowledge and understanding of their application to specific tasks.

8.1 Applications

Standard precautions apply to:

- all potentially infectious material — all body fluids, secretions, excretions (except sweat), and tissue specimens, regardless of whether they contain visible blood; and

- nonintact skin and mucous membranes of a patient or healthcare worker.

The primary intent of standard precautions is to prevent all potentially infectious material from making contact with the nonintact skin or mucous membranes of healthcare workers. The secondary intent is reducing the duration of contact if it occurs inadvertently.

Standard precautions do not affect other types of infection control strategies, such as the identification and handling of infectious laboratory specimens or waste during shipment; protocols for disinfection, sterilization, or decontamination; or laundry procedures.

Standard precautions dictate that quality control and proficiency testing materials, as well as calibrators, be handled like all other laboratory specimens.

Whenever possible, the risks of laboratory worker contact with blood and other potentially infected material are to be eliminated or minimized through the use of engineering controls (e.g., plastic capillary and blood collection tubes) and work practice controls (e.g., no-hands procedures in handling contaminated sharps). Because these approaches to control have limitations, standard precautions (“universal precautions” in the OSHA documents) remain an integral part of the strategy to interrupt disease transmission in hospitals and laboratories.

8.2 Components

8.2.1 Hand Hygiene

Recent developments in the field of hand hygiene stimulated development of guidelines, published in 2002, designed to improve hand hygiene practices in healthcare facilities.40 These guidelines recognize the efficacy of alcohol-based hand rubs and incorporate their use into hand hygiene.
• Decontaminate hands after touching all potentially infectious material, whether or not gloves are worn.
  a) When hands are visibly dirty or contaminated with potentially infectious material, wash hands with soap and water.
  b) If hands are not visibly soiled, either an alcohol-based hand rub or soap and water may be used.
• Remove gloves promptly after the task is completed.
• Decontaminate hands immediately after gloves are removed and when otherwise indicated to avoid transfer of microorganisms to other surfaces and environments.
• When performing phlebotomy, gloves should be changed between patients. Decontaminate the hands after glove removal and before donning new gloves.
• Hands should also be decontaminated:
  — after the completion of work and before leaving the laboratory;
  — before eating, drinking, smoking, applying makeup, changing contact lenses, and before and after using lavatory facilities; and
  — before all other activities which entail hand contact with mucous membranes, eyes, or breaks in the skin.
• Soap products that may disrupt skin integrity should be avoided. Using a moisturizing hand cream may reduce skin irritation caused by frequent hand washing. Some nonpetroleum-based hand creams may affect glove integrity.\textsuperscript{40}
• Do not wear artificial fingernails or extenders when having direct contact with patients at high risk for infections, such as those in intensive care units or operating rooms.\textsuperscript{8}

8.2.2 Gloves
• Wear gloves (clean, nonsterile gloves are adequate) when touching blood, other potentially infectious material, or surfaces contaminated with these materials.
• Wear gloves when performing routine laboratory work with blood or other potentially infectious material.
• Put on clean gloves before touching mucous membranes and nonintact skin of all patients.
• Wear gloves when performing phlebotomy.
• Remove gloves promptly after use, before touching noncontaminated items and environmental surfaces, and wash hands immediately to avoid transfer of microorganisms to other patients or environments.
• Always decontaminate hands immediately after removing gloves.
8.2.3 **Mask, Eye Protection, Face Shield**

Wear a mask and eye protection or a face shield to protect mucous membranes of the eyes, nose, and mouth during procedures that are likely to generate splashes or sprays of blood or other potentially infectious material. Splashguards may serve as an acceptable alternative to plastic face shields.

8.2.4 **Gown**

Wear a gown (a clean, nonsterile gown is adequate), apron, or laboratory coat to protect skin and to prevent soiling of clothing during procedures that are likely to generate splashes or sprays of blood or other potentially infectious material.

Select a gown, apron, or laboratory coat appropriate for the activity and the amount of fluid likely to be encountered.

Remove a soiled gown, apron, or laboratory coat as promptly as possible and decontaminate hands to avoid transfer of microorganisms to other surfaces or environments. Gowns and laboratory coats, soiled or not, should be removed prior to leaving the laboratory.

8.2.5 **Equipment**

Handle equipment or devices soiled with blood or other potentially infectious material in a manner that prevents skin and mucous membrane exposures, contamination of clothing, and transfer of microorganisms to other surfaces or environments.

Ensure that reusable equipment is not used for the care of another patient until it has been cleaned and processed appropriately (e.g., biopsy needles).

Ensure that single-use items are discarded appropriately.

8.2.6 **Environmental Control**

Ensure that the laboratory has adequate procedures for the routine care, cleaning, and disinfection of environmental surfaces and frequently touched items, and that these procedures are being followed.

8.2.7 **Usage of “Sharps”**

Minimize use of needles in laboratories. Utilize a protective needle device to minimize the risk of a needlestick (see Section 9.2.1).

Take care to prevent injuries when using needles, scalpels, lancets, and other sharp instruments or devices; when handling sharp instruments after procedures; when cleaning used instruments; and when disposing of used needles.

- Never recap used needles, or otherwise manipulate them using both hands or use any other technique that involves directing the point of a needle toward any part of the body; rather, use either a one-handed resheathing technique or a mechanical device designed for holding the needle sheath.
- Specimens contained in a needle with or without a syringe should be placed in a sharps container for transport to or within the laboratory.
- Do not remove used needles from disposable syringes by hand, and do not bend, break, or otherwise manipulate used needles by hand.
• Place used disposable syringes and needles, scalpel blades, lancets, and other sharp items in a sharps container, which should be easily accessible and located as close as is feasible to the immediate areas where sharps are used or are reasonably anticipated to be found.

• Place reusable syringes and needles, e.g., biopsy needles, in a sharps container for transport to the reprocessing area.

8.2.8 Resuscitation Equipment

Use mouthpieces, resuscitation bags, or other ventilation devices as an alternative to mouth-to-mouth resuscitation methods in areas where the need for resuscitation is predictable.

8.3 Warning Labels for All Potentially Infectious Material

Standard precautions eliminate the need for using specific biohazard warning labels (other than the universal biohazard symbol) on specimens obtained from patients infected with HBV, HIV, or other pathogens including antibiotic resistant organisms. This practice logically follows from the principle that all specimens should be treated as infectious and capable of transmitting disease. All samples of potentially infectious material should be transported in approved, leakproof containers or placed in leak-proof secondary containers. When these types of precautions are followed, there is no need for additional labeling.

A special circumstance exists in the blood bank when autologous blood is drawn from patients with HBV, HIV, or other infection caused by a blood-borne pathogen. Such units should bear biohazard warning labels to prevent accidental transfusion to uninfected patients.

State and local regulations may require the use of warning labels on specimens suspected of being infectious for HBV, HIV, or other pathogens. Obviously, local conditions must prevail. OSHA regulations stipulate that any specimen potentially containing blood-borne pathogens must have a biohazard warning label when transported from one facility to another.

9 Special Precautions for Laboratories

All clinical specimens should be treated as infectious and appropriate precautions should be followed.

Biosafety Level 2 practices should be followed when handling clinical specimens, blood, body fluids, or tissues. Cultures or specimens suspected of containing highly infectious agents might need to be handled in a Class II biological safety cabinet. (See Appendix B for details)

9.1 Facilities and Practices

• Laboratory space should be sufficient to minimize crowding, which may contribute to laboratory accidents.

• Laboratory surfaces, counters, and floors should be made of impervious materials to facilitate decontamination.

• Eating, drinking, and smoking should not be permitted in the laboratory. Direct and indirect hand-to-face contact should be avoided (e.g., application of cosmetics, insertion or removal of contact lenses).
- Canvas or open-toed sandals are inappropriate in the laboratory. Leather or synthetic, fluid impermeable footwear is recommended. See the current edition of CLSI/NCCLS document \textit{Clinical Laboratory Safety}.

- Adequate and conveniently located biohazard containers for disposal of contaminated materials should be provided.

- Adequate decontaminating containers for reusable supplies should be provided.

- According to OSHA standards, where engineering controls will reduce risk of exposure they must be used (e.g., engineered needle safety device on syringes and plastic capillary tubes instead of glass).

- If engineering and work practice controls do not eliminate exposure, then PPEs are required.

- Written decontamination, disinfection, and sterilization protocols should be developed for processing reusable supplies, laboratory equipment, laboratory waste, machine effluent, and environmental surfaces. OSHA requires that written protocols be developed and enforced.

- Facilities for hand washing and/or alcohol-based gels should be provided in each laboratory area. These should be separate from those used for washing equipment or for waste disposal. The use of foot, knee, or automatic faucets will reduce contamination of the faucets.

- Only authorized personnel should be allowed in the laboratory; casual visitors should not be admitted. Nonlaboratory personnel should be closely supervised and should use appropriate protective measures to ensure that they do not cause a hazard to themselves or to the laboratory staff.

- Monitoring compliance is a major responsibility of both the staff and management of the laboratory. The necessary educational, monitoring, and remedial programs should be defined, documented in writing, and consistently applied. The cooperation of the institutional quality assurance program should be enlisted.

Additional information is contained in CLSI/NCCLS document \textit{Procedures for the Handling and Processing of Blood Specimens}.

\subsection*{9.2 Blood Collection}

Whether collected at the bedside or in a dedicated bleeding site in the laboratory or office, all blood specimens should be regarded as potentially infectious. Care should be taken not to spill or splash blood on environmental surfaces, the patient, or the laboratory worker. Absorbent paper may be used to cover environmental surfaces and should be discarded after use. Special diligence should be exercised to avoid accidental needlesticks. For complete protection, gloves and an OSHA-approved laboratory coat/gown must be worn when collecting blood specimens. Gloves must be the appropriate size and substance. Any resulting environmental contamination should be decontaminated immediately as recommended in Section 6.4. Phlebotomists must adhere to standard precautions at all times and, when collecting blood from a patient on special precautions, follow the directions posted on the isolation sign (e.g., airborne, droplet, or contact precautions). In addition, they should only take necessary phlebotomy supplies into the patient’s room. The manufacturer’s instructions for the use of blood-collection devices and the institutional guidelines for the collection of blood specimens should be followed.

\textbf{NOTE}: Blood collection using a syringe and needle or winged infusion set should be used only if no alternative is feasible.
If a syringe has been used, the blood can be transferred to an evacuated tube by removing and discarding the needle and safety device. Apply a safety transfer device to the syringe, and puncture the diaphragm of the rubber stopper. Allow the correct amount of blood to flow slowly into the tube along the wall. The tube should be placed in a fixture and should not be hand-held when puncturing the top. Blood should never be forced into an evacuated tube or blood culture bottle by exerting pressure on the syringe plunger. This may cause the tube stopper to pop off, spraying blood. Caution should be applied when removing needles from evacuated tubes or blood culture bottles, as blood may continue to flow from the syringe.

9.2.1 Blood Collection Equipment and Safety Devices

Blood-borne pathogen exposures are estimated to be between 600,000 and 800,000 injuries annually. Data suggests that at an average hospital, approximately 30 needlestick injuries per 100 beds per year occur to a variety of healthcare workers. Most are preventable; 75% of all incidents are associated with disposable syringes and winged infusion sets and could be prevented by using safer equipment (engineering controls). In the United States, Congress passed the Federal Needlestick Safety and Prevention Act (HR5178) (2001) that mandates OSHA to revise the Bloodborne Pathogens Standard to strengthen the use of any sharps with engineered sharps injury protection. Many states have enacted stricter mandates regarding the use of needleless and safety engineered sharps devices. The use of needleless and safety-engineered sharps devices is critical to reducing sharps injuries in a healthcare setting.

When choosing safer equipment to minimize risk, the following features should be evident:

- provides a barrier between the hand and needle, with the worker’s hand always remaining behind the needle;
- preferably, requires no activation by the user;
- is an integral part of the collection device and not an accessory;
- is in effect before disassembly and remain in effect after disposal to protect others (i.e., cannot be deactivated);
- the device performs reliably; and
- is simple and requires little or no training.

To be in compliance with OSHA, the safety device must be:

- evaluated for effectiveness on a regular basis;
- evaluated regularly from data collected on its use;
- acceptable to employees;
- used for employee training; and
- maintained, examined, and repaired regularly by the employer.

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b Assistance for compliance with OSHA regulations can be found in CLSI/NCCLS document X3—Implementing a Needlestick and Sharps Injury Prevention Program in the Clinical Laboratory. Additional information can be found at http://www.healthsystem.virginia.edu/internet/epinet.
9.2.2 Phlebotomy and Arterial Puncture

Phlebotomy and arterial puncture are frequently accompanied by the leakage of blood from the puncture site or the dropping of blood from the needle on withdrawal from the blood vessel. Facial protection should be worn during arterial puncture. A dry gauze square is usually pressed onto the puncture site until bleeding ceases. After the bleeding has stopped, the skin may be cleansed with an antiseptic such as alcohol or povidone-iodine and covered with an adhesive bandage. Grossly contaminated gauze pads should be discarded into the biohazardous waste.

Concern has been expressed over wearing gloves during these procedures, because gloved hands are less sensitive. The skill needed to perform safe vascular puncture is readily achieved. Wearing gloves is required in the U.S. For detailed recommendations, see the OSHA Directive CPL 2-2.69 and the most current editions of the following CLSI/NCCLS documents:

- H3—Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture;
- H11—Procedures for the Collection of Arterial Blood Specimens; and

9.2.3 Skin Puncture

Skin puncture procedures may result in small amounts of blood to exude onto the patient’s skin, thereby, posing a potential hazard to the laboratory worker. Therefore, gloves should be worn when performing skin punctures. OSHA’s Final Rule encompasses minimizing risk with all “sharps” or sharp devices and therefore plays a dominant role in selecting skin puncture safety devices. When choosing safer capillary-puncturing equipment, the device must be single use and be retractable. The patient is frequently a newborn or infant who is moving about, and accidental fingersticks are commonly self-inflicted by the laboratory worker. Extreme care is warranted. After sample collection, pressure is usually applied with a dry gauze square until bleeding stops.

In adults the puncture site may be covered with an adhesive bandage. Skin punctures in infants less than two years old should not be covered with an adhesive bandage.

The OSHA final rule on blood-borne pathogens does not consider gauze pads with minimal blood to be regulated medical waste, and therefore, OSHA permits their disposal into the general hospital waste stream (see Section 9.2.2). Grossly contaminated gauze pads should be discarded into the biohazard waste. Local and regional regulatory policy should be followed.

9.3 Specimen Collection, Handling, and Transportation

All specimens should be collected or transferred into a leakproof primary container with a secure closure. Snap-top closures may produce a spray when opened, and their use should be avoided. Care should be taken by the person collecting the specimen not to contaminate the outside of the primary container. Filter paper used to collect blood when dried should be placed into a paper envelope or sleeve as described in the most recent edition of CLSI/NCCLS document LA4—Blood Collection on Filter Paper for Newborn Screening Programs.

The laboratory should evaluate performance of containers prior to purchase. (For detailed recommendations regarding urine specimens, see the most recent edition of CLSI/NCCLS document GP16—Urinalysis and Collection, Transportation, and Preservation of Urine Specimens.)
Within the institution, the primary container should be placed into a secondary container, which will contain the specimen if the primary container breaks or leaks in transit to the laboratory.

For additional information, see the most recent edition of CLSI/NCCLS document H4—Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens.

9.3.1 Manipulation of Clinical Material

Serum, plasma, or blood used to prepare aliquots should be pipetted using a disposable transfer pipette. Aliquots should not be poured into tubes or sample cups, since spillage is common.

- Mechanical pipetting devices should be used for all liquids in the laboratory.
- Mouth pipetting is extremely dangerous and is prohibited.
- Mechanical pipettes or diluting devices should be used in place of Thoma-type pipettes in making precise dilutions of blood, semen, or other body fluids.
- All specimen processing should be performed wearing appropriate PPEs and either behind a barrier or while wearing a face shield.

9.3.2 Laboratory Requisition Slips

Laboratory requisition slips should be protected from contamination and separated from the primary container. Grossly contaminated requisition slips should be discarded in the biohazardous waste and replaced. If the original requisition must be retained, it should be placed in a biohazard bag and archived.

Disposable plastic bags with separate pockets for the laboratory slip and specimen are available to minimize contamination of the laboratory slips.

9.3.3 Storage

Specimens should be stored in a secure, well-organized area and should be segregated from reagents. OSHA requires that the biohazard symbol be placed on storage areas containing all potentially infectious materials, including refrigerators or freezers.

9.4 Local Transport

Personnel who transport specimens must be trained in safe handling practices and in decontamination procedures in case of a spill. After primary containers are placed into externally uncontaminated secondary containers, they may be transported without gloves. If the outside of the specimen container is grossly contaminated, a new specimen should be requested. Within the laboratory, gloves should be worn when removing specimens from the secondary container and for all manipulations of the primary container.

9.5 Pneumatic Tube System

If specimens are transported via a pneumatic tube system, the primary and secondary containers should be tested and shown to be leakproof under the conditions present in the pneumatic system. If a spill occurs, it should be decontaminated according to the manufacturer’s instructions.

It may be inappropriate for some samples to be sent through a pneumatic tube system. This may include samples of increased volume, irreplaceable samples (e.g., biopsy), or flammable materials. Local policy
should be established to identify specimens that should never be transported through the pneumatic tube system.

9.6 Contamination and Breakage

Upon receipt in the laboratory, all specimens should be examined for visible contamination or breakage before being removed from the secondary container. Contaminated primary containers should be decontaminated or recollected before being sent to the work areas for testing, or the contents transferred to a clean container. Local policy should be developed for decontamination and clean up of these materials.

9.7 Shipping Specimens

Transportation of infectious agents from one laboratory to another facility is a closely regulated practice, because improper packaging may result in unsafe exposures of the public, and carriers and workers in the receiving facility to potentially significant pathogen or toxic agents and materials. The basis of requirements comes from three national and international authorities.

The International Civil Aviation Organization (ICAO), first created in 1944, is a specialized agency of the United Nations with representation of 188 states. ICAO has the mandate and authority to establish international standards and recommended practices (SARPs) addressing technical and operational aspects of international civil aviation, including safety, licensing, aircraft operations, airports, air traffic services, accident investigation, and the environment. ICAO standards are implemented worldwide, and are audited for compliance under the Universal Safety Oversight Audit Programme.

The International Air Transport Association (IATA) is an organization of the international airlines and their industry partners. IATA has the authority to establish guidelines of practice, and to create its Dangerous Goods Regulations (DRG), which is a “field manual” of the ICAO standards established by ICAO. The DGR is written and edited by airline dangerous goods experts, and may be stricter in the requirements than the ICAO Technical Instructions.

In most countries, a federal department or ministry is responsible for implementing the specific requirements for transportation. Domestic transport requirements are based in part on the standards and regulations of ICAO and IATA, but extend beyond to address the issues of transport on road, rail, and marine, as well as air. In each country, the federal department or ministry has final authority. In the United States, the authority lies with the Department of Transportation.

Hazardous materials are divided into nine classes. Infectious materials and diagnostic specimens are placed in Class 6, Division 6.2. Dry ice is placed in Class 9 and liquid nitrogen is in Class and Division 2.2.

Compliance with transport regulations for infectious agents requires ensuring that specimens and samples are classified and packaged correctly. Requirements for packaging are generally based on a three-container system, with the primary and secondary packages required to be watertight. Absorbency is required between the primary and secondary packages in case of accidental breakage and spill. The package system must meet the UN performance tests detailed by each regulatory authority identified above. All packages offered for transport must be capable of meeting conditions normal to transport.

For some packaging, for example when transporting cultures, the secondary container requires high integrity and protection against damage. For diagnostic samples, the packaging requirements are similar, but the performance test requirements are less stringent. The outer packaging usually consists of a sturdy fiberboard of sufficient size to accommodate the required labels and external markings on a single surface, without going over or around an edge.
Packages require other specific external markings to designate the contents and the inherent risk. This includes the designation of a UN number (UN 2814, “infectious substance affecting humans”; UN 2900, “infectious substance affecting animals; UN3373, “diagnostic specimen with no known serious human or animal disease”), and in some instances appropriate safety labels that include the international symbol for infectious substances (see figure). Packages may also require the creation of a waybill for tracking purposes.

![International symbol for infectious substances](image)

Dry ice, often essential for the transport of infectious agents, may, if improperly packaged, pose greater risk to transporters and the public than the agents which they are trying to protect. Dry ice, trapped within a sealed container, will turn to gas and expand creating pressure often with explosive force. Additionally, in confined spaces, release of carbon dioxide can be potentially hazardous to the breathing of transport workers.\(^4^1\) It is a requirement to report the use of dry ice with all packages.

It is mandatory in the United States that all laboratory personnel who ship infectious material be certified as knowledgeable about packaging requirements and that the certification is based upon a training program (see 49 CFR, 172.700). It is the responsibility of the employer, and not the trainer, to certify that the person is knowledgeable. Under IATA regulations, recertification is required yearly for packaging for air transport and every second year for all other modes of transport. In the United States, the Department of Transportation only requires recertification every three years. If “diagnostic specimens” are the only material transported, lesser training requirements are specified (49 CFR 173.199).

The shipment of specimens can be a complex task. Studies concerning the compliance of laboratories and other packagers of infectious agents indicate that not all facilities are always in compliance.\(^4^2\) International surveys have indicated that not all packages comply with packaging requirements. While there are many reports of worker safety being compromised by the transport of waste materials containing infectious agents,\(^4^3\) examples of transport workers or the public harmed by the transport of improperly packaged samples or cultures are difficult to find. However, laboratorians have the responsibility to ensure public safety with the transport of any and all materials that leave the confines of their facility. Packages that are improperly packaged that result in leakage of liquid onto another surface can result in activation of security protocols, cause considerable disruption of workflow, and potentially result in significant fines and penalties.

More specific information on packaging requirements can be obtained through the U.S. Department of Transportation Hazardous Materials Regulations (Title 49 CFR Parts 100-185) (http://hazmat.dot.gov/rules.htm).

Penalties for inappropriate or inadequate compliance may be applied to both the individual as well as to the institution. For reasons of safety, due diligence, and liability, it is strongly recommended that institutions be aware of the local regulatory requirements, and ensure packaging of all cultures and diagnostic samples is performed or checked by an individual whose certification is current.

A list of organizations that can provide training is available through the Office of Hazardous Materials Safety (http://hazmat.dot.gov/thirdpty.htm), although it is important to be aware that the OHM does not endorse, validate, and review any organizations listed.

9.8 Areas Needing Special Attention

9.8.1 Blood Banks and Transfusion Services

Blood banks and transfusion services should follow standard precautions when processing blood.

- Healthcare facility blood bank/transfusion workers should be alert when handling returned units of blood, which may have an unsheathed needle attached to the tubing. The needle should be removed at the point of use, by clamping or tying the tubing and then disposing of it into a sharps container.

- The empty blood bag should be placed into a secondary container labeled with the biohazard label (e.g., a self-sealing plastic bag) on the ward before being returned to the blood bank. Plastic bags should be sent from the blood bank to the ward with the blood to facilitate proper return. Tubing returned to the blood bank with the needle attached should be heat-sealed, clamped, or tied and then cut and the needle discarded.

- Blood bank/transfusion workers who draw blood from patients for therapeutic purposes or from patients for autologous transfusion should wear gloves and a gown or laboratory coat during the procedure.

9.8.2 Microbiology Laboratories

Microbiology laboratories are accustomed to handling infectious specimens and cultures. Routine microbiological techniques, in addition to standard precautions, are generally sufficient for protection of the workers. Aerosol-producing manipulations of highly infectious agents should be performed in a BSC. See Appendix A for BSL2 standard and special practices and procedures.

Special care is needed when entering bottles of inoculated media with a needle and syringe, as well as removal of the needle and syringe, because a positive differential pressure may exist between the contents of the bottle and the atmosphere, and spraying of the contents may result. To contain spraying, the procedure should be performed in a BSC or behind a shield.

Regardless of the system, all blood culture collections require a phlebotomy procedure, either using a “needle and syringe” or a “vacuum draw” apparatus according to the manufacturer’s recommendations. (For detailed recommendations regarding the collection of blood cultures, see Blood Cultures III Cumitech 1B, 1997, American Society for Microbiology, Washington, DC.) Both procedures can be associated with the risk of needlestick injury. Injuries occur especially during the process of inoculating the bottle, resheathing the needle, and needle disposal. The blood bottle should not be hand-held but rather be secured in a device that secures the bottle to permit easy entry and removal of the needle. Resheathing of the needles is strongly discouraged, and the use of approved, safe sharps disposal containers is strongly encouraged.

Microbiology laboratories may receive specimens in a needle attached to a syringe. This procedure should be discouraged. The needle should have been removed and the syringe recapped after obtaining the specimen. Extreme caution should be used while inoculating media and preparing slides. After expressing the sample, the needle and syringe should be discarded as a unit into a sharps container.
NOTE: Unfixed slides may contain infectious material.

9.8.3 Cytology Laboratories

Cytology laboratories may receive aspirates and fine-needle biopsies in a syringe with needle attached. The needle should be resheathed using a one-handed technique by the person obtaining the specimen. Upon receipt in the laboratory, the contents of the needle should be expressed onto a slide contained on a tray or holder. Further processing of the aspirate must be carried out following standard precautions. The needle may then be resheathed using a one-handed technique (see Section 9.9.3), removed, and discarded into a sharps container labeled with the biohazard symbol if a reusable syringe is used. If a disposable syringe is used, the entire needle and syringe assembly should be discarded without removing or resheathing the needle. An alternative approach is to prepare the slides at the specimen collection location, eliminating the need to transport the needle to the laboratory.

9.9 Disposal of Needles and Sharps

Needles, scalpel blades, skin lancets, bleeding-time devices, and any other sharps that can easily puncture the skin should be handled with extreme caution. Clinical HBV infection and HIV seroconversion have been reported after skin puncture with contaminated needles.

9.9.1 Disposal

Used, disposable needles and other sharps should be placed into a rigid, puncture-resistant, disposable container with a lid and a prominent biohazard label (sharps container). Disposable syringes with attached needles should be disposed of as one unit without separation of the needle from the syringe. The sharps container should be easily recognized (e.g., red) and clearly marked as a biohazard. Rigid plastic, metal, or stiff paperboard (cardboard) should be used. If paperboard containers are used, they should be of at least 0.015 gauge. Sharps containers with integral devices that facilitate removing needles from evacuated blood tube adapters without handling the needle are available from many manufacturers.

Sharps containers should be readily available in the laboratory. In addition, a sharps container should be on each phlebotomy tray. The containers should be at a level where the top opening can be seen, should not be filled above the “fill line,” and needles should not project from the top of the container. To discard the containers, close and seal the lid without shaking before discarding into the biohazardous waste.

9.9.2 Resheathing

Needles should not be resheathed, bent, broken, crimped, or manually cut. Needles should not be removed from disposable syringes; the syringe with the needle in place should be discarded.

Many types of needle protection devices are available that protect the needle after use and which eliminate the requirement to resheathe the needles. Their use, if feasible, is recommended.

If needles must be resheathed, a one-handed technique is used (see Section 9.9.3).

9.9.3 One-Handed Technique for Manual Removal or Resheathing of Needles

If a needle must be removed from a syringe, gloves should be worn and immediately discarded if they become contaminated with blood. A one-handed technique may be used to remove the needle, such as with a sharps container that has an integral device that enables one to remove the needle without having to touch it. Any recapping device that requires the use of two hands, one holding the needle and syringe/adapter and one holding the resheathing device, should NOT be used, as the chance of accident is high.
See Sections 9.8.2 and 9.8.3 concerning microbiology specimens and fine-needle aspirates contained in needles.

If manual removal is necessary, the following one-handed procedures may be useful:

- **Needle removal** using a commercially available sharps container that has a slot in the top to be used to unscrew the needle from the adapter. After phlebotomy, the adapter with needle attached is inverted using one hand and the needle guided into the slot. The adapter is rotated counter-clockwise, and the needle drops into the sharps container. Do not hold the sharps container during this maneuver.

- **Resheathing needles** can be done with another one-handed procedure by placing the needle sheath on a nearby convenient flat surface after it is removed from the needle with the opening facing the phlebotomist. After the needle is withdrawn from the vein, the sheath is speared holding the adapter with only one hand (Figure 1). The sheath should not be held during this procedure. Once the needle tip is in the sheath, the sheath may be firmly secured and the sheathed needle removed and discarded.

![Figure 1. One-handed Technique for Resheathing Needles](image.png)

Commercial sharps containers are available which hold the sheath in a convenient position for one-handed resheathing.

Small, plastic needle sheath holders intended to hold a sheath during phlebotomy are commercially available.

**Inexpensive single-use needle adapters and needles with integral adapters are available.** Correct use will obviate the need to remove the needle after use. Many types of needle protection devices are available that protect the needle after use and eliminate the requirement to resheathe the needles. Their use is preferred and recommended, and is required in the U.S.
10 Anatomical Pathology

10.1 The Autopsy

10.1.1 General Considerations

The autopsy should be carried out with adequate assistance. The prosector should be alert, not fatigued, and should take particular care not to rush through the procedure. If more than one autopsy table is in the morgue, the table with the lowest traffic should be used for autopsies known to involve communicable diseases.

All autopsies should be considered to be infectious, and standard precautions should be followed. The entire autopsy suite and its contents should be designated as a biohazardous area. The autopsy suite should be posted with a biohazard sign listing the biohazards and the required precautions. In some jurisdictions, a dedicated autopsy suite is reserved for cases involving high-risk infectious agents.

The guidelines that follow should be used for all cases and are considered suitable for autopsies on individuals infected with HIV, HCV, or HBV. The goal should be to obtain the maximum useful information from the autopsy while minimizing exposure risk to the autopsy team. It should be emphasized that the transmission of HBV or HIV has been documented from accidental inoculation at an autopsy or during embalming.

It may be desirable to collect blood, cerebrospinal fluid, other body fluids, and tissues for the detection of HIV antibodies, HIV antigen, HIV DNA by PCR, or HIV culture. Some states and organizations require specific consent from the individual authorizing the autopsy. In the absence of such a restriction, it is standard practice to obtain body fluids and tissue for culture, or for chemical and immunological examination.

Autopsy rooms should be under negative pressure with respect to adjacent areas, provide at least 12 air exchanges per hour, and be exhausted directly to the outside of the building. If these conditions cannot be met, the use of ultraviolet germicidal irradiation and recirculation of air within the room through HEPA filters should be considered.

10.1.2 Fixatives

Ten percent formalin (3.7% formaldehyde) present in at least ten times the volume of tissue, which has been properly sectioned and adequately permeated, will inactivate all important infectious agents except the agent of Creutzfeldt-Jakob disease (CJD). Embalming fluid containing glutaraldehyde is similarly effective.

Central nervous system tissues pose the greatest risk of transmitting CJD agent, and the autopsy of suspected CJD patients should be restricted to brain removal. The brain can be double-bagged and placed in a plastic container for freezing, or it can be fixed in 3.7% to 4% formaldehyde. Before slide preparation, small blocks of tissue (<5 mm thick) are soaked in 95% to 100% formic acid for one hour, followed by soaking in fresh 4% formaldehyde for at least 48 hours. For tissues and fluids not associated with the central nervous system, standard precautions are adequate to protect against occupationally acquired CJD infection. See Appendix D.

Decontamination after an autopsy should utilize an appropriate chemical germicide for the agent(s) suspected to be present, e.g., HBV, HCV, HIV, CJD agent (see Appendix D), or M. tuberculosi.
10.1.3 Preparation

Preparation of the body should follow standard precautions.

- The handling of all intravenous lines, nasogastric tubes, endotracheal tubes, catheters, electrical impulse devices, soiled bandages, and clothing should follow the institutional policy and standard precautions.

It is common practice to leave all IVs, tubes, catheters, etc. inserted in the body to allow the pathologist a full clinical appreciation of the therapeutic measures in use at the time of death. These lines should be clamped or tied at the bedside before transporting the body to the morgue. Morgue personnel should be extremely cautious when removing these devices.

Alternatively, these items may be removed and discarded at the bedside.

- All open lesions, cut-downs, and unnatural openings in the skin should be bandaged.

- The genitalia should be covered with a sanitary napkin if oozing is present.

- If rectal sphincter tone has relaxed, the anus should be covered with a sanitary napkin.

- The body should be covered with a plastic shroud or placed in a leakproof body bag for transportation to the morgue.

- For potential CJD or other prion agent cases, the autopsy table and other surfaces should be covered with disposable, fluid-impervious covers to minimize contamination.34

10.1.4 Morgue Personnel

Morgue personnel should receive specific training and retraining at regular intervals. Special attention should be paid to the management of accidental injuries (see Section 11).

Personnel present during an autopsy should be limited to a prosector, an assistant (if desired), and a circulator (if available). Standard precautions and good laboratory practices should be followed. If observers are permitted at an autopsy, they should observe all required precautions.

Persons with uncovered wounds or dermatitis should not actively be engaged in the autopsy unless the nonintact skin can be completely covered with a water-impermeable, occlusive dressing or other acceptable barrier (e.g., gloves).

If a worker has an immunosuppressive disorder or must take medication that produces immunosuppression, consultation should be sought and specific permission should be obtained from the institutional employee health service and/or the employee’s personal physician for the employee to work in the morgue.

Many HIV-infected individuals may also be infected with HTLV I/II, HBV, or HCV, and most are infected with cytomegalovirus (CMV). Aside from the potential risk to the fetus should the mother be infected with HIV, pregnant women should be aware of the potential hazard of HBV and CMV infection to the fetus. Pregnant employees should not be arbitrarily excluded from participating in autopsies; however, they should voluntarily consent to participate after having been adequately counseled.
10.1.4.1 Circulator

The circulator is a trained individual who remains uncontaminated, assists the prosector, and generally facilitates the performance of the autopsy, while limiting any contamination of the autopsy room, equipment, and containers. The circulator:

- prepares the room and equipment for the autopsy;
- assists in photography, as well as collection of specimens and cultures to avoid contamination of equipment not on the autopsy table;
- acts as a communicator, making all telephone or written communications and recording data during the autopsy. A foot-activated recorder should be used if dictation is done in the autopsy room. The use of speakerphones will avoid contact with the telephone; and
- should wear protective clothing, including a gown and gloves. If these become contaminated, they should immediately be changed.

10.1.5 Personal Protective Equipment

Barriers are especially important during an autopsy because of the exposure of personnel to large amounts of blood and the high frequency of accidents. The following protective devices, all of which should be disposable or easily decontaminated, are recommended for persons participating in the autopsy:

- Caps or hoods that completely cover the hair.
- Facial protection is best provided by a plastic face shield covering the entire face and neck region. If a face shield is not used, eye protection (e.g., goggles with a plastic cushion seal) and a fluid-resistant mask (N-95 particulate respirator) should be used. Ordinary prescription glasses are not adequate protection.
- An N-95 particulate respirator or other respirator (e.g., N-99, N-100, powered air-purifying respirator) should be worn for all autopsies to prevent inhalation of airborne microorganisms (see Section 6.2.3).
- Protective clothing — long-sleeved, fluid-resistant jump suits that cover the body from neck to feet are preferred. These are available made of spun plastic. Fluid-resistant, launderable, cloth surgical gowns as used in operating rooms together with surgical scrub shirts and pants are adequate. Fluid-proof aprons should be worn over any fluid-resistant clothing.

The circulator and observers may wear surgical gowns.

If desired, fluid-proof plastic gowns or plastic sleeve covers are available to protect against soak-through of blood on the arms. Polyethylene gloves of elbow and shoulder length are available for similar purposes.

- Double gloves (see Section 6.2.1.4) are recommended by the working group. The outer glove should cover the cuff of the sleeve. The circulator may wear single gloves.

In the interest of safety, gloves that resist accidental puncture may be worn as the outer glove. Although tactile sensitivity is decreased, the added safety provided is substantial. Heavy neoprene, latex, nitrile, or butyl utility gloves intended to protect the hands from corrosive chemicals are available from chemical supply houses and vendors of laboratory safety supplies.
Similar heavyweight utility gloves may be obtained in stores that sell home cleaning and dishwashing supplies.

- Stainless steel mesh gloves will protect the prosector from large cutting objects (e.g., scalpels and bone edges) but do not offer protection from needlesticks. These should be used during hazardous portions of the autopsy such as: blind removal of the larynx, rectum, and pelvic contents; removal of the sternum, vertebrae, or calvarium; or other times when saws, chisels, or bone cutters are used. Other procedures requiring the use of cut-resistant gloves may be identified by a task analysis. The mesh gloves should be covered with latex gloves to provide slip resistance and protection from fluids.

Stainless steel gloves are available made of coarse chain-mail or of finely woven stainless steel fabric. The latter are almost as flexible as thin cotton gloves and are also available with plastic imbedded in the fingertips to protect against needlesticks.

- “Fish scaling” gloves made of cut-resistant fabric are available in sporting goods stores and are less expensive than stainless steel or “bullet-proof” gloves.

- Fluid-proof foot covers or protective boots.

10.1.6 Autopsy Procedures

Routine procedures may be modified as needed to diminish risks of contamination.

- Evisceration may be modified to avoid splashing of blood or blind dissection. For example, if a Rokitansky evisceration is used, the trachea may be transected and blind removal of the larynx omitted if the risk is considered too high. If blind evisceration of the pelvis and neck is performed, stainless steel mesh gloves should be worn.

A Virchow evisceration with the removal of individual organs may offer less opportunity for an accident or splashing of blood.

- A single scalpel should be the only sharp device present on the autopsy table. Disposable scalpels may be used to obviate blade changes. Only the prosector is allowed to use the scalpel. If it is necessary to change the scalpel blade during the autopsy, stainless steel mesh gloves should be worn or a scalpel-blade remover should be used. Some pathologists prefer to prepare six scalpels before the autopsy, so no blade changes will be needed during the autopsy.

If possible, the scalpel should be used only to open the skin. The rest of the autopsy should be performed by blunt dissection using blunt-tipped scissors.

If specimens must be collected with a needle and syringe, such as a cardiac puncture for blood culture, the needle and attached syringe should be discarded immediately after use. The needle should not be permitted to remain on the autopsy table. Standard precautions for needles should be followed. Culture bottles and toxicology containers should not be hand-held while introducing the specimen.

- Devices should not be passed by hand during the autopsy. All devices should be placed on the table, picked up only by the prosector, and returned to the table after being used. The prosector should announce in advance any movements that involve repositioning a sharp device. It may be convenient to use a magnet to pick up scalpels and needles when the gloves are wet to avoid slippage.

- All tissues and contaminated devices should be retained on the autopsy table. Any tissue that must be removed from the autopsy table (e.g., for photography) should be placed into a tray for transport within the morgue or placed into a container for storage or disposal.
• Stainless steel mesh gloves should be worn when working with bone. Latex gloves should be worn outside of the mesh gloves to give better slip resistance and resistance to fluids. TFE-fluorocarbon-coated gloves and leather glove covers have been developed to offer some puncture resistance.

• Bone saws should be fitted with a vacuum attachment to minimize dispersal of bone dust and fine droplets. An effective personal respirator should be worn when cutting bone on individuals who may have tuberculosis at the time of death to prevent inhalation of potentially infectious airborne particles (e.g., *M. tuberculosis*—see Sections 5.3.1 and 6.2.3). The saw may be wrapped in plastic with only the blade exposed in an effort to prevent the dispersal of bone dust by exhaust air from the motor. Bone surfaces should be wet with water prior to being cut to minimize dispersal of bone dust.

• The skull should be opened at the end of the autopsy to minimize exposure to airborne bone dust and droplets. In an effort to contain bone dust and spray, the entire head may be enclosed in a large plastic bag or box during the use of a bone saw to open the skull. Plastic head covers are currently available for use with aerosolized pentamidine. The bag/box is fitted over the head and neck, and the saw and hands are introduced through a large hole made in the bottom of the bag/box.

• In some jurisdictions, a dedicated set of equipment is used only for cases of suspected CJD/spongiform encephalopathy to avoid contamination of other sets.36

• When removing the sternum, jagged rib edges should be avoided. The cut ends of the rib cage should be covered with towels during the autopsy to prevent accidental scratches or cuts.

• Bone marrow specimens may be obtained from a cut rib by using hemostats to manually express the marrow contents. An alternate method for obtaining marrow from vertebral bodies or either the anterior or posterior iliac crests is to use a Jamshidi bone marrow needle. A rigid plastic shield may be fashioned to contain spatter when removing vertebral bodies.

• If the calvarium has been removed, the spinal cord may be removed from above with a spinal cord extractor to avoid the removal of multiple vertebral bodies. Since damage to the cord is possible, only experienced prosectors should attempt this procedure.

• Tissue specimens should be placed into fixative on the autopsy table. The outside of all specimen containers should be decontaminated before being removed from the autopsy table.

Any unfixed tissue or other specimen sent from the morgue to the laboratory for testing (e.g., culture or chemistry) should be placed into a sealed, leakproof container, which is placed into a sealable secondary container for transport. The specimen should be labeled as a biohazard.

• Frozen sections should not be cut on unfixed tissue unless there is a pressing need for public health reasons. If frozen sections are performed, see Section 10.2.2, Handling Surgical Specimens.

• Photography should be carried out with great care. Organs to be photographed should be placed into a pan for transport to the photography stand. The prosector should rinse his/her hands and cover them with a towel before leaving the autopsy table to arrange the organs, in order to avoid dropping blood on the floor or fixtures. The camera should be handled only by the circulator to prevent contamination. When photography is completed, the organs should be returned to the autopsy table or fixed, and the photography stand should be decontaminated using a hospital disinfectant.

Photographs may be taken at the autopsy table using a hand-held camera, or the tissue may be fixed before being photographed to avoid removing unfixed tissues from the autopsy table. Kaiserling’s solution may be used as a fixative to preserve tissue color.
• Large specimens (organs) should be cut into multiple thin slices (“breadloaved”) before fixation to ensure adequate permeation of fixative.

Organs and tissues that will be retained unfixed should be minimized. These should be placed into sealed, leakproof containers or sealable plastic bags. These, in turn, should be placed into a secondary, sealable, leakproof container.

All unfixed, retained material should be conspicuously labeled as a biohazard. When retained tissues have served their purpose, they should be incinerated on-site or shipped to a licensed off-site incineration facility or disposed of in accordance with state and local regulations pertaining to pathological and autopsy wastes.

Unfixed organs that are not to be retained should be placed into a plastic bag and returned to the body cavity at the end of the autopsy.

• At the end of the autopsy, the body should be sutured carefully with a sharp needle. When suturing the body wall, the skin flaps should not be held with the hands, as needlesticks are common. A large toothed forceps or toothed clamp should be used. The incision may be closed with surgical clips or staples.

• The closed body should be washed with a detergent solution, followed by an antiseptic solution or diluted household bleach, and rinsed with water before being covered with a leakproof shroud or body bag. OSHA requires that both the body tag and the shroud/bag should be labeled with a biohazard label stating the nature of the specific risk to alert the mortician to any potential biohazard. When autopsies are done on patients known to harbor blood-borne pathogens, the mortician should be notified directly.

• At the conclusion of the autopsy, the circulator may perform duties that bring him/her into contact with blood or contaminated surfaces. Under these circumstances, the circulator should use the barrier protection recommended for the prosector during the autopsy.

• Review of autopsy organs may, preferably, be done on fixed organs to minimize exposure to contaminated blood and tissues. Any review of unfixed autopsy specimens should be carried out using all of the recommended precautions as if a full autopsy was being performed.

• If reusable body bags are used, they should be decontaminated.

10.1.7 Decontamination (see also Section 6.4)

• The table and all pans, trays, buckets, etc. should be washed with a detergent solution, rinsed with water, wet thoroughly with a 1:10 or 1:100 dilution of household bleach or other suitable chemical germicide, and finally rinsed with water.

• Devices should be washed with a detergent solution, rinsed with water, and decontaminated with a 1:10 or 1:100 dilution of household bleach or other suitable chemical germicide. A brief exposure (ten minutes) should be sufficient; longer periods may corrode devices. Aluminum and stainless steel devices may require immersion in 2% aqueous glutaraldehyde, because sodium hypochlorite damages aluminum and stainless steel.

Scalpels with blades attached should be decontaminated before removing and disposing of the blade. Disposable or safety scalpels should be used whenever possible.
• Care should be taken at all times not to splash water, blood, or body fluids from the autopsy table. All drains, vacuum breakers, and vacuum lines should be clear to prevent back-up of liquids.

• All contaminated disposable clothing and supplies should be placed into a biohazard container for subsequent disposal or should be autoclaved in the laboratory prior to disposal. If reusable clothing, towels, etc. have been soaked with blood or are wet, they should be placed into a leakproof biohazard bag for transport. Dry, contaminated, reusable clothing should be placed in a labeled or color-coded bag and sent to the institutional laundry.

• All surfaces adjacent to work areas should be cleaned with a detergent solution, decontaminated, and flushed with water at the conclusion of the autopsy. This should include the floor and areas surrounding the autopsy table, the photography stand (and camera if contaminated), and areas used to change clothing.

• After the mortician has removed the body, the morgue cooler tray should be decontaminated.

• Reusable plastic aprons should be washed with a detergent solution, decontaminated, flushed with water, and dried after use.

10.2 Surgical Specimens

10.2.1 Personal Protective Equipment

All personnel who handle surgical specimens should wear gowns, aprons, and gloves. Double gloves should be worn by those who handle or dissect unfixed specimens. (See Section 6.2.1.4.) When large or bloody specimens are handled, facial barrier precautions should be followed, or the specimen should be processed in a BSC.

10.2.2 Handling Surgical Specimens

Surgical specimens, including placentas, should be placed into sealable, leakproof containers, sealable plastic bags, or fixative in the operating room. The primary container, including bottles of fixed tissue, should be placed into a secondary, outer, sealable, leakproof container before being transported to the laboratory. The laboratory requisition slip should be kept uncontaminated, preferably in a plastic bag. If the requisition becomes contaminated, it should be discarded and replaced. All surgical specimens are potentially infectious and should be handled with the appropriate PPE until fixed with a germicidal fixative or stained and covered.

Biopsies and smears taken in physicians’ offices and other remote sites should be handled using standard precautions and should be handled as described in this guideline.

• Frozen sections done on unfixed tissue pose a high risk, because accidents are common. Freezing of tissue does not inactivate infectious agents. Freezing propellants under pressure should not be used for frozen sections, as they may cause the spattering of droplets of infectious material. Gloves and an N-95 particulate respirator should be worn during frozen sectioning.

The contents of the cryostat should be considered to be contaminated and should be decontaminated frequently with 70% alcohol. The trimmings and sections of tissue that accumulate in the cryostat should be considered to be contaminated and should be removed during decontamination. The cryostat should be defrosted and decontaminated with a tuberculocidal hospital disinfectant once a week and after tissue known to contain blood-borne pathogens or M. tuberculosis is cut. Extreme care should be taken when handling microtome knives. Stainless steel mesh gloves should be worn.
when changing knife blades. Solutions used for staining frozen sections should be considered to be contaminated.

- Imprints, cytological smears, bone marrow preparations, and body fluid smears should be considered to be contaminated until fixed with a germicidal fixative (e.g., alcohol or formalin) or until stained and covered. Air-dried slides are infectious for a period of time after preparation.

- Routine specimens should be fixed as soon as possible. If unfixed specimens are to be retained, they should be placed into double, sealable plastic bags, and stored in a refrigerator or freezer labeled as containing a biohazard. The exteriors of all specimen containers should be considered to be contaminated.

- Body fluids are potentially infectious and should be handled using standard precautions. While decanting or fractionating large quantities of fluid, workers should wear double gloves, gowns, aprons, and facial protection (e.g., face shields). When the risk of substantial spatter or aerosolization is present, the procedure should be carried out in a biological safety cabinet to contain any spattered fluid. Safety centrifuge cups with sealable tops should be used for specimens containing airborne agents (e.g., *M. tuberculosis*).

- Teeth, calculi, implants, and foreign bodies should be handled as tissues. If they cannot be fixed, they should be stored in a double, sealable, leakproof container and labeled as a biohazard. Bone should be handled as recommended under the autopsy. Bone should be fixed before sectioning, if possible.

- Unfixed tissues for electron microscopy should be handled with proper barrier protection until they are adequately fixed.

### 10.2.3 Decontamination

The surgical dissecting area should be decontaminated in the same manner as the autopsy area (see Sections 6.4 and 10.1.7). The outside of all containers used to store fixed surgical specimens should be considered to be contaminated. Paraffin blocks and cover-slipped, fixed, and stained slides should not be considered to be infectious.

### 10.3 Autopsy Rooms

Autopsy rooms should be at negative pressure with respect to adjacent areas, and the room air should be exhausted directly to the outside of the building. ASHRAE recommends that autopsy rooms have ventilation that provides at least 12 air changes per hour. The effectiveness of this ventilation level has not been evaluated for reducing the risk of *M. tuberculosis* transmission. Other provisions could include recirculation of air within the room through HEPA filters or the use of ultraviolet germicidal irradiation. After performing an autopsy on a corpse with suspected or proven tuberculosis, allow adequate time for removal of *M. tuberculosis*-contaminated air before performing another procedure, or continue to wear respirators while in the room.
11 Management of Laboratory Accidents

11.1 Postexposure Management of Laboratory Accidents

All healthcare workers (HCWs) should be educated and counseled about the risk and prevention of the three most common blood-borne pathogens involved in occupational transmission—hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV), as well as other infectious agents—as part of job orientation and ongoing job training. The employee's understanding of the management of laboratory accidents should be documented (e.g., by written examination), and documentation should become part of the employee's personnel record. The essential components of postexposure management should include medical surveillance for all highly infectious agents, exposure reporting, wound management, evaluation of transmission risk, and consideration of postexposure prophylaxis (PEP). PEP is subject to change, and the reader is encouraged to seek the most recent recommendations. For a comprehensive review of the risk and management of blood-borne infections, the reader should refer to recent publications.46,47

11.1.1 Exposure Report

The incident must be reported to the supervisor, and the routine policies of the healthcare institution should be followed regarding reporting the incident. In the U.S., OSHA requires the recording of occupational exposure to blood or potentially infectious materials. The exposure report should include, if known:

- date and time of exposure;
- details of the procedure performed, including when, where, and how exposure occurred and with what type device. In the U.S., federal regulations require that the brand name of the device be recorded;
- details of the exposure, including route, body substance involved, volume, and duration of contact;
- information about the source person, including whether he/she is HIV-infected, the stage of disease, the history of antiretroviral therapy, antiretroviral resistance of the isolate, and the viral load status, if known;
- details about counseling, postexposure management, and follow-up; and
- details about the exposed person (e.g., HBV vaccination and vaccine response).

11.1.2 Exposure Management

The acute management of skin puncture or mucosal surface contamination should be routine first aid, consisting of washing the skin site with soap and water while permitting bleeding, and then, if appropriate, bandaging the site. Contaminated mucosal and conjunctival sites should be washed with large quantities of water. There is no evidence of benefit for application of antiseptics or disinfectants or squeezing (milking) puncture sites in the prevention of infection. Avoid the use of bleach and other agents caustic to skin.

11.1.3 Assessment of Infection Risk

The type and severity of an occupational exposure should be evaluated for transmission risk. The blood-borne status of the source person and the exposed HCW should be evaluated, including serologic testing of the employee for baseline status with follow-up testing (Table 8).
11.1.4 Postexposure Prophylaxis (PEP)

The routine practices of the institution regarding HBV and HIV prophylaxis should be based on current recommended guidelines.46,47 Authoritative sources should be reviewed periodically for any changes (http://www.cdc.gov).


<table>
<thead>
<tr>
<th>Infection status of source patient</th>
<th>Recommended serologic test at:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
</tr>
<tr>
<td>HIV-positive</td>
<td>HIV antibody testing using EIA*</td>
</tr>
<tr>
<td>HBsAg-positive</td>
<td>Anti-HBs if previously vaccinated against HBV and response to vaccination unknown</td>
</tr>
<tr>
<td>Anti-HCV-positive</td>
<td>HCV antibody testing using EIA†; ALT measurement</td>
</tr>
<tr>
<td>Unknown</td>
<td>HIV antibody testing using EIA; anti-HBs if previously vaccinated to HBV and response to vaccination unknown; HCV antibody testing using EIA; ALT measurement</td>
</tr>
</tbody>
</table>

* Confirmation by Western blot testing of all anti-HIV results reported as reactive by EIA.
† Confirmation by supplemental anti-HCV (i.e., recombinant immunoblot assay [RIBA]) testing of all anti-HCV results reported as repeatedly reactive by EIA.
‡ If earlier diagnosis of HCV infection is desired, testing for HCV RNA may be performed at four to six weeks.

11.2 Postexposure to HBV

Any HCW who performs tasks involving contact with blood, blood-contaminated body fluids, other body fluids, or sharps should be vaccinated with hepatitis B (HB) vaccine. In the standard protocol, the primary dose is followed by a second dose at one month and a third dose at six months after the primary dose.

Postvaccination testing for antibody to hepatitis B surface antigen response is indicated for HCWs who have frequent blood contact and are at risk for injuries with sharp instruments or needlesticks.

It is recommended that vaccination be completed during training in schools of medicine, dentistry, nursing, laboratory technology, and other allied health professions. Vaccinating trainees in these disciplines is especially important, because the risk of infection is often highest during the professional training period.
It is recommended that all laboratory workers be immunized to hepatitis B. The OSHA Federal standard requires employers to offer HB vaccine at no cost to employees who are occupationally exposed to blood or other potentially infectious materials. HCWs may decline vaccination but must sign a declination document.30

11.2.1 ACIP and HICPAC Recommended Practices

The Advisory Committee on Immunization Practices (ACIP) in consultation with Hospital Infection Control Practices Advisory Committee (HICPAC) recommends the following practices after percutaneous or permucosal exposure to blood.48

The use of immunoprophylaxis is conditioned by the hepatitis B surface antigen (HBsAg) status of the source patient and the HB vaccination status of the exposed worker. Following any exposure, if the source sample cannot be obtained, a blood sample should be obtained from the source patient. The source patient blood should be tested for HBsAg. The HB vaccination status and anti-HBs response status (if known) of the exposed worker should be reviewed.

For greatest effect, passive prophylaxis with hepatitis B immune globulin (HBIG) should be given as soon as possible after exposure. The value of HBIG beyond seven days is unclear. For any exposure of a worker not previously vaccinated, HB vaccination is recommended.46

11.3 Postexposure to HCV

The ACIP and HICPAC currently do not recommend postexposure prophylaxis after percutaneous exposure to blood of a patient infected with HCV.48 There are no data to support the use of immune globulin or antiviral agents (e.g., interferon) to prevent HCV infection.49

Occupational HCV postexposure follow-up should include the following recommendations50:

- baseline testing for anti-HCV and ALT activity;
- follow-up testing for anti-HCV (e.g., four to six months) and ALT activity. (For earlier diagnosis of HCV infection, HCV-RNA may be performed at two to six weeks.); and
- confirmation by supplemental anti-HCV testing of all anti-HCV results reported as positive by EIA.

To date, there are no data demonstrating the superiority efficacy of any intervention for the management of healthcare workers exposed to HCV. Two strategies, preemptive therapy and watchful waiting, have been recommended as interim approaches until a definitive management plan can be developed.49

11.4 Postexposure to HIV

Employers should make available to HCWs at risk of acquiring HIV a system that includes written protocols for prompt reporting, evaluation, counseling, treatment, and follow-up of occupational exposures. OSHA requires employers to establish an exposure-control plan, including postexposure follow-up for their employees, and to comply with incident reporting requirements.

Physicians who provide postexposure care should have access to PEP drugs for timely administration. Individuals responsible for providing postexposure counseling should be familiar with evaluation and treatment protocols and institutional procedures for obtaining drugs for PEP.

HCWs who are at risk of occupational exposure should be educated on the principles of postexposure management and the need to report exposures immediately after they occur. See current recommendations
for the management of HCWs who have occupational exposure to blood and other body fluids that may contain HIV.\textsuperscript{36,47}

11.4.1 Evaluation of Occupational Exposure and Need for PEP

11.4.1.1 Evaluation of Exposure: Determination of Exposure Type

- If the source material is blood, body fluid containing visible blood, other potentially infectious material, or if an instrument is contaminated with one of these substances, further evaluation is required.

- If any unprotected, direct contact to concentrated HIV in a research laboratory or production facility occurs, further clinical evaluation is required to determine the need for PEP.

- If mucous membrane or nonintact skin (e.g., dermatitis, abrasion, or open wound) is exposed, follow-up is indicated.

- If percutaneous exposure occurs, follow-up is indicated.

11.4.1.2 Evaluation and Testing of an Exposure Source

- If the source is HIV-seronegative, has no risk factors for HIV, and has no clinical evidence of acquired immunodeficiency syndrome (AIDS) or symptoms of HIV infection, no PEP for the exposed worker is needed.

- If the source is HIV-positive, initiation of PEP for the exposed worker, if indicated, should not be delayed.

  — HIV antibody testing (EIA) of a source should be performed as soon as possible. An FDA-approved, rapid HIV-antibody test should be considered, particularly if testing by EIA cannot be completed within 24 to 48 hours.

  — Direct virus assays (e.g., HIV p24 antigen EIA or PCR for HIV RNA) to detect infection in exposed HCWs are not recommended.

  — Other laboratory test results (e.g., prior HIV testing, HIV PCR, HIV p24 antigen, CD4+ T-cell count), clinical symptoms, and history of possible HIV exposures in a source patient should be considered.

- If the source serostatus is unknown, the source person should be informed of the incident, and if consent is obtained, tested for HIV antibody. If consent cannot be obtained, procedures should be followed for testing according to institutional policy, and local and regional regulations.

- If the source is unknown, the setting where the exposure occurred should be assessed for risk for HIV transmission.

11.4.1.3 Clinical Evaluation and Baseline Testing of Exposed HCWs

- Baseline testing for HIV antibody should be performed at the time of exposure.

  — If the source person is seronegative for HIV and has no risk factors for HIV, further follow-up is not needed.
• The clinical evaluation should include a history of the HCW’s current or underlying medical condition for PEP considerations.

• Pregnancy testing should be available to all nonpregnant women of childbearing age whose pregnancy status is unknown.

11.4.2 Recommendation for HIV PEP

Considerations for using PEP should be based on the potential risk for HIV transmission and the toxicity of the drugs used. Most occupational HIV exposures do not result in the transmission of HIV, and the potential toxicity of PEP treatment regimens must be carefully considered. When possible, these recommendations should be implemented in consultation with persons having expertise in antiretroviral therapy and HIV transmission.

11.4.3 Follow-up of HCWs Exposed to HIV

All HCWs with occupational exposure to HIV should receive follow-up counseling, postexposure testing, and medical evaluation, regardless of whether they receive PEP.

11.4.3.1 Antibody Testing (Table 8)

• HIV antibody testing should be performed for at least six months postexposure (e.g., at six weeks, 12 weeks, and six months).

• HIV testing using EIA should be performed on any HCW who has an illness that is compatible with acute retroviral syndrome (e.g., fever, rash, flu-like illness).

• HIV antibody testing using EIA should be used to monitor for seroconversion.

11.4.3.2 Counseling and Education

The emotional and psychological impact of an occupational HIV exposure may be substantial; therefore, supportive counseling should be an important part of management.

• Exposed HCWs should be advised of the potential drug interactions and side effects of PEP drugs.

• Exposed HCWs should be advised of measures to prevent secondary transmission during the follow-up period, especially during the first six to 12 weeks after the exposure (i.e., sexual abstinence or condom use; no blood, semen, or tissue donation).

• Exposed HCWs should be advised to seek medical evaluation for any acute illness (e.g., fever, rash, flu-like symptoms) that occurs during the follow-up period.

• HCWs who are breast-feeding should be counseled about the risk for HIV transmission and drugs passing through breast milk.

11.4.4 HIV PEP Resources and Registries

Clinicians who seek consultation on HIV PEP for assistance in managing an occupational exposure should assess local experts in HIV treatment. In addition, see Table 9 for the National Clinicians’ Postexposure Prophylaxis Hotline as well as other resources which have been created to assist clinicians with these issues.
Table 9. HIV Postexposure Prophylaxis Resources and Registries

<table>
<thead>
<tr>
<th>Resources or registry</th>
<th>Contact information</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Clinicians’ Postexposure Hotline (PEPline)</td>
<td>Ph: (888) 448-4911</td>
</tr>
<tr>
<td>Antiretroviral Pregnancy Registry</td>
<td>Ph: (800) 258-4263 Fax: (800) 800-1052 Write: 1410 Commonwealth Drive Suite 215 Wilmington, NC 28405</td>
</tr>
<tr>
<td>CDC (for reporting unusual or severe toxicity to antiretroviral agents)</td>
<td>Ph: (800) 332-1088</td>
</tr>
<tr>
<td>CDC (for reporting HIV seroconversions in HCWs who received PEP)</td>
<td>Ph: (800) 893-0485</td>
</tr>
<tr>
<td>Division of Healthcare Quality Promotion</td>
<td><a href="http://www.cdc.gov/ncidod/hip/blood/exp_blood.htm">http://www.cdc.gov/ncidod/hip/blood/exp_blood.htm</a></td>
</tr>
</tbody>
</table>

11.5 Postexposure to Other Laboratory-Associated Infectious Agents

Despite improved control measures (engineering control, work practice modification, and personal protection equipment), laboratory personnel remain at risk for acquiring laboratory-associated infectious agents. The cases of fatal meningococcemia in clinical laboratory workers underscore the potential risks of handling clinical samples and cultures. In addition to percutaneous inoculation, other routes of acquiring infection include aerosolization, direct skin contact, splash to mucous membranes, and multiple modes of transmission. Microorganisms likely to cause infection in hospital laboratory workers, modes of transmission, and appropriate control measures for preventing infections have recently been reviewed. Medical surveillance of laboratory personnel can help ensure that workers who are at risk and develop clinical symptoms receive appropriate medical care. Personnel at risk should immediately contact their supervisors in the event of a recognized exposure or development of symptoms associated with infection by a particular agent.

11.5.1 Prevention

The current CDC guidelines on immunization of healthcare workers provide recommended practices for hospital workers, including laboratory personnel. Specific recommendations for vaccination of laboratory workers in high-risk situations are listed in Table 10. Vaccination, however, should not be an alternative to good laboratory practices when handling specimens and cultures.

11.5.2 Postexposure Treatment and Prophylaxis

Instructions for general first aid, specific treatment, prophylaxis, and counseling should be included in the laboratory safety and procedure manual. Immediate care should be directed toward removal of the infectious material and the institution of first aid. General care for direct contact of potentially infectious material should consist of washing the site of contact with soap and water. For contaminated mucosal and conjunctival sites, flush with large quantities of water. An antiseptic mouthwash can also be used for oral contamination. Specific recommendations for exposure treatment and prophylaxis depend on the infectious agents and the assessment of the potential risk of infection.

11.5.3 Surveillance and Follow-Up

Accident reports should be filled out according to institutional policy and format, no matter how inconsequential the accident or injury may be. The employee should inform his or her supervisor of the accident, document the incident, and seek medical evaluation by an occupational health practitioner or private physician. The immediate reporting of the accident will help establish a time relationship if
infection develops, and will allow preventative measures to be taken. Follow-up of the accident report data is also important to identify common patterns, eliminate risk factors, and develop a correct action plan to prevent or minimize future incidents.

Table 10. Immunization Available for Laboratory Workers in Special Circumstances (Modified from CDC. MMWR. December 26, 1997;46[RR-18]:1-42).

<table>
<thead>
<tr>
<th>Generic name</th>
<th>Primary/booster dose schedule</th>
<th>Indications</th>
<th>Major precautions/contraindications</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG vaccine (tuberculosis)</td>
<td>One percutaneous dose of 0.3 mL; no booster recommended</td>
<td>Not routinely indicated. Laboratory personnel who process large volumes of specimens from which <em>M. tuberculosis</em> is isolated or high proportion of <em>M. tuberculosis</em> resistant to isoniazid and rifampin</td>
<td>Immunocompromised state and pregnancy</td>
</tr>
<tr>
<td>Hepatitis A vaccine</td>
<td>Two doses IM, either 6-12 mo apart or 6 mo apart</td>
<td>Not routinely indicated. Laboratory personnel who work with HAV-infected primates or with HAV in a research setting</td>
<td>History of anaphylactic reaction to alum or the preservative 2-phenoxethanol; vaccine safety in pregnant women has not been evaluated—risk to fetus is likely low and should be weighed against the risk of hepatitis A in women at high risk.</td>
</tr>
<tr>
<td>Meningococcal polysaccharide vaccine</td>
<td>One dose in volume and by route specified by manufacturer; need for boosters is unknown</td>
<td>Not routinely indicated. Research, industrial, and clinical laboratory personnel who are likely to encounter meningococcal isolates may have increased risk of infection and should consider vaccination.</td>
<td>Vaccine safety in pregnant women has not been evaluated; vaccine should not be given during pregnancy unless risk of infection is high.</td>
</tr>
<tr>
<td>Polio vaccine</td>
<td>IPV, two doses SC given 4-8 wk apart, followed by 3rd dose 6-12 mo after 2nd dose; booster may be IPV or OPV</td>
<td>Laboratory personnel handling specimens that may contain wild poliovirus</td>
<td>History of anaphylactic reaction after receipt of streptomycin or neomycin; safety in pregnant women has not been evaluated.</td>
</tr>
<tr>
<td>Rabies vaccine</td>
<td>Primary, HDCV or RVA, IM, 1.0 mL (deltoid area) one each on days 0, 7, 21, and 28, or HDCV, ID 1.0 mL, one each on days 0, 7, 21, and 28; booster, HDCV or RVA, IM, 0.1 mL (deltoid area), day 0 only, or HDCV, ID, 0.1 mL, day 0 only.</td>
<td>Laboratory personnel who work with rabies or infected animals in diagnostic or research activities</td>
<td>The frequency of booster doses should be based on frequency of exposure.</td>
</tr>
<tr>
<td>Generic name</td>
<td>Primary/booster dose schedule</td>
<td>Indications</td>
<td>Major precautions/contraindications</td>
</tr>
<tr>
<td>--------------</td>
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</tr>
<tr>
<td>Tetanus and diphtheria (Td) vaccine</td>
<td>Two doses IM 4 wk apart; 3rd dose 6-12 mo after 2nd dose; booster every 10 yr</td>
<td>All adults; tetanus prophylaxis in wound management</td>
<td>First trimester of pregnancy; history of a neurological reaction or immediate hypersensitivity reaction. History of (Arthus-type) reaction after previous dose of Td vaccine—should not be given further routine or emergency doses of Td for 10 yr</td>
</tr>
<tr>
<td>Typhoid vaccine (IM, SC, and oral)</td>
<td>IM vaccine: One 0.5-mL dose, booster of 0.5-mL every 2 yr. (Vi capsular polysaccharide) SC vaccine: Two 0.5-mL doses, ≥ 4 wk apart, booster 0.5 mL SC or 0.1 ID every 3 yr if exposure continues. Oral vaccine: Four doses on alternate days (Ty21a); vaccine manufacturer’s recommendation is revaccination with the entire four-dose series every 5 yr.</td>
<td>Personnel in microbiology laboratories who frequently work with Salmonella typhi</td>
<td>Severe local or systemic reaction to a previous dose of typhoid vaccine; Ty21a vaccine should not be given to immunocompromised personnel or individuals receiving antimicrobial agents</td>
</tr>
<tr>
<td>Vaccinia vaccine (smallpox)</td>
<td>One dose administered with a bifurcated needle; boosters every 10 yr.</td>
<td>Laboratory personnel who directly handle cultures of or animals contaminated with recombinant vaccinia viruses or orthopox viruses that infect humans</td>
<td>Pregnancy, presence or history of eczema, or immunocompromised status in potential vaccines or in their household contacts</td>
</tr>
</tbody>
</table>

HDCV, human diploid cell rabies vaccine; RVA, rabies vaccine absorbed; IPV, inactivated poliovirus vaccine; OPV, oral poliovirus vaccine; ID, intradermally; IM, intramuscularly; SC, subcutaneously

12 Protection from Laboratory Instruments and Test Equipment

This section deals with potential infectious hazards facing the users of laboratory test equipment. The list of users encompasses healthcare professionals (laboratory personnel, physicians, nurses, and students, etc.); industrial workers (manufacturing personnel, repair workers, and refurbishers); and research staff.

The biohazards as described in previous chapters are the same, except they may be encountered in differing ways. Infectious specimens and samples, including blood, body substances, tissues, and in-laboratory working materials can contaminate equipment on contact. In this section we inform the reader of potential device biohazards and ways to avoid them. We discuss design safety considerations that must be incorporated in new devices and their operations. The consequences of exposure to the infectious agents may be a serious health hazard, and a working knowledge of how to protect oneself is vital.

Laboratory equipment can be contaminated in many different ways and by many different agents. This guideline will utilize the hepatitis B virus (HBV) and the human immunodeficiency virus type 1 (HIV-1), as well as other agents as examples.
12.1 Prevention of Accidental Injuries

Take extraordinary care to avoid accidental injuries caused by laboratory instruments when performing test procedures, cleaning instruments (e.g., sample and liquid-level sensor probes), and handling sharp instruments. Engineer and work practice controls should be utilized to minimize the risk of sharps-related injury.

**NOTE:** No needles should be used in the laboratory, except for phlebotomy or where there is no other alternative. Laboratories should implement policies that strongly discourage submission of aspirated samples to the laboratory within a needle and syringe.

12.2 Specimen Preparation

Specimen separation and concentration should be done in a way to minimize contamination of the worker, the workspace, and the environment. For details, see Section 6, Protection Techniques.

12.2.1 Centrifugation

All centrifuges should have lockable lids that should be secured while the rotor is moving. In normal use, when there is no tube breakage, airborne particles (aerosol or droplets) may be generated during centrifugation. Tubes should be properly capped and sealed before insertion into the centrifuge. Care must be taken when opening the tubes. Preferably, to reduce the risks associated with aerosols, all centrifuges should be equipped with sealed rotors or safety cups. Sealed rotors or safety cups should be used for processing highly concentrated or large volumes of infectious agents that are spread by airborne transmission (see Section 5.3). Sealed rotors or safety cups should be opened inside a BSC after centrifugation is complete. Where safety cups and/or sealed rotors cannot be used, the centrifuge should be placed in a containment device or BSC designed for this purpose, since the motor may produce strong air currents and turbulence that may disrupt the laminar airflow. (See Appendix B.)

12.2.1.1 Plastic Tubes

Plastic centrifuge tubes with seal-forming screw tops should be used whenever possible. Plastic tubes should be closely examined for cracks or imperfections prior to use. While they may remain structurally intact, they may leak, resulting in contamination.

12.2.1.2 Glass Tubes

All glass tubes should be inspected before being used; cracked or scratched tubes should not be used, as these may break during centrifugation.

12.2.1.3 Overflow

To avoid spills, tubes should not contain a volume that will overflow during centrifugation.

12.2.1.4 Tube Breakage

If a tube breaks or leaks in the centrifuge, the rotor lid should be left closed or immediately be reclosed for at least a half hour to allow fine droplets to settle. The operator should don appropriate personal protective equipment, the lid should then be opened, and the broken glass carefully removed by using a hemostat or another device. Any remaining intact tubes removed from the unit should be considered contaminated and should be decontaminated accordingly. The chamber should be disinfected prior to further work.
12.2.2 Sedimentation and Filtration Equipment

Sedimentation and filtration equipment should be set up so that it is stable and not prone to tip over. A mechanical vacuum pump with an in-line, liquid disinfectant trap should be used. The filter material and liquid trap contents should be considered hazardous and disposed of accordingly.

12.2.3 Vacuum Pumps

If a mechanical vacuum apparatus is used, it should be connected to a liquid disinfectant trap with a hydrophobic filter to collect any contaminated aerosols. All the components should be decontaminated after disposing of the contents.

12.2.4 Dialysis Apparatus

Extreme care should be used when handling dialysis apparatus (e.g., ultrafilters, bags, presses, etc.) to concentrate infectious agents. All used filter membranes should be considered potentially infectious and discarded accordingly.

12.3 Aliquoting and Transfer

Care should be taken during transfer or aliquoting operations to avoid aerosol production and splashes. Pipette tips should be positioned at or below the surface to reduce aerosol formation. It may be necessary to place the device in a biological safety cabinet to contain aerosols. Point tubes away from the face when removing caps, or remove caps behind splashguards.

12.3.1 Transferring to Tubes When Syringe and Needle are Used

Syringe method of drawing venous blood is not recommended, since it is much safer to use a closed venous blood collection system. If no alternative is feasible and it is necessary to use a syringe, proceed with the following recommendations to transfer the blood from a syringe to a blood collection tube:

- Use the same “order of draw” as for an evacuated tube system (see CLSI/NCCLS document H3—Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture for more information).
- Rubber stoppers should not be removed from evacuated tubes to transfer blood to multiple tubes.
- To transfer blood from the syringe to an evacuated tube, use a safety syringe shielded transfer device or carefully remove the winged blood collection set and attach a 19- to 21-gauge sterile needle, if needed.
- The safety syringe shielded transfer device is used with the tube, or the tube is attached to a device designed to transfer blood from a syringe to evacuated tubes.
- To avoid accidental needlestick, the tube must not be held with the hand when inserting the needle. Great care should be exercised when removing the needle.
- The stopper is pierced with the needle, and the tube is allowed to fill (without applying any pressure to the plunger) until flow ceases. This technique helps to maintain the correct ratio of blood to additive if an additive tube is being used.
- Mix additive tubes by inversion.
To avoid spills, specimen cups should not be overfilled. Specimen cups should be filled using a mechanical transfer device and not filled by pouring the sample from a primary container into the cup.

Care should be taken to assure that all disposable pipettes and pipette tips that are contaminated or potentially contaminated during the process of aliquoting are disposed of into a container designated for contaminated waste.

12.4 Storage and Retention of Specimens and Microorganisms

Specimens should be stored separately from reagents. The specimen containers, refrigerators, and freezers used for the storage specimens should be clearly marked with the universal biohazard symbol. Food should never be stored with specimens. Specimens should be stored in a secure, well-organized, and separate area with restricted access.

Tubes and vessels containing specimens should be placed in appropriate racks or other devices to maintain them upright. They should not be laid on their sides.

Organisms of elevated risk should be kept in a clearly identified separate area.

12.4.1 Room-Temperature Storage

Samples maintained at room temperature in the work area should be capped and placed in a suitable rack that will prevent breaking and spilling. Samples should be stored away from high-traffic areas to prevent accidental spillage.

12.4.2 Refrigerator Storage

Refrigerated samples should be capped/covered and placed in a suitable rack that will prevent breaking and spilling. Refrigerators should be easy to clean in a safe manner. Surfaces should be smooth, seam-free, and preferably of unit construction, with each section easily accessible.

The defrost system, including the water tray, a potential source of laboratory contamination, should be easily accessible and cleanable. A regular cleaning schedule for refrigerators and freezers should be established.

12.4.3 Freezer Storage

Prevent accidental freezer breakage by storing samples only in containers designed for low-temperature storage. Plastic containers should be used whenever possible. If glass containers are used, they should be made of borosilicate glass.

Containers selected for freezing should be tested according to requirements using a salt solution with a density of 1.06. When storing specimens, it is recommended that containers are filled no more than two-thirds of their capacity and are initially frozen horizontally to a 45° angle before being stored upright.

If a tube breaks in a freezer, the employee should don appropriate personal protective equipment, remove the tube, and decontaminate the area. Any remaining intact tubes removed from the unit should be considered contaminated and should be decontaminated accordingly. The freezer should be disinfected prior to further work. However, if the specimen is to be salvaged, and is not in a secondary container, the frozen specimen should be placed into a secondary container, be allowed to thaw, and then transferred to a new container and refrozen.
12.4.4 Liquid Nitrogen Storage

Handle liquid nitrogen only when using thermal protective gloves; face shields should also be worn.

To prevent breakage, samples should be in containers that will withstand severe thermal shock. Care should be taken to prevent liquid nitrogen from infiltrating a vial during storage, because the gas expands rapidly when the temperature rises upon removal and may result in bursting the vial.

Vapor-phase liquid nitrogen freezers are recommended to avoid this potential hazard. If large numbers of these are concentrated in an area, the room air should be monitored to ensure that adequate amounts of oxygen are present in the air.

12.5 Pretreatment of Specimens

All manipulations of clinical material such as precipitation, extraction, vortexing, mixing, grinding, mincing, etc. that may generate aerosols, spatters, or particle dispersion should be performed in a manner to protect the worker and contain possible infectious agents. Vortexing should only be done in a closed vessel to prevent spatter or aerosolization.

Tissue processed with a tissue pulverizer should be in sealable bags (preferably heat-sealed), of adequate thickness to resist bursting and to securely contain the specimen. Great effort should be made to avoid trapping air within the bag.

To avoid splatter, tissue homogenizers and pulverizers can be operated within a Class II biological safety cabinet, provided the equipment does not interfere with airflow dynamics. Alternatively, a flexible, autoclavable, plastic film cover or enclosure can be placed over the equipment.

12.6 Design, Maintenance, and Repair of Devices

A preventative maintenance policy and procedure manual should be available in the laboratory. All service and maintenance activities should be performed under standard precautions. Devices to be repaired or serviced should be decontaminated prior to servicing at the site, at the manufacturing location, or at a third-party location. If the device is not, or cannot be decontaminated, it should be so marked with a special biohazard tag to alert service personnel as to the equipment status. Service personnel should wear gloves and other appropriate barrier protection if potentially exposed to blood and body substances. Devices used by service personnel to maintain or repair equipment may be decontaminated as described in Section 6.4.

The effluent from laboratory devices should be regarded as potentially infectious and should be disposed of in accordance with local, state, and federal regulations. Special care is needed in opening fluid lines under pressure to avoid spraying droplets.

Devices or components returned to in-house service departments, outside service organizations, or vendors for service should have all dried blood or body substances removed and should be decontaminated before leaving the user’s facility.

The manufacturer’s service and maintenance personnel should not be permitted to enter a laboratory area until the applicable safety requirements have been reviewed and/or special training has been provided by the manufacturer.

The laboratory management has the responsibility for the safety of the service personnel while in the laboratory.
12.6.1 Contaminated Portions of Devices

Portions of any device that contact blood, body substances, tissues, cultures, etc. are to be considered contaminated. The exterior of the device in the area of the sampling device and the waste effluent should be considered contaminated, even if no visible contamination is present. Any area in which a leak of sample-containing fluid has occurred is contaminated. The fluid handling system in which the sample is transferred is contaminated.

Any portion of a device may be contaminated if touched by contaminated gloves or hands during use. Gloves should be removed before touching uncontaminated parts of the device or leaving the contaminated workstation for other, uncontaminated areas of the laboratory.

Exercise caution when reaching around or removing modular components of a device, as broken blood tubes, syringes, broken glass, and other sharps may have fallen into these areas.

Prior to maintenance or repair of contaminated portions of a device, the portion to be worked on should be decontaminated.

12.6.2 Designing Devices

Devices should be designed in such a way as to facilitate servicing, cleaning, and decontamination, and to minimize cross-contamination of other areas of the device in case of failure. One way to achieve this is through the segregation of functions in the devices, e.g., sample-handling area separated from the electronic circuit boards.

12.6.3 Disassembling Devices

Prior to disassembling a device, clean potentially contaminated surfaces with an appropriate detergent and disinfectant. When possible, decontaminate internal components by prolonged purging, e.g., ten minutes, with a disinfectant that will not damage the device. Any disinfectant used must be compatible with the device according to the manufacturer's instructions. For devices that cannot be purged with disinfectant, use a water or buffer solution as specified by the manufacturer.

12.6.4 Decontamination Procedures

Because of the potential biohazards involved in maintenance and repair of devices, manufacturers are urged to identify biological hazards related to the operation of the unit and its preventative maintenance. This biosafety information should be included in the procedure manual and personnel training. If the manufacturer provides no instructions, the recommendations in this guideline may be followed at the user's discretion.

NOTE: Follow the manufacturer’s decontamination instructions (if given) for materials, processes, and contact time in order to avoid device damage. CLSI makes no claim that the procedures recommended will not damage a device. The user assumes full responsibility for any damage that may occur.

The working group urges manufacturers to develop standard operating procedures (SOPs) for the user and its own service personnel to follow in decontaminating their devices. If the equipment cannot be decontaminated, it should be appropriately labeled as to the portion that cannot be decontaminated.

12.6.4.1 Assembled Devices

The following decontamination procedure should be followed for assembled devices:
(1) Don appropriate personal protective equipment (e.g., gloves, laboratory coat, and face shield or mask).

(2) Remove all specimens, disposables, and reagents from the unit.

(3) Flush/rinse probe and/or fluid pathway with water, buffer, or disinfectant as specified by the manufacturer.

(4) Wipe contaminated surfaces with a detergent solution followed by a disinfectant (or the disinfectant recommended by the device manufacturer).

For shipping or transport, additional steps should be taken:

(5) Empty all waste containers and rinse with a disinfectant.

(6) As much as possible, clear fluid pathways.

The exposed surfaces of assembled devices may be decontaminated as follows:

Remove all dried blood or body substance from a surface or medical device before disinfection. The dried blood should be removed with a detergent or disinfectant recommended by the manufacturer. Otherwise, wet and soften the substance with diluted bleach, detergent, or disinfectant before removal to prevent scatter of potentially infectious material and to facilitate complete removal.

After removal of the dried blood, decontaminate the surface of the device with a detergent solution followed by healthcare facility disinfectant.

12.6.4.2 Disassembled Devices

Contaminated device components should be decontaminated according to the manufacturer’s instructions before being reused. Components may be decontaminated as follows:

(1) Wear gloves, laboratory coat, and facial protection to disassemble the device.

(2) Soak the components in detergent solution for ten minutes.

(3) Brush or scrub off any dried blood or serum that has accumulated on the components.

(4) Soak the components in disinfectant again for ten minutes or as recommended by the manufacturer. If dried blood or serum was present on the component and could not be completely removed, the part should be soaked in disinfectant for 30 minutes.

(5) Wash the component in water and dry to prevent corrosion or rusting.

12.6.4.3 Preparation for Shipment or Disposal

After decontamination, all fluid should be drained and discarded. Follow the manufacturer's instructions and local regulatory body recommendations for packing, labeling, and shipping. All internal shipping containers should be labeled with the following information:

- name of the institution and individual responsible for decontamination;
- date of decontamination; and
• decontamination protocol used.

Use the manufacturer’s label to label the shipping container. This will notify the repair facility that appropriate decontamination precautions have been taken.

See also the most current edition of CLSI/NCCLS document **GP5—Clinical Laboratory Waste Management**.

### 12.6.5 Receipt of Potentially Contaminated Devices

Upon receipt at the service facility, the personnel should look for a certification that the device has been decontaminated. The shipping container should be opened using standard precautions until the status of the contents can be ascertained. If a device is received without a certification that it has been appropriately decontaminated, it should be presumed contaminated and should be decontaminated upon receipt.

Containers with a biohazard label should only be opened in a separate, designated biohazard receiving area by trained, authorized personnel following standard precautions. Necessary barrier protection devices should be used.

Equipment and supplies for decontamination of contaminated devices should be available in the receiving area, and personnel should be trained in decontamination practices similar to those given in Section 6.4.

### 12.7 Selected Device Biohazards

#### 12.7.1 Automated Analyzer

*Special Preparation* — Automated analyzers frequently have features that need attention. Specimen preparation should minimize worker contact with the specimen.

- Sample probes that move rapidly or deliver fluid rapidly may generate a fine spray of sample. The surface of the analyzer should be examined frequently for visible contamination and should be decontaminated routinely. Shields may be needed around the probe to contain any spray.

- Any hand movement in the vicinity of the sample probe or liquid-level sensor should be done with extreme care. Wiping sample probes after sampling should be done with extreme caution. Gloves should be worn. Gauze pads or tissues that are used should be discarded frequently to avoid their being soaked through with blood or serum. Gauze pads with an impermeable plastic coating on one side are available to reduce contamination of the gloves.

- Sample trays that contain a number of plastic or glass sample cups or tubes should be handled with caution to prevent spillage of specimens. Sample cups should be filled using mechanical devices, e.g., Pasteur pipettes. Samples should not be decanted.

- The effluent of clinical analyzers should be considered contaminated and may be discarded directly into the sanitary sewer system or into a sink if allowed by local and state regulations.

#### 12.7.2 Blood Gas Analyzer Precautions

For blood gas measurements, the following precautions are important:

- Bedside practices with arterial puncture may pose an extreme hazard. The bare needle should not be removed by hand from the syringe. Several methods are available to remove the needle at the
bedside, e.g., the needle may be resheathed using a one-handed procedure, following which the needle is discarded and the syringe capped and sent to the laboratory (see Section 9.9.3). After the needle has been removed at the bedside, and the tip of the syringe has been covered with a cap (provided by vendors of blood gas syringes), the syringe should be placed in a secondary container for transportation to the laboratory.

- At the time of measurement, the tip of the syringe should be covered with a plastic-backed gauze pad if a small amount of blood is to be expressed. The probe of the analyzer should be introduced into the syringe and the sample aspirated by the analyzer. If there is no automatic sampling, the sample should be injected slowly into the blood gas analyzer to prevent spraying the specimen. Gloves should be worn when operating a blood gas analyzer.

- Capillary tubes containing blood are almost always contaminated on the outside. They should be handled with great care to prevent breakage and self-inflicted wounds. A capillary sampling device in which the capillary is enclosed in a plastic cartridge is available.

- The effluent of blood gas analyzers contains a high concentration of blood and should be discarded with care into the sanitary sewer system if allowed by local and state regulations. Although not required, disinfectant may be added to the effluent container during use or before disposal such that, when the container is full, the final concentration of disinfectant is 10% household bleach.

### 12.7.3 Flow Cytometry

Analytical flow cytometers do not generally produce aerosols. Cell sorters may produce aerosols or, rarely, fine droplets which are released into the atmosphere. They should be operated behind a shield that prevents droplet splattering onto the operator, or the operator may use barrier protection. The chamber should be evacuated via an in-line filter. If the fluid being sorted potentially contains organisms (e.g., *M. tuberculosis*) that are transmitted by the airborne route, and the cell sorter produces respirable aerosols, a personal respirator should be worn (see Section 6.2.3). The device and the work area should be decontaminated after use. Back-drip from the sample tube is another potential hazard in older cell sorters. When analyzing samples from potentially infected patients, the operator should wear a respirator and gloves and wash the back flush tray and surrounding areas with ethanol after each specimen.

### 12.7.4 Hematology

Hematology laboratories should use special caution with microhematocrit tubes. These tubes are prone to breakage, and fingersticks are common. Broken tubes and fragments in microhematocrit centrifuges should be removed with forceps. Clay slabs used to seal microhematocrit tubes pose a hazard. These slabs become contaminated with blood and possibly small fragments of glass. They should not be recycled; that is, the clay slabs should not be reformed to extend their life. Rather, they should be replaced at appropriate intervals.

The U.S. Food and Drug Administration issued a joint FDA/NIOSH/CDC/OSHA Advisory in 1999 recommending that users consider blood collection devices less prone to accidental breakage (www.fda.gov/cdrh/safety.html; www.cdc.gov/niosh). Plastic, nonbreakable microhematocrit tubes and self-sealing tubes that eliminate the use of clay sealers are strongly recommended.

Sedimentation tube racks should be decontaminated frequently.

Unfixed or unstained slides should be considered potentially infectious. They should be discarded into a sharps container. Wright-stained slides are not biohazardous.
12.7.5  Virology Laboratories

Research laboratories that work with high-titer virus cultures are outside the scope of this guideline. Clinical laboratories undertaking virus cultures should have adequately trained personnel and proper containment facilities for the specimens being processed and the agents being cultured. The safety practices recommended for other sections of the clinical laboratory apply also to virology laboratories.

12.8  Other Laboratory Equipment

While it is not possible to cover all laboratory equipment, there are some general categories of risks that may apply and should be taken into account when working with these units.

12.8.1  Sample and Liquid-Level Sensor Probes

Sample and liquid-level sensor probes are generally sharp and are the most contaminated portions of the device. Laboratory personnel should never place their hands in an area of an operating or moving probe. Where possible, the probe should be cleaned/flushed before contact. If air is used, place a gauze pad over the probe to prevent an aerosol.

12.9  Policies

Laboratory policies should dictate which portions of devices can be touched with gloved hands. Where computer keyboards are used, keyboard covers should be used.

12.10  Maintenance

Devices should be properly maintained per the manufacturer’s instructions. Any problems or misalignments must be corrected by appropriately trained personnel.

13  Safety Training and Monitoring of Personnel

The safety training and monitoring program should be audited as a part of the institutional and laboratory quality assurance program. It is imperative that site-specific information be included in training and include occupational hazards associated with blood and other potentially infectious materials.

13.1  Initial Training

Initial training should take place before a new employee or volunteer begins working and at least annually thereafter, and when new procedures are performed or an employee rotates into a new laboratory section.

In the U.S., training and monitoring must follow OSHA, CDC, and equivalent local requirements. These include:


- OSHA Instruction, Subject: Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens (29 CFR 1910.1030) Directives Numbers: CPL 2-2.69D; Effective: November 27, 2001; and
OSHA requires strict training and recordkeeping.

Initial training of new employees, trainees, and students and the continued education of current employees should include specific principles of infectious disease epidemiology with special reference to HBV, HIV, HCV, syphilis, tuberculosis, and other areas of great concern to laboratory workers. Both the hazards and precautions should be stressed to reassure the worker of the relatively low risk of laboratory-acquired infection if proper precautions are taken.

- Annual training should include new information discovered. It must be appropriate to employee education, literacy, and language.
  - Training must include the use of sharps with engineered safety devices that have been determined to improve safety through input and evaluation by those employees who utilize these devices in direct patient care. The consideration and documentation of new devices evaluated annually and their selection criteria should be communicated to the employee. Every change in safety devices requires retraining of those employees utilizing the new equipment.
  - Employees must be trained to report and carefully log each sharps injury with a minimum of information, including 1) the identification of the brand and type of device; 2) the location of the injury; and 3) the circumstances surrounding the exposure incident.

- The training program should be developed in cooperation with the infection control department and safety office of the institution or other professional group knowledgeable in blood-borne pathogens and other biological safety issues. The contents and details of the training program should be contained in a procedure manual, readily available for reference. All training sessions should be documented and records kept for the Joint Commission on the Accreditation of Health Organizations (JCAHO), OSHA, and other inspecting agencies. Training records must be maintained for at least three years from the training date.

- All employees who use a respirator must complete respirator protection training (see Section 6.2.3).

- A number of professional organizations have produced training materials to assist the trainer.

- However, training cannot be through video format or distant learning, unless the trainer can be interactive and available at the same time that training is occurring, so training is not delayed. Trainers must be able to respond to student questions as they occur, during the training process.

- The trainer should be specifically designated and have clearly defined responsibilities. The trainer must have demonstrated competent, current, technical background, familiarity with regulatory guidelines, and should have knowledge of educational methodologies. The trainer should be given sufficient time and resources to prepare training programs, to keep current with changing technologies, and to maintain competence.

- Safety-awareness signs should be obtained from commercial vendors or developed in-house. They should be posted in conspicuous locations and changed regularly to avoid desensitization. Written signs should be bilingual if appropriate. Biohazard signs should be posted at the entrance to each potentially contaminated work area of the laboratory.
13.2 Monitoring

OSHA requires that a written exposure control plan be developed and enforced. In addition, all areas and operations of each workplace, including office operations, must be inspected at least annually and more frequently where there is increased risk of exposure (www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=11276). OSHA will accept locally developed exposure-control policies, as long as they are consistent with CDC and OSHA recommendations. The plan should be realistic and achievable, as OSHA will hold the institution to the contents of the plan.

The safety practices of the personnel should be monitored at scheduled intervals. The supervisors should also pay constant attention to the extent to which standard precautions and special precautions are followed. The cooperation of the institutional safety officer, the laboratory safety officer, and the infection control department should be sought to ensure proper monitoring of safety practices.

When breaches in recommended precautions are detected, the employee should be counseled and re-educated on the proper precautions to be used and should be required to follow them. If necessary, disciplinary action may be needed for an employee who refuses to observe recommended precautions.

The safety precautions implemented in the laboratory should be monitored annually by the institution. Items to be audited include:

- the existence and effectiveness of the training programs;
- competence and qualifications of the trainer;
- the existence and effectiveness of the written job descriptions of the safety officers and trainers;
- the adequacy of the laboratory facilities and equipment to permit safe operation;
- the adequacy of the safety policies and SOPs;
- the adequacy of the recordkeeping and documentation of safety-related activities;
- understanding and application of safety policies and SOPs;
- adherence to requirements by visitors; and
- safety training records which should be maintained for three years.

13.3 Regulatory Requirements

The U.S. Department of Labor (DOL) and the Department of Health and Human Services (HHS) have published a Joint Advisory Notice. The contents of the Joint Advisory Notice have been integrated into the OSHA final regulations. Additionally, OSHA has published directives (CPL 22.44.D and CPL 2-2.69) to further clarify enforcement guidelines and interpretations of the original Occupational Exposure to Bloodborne Pathogens Standard (29 CFR 1910.1030) published in 1992.

State OSHA and local regulations may also apply.

The Joint Advisory Notice recommends the establishment of several systems in the laboratory.
• Administrative
  — Identify high-risk job categories
  — Identify employees in these high-risk positions
  — Develop SOPs for all high-risk procedures

• Training and education

• Engineering controls

• Safe work practices

• Personal protective equipment

• Medical - HB vaccine program

• Recordkeeping

14 Changes in the Regulatory Environment

Safety in the healthcare workplace is a dynamic subject governed by new information and evolving worldwide regulatory requirements. New guidelines or standards from CDC, ISO, and WHO, or revised regulations from OSHA, may arise at any time and supersede the recommendations of this document. It is not possible for this document to encompass every area of safety in the healthcare workplace. Likewise, it is not the purpose of this document to exclude other approaches or systems that foster safety in the healthcare workplace.
References


2. CEN. Elimination or reduction of risk of infection related to in vitro diagnostic reagents. rEN 13641. Brussels: European Committee for Standardization; 2002.


18. CDC. Laboratory-acquired meningococcal disease, United States. MMWR. 2002;51:141-144.


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44 The College of American Pathologists Checklist for Laboratory Accreditation, question 08:3415.


Appendix A. Criteria for Biosafety Level 2


**Biosafety Level 2** is similar to Biosafety Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs from BSL-1 in that (1) laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists; (2) access to the laboratory is limited when work is being conducted; (3) extreme precautions are taken with contaminated sharp items; and (4) certain procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.

The following standard and special practices, safety equipment, and facilities apply to agents assigned to Biosafety Level 2:

**A1.1 Standard Microbiological Practices**

1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

2. Persons wash their hands after they handle viable materials, after removing gloves, and before leaving the laboratory.

3. Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the work areas. Food is stored outside the work area in cabinets or refrigerators designated for this purpose only.

4. Mouth pipetting is prohibited; mechanical pipetting devices are used.

5. Policies for the safe handling of sharps are instituted.

6. All procedures are performed carefully to minimize the creation of splashes or aerosols.

7. On completion of work or at the end of the day and after any spill or splash of viable material, work surfaces are decontaminated with disinfectants that are effective against the agents of concern.

8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leakproof container and closed for transport from the laboratory. Materials to be decontaminated off-site from the facility are packaged in accordance with applicable local, state, and federal regulations, before removal from the facility.

9. An insect and rodent control program is in effect.

**A1.2 Special Practices**

1. Access to the laboratory is limited or restricted by the laboratory director when work with infectious agents is in progress. In general, persons who are at increased risk of acquiring infection, or for whom infection may have serious consequences, are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at increased risk of acquiring infections. The laboratory director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory or animal room.
Appendix A. (Continued)

2. The laboratory director establishes policies and procedures whereby only persons who have been advised of the potential hazards and meet specific entry requirements (e.g., immunization) may enter the laboratory.

3. A biohazard sign must be posted on the entrance to the laboratory when etiologic agents are in use. Appropriate information to be posted includes the agent(s) in use, the biosafety level, the required immunizations, the investigator's name and telephone number, any personal protective equipment that must be worn in the laboratory, and any procedures required for exiting the laboratory.

4. Laboratory personnel receive appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing).

5. When appropriate, considering the agent(s) handled, baseline serum samples for laboratory and other at-risk personnel are collected and stored. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the facility.

6. Biosafety procedures are incorporated into standard operating procedures or in a biosafety manual adopted or prepared specifically for the laboratory by the laboratory director. Personnel are advised of special hazards and are required to read and follow instructions on practices and procedures.

7. The laboratory director ensures that laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates or additional training as necessary for procedural or policy changes.

8. A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

   a. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plastic ware should be substituted for glassware whenever possible.

   b. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) are used for injection or aspiration of infectious materials. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Nondisposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.

   c. Syringes which resheathe the needle, needleless systems, and other safety devices are used when appropriate.

   d. Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass are decontaminated before disposal, according to any local, state, or federal regulations.
Appendix A. (Continued)

9. Cultures, tissues, specimens of body fluids, or potentially infectious wastes are placed in a container with a cover that prevents leakage during collection, handling, processing, storage, transport, or shipping.

10. Laboratory equipment and work surfaces should be decontaminated with an effective disinfectant on a routine basis, after work with infectious materials is finished, and especially after overt spills, splashes, or other contamination by infectious materials. Contaminated equipment must be decontaminated according to any local, state, or federal regulations before it is sent for repair or maintenance or packaged for transport in accordance with applicable local, state, or federal regulations, before removal from the facility.

11. Spills and accidents that result in overt exposures to infectious materials are immediately reported to the laboratory director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

12. Animals not involved in the work being performed are not permitted in the laboratory.

A1.3 Safety Equipment (Primary Barriers)

1. Properly maintained biological safety cabinets, preferably Class II, or other appropriate personal protective equipment or physical containment devices are used whenever:

   a. Procedures with a potential for creating infectious aerosols or splashes are conducted. These may include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of infectious materials whose internal pressures may be different from ambient pressures, inoculating animals intranasally, and harvesting infected tissues from animals or embryonate eggs. See Section 12.2.1.1, Plastic Tubes.

   b. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory if sealed rotor heads or centrifuge safety cups are used, and if these rotors or safety cups are opened only in a biological safety cabinet.

2. Face protection (goggles, mask, face shield, or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials to the face when the microorganisms must be manipulated outside the BSC.

3. Protective laboratory coats, gowns, smocks, or uniforms designated for laboratory use are worn while in the laboratory. This protective clothing is removed and left in the laboratory before leaving for non-laboratory areas (e.g., cafeteria, library, administrative offices). All protective clothing is either disposed of in the laboratory or laundered by the institution; it should never be taken home by personnel.

4. Gloves are worn when hands may contact potentially infectious materials, contaminated surfaces, or equipment. Wearing two pairs of gloves may be appropriate. Gloves are disposed of when overtly contaminated, and removed when work with infectious materials is completed or when the integrity of the glove is compromised. Disposable gloves are not washed, reused, or used for touching “clean” surfaces (keyboards, telephones, etc.), and they should not be worn outside the laboratory. Alternatives to powdered latex gloves should be available. Hands are washed following removal of gloves.
Appendix A. (Continued)

A1.4 Laboratory Facilities (Secondary Barriers)

1. Provide lockable doors for facilities that house restricted agents.  

2. Consider locating new laboratories away from public areas.

3. Each laboratory contains a sink for hand washing.

4. The laboratory is designed so that it can be easily cleaned. Carpets and rugs in laboratories are inappropriate.

5. Bench tops are impervious to water and are resistant to moderate heat and the organic solvents, acids, alkalis, and chemicals used to decontaminate the work surfaces and equipment.

6. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a nonfabric material that can be easily decontaminated.

7. Install biological safety cabinets in such a manner that fluctuations of the room supply and exhaust air do not cause the biological safety cabinets to operate outside their parameters for containment. Locate biological safety cabinets away from doors, from windows that can be opened, from heavily traveled laboratory areas, and from other potentially disruptive equipment to maintain the biological safety cabinets’ airflow parameters for containment.

8. An eyewash station is readily available.

9. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

10. There are no specific ventilation requirements. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory. If the laboratory has windows that open to the exterior, they are fitted with fly screens.

References for Appendix A


Appendix B. Biological Safety Cabinets

B1. Biological Safety Cabinets

The biological safety cabinet (BSC) is the principal device used to provide containment of infectious splashes or aerosols generated by many microbiological procedures. Three types of biological safety cabinets (Class I, II, III) used in microbiological laboratories are described and illustrated in *Biosafety in Microbiological and Biomedical Laboratories*.

Open-fronted Class I and Class II biological safety cabinets are primary barriers that offer significant levels of protection to laboratory personnel and to the environment when used with good microbiological techniques. The Class II biological safety cabinet also provides protection from external contamination of the materials (e.g., cell cultures, microbiological stocks) being manipulated inside the cabinet. The gas-tight Class III biological safety cabinet provides the highest attainable level of protection to personnel and the environment.

The **Class I BSC** is designed for general microbiological research with low- or moderate-risk agents, and is useful for containment of mixers, blenders, and other equipment. These cabinets are not appropriate for handling research materials that are vulnerable to airborne contamination, since the inward flow of unfiltered air from the laboratory can carry microbial contaminants into the cabinet.

**NOTE:** Class I BSCs are currently being manufactured on a limited basis; many have been replaced by Class II BSCs.

The **Class III BSC** is a totally enclosed, ventilated cabinet of gas-tight construction and offers the highest degree of personnel and environmental protection from infectious aerosols, as well as protection of materials from microbiological contaminants. Class III cabinets are most suitable for work with hazardous agents that require Biosafety Level 3 or 4 containment.

The most commonly used primary barrier when manipulating infectious agents in both clinical and research laboratories is the open-fronted **Class II BSC**. A properly used and maintained Class II BSC will provide a high degree of containment when laboratory personnel, the external environment, and the material being manipulated inside the cabinet must all be protected from potential contamination. Good microbiological techniques are essential for containment of potentially infectious materials.

Properly maintained Class II BSCs, when used in conjunction with good microbiological techniques, provide an effective containment system for safe manipulation of moderate- and high-risk microorganisms (Biosafety Level 2 and 3 agents). Class II BSCs have inward face velocities (75 to 100 linear feet per minute) that provide comparable levels of containment to protect laboratory workers and the immediate environment from infectious aerosols generated within the cabinet. Class II BSCs also protect the research material itself through high-efficiency particulate air filtration (HEPA filtration) of the airflow down across the work surface (vertical laminar flow).

The Class II BSC is designed with inward airflow at a velocity to protect personnel (75 to 100 lpm), HEPA-filtered downward vertical laminar airflow for product protection, and HEPA-filtered exhaust air for environmental protection. Design, construction, and performance standards for Class II BSCs, as well as a list of products that meet these standards, have been developed by and are available from the National Sanitation Foundation International (NSF), Ann Arbor, Michigan. Utilization of this standard and list should be the first step in selection and procurement of a Class II BSC.

Class II BSCs are classified into Type A1 and A2 based on construction, airflow velocities and patterns, and exhaust systems. Basically, Type A1 cabinets are suitable for microbiological research *in the absence of* volatile or toxic chemicals and radionuclides, since air is recirculated within the cabinet. Type A1 cabinets may be exhausted into the laboratory or to the outdoors via a “thimble” connection to the building exhaust system.
Appendix B. (Continued)

Type A2 cabinets have a face velocity of 100 lfpm and all contaminated ducts are surrounded by negative pressure plena. These cabinets may recirculate exhaust air into the laboratory, or be connected to the building exhaust by an exhaust canopy in accordance with the guidance contained in the revised National Sanitation Standard. When an exhaust canopy is used, Type A2 cabinets allow work with low levels of toxic chemical or radionuclides.

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

As with any other piece of laboratory equipment, personnel must be trained in the proper use of the biological safety cabinets. Of particular note are activities that may disrupt the inward directional airflow. Repeated insertion and withdrawal of the workers’ arms into and out of the work chamber, opening and closing doors to the laboratory or isolation cubicle, improper placement or operation of materials or equipment within the work chamber, or brisk walking past the BSC while it is in use have been demonstrated to cause the escape of aerosolized particles from within the cabinet. Class I and II cabinets should be located away from traffic patterns and doors. Airflow from fans, room air supply louvers and other air-moving devices can disrupt the airflow pattern at the face of the cabinet. Strict adherence to recommended practices for the use of BSCs and their proper placement in the laboratory are as important in attaining the maximum containment capability of the equipment as is the mechanical performance of the equipment itself.

**B2. Work Practices and Procedures**

**B2.1 Personal Protective Equipment**

Laboratory coats should be worn buttoned over street clothing; a solid front, back-closing laboratory gown provides better protection of personal clothing than a traditional laboratory coat. For personnel working with blood or other potentially infectious body fluids, the laboratory coat or gown should be made of fluid-resistant material.

Gloves are worn to provide hand protection. Gloves should be pulled over the knitted wrists of the gown, rather than worn inside. Elasticized sleeves can also be worn to protect the investigator's wrists.

Respirators are not necessary for work with clinical specimens or with concentrations of organisms under conditions normally considered to be safely handled with Biosafety Level 2 containment. For organisms and/or conditions where there is a risk of exposure to infectious aerosols while working within the BSC, Biosafety Level 3 containment, including the use of a respirator, should be considered.

**B2.2 Preparation of the Workspace**

The work surface, the interior walls (not including the supply filter diffuser), and the interior surface of the window should be wiped with 70% ethanol (EtOH), a 1:100 dilution of household bleach (i.e., 0.05% sodium hypochlorite), or other disinfectant as determined by the investigator to meet the requirements of the particular activity. When bleach is used, a second wiping with sterile water is needed to remove the residual chlorine, which may eventually corrode stainless steel surfaces. Wiping with nonsterile water may recontaminate cabinet surfaces, a critical issue when sterility is essential (e.g., maintenance of cell cultures).
Appendix B. (Continued)

Similarly, the surfaces of all materials and containers placed into the cabinet should be wiped with 70% ETOH to reduce the introduction of contaminants to the cabinet environment. Further reduction of microbial load on materials to be placed or used in BSCs may be achieved by periodic decontamination of incubators and refrigerators.

Before beginning work, the investigator should adjust the stool height so that his/her face is above the front opening. A written checklist of materials necessary for a particular activity should be prepared. Materials necessary for the activity should be placed in the BSC before beginning work; this serves to minimize the number of arm-movement disruptions across the fragile air barrier of the cabinet.

Manipulation of materials should be delayed for approximately one minute after placing the hands/arms inside the cabinet. This allows the cabinet to stabilize and to “air sweep” the hands and arms to remove surface microbial contaminants. When the user’s arms rest flatly across the front grille, room air may flow directly into the work area, rather than being drawn through the front grille. Raising the arms slightly will alleviate this problem. The front grille must not be blocked with research notes, discarded plastic wrappers, pipetting devices, etc. All operations should be performed at least four inches from the front grille on the work surface.

The rapid movement of a worker’s arms in a sweeping motion into and out of the cabinet will disrupt the air curtain and may compromise the partial barrier containment provided by the BSC. Moving arms in and out slowly, perpendicular to the face opening of the cabinet, will reduce this risk. Other personnel activities in the room (e.g., rapid movement, open/closing room doors, etc.) may also disrupt the cabinet air barrier.

Materials or equipment placed inside the cabinet may cause disruption to the airflow, resulting in turbulence, possible cross-contamination, and/or breach of containment. Extra supplies (e.g., additional gloves, culture plates or flasks, culture media) should be stored outside the cabinet. Only the materials and equipment required for the immediate work should be placed in the BSC.

Cabinet blowers should be operated at least three to five minutes before beginning work to allow the cabinet to “purge.” This purge will remove any particulates within the cabinet.

BSCs are designed to be operated 24 hours per day, and some investigators find that continuous operation helps to control the laboratory's level of dust and other airborne particulates. Although energy conservation may suggest BSC operation only when needed, especially if the cabinet is not used routinely, room air balance is an overriding consideration. In some instances, room exhaust is balanced to include air discharged through ducted BSCs.

B2.3 Material Placement Inside the BSC

Plastic-backed absorbent toweling can be placed on the work surface (but not covering the front or rear grille openings or obstructing them in any way). This toweling facilitates routine cleanup and reduces splatter and aerosol formation during an overt spill. The toweling can then be folded with the absorbent side inward and disposed as biohazardous waste when work is completed.

All materials should be placed as far back in the cabinet as practical, toward the rear edge of the work surface and at least four inches away from the front grille of the cabinet. Similarly, aerosol-generating equipment (e.g., vortex mixers) should be placed toward the rear of the cabinet. Active work should flow from the clean to contaminated area across the work surface (working left-to-right or right-to-left, depending on the worker's preference). Bulky items such as biohazard bags, discard pipette trays, and suction collection flasks should be placed to one side of the interior of the cabinet.
Appendix B. (Continued)

Certain common practices may interfere with the operation of the BSC. The autoclavable biohazard collection bag should not be placed outside of the cabinet. Upright sharps collection containers should not be used inside BSCs nor placed on the floor outside the cabinet. The frequent inward/outward movement needed to place objects into these containers is disruptive to the integrity of the cabinet air barrier and can compromise both personnel and product protection. Only horizontal pipette discard trays (containing an appropriate chemical disinfectant, if desired) should be used within the cabinet. Furthermore, potentially contaminated materials should not be brought out of the cabinet until they have been surface decontaminated. Alternatively, contaminated materials can be placed into a closable container for transfer to an incubator, an autoclave, or for other decontamination treatment.

B3. Operations Within a Class II BSC

B3.1 Laboratory Hazards

Many common procedures conducted in BSCs may create splatter or aerosols. Good microbiological techniques should always be used when working in a biological safety cabinet. For example, techniques to reduce splatter and aerosol generation will minimize the potential for personnel exposure to infectious materials manipulated within the cabinet. Class II cabinets are designed so that horizontally nebulized spores will be captured by the downward flowing cabinet air within 14 inches of travel. Therefore, as a general rule of thumb, keeping clean materials at least one foot away from aerosol-generating activities will minimize the potential for cross-contamination.

The general workflow should be from “clean to contaminated (dirty).” Materials and supplies should be placed in such a way as to limit the movement of “dirty” items over “clean” ones.

Several measures can be taken to reduce the chance for cross-contamination when working in a BSC. Opened tubes or bottles should not be held in a vertical position. Investigators working with petri dishes and tissue culture plates should hold the lid above the open, sterile surface to minimize direct impaction of downward air. Bottle or tube caps should not be placed on the toweling. Items should be recapped or covered as soon as possible.

Open flames are not recommended by some manufacturers in the near-microbe-free environment of a biological safety cabinet. On an open bench, flaming the neck of a culture vessel will create an upward air current that prevents microorganisms from falling into the tube or flask. An open flame in a BSC, however, creates turbulence that disrupts the pattern of air supplied to the work surface. When deemed absolutely necessary, touch-plate microburners equipped with a pilot light to provide a flame on demand may be used. Internal cabinet air disturbance and heat buildup will be minimized. The burner must be turned off when work is completed. Small electric “furnaces” are available for decontaminating bacteriological loops and needles and are preferable to an open flame inside the BSC. Disposable sterile loops can also be used.

Aspirator bottles or suction flasks should be connected to an overflow collection flask containing appropriate disinfectant, and to an in-line HEPA or equivalent filter. This combination will provide protection to the central building vacuum system or vacuum pump, as well as to the personnel who service this equipment. Inactivation of aspirated materials can be accomplished by placing sufficient chemical decontamination solution (at the concentration recommended for use) into the flask to kill the microorganisms as they are collected. Once inactivation occurs, liquid materials can be disposed of appropriately as noninfectious waste.
Appendix B. (Continued)

Investigators must determine the appropriate method of decontaminating materials that will be removed from the BSC at the conclusion of the work. When chemical means are appropriate, suitable liquid disinfectant should be placed into the discard tray before work begins. Items should be introduced into the tray with minimum splatter, and allowed appropriate contact time as per manufacturer’s instructions. Alternatively, liquids can be autoclaved prior to disposal. Contaminated items should be placed into a biohazard bag or discard tray inside the BSC. Water should be added to the bag or tray prior to autoclaving, so that steam will be generated within the interior of the container during the autoclave process.

When a steam autoclave is to be used, contaminated materials should be placed into a biohazard bag or discard tray containing enough water to ensure steam generation during the autoclave cycle. The bag should be taped shut, or the discard pan should be covered in the BSC prior to removal to the autoclave. The bag should be transported and autoclaved in a leakproof tray or pan.

B4. Decontamination

B4.1 Routine Decontamination

All containers and equipment should be surface decontaminated and removed from the cabinet when work is completed. At the end of the workday, the final surface decontamination of the cabinet should include a wipe-down of the work surface, the cabinet's sides and back, and the interior of the glass.

Investigators should remove their gloves and gowns and wash their hands as the final step in safe microbiological practices.

B4.2 Spill Decontamination

Small spills within the BSC can be handled immediately by removing the contaminated absorbent paper toweling and placing it into a biohazardous waste container. Any splatter onto items within the cabinet, as well as the cabinet interior, should be immediately wiped with a towel dampened with decontaminating solution. Gloves should be changed after the work surface is decontaminated and before placing clean absorbent toweling in the cabinet. Hands should be washed whenever gloves are changed or removed.

Spills large enough to result in liquids flowing through the front or rear grilles require more extensive decontamination. All items within the cabinet should be surface-decontaminated and removed. After ensuring that the drain valve is closed, decontaminating solution can be poured onto the work surface and through the grille(s) into the drain pan.

Twenty to 30 minutes is generally considered an appropriate contact time for decontamination, but this varies with the disinfectant and the microbiological agent. The manufacturer's use instructions should be followed for the organism or material being manipulated. The spilled fluid and disinfectant solution on the work surface should be absorbed with paper towels and discarded as biohazardous waste. The drain pan should be emptied into a collection vessel containing disinfectant. A flexible tube should be attached to the drain valve and be of sufficient length to allow the open end to be submerged in the disinfectant within the collection vessel. This procedure serves to minimize aerosol generation. The drain pan should be flushed with water and the drain tube removed.

Should the spilled liquid contain radioactive material, a similar procedure can be followed. Radiation safety personnel should be contacted for specific instructions.
Appendix B. (Continued)

B4.3 Gas Decontamination

BSCs that have been used for work involving infectious materials must be decontaminated before HEPA filters are changed or internal repair work is done.

Before a BSC is relocated, a risk assessment which considers the agents manipulated within the BSC must be done to determine the need for decontamination. The most common decontamination method uses formaldehyde gas, although more recently hydrogen peroxide vapor has been used successfully. This environmentally benign vapor is useful in decontaminating HEPA filters, isolation chambers, and centrifuge enclosures. Consult an NSF-certified cabinet certifier for decontamination information.

References for Appendix B


2. National Sanitation Foundation International (NSF), Ann Arbor, Michigan.

3. NSF 49 Class II (laminar flow) Biosafety Cabinetry. NSF/ANSI 49-04 Ann Arbor, MI: NSF International; 2004

Appendix C. Regulation of Antimicrobial Chemicals

Until 1996, chemical germicides used in the healthcare setting were regulated by two government agencies: the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA). Chemical germicides formulated as disinfectants or sterilants were regulated and registered by the Disinfectants Branch, Antimicrobials Division, EPA. The authority for this responsibility comes under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The EPA required manufacturers of chemical germicides formulated as sanitizers, general disinfectants, or disinfecting/sterilizing (sporicide) products to test formulations by using specific protocols for microbicidal activity, stability, and toxicity to humans. If a germicidal chemical was advertised and marketed for use on a specific medical device, e.g., a hemodialysis machine or a flexible fiberoptic endoscope, then the germicide came under the additional regulatory control of the FDA, Center for Devices and Radiological Health, which is the federal agency that regulates medical devices. Under the authority of the 1976 Medical Device Amendment to the Food, Drug and Cosmetic Act, a germicide that was marketed for use on a specific medical device is itself considered a medical device in a regulatory sense, and the manufacturer must, in addition to EPA registration, contact FDA and submit a premarket notification—510(k)—before the product could be legally marketed.

In the early 1990s, the FDA began actively regulating all liquid chemical germicides with healthcare indications. In order to avoid the potential problem of regulating the same product under multiple classes, the FDA decided to regulate liquid chemical germicides as a separate type of medical device; therefore, it determined that these were unclassified devices. In an effort to ease the burden of this dual regulation, a memorandum of understanding (MOU) was signed between the FDA and the EPA that gave the FDA primary responsibility for premarket efficacy data review of liquid chemical sterilants/high-level disinfectants, and gave the EPA primary responsibility for premarket efficacy data review of general-purpose disinfectants.

Additionally, the FDA adapted the basic terminology and classification scheme described by Spaulding¹ to categorize medical devices, and the four levels of processing as proposed by the Centers for Disease Control and Prevention (CDC): sterilization, high-level disinfection, intermediate-level disinfection, and low-level disinfection. Also, the FDA regulatory authority over a particular instrument or medical device dictates that the manufacturer is obligated to provide the user with adequate instructions for the “safe and effective” use of that instrument or device. These instructions must include methods to clean and disinfect or sterilize the item if it is marketed as a reusable medical device. Manufacturers must provide the users of these germicides with specific direction for use on the product label.

The FDA regulates chemical germicides formulated as antiseptics, preservatives, or drugs that are used on or in the human body or as preparations to be used to inhibit or kill microorganisms on the skin. However, the method used to regulate and assess potency for these formulations is significantly different from the methods used for sterilants and disinfectants. The FDA has an advisory panel that reviews nonprescription antimicrobial drug products. Manufacturers of such formulations voluntarily submit data to the panel, which in turn categorizes the products for their intended use, e.g., healthcare personnel hand washes, patient preoperative preparations, and surgical hand scrub.²

The CDC is not a regulatory agency and does not test, evaluate, or otherwise recommend specific brand-name products of chemical germicides formulated either as disinfectants or sterilants, or as antiseptics, or as soaps for skin preparations. However, CDC has published several guidelines containing general considerations for methods and indications for hand washing, as well as strategies for sterilizing or disinfecting medical instruments and environmental surfaces.³⁻⁵
Appendix C. (Continued)

The following Internet sites can be used to obtain more information on chemical germicides from the three Federal agencies in the United States:

FDA   http://www.fda.gov/cdrh/index.html
EPA   http://www.epa.gov/oppad001
       http://www.epa.gov/epahome/search.html
CDC   http://www.cdc.gov/ncidod/hip/default.htm

The choice of specific disinfectants in association with protocols for cleaning is a decision made broadly and at various levels of hospital and other healthcare facilities. No single chemical germicide procedure is adequate for all disinfection or sterilization purposes, and the realistic use of chemical germicides depends on a number of factors, which should be considered in selecting among the available procedures. These include the degree of microbial killing required; the nature and composition of the surface item or device to be treated; and the cost, safety, and ease of use of the available agents.6

References for Appendix C


Appendix D. Prions and CJD: The Special Case of Prions and CJD in Instrument Reprocessing

D1. Introduction

The purpose of this section is to provide general guidance to hospital central sterilization service departments for reprocessing instruments and medical devices that have been exposed to patients known or suspected to have Creutzfeldt-Jakob disease (CJD). This section is not intended to provide a detailed review. Healthcare facilities may consider other procedures, as technologies are developed to inactivate prions.

CJD is a degenerative neurological disorder of humans with an incidence in the United States of approximately one case/million population/year. The disease is thought to be caused by a proteinaceous infectious agent or prion. CJD is related to other human transmissible spongiform encephalopathies (TSEs) that include kuru (0 incidence, now eradicated), Gertsmann-Straussler-Sheinker (GSS) syndrome (1/billion), and fatal insomnia syndrome (FFI) (<1/billion). Prion diseases do not elicit an immune response, result in a noninflammatory pathologic process confined to the central nervous system, have an incubation period of years, and usually are fatal within one year of diagnosis.

A recently recognized new variant form of CJD (vCJD) is acquired from cattle with bovine spongiform encephalopathy (BSE) or mad-cow disease. vCJD remains a rare illness. Between March 1996 and January 2004 there have been 153 cases worldwide. Compared with CJD patients, vCJD patients are younger (29 vs. 65 years of age), have a longer duration of illness (14 vs. 4.5 months), and present with sensory and psychiatric symptoms that are uncommon with CJD. The agents of CJD and other TSEs exhibit an unusual resistance to conventional chemical and physical decontamination methods. Since the CJD agent is not readily inactivated by conventional disinfection and sterilization procedures, and because of the invariably fatal outcome of CJD, the procedures for disinfection and sterilization of the CJD prion have been both cautious and controversial for many years.

CJD occurs as both a sporadic and familial disease. Less than 1% of CJD episodes have results from healthcare-associated transmission, and only two confirmed cases and four unconfirmed cases have been associated with reprocessed surgical instruments; these cases occurred more than 25 years ago in Europe. No cases of CJD or vCJD associated with surgical or medical instruments have been reported since that time. The vast majority of healthcare-associated transmission cases have resulted from use of contaminated tissues (e.g., pituitary hormones) or grafts. Iatrogenic CJD has been described in humans in three circumstances:

a) after patients received extracted pituitary hormones (>130 cases);

b) after patients received an implant of contaminated grafts from humans (cornea, three cases; dura mater, >110 cases);

c) and, as mentioned above, after use of contaminated medical equipment on patients undergoing invasive procedures (two confirmed and four unconfirmed cases).

All known instances of iatrogenic CJD have resulted from exposure to infectious brain, pituitary, or eye tissue. Tissue infectivity studies in experimental animals have determined the infectiousness of different body tissues. Tissues that have the highest prion concentration are brain and dura mater. Transmissibility is directly related to the concentration of prions in tissues. Transmission via stereotactic electrodes is the only convincing example of transmission via a medical device. The electrodes had been implanted in a patient with known

* This appendix is reprinted from a section in the chapter “Chemical Disinfection of Medical and Surgical Materials” by Martin S. Favero and Walter W. Bond. In Block SS, ed. Disinfection, Sterilization and Preservation. 5th ed. Lippincott Williams and Wilkins; 2001. Reprinted with permission of the authors and Lippincott Williams and Wilkins.
Appendix D. (Continued)

CJD and then cleaned with benzene and sterilized with 70% alcohol and formaldehyde vapor produced by a formaldehyde generator using solid paraformaldehyde. Two years later, these electrodes were retrieved and implanted into a chimpanzee in which the disease developed. The method used to sterilize these electrodes would not currently be considered an adequate method for sterilizing medical devices.

Retrospective studies suggest that four other episodes may have resulted from use of contaminated instruments in neurosurgical operations. An index CJD case was identified in only one case and in this instance, the surgical instruments were cleaned with soap and water and then exposed to dry heat for an unspecified time and temperature. The other three cases had no associated index case. They did have a neurosurgical procedure within a two-year period prior to being diagnosed with CJD.

All six cases of CJD associated with neurosurgical instruments occurred in Europe between 1953 and 1976, and details of the reprocessing methods for the instruments are incomplete. There are no known episodes of CJD attributable to the reuse of devices contaminated with blood or to transfusion of blood products.

The infrequent transmission of CJD via contaminated medical devices probably reflects the inefficiency of transmission (except for neural tissue) and the effectiveness of conventional cleaning and current disinfection and sterilization procedures. To minimize the possibility of use of neurosurgical instruments that have been potentially contaminated during procedures performed on patients in whom CJD is later diagnosed, healthcare facilities should consider using the sterilization guidelines outlined below for neurosurgical instruments used during brain biopsy done on patients in whom a specific lesion has not been demonstrated (e.g., by magnetic resonance imaging or computerized tomography scans). Alternatively, neurosurgical instruments used in such patients could be disposable, or the instruments could be quarantined until the pathology of the brain biopsy is reviewed and CJD excluded.

Several investigators have studied the inactivation of prions by disinfectant and sterilization processes, but these studies do not reflect the reprocessing procedures in a clinical setting:

a) These studies have not incorporated a cleaning procedure that normally reduces microbial contamination by 4 log10 and reduces protein contamination.

b) The prion studies have been done with tissue homogenates dried onto carriers. The protective effect of the tissue and the drying of the tissue may explain, in part, why the CJD agent is difficult to inactivate in these experimental studies.

c) Results of inactivation studies of prions have been inconsistent due to the use of differing methodologies, which have varied by prion strain; prion concentration; test tissue (intact brain tissue, brain homogenates, partially purified preparations); test animals; duration of follow-up of inoculated animals; exposure container; method of calculating log-reductions in infectivity; concentration of the disinfectant at the beginning and end of an experiment; cycle parameters of the sterilizer; and exposure conditions.

Despite these limitations, there is some consistency in the results.

In order to provide scientifically-based recommendations, research should be undertaken in which actual medical instruments are contaminated with prions (including variant CJD), cleaned, and then subjected to
Appendix D. (Continued)

either conventional sterilization or disinfection or special prion reprocessing. The disinfection studies mentioned above showed that many, but not all, disinfection processes fail to inactivate clinically significant numbers of prions. There are four chemicals that reduce the prion titer by \(>3 \log_{10}\) in one hour: chlorine (sodium hypochlorite); a phenolic (based on ortho-phenylphenol, p-tertiary-amylphenol, and ortho-benzyl-para-chlorophenol) at \(>0.9\%\); guanidine thiocyanate; and sodium hydroxide. Of these four chemical compounds, chlorine has provided the most consistent prion inactivation results. However, the corrosive nature of chlorine makes it unsuitable for many devices, such as surgical instruments and endoscopes.

Recently there have been several studies published in the literature that demonstrate alkaline detergent cleaners alone or in combination with hydrogen peroxide gas plasma or certain biocides can significantly reduce and inactivate prion challenges.\(^8\text{-}10\)

Prions also exhibit an unusual resistance to conventional physical decontamination methods.\(^6\) While there is some disagreement on the ideal time and temperature cycle for steam sterilization, the recommendation for 134 °C for \(>18\) minutes (prevacuum) and 132 °C for 60 minutes (gravity-displacement) are based on the scientific literature.\(^9\) Some investigators also have found that combining sodium hydroxide with steam sterilization for one hour at 121 °C results in complete loss of infectivity.\(^11\) However, the combination of sodium hydroxide and steam sterilization can be deleterious to surgical instruments and sterilizers, as well as to sterilizer operators.

Historically, recommendations for inactivating the agent of CJD have been based on studies using infected tissues and injecting animals known to be susceptible to CJD. Any of the existing recommendations are based on the assumptions that exposure to any tissue, body fluid, secretion, or excretion from a CJD patient will result in a transmissible infectious dose of CJD, and that no conventional processing regimen of cleaning followed by disinfection or sterilization will be effective in rendering the device or fomites safe for reuse. However, based on the epidemiology of iatrogenic and nosocomial episodes of CJD mentioned above, it is clear that the only exposures in patient-care settings that have resulted in infection are those instances involving devices that cannot be cleaned and that are contaminated with high-risk tissue from the central nervous system.

There have been other approaches that consider tissues containing the highest prion load to carry the highest risk of transmission by instruments.\(^12\text{-}14\)

The disinfection and sterilization recommendations for CJD in this guideline are based on the belief that infection control measures should be predicated on epidemiologic evidence linking specific body tissues or fluids to transmission of CJD; quantitative infectivity assays demonstrating that body tissues or fluids are contaminated with infectious prions; cleaning data using biological indicators and proteins; inactivation data on prions; the risk of disease transmission with the use of the instrument or device; and a review of other recommendations.

The three parameters considered in this guideline that are integrated into strategies for disinfection and sterilization processing are:

- the risk of the patient for having a prion disease;
- the comparative infectivity of different body tissues (e.g., the prion load); and
- the intended use of the medical device.
Appendix D. (Continued)

High-risk patients include those with known prion disease; those with rapidly progressive dementia consistent with possible prion disease; those with a familial history of CJD, GSS, or FFI; patients known to carry a mutation in the PrP gene involved in familial TSEs; patients with a history of dura mater transplants; and patients with a known history of cadaver-derived pituitary hormone injection. High-risk tissues include brain, spinal cord, and eye. All other tissues are considered low or no risk.2,6 (http://www.cdc.gov/ncidod/diseases/cjd/cjd_inf_ctrl_qa.htm)

Critical devices are defined as devices that enter sterile tissue or the vascular system (e.g., implants, curettes).

Semicritical devices are defined as devices that contact nonintact skin or mucous membranes (e.g., endoscopes).6,14-16

D2. Processing Devices Contaminated With High-Risk Tissue

The following recommendations apply to devices and equipment contaminated with high-risk tissues (defined as brain [including dura mater], spinal cord, and eye tissue) from high-risk patients (i.e., those known or suspected to have CJD):

1) Devices that are constructed so that cleaning procedures result in effective tissue removal (e.g., surgical instruments) can be cleaned and then steam sterilized at 134 °C for >18 minutes in a prevacuum sterilizer or at 121 °C to 132 °C for one hour in a gravity-displacement sterilizer.

2) Devices that are impossible or difficult to clean can be discarded. Alternatively, the contaminated device can be placed in a container filled with a liquid (e.g., saline, water, or phenolic solution) to retard adherence of material to the medical device, then initially decontaminated by steam sterilizing it at 134 °C for 18 minutes in a prevacuum sterilizer (liquids must be removed before the device is sterilized) or at 121 °C to 132 °C for one hour in a gravity-displacement sterilizer or by soaking it in 1N NaOH for one hour. The device is then cleaned, wrapped, and terminally sterilized by conventional means.

NOTES:

1) Most steam sterilizers have multiple cycles that would allow an extended CJD cycle to be set by the operator. For those sterilizers that require exposure times and temperatures to be adjusted to other than manufacturer-recommended settings, users should reset the exposure and temperature settings.

2) Under no circumstances should devices or instruments be placed in NaOH solutions and steam sterilized. This procedure can ruin sterilizers and is dangerous to staff members.

3) To minimize drying of tissues and body fluids on the object, devices should be kept moist until cleaned and decontaminated.

4) Flash sterilization should not be used for reprocessing these devices.

5) Contaminated items that have been in contact with high-risk tissue and have not been processed according to these recommendations (e.g., medical devices used for brain biopsy prior to diagnosis) should be recalled and appropriately reprocessed.
Appendix D. (Continued)

6) A tracking system should be in place that permits recall of devices used on high-risk tissue and high-risk patients. This tracking system should permit identification of the patient on which the devices were used, the date they were used, the procedure performed, and the surgeon’s name. Facilities that do not have a commercially available or automated system should create a manual system. A simple system can be created using a steam-sterilizable, two-part card, with an external chemical indicator that is affixed to the outside of instrument trays. When the tray is used, the bottom part of the card is removed and affixed to the patient’s chart to identify all items used on the patient. To ensure accurate tracking of sets and devices, all items should be given a unique number. For example, if the facility has four craniotomy trays, they should be numbered #1, #2, #3, and #4 to identify the specific tray used on the patient.

7) Environmental surfaces (noncritical) contaminated with high-risk tissues (e.g., laboratory surfaces in contact with the brain tissue of a person infected with CJD) should be cleaned with a detergent and then spot-decontaminated with 5000 mg/L sodium hypochlorite. This concentration usually results from a 1/10 dilution of household bleach. However, the label should be checked for the amount of sodium hypochlorite present; concentrations in U.S. products can range from 3% to over 6% sodium hypochlorite.

8) Noncritical equipment contaminated with high-risk tissue should be cleaned and then disinfected with 5000 mg/L sodium hypochlorite or 1 N NaOH, depending on material compatibility. All contaminated surfaces must be exposed to the disinfectant.

9) Equipment that requires special prion reprocessing should be tagged after use. Clinicians and reprocessing technicians should be thoroughly trained on the proper tagging of equipment and on the special prion reprocessing protocols.

10) Use of power drills or saws that are likely to contact high-risk tissue should be avoided. Power drills and saws by their very nature and design are difficult to clean and too expensive to discard.15

D3. Processing Devices Contaminated With Low-Risk Tissue

The following recommendations apply to devices and equipment contaminated with low-risk tissues (defined as cerebrospinal fluid, kidney, liver, spleen, lung, and lymph node tissue) from high-risk patients:

1) Devices can be cleaned and disinfected or sterilized using conventional protocols of high-level disinfection thermal sterilization, or chemical sterilization.

2) Environmental surfaces contaminated with low-risk tissues require only standard disinfection using disinfectants recommended by OSHA for decontaminating blood-contaminated surfaces (e.g., 500 to 5000 mg/L sodium hypochlorite).

D4. Processing Devices Contaminated With No-Risk Tissue

The following recommendations apply to devices and equipment contaminated with no-risk tissue (defined as peripheral nerve tissue, intestinal tissue, bone marrow, blood, leukocytes, serum, thyroid gland tissue, adrenal gland tissue, heart tissue, skeletal muscle, adipose tissue, gingiva, prostate tissue, testicular tissue, placental tissue, tears, nasal mucus, saliva, sputum, urine, feces, semen, vaginal secretions, milk) from high-risk patients.
Appendix D. (Continued)

1) Devices can be cleaned and disinfected or sterilized using conventional protocols of high-level disinfection thermal sterilization, or chemical sterilization.

2) Endoscopes (except neurosurgical endoscopes) are likely to be contaminated only with no-risk materials. Standard cleaning and high-level disinfection protocols are adequate for reprocessing.

3) Environmental surfaces contaminated with no-risk tissues or fluids require only standard disinfection using disinfectants recommended by OSHA for decontaminating blood-contaminated surfaces (e.g., 500 to 5000 mg/L sodium hypochlorite).

References for Appendix D


Appendix D. (Continued)


Appendix E. Occupational Safety and Health Administration (OSHA) Instruction

OSHA Instruction CPL2-2.69 (November 27, 2001) provides uniform inspection procedures and guidelines to be followed when conducting inspections and issuing citations under Section 5(a)(1) of the Act and pertinent standards for healthcare workers potentially exposed to HBV, HIV, HCV, or any bloodborne pathogens that can cause disease. The following is a list of OSHA offices that may be contacted for further information.

**OSHA Offices**

**REGION 1**

Regional Office
JFK Federal Building, Room E340
Boston, Massachusetts 02203
(617) 565-9860
FAX (617) 565-9827
Area Offices: Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island, Vermont

**REGION 2**

Regional Office
201 Varick Street, Room 670
New York, New York 10014
(212) 337-2378
FAX (212) 337-2371
Area Offices: New Jersey, New York, Puerto Rico, Virgin Islands

**REGION 3**

Regional Office
U.S. Department of Labor/OSHA
The Curtis Center-Suite 740 West
170 S. Independence Mall West
Philadelphia, Pennsylvania 19106-3309
(215) 861-4900
FAX (215) 861-4904
Area Offices: District of Columbia, Delaware, Maryland, Pennsylvania, Virginia, West Virginia

**REGION 4**

Regional Office
61 Forsyth Street, SW
Atlanta, Georgia 30303
(404) 562-2300
FAX (404) 562-2295
Area Offices: Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee

**REGION 5**

Regional Office
230 South Dearborn Street, Room 3244
Chicago, Illinois 60604
(312) 353-2220
FAX (312) 353-7774
Area Offices: Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin

**REGION 6**

Regional Office
U.S. Department of Labor/OSHA
525 Griffin Street, Room 602
Dallas, Texas 75202
(214) 767-4737
FAX (214) 767-4693
Area Offices: Arkansas, Louisiana, New Mexico, Oklahoma, Texas

**REGION 7**

Regional Office
City Center Square
1100 Main Street, Suite 800
Kansas City, Missouri 64105
(816) 426-5861
FAX (816) 426-2750
Area Offices: Iowa, Kansas, Missouri, Nebraska

**REGION 8**

Regional Office
1999 Broadway, Suite 1690
Denver, Colorado 80202-5716
(303) 844-1600
FAX (303) 844-1616
Area Offices: Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming
Appendix E. (Continued)

REGION 9
Regional Office
71 Stevenson Street, Room 420
San Francisco, California 94105
(415) 975-4310 (Main Public - 8:00 AM - 4:30 PM Pacific)
(800) 475-4019 (For Technical Assistance)
(800) 475-4020 (For Complaints - Accidents/Fatalities)
(800) 475-4022 (For Publication Requests)
FAX (415) 975-4319
Area Offices; Arizona, California, Hawaii, Nevada, American Samoa, Guam, Saipan

REGION 10
Regional Office
1111 Third Avenue, Suite 715
Seattle, Washington 98101-3212
(206) 553-5930
FAX (206) 553-6499
Area Offices: Alaska, Idaho, Oregon, Washington

Washington D.C.
Office of Health Enforcement, Room N3119
U.S. Department of Labor
200 Constitution Avenue, NW
Washington, D.C. 20210
(202) 693-2190
FAX (202) 693-1681
Summary of Comments and Subcommittee Responses

M29-A2: Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Second Edition

Section 6.4.3, Spill Clean-Up Procedure

1. Emphasis is made in the spill cleanup section on absorbing the bulk of spilled blood or serum prior to decontamination. In the CLSI/NCCLS video based on this document (M29-A-V), cleanup of a blood spill involving a dropped glass tube is shown in which no disinfectant is used until after both (1) glass fragments are forceps-transferred but hand-wrapped in absorbent sheets and then hand-carried to a suitable biowaste container, and (2) absorbent sheets have been used to pick up the bulk of the spill by being hand-applied to it. Concern I have is that bloody glass may penetrate the gloves when glass fragments are being wrapped or while they are being moved to waste, or during bulk liquid wipe up if some glass fragments were missed earlier. Is there reason to be concerned about potential for parenteral inoculation in this scenario?

- The video is to be revised to be consistent with the current document.

Section 11.2.1, ACIP and HICPAC Recommended Practices (Formerly Section 9.2.1)

2. In Table 9 (PEP for HBV), the abbreviation for HBsAg is spelled incorrectly in two different ways: HbsAg and HBSAg instead of HBsAg; thus, in one table we have three different spellings for the same antigen. Please note for next edition.

- Table 9 (Pep for HBV) has been deleted.
Summary of Delegate Comments and Working Group Responses

M29-A3: Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition

General

1. In general, this document refers in large part to blood-borne infections (HIV, HBV, HCV) and to some extent to airborne infections (TB) but falls short in dealing in detail with protecting laboratory workers from airborne or droplet exposures to the same level of detail as blood-borne infections.

   • In the evolution of this document, the initial emphasis was on blood-borne infections due to their greater risk and severity of disease. With each revision, the scope has expanded to include other agents associated with laboratory-acquired infections as new information is published. The working group expects this trend to continue in subsequent revisions.

Foreword

2. This section should also refer to Biosafety in Microbiological and Biomedical Laboratories, 4th Edition. If this is intended for international communities, the WHO also has a guideline under revision that could be included.

   • The cited references have been added to the Foreword.

Section 1, Scope

3. I assume this document does not apply to laboratory animal activities. Perhaps this should be noted here.

   • The following paragraph has been added to the Scope: “This guideline deals not only with issues concerning clinical laboratories; it also includes detailed discussion of common functions and practices that may affect many other healthcare workplaces or research and animal facilities. Although this document does not specifically address these areas, information may be extracted from this guideline for use in other areas that handle potentially infectious material.”

Section 3, Definitions

4. Many questions came up here in connection with the definitions, particularly concerning aerosols:

   a. The size distribution need not be limited to 1-5 μm.

   • The definition of aerosol has been revised to read: “a system of respirable particles dispersed in a dust, gas, smoke, vapor, or fog that can be retained in the lungs (modified from ISO 15190); NOTE: Aerosol particles generally are ≤5 μm in size.”

   b. Airborne transmission is not only the spread of droplet nuclei, but also includes other airborne dusts.

   • See response to Comment 4a.

Section 5.2.4, Airborne Transmission

5. Airborne nuclei sizes may vary. Aerosols are not always invisible particles.

   • The first sentence of Section 5.2.4 has been revised to read: “Aerosols are particles—generally ≤5 μm in size—that float on air currents.”

Section 5.2.5.1, Effects of Drying: “NOTE”

6. Other groups (particularly the U.N. Dangerous Goods Commission) do not recommend the same precautions for shipping dried blood spots as with liquid blood. Has the group information that supports the viability of pathogens in dried blood?

   • The text has been revised to clarify that the note refers to dried blood found in the laboratory. The current edition of CLSI/NCLCS document LA4—Blood Collection on Filter Paper for Newborn Screening Programs addresses the shipment of dried blood spots. The working group is not aware of data specifically addressing the viability of infectious agents in dried blood; but felt it prudent to consider dried blood as potentially infectious to laboratory workers until data to the contrary becomes available.
Section 5.3.1, Airborne or Droplet Transmission

7. There is word that a new CDC TB guideline is in development which will include respiratory issues identified by NIOSH and CDC’s National Center for Infectious Diseases. This CLSI/NCCLS document may benefit from waiting for that guideline to be issued.

- To be consistent with the CDC draft TB guideline, text has been added to Sections 5.3.1, 6.2.3, 10.1.6, and 10.3.

8. This section deals with airborne or droplet transmission by agent. It gives great detail about TB that applies to other agents in this category. Because these include administrative and engineering controls, could this information be moved so that it applies to other agents transmitted in the same way?

- The text has been moved as recommended. It now appears as the second paragraph of Section 5.3.1.

9. The SARS-CoV section recommends a medical surveillance program. One should be instituted for all infectious agents, not just SARS.

- The working group agrees. Text has been added in the first paragraph of Sections 5.3.1 and 11.1 to include medical surveillance in the postexposure plan for all highly infectious agents.

Section 5.3.3, Transmission by Contact

10. Why is West Nile Virus here when the infections are not solely from contact?

- The working group agrees that laboratory acquired West Nile virus infections may occur via transmission routes other than direct contact. However, the greatest risk appears to be from percutaneous inoculation, emphasizing another agent that can be transmitted by accidental exposure to sharps. The text has been revised to include other transmission routes.

Section 6.2, Barrier Protection

11. Hand Protection raises issues, some of which NIOSH has engaged. NIOSH research concerning antineoplastic drug hazards to workers includes participation in an ASTM Rubber subcommittee on “antineoplastic gloves.” This subcommittee is meeting to evaluate performance and recommend specific types of gloves. Certainly, recommendations contained in the section pertaining to Regulation of Antimicrobial Chemicals (Appendix C) may raise issues concerning health care worker safety when using these chemicals. (It is unknown whether ASTM either has or will look at other glove performance in other medical contexts, but it might be useful to check.)

- The type of glove used for handling chemicals should be addressed in the laboratory’s Chemical Hygiene Plan.

Section 6.2.1, Gloves

12. Is this whole section about disposable gloves? If so, perhaps the title could indicate that, otherwise, where the narrative refers to disposable gloves, please indicate that.

- The text has been changed to “disposable gloves” where appropriate, as recommended.

Section 6.2.1.2, General Recommendations

13. Do laboratory workers really need to wear gloves when transporting/handling a specimen collection (vacutainer) container when there is no visible soiling of the container and there is no intent to “open” the vacutainer tube. Example would be a specimen transporter within the laboratory.

- Laboratory workers are advised to wear gloves when handling material or working in areas that may be contaminated with blood or other potentially infectious material. Contamination is not always visible.

Section 6.2.2, Facial Protection

14. Referring to Facial Protection, face shields do not always offer adequate protection. They may be adequate to protect from splatter but not from aerosols. We need a better understanding of those specific tasks which might generate an aerosol before it will be possible to specify the appropriate PPE. Bone saws and other autopsy procedures, for instance, may generate aerosols.
• The text in Section 6.2.2 has been modified to indicate that face shields do not protect against aerosols, and bone saws have been added to the list of procedures that may generate aerosols in Section 5.3. The risk associated with the use of bone saws is also discussed in Section 10.1.6.

15. Face shields do not offer sufficient eye protection for some tasks. Similar task-specific analysis would be needed.

• Face shields generally offer protection to the entire face and neck region. Alternative eye protection is also listed in Section 6.2.2. Facial barrier protection should be worn if there is a reasonably anticipated potential for spattering and splashing blood or body substances. A list of all laboratory tasks associated with the potential of splashing or spattering blood or body substances is beyond the scope of this document.

Section 6.2.3, Respiratory Protection

16. Surgical masks are not respirators and we would recommend that the two categories of devices not be lumped together in a manner that might lead the reader to equate them. Consistency in language on this point would be advised. Also in regard to this section, please review the specified filtration characteristics of the N95 particulate respirator against the appropriate NIOSH document.

• The text has been revised as recommended.

17. This section should be expanded to include development of a respiratory protection program, respirator types, etc.

• The text has been revised as recommended.

18. A comment on page 89 states: “CDC is not a regulatory agency and does not test, evaluate or otherwise recommend specific brand name products...” This statement may need to be adjusted since, NIOSH at least, does some testing and evaluation of products, specifically respirators.

• The text in Section 6.2.3 has been revised to indicate that respirators must be certified and approved by NIOSH.

Section 6.3, Biological Safety Cabinet

19. A biological safety cabinet is required for work with BSL-3 organisms. This should be stated here.

• The text has been revised as recommended.

Section 6.4.1.1.1, Sodium Hypochlorite

20. Laboratory staff and housekeeping staff need to be educated on the dangers of using Sodium Hypochlorite cleaning solution around other laboratory reagents or other cleaners. The combination can release a toxic/fatal hypochloride gas.

• The text has been revised as recommended.

Section 7.3, Packaging

21. This refers to OSHA-regulated waste. Are there recommendations for nonregulated waste?

• The working group believes that nonregulated waste is not biohazardous and therefore doesn’t pose a significant infectious risk to laboratory workers.

Section 7.5, Transport

22. Please include the U.S. DOT reference.

• The reference has been added to the text.

Section 8, Standard Precautions

23. Please include reference 4 here as well.

• The reference has been added to the text.
Section 8.2.1, Hand Hygiene

24. Please reference the Infection control guidelines as they relate to artificial fingernails or extenders that should not be worn for contact with high-risk patients, such as in the intensive-care units or operating rooms.

- The last bullet in Section 8.2.1 has been added, including a reference, as recommended.

Section 8.2.3, Mask, Eye Protection, Face Shield

25. This section should be expanded to describe the type of mask, eye protection, and face shield to be used under different circumstances. How does one decide?

- The working group’s recommendation is to use PPE (e.g., mask, eye protection) to protect the mucous membranes of the eyes, nose, and mouth from splashes or sprays of infectious material, but believes that the selection and purchase of a specific type of PPE is a local decision.

Section 8.2.4, Gown

26. Gowns or lab coats (even those without stains) worn in the testing area must be removed prior to leaving the testing area.

- A sentence has been added to the end of Section 8.2.4 as recommended.

Section 9.2.1, Blood Collection Equipment and Safety Devices

27. Please add a statement to support more attention to the use of safe blood collection equipment and safety devices.

- A sentence has been added to the end of the first paragraph of Section 9.2.1 as recommended.

Section 9.5, Pneumatic Tube System

28. Our facility is still looking for scientific based recommendations on the use of pneumatic tubes for blood specimen transportation which would include single vs. double bagging. What PPE does or does not need to be used by the laboratory worker who just takes the “bagged specimens out of the pneumatic tube.”

- The working group recommends that specimens transported in a pneumatic tube be placed in a leakproof primary and secondary container to prevent contamination of the pneumatic tube and potential exposure of the laboratory worker to an infectious agent in the event that a body fluid container breaks or leaks. Laboratory workers who handle or work in areas potentially contaminated with blood and other potentially infectious material should wear gloves.

Section 9.8.3, Cytology Laboratories

29. Many cytopathology laboratories will no longer accept syringes with needles attached and do not normally practice the resheathing technique. Please add an alternate solution to removal/disposal of an unsheathed needle.

- A sentence has been added to the end of Section 9.8.3 as recommended.

Section 10.1.5, Personal Protective Equipment

30. Under Personal Protective Equipment, there are comments concerning the N95 particulate respirator that may suggest to the reader that either a face shield OR a respirator with goggles may be used, when, in fact, some tasks may require that one or the other or both are necessary.

- The second bullet in Section 10.1.5 has been revised for clarity.

Section 10.1.5, Personal Protective Equipment, and Section 10.1.6, Autopsy Procedures

31. Several tasks described the need for steel mesh or “fish scaling” gloves. Some further consideration might be appropriate before such recommendations are made. A task analysis may provide valuable insights.

- The recommendation for the use of cut resistant gloves during the listed procedures was based on the obvious risk from sharp bones and cutting tools. The sixth bullet in Section 10.1.5 has been revised to recommend a task analysis to identify other procedures requiring the use of cut-resistant gloves.
Section 10.2.1, Personal Protective Equipment

32. This does not reflect the statements about double-gloving in 6.2.1.5.

- A cross reference to Section 6.2.1.5 has been included in Section 10.2.1.

Section 10.3, Autopsy Rooms

33. Ventilation standards in autopsy or other laboratory or procedure rooms offer no less complexity than PPE selection and I apologize for and regret that I did not consult the appropriate NIOSH industrial hygiene staff, those with expertise in ventilation design and performance, for comments.

- The working group used ASHRAE recommendations addressing ventilation in autopsy rooms. ASHRAE recommends that autopsy rooms have ventilation that provides at least 12 air exchanges per hour.

Section 11.1.1, Exposure Report

34. For respiratory exposures or infections and some contact exposures, there will not necessarily be knowledge of date and time of exposure or many details. Perhaps a caveat, “if known” should be added here.

- The text has been revised as recommended.

Sections 12.2, Specimen Preparation (Formerly Equipment Type) and 12.3 (Formerly Specimen Preparation)

35. One refers to equipment type and the other to specimen preparation, yet the text that follows is about both. In addition, specific equipment types are located in another section (12.8). Section 12.2 looks out of place here.

- Section 12.2, “Equipment Type” has been deleted.

Section 12.7.3, Flow Cytometry

36. For many cell sorters, the biggest hazard for exposure is the back-drip from the sample tube. This needs to be examined and some dialogue provided here.

- A sentence has been added to the end of Section 12.7.3 as recommended.

Section 13.1, Initial Training

37. Under Initial Training, it is suggested that the authors revise the contents to include a discussion of respirator protection training. The OSHA standard for respirator training should be referenced where appropriate, e.g., fit testing.

- A bullet has been added to Section 13.1, and the text in Section 6.2.3 has been revised as recommended.

Section 13.2, Monitoring

38. I believe OHSA requires annual surveys of the work areas. This should be included here.

- The text has been revised as recommended.

Appendix B. Biological Safety Cabinets

39. Type A2 cabinets are not hard-ducted, and currently there are no A2 cabinets. These are Type A, which recirculate air. Type B cabinets are connected to the building exhaust system. This information is available in the BMBL (See Reference 4.).

- The working group used the revised National Sanitation Standard (NSF) Number 49, “Class II (laminar flow) Biosafety Cabinetry” (current version is NSF/ANSI 49-04) for the description of BSCs. Class II, Type A cabinets are defined as Class II Type A1 cabinets and Class II, Type B3 are defined as Class II Type A2 cabinets. The latter cabinets are connected to the building exhaust system by an exhaust canopy.

Appendix B. Section B4.3, Gas Decontamination

40. The last sentence is not correct. Replace it with, “Consult an NSF-certified cabinet certifier for decontamination information.”

- The text has been revised as recommended.
Additional Voting Comments Following Delegate Review

M29-A3: Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition

Section 3. Definitions

1. The definition of “blood-borne pathogens” is not consistent with the OSHA definition. Furthermore, you should not include “other potentially infectious material” as a source of blood-borne pathogens unless you qualify that with “contaminated with blood.”
   - The definition of “blood-borne pathogens” has been revised as recommended.

2. The definition of “contact transmission” needs to be revised on two levels. First, the statement should reflect the same style as that for “airborne transmission.” Second, what you have for “contact transmission” reflects only half of the process. You need to include the fact that transmission of the infectious agent occurs when the hands transfer the agent from the person or surface that was touched to an appropriate portal of entry. You should also include the notion that infections such as influenza are largely transmitted via direct contact through the dispersion of infected respiratory secretions in the immediate vicinity of other persons.
   - The definition of “contact transmission” has been revised to reflect information contained in Reference 8.

3. Disinfectants “effect” disinfection, not “cause.” I suggest deleting this draft definition of “disinfection” in favor of that promulgated by CDC, used in the U.S. for decades, and accepted worldwide. See the CDC “Guidelines for Environmental Infection Control in Health-Care Facilities” for the definition. What is given here is more of a definition for “cleaning.”
   - The definitions of “disinfectant” and “disinfection” have been revised.

4. In the definition of “droplet precautions,” add the particle size in parentheses to remind the reader that the precautions apply to those droplets that may remain suspended in air for a short time.
   - The particle size of droplets has been added to the definition.

5. The definition for “hospital disinfectant” should include the fact that this is a registration category of the U.S. EPA. All the additional explanatory material included in this definition should be moved to a paragraph in the text that better explains these concepts in the context of the regulations.
   - The text has been revised as recommended. The additional explanatory information has been deleted.

6. The definition of “infectious waste” should include text to indicate that exposure involves a proper portal of entry (i.e., either percutaneous injuries or inhalation of potentially infectious aerosols).
   - The text has been revised as recommended.

7. The definition of “medical waste” should be revised to say something like this: “that portion of the infectious waste stream regulated by the authority having jurisdiction and for which some decontamination treatment is indicated.”
   - The text has been revised as recommended.

8. The definition of “microbial aerosol” is not contingent upon the “infectivity” of the microbes present. Infectivity is independent of the size property of the particle and the likelihood that the particle will be drawn down deeply into the lungs.
   - The text has been revised as recommended.

9. The definition of “prions” should be revised. Prions are membrane proteins with an abnormal beta-sheet conformation that appears to confer a degree of resistance to conventional disinfection or sterilization processes. These abnormally folded proteins are associated with the development of transmissible spongiform encephalopathies.
   - The text has been revised as recommended.
Section 5.2.2, HBV Indirect Contact

10. What is the evidence that documents HBV transmission from objects that have been touched by hand? While it may be true that these objects may have HBV isolated from their surfaces subsequent to blood contamination of the item, where is the report documenting that HBV infection has occurred?

- The working group agrees and has revised the text as recommended.

Section 5.2.5.3, Relation to Laboratory Environment

11. I suggest deleting the first sentence of this paragraph and/or revising this paragraph altogether. In reality, most laboratory devices and items will be cleaned first, then subjected to low- to intermediate-level disinfection or sterilization. I am not aware of any routine laboratory item that is targeted to receive high-level disinfection. Ultimately, there should be nothing different in laboratory surface decontamination procedures simply because blood may potentially contain HIV.

- The words “high-level” have been deleted.

Section 5.3.1, Airborne or Droplet Transmission

12. Reconcile the first statement of this paragraph with the information reported in the first paragraph of Section 5.3. Where is the documentation in support of this statement in Section 5.3.1?

- The statement has been revised to state that infectious agents transmitted by aerosols are a risk for laboratory-acquired infections. The working group feels that information on select agents is available at the listed websites.

Section 5.3.1, Bacillus Anthracis

13. Add a qualifier to that first sentence to indicate what laboratory factors were associated with anthrax transmission. Obviously this information is coming from many years ago.

- The text has been revised to include only the recent cases of cutaneous anthrax. The transmission risks for laboratory personnel are listed in the text.

Section 5.3.3, Transmission by Contact

14. First paragraph, last sentence. I think this statement is confusing. I believe the point being made is that laboratorians at CDC use a Class II BSC and gloves when working with VISA isolates. I know of no recommendations for routine clinical labs, however, and could not find them on the CDC websites listed. The sentence as written may be confusing for clinical labs. Practically speaking, microbiology technologists will have handled a VISA or VRSA isolate under normal conditions until it is recognized to be aberrant. Should this information be added to M29 without a reference for these special handling recommendations?

- The text has been revised to emphasize that the routine use of safety practices such as decontamination of work surfaces, appropriate barrier protection, and proper hand hygiene reduce the potential risk for skin and/or nasal colonization or infection by multidrug-resistant organisms.

15. The decontamination of work surfaces is not directly preventing worker colonization with an MRSA, VISA, or VRSA. Decontamination will help to reduce an environmental surface reservoir; it’s the handwashing that will actually help the worker.

- See the response to Comment 14 above.

Section 5.3.3, Transmission by Contact, WNV

16. Inclusion of WNV in the discussion of “Transmission by Contact” is at odds with the definition of “contact transmission.” Nothing you have listed here for WNV fits with the definition. I suggest reverting back to conventional mode of transmission terminology, since what you have here is confusing.

- The working group agrees that laboratory-acquired West Nile virus infections may occur via transmission routes other than direct contact. However, the greatest risk appears to be from percutaneous inoculation, emphasizing another agent that can be transmitted by accidental exposure to sharps. The text has been revised to include other transmission routes.
Section 6.2.1, Gloves

17. You may want to clarify that the statement about use of medical gloves is directed at bench activities. Housekeeping gloves may be more appropriate for support function tasks (e.g., glassware/instrument reprocessing, housekeeping, decontamination). The statement “Regulatory agencies may require higher standards” should be explained further. State which agencies you’re referring to and what regulations bear on this topic. In the paragraph outlining where gloves are to be worn, add “areas in which MRSA, VISA, and VRSA are present.” This would make this statement consistent with the message given earlier on the importance of preventing colonization with these organisms.

- The text has been revised as recommended and the reference to “regulatory agencies” deleted. See the response to Comment 14 for the text regarding MRSA, VISA, and VRSA.

Section 6.4.1.1.1, Sodium Hypochlorite

18. Since this guideline chapter is largely targeted at U.S. audiences, you should emphasize that EPA-registered hypochlorites, used in accordance with label instructions, is the preferred choice. This emphasis will make this document consistent with the recommendations in CDC’s “Guidelines for Environmental Infection Control in Health-Care Facilities.” For example, use of many grocery store bleaches as disinfectants is considered by EPA as an “off-label” use. Additionally, many of the proprietary bleaches are now 6.15% hypochlorite (61500 mg/L of free available chlorine). Adjust this value accordingly in the statements of the text and in Table 6.

- The text has been revised as recommended.

19. In the very last paragraph of this subtopic, you mention the use of hospital disinfectants for large spills. This is not consistent with OSHA regulations, unless you are referring specifically to those quaternary ammonium compounds (quats) that have label claims for HBV inactivation. Make this clarification. The hospital disinfectants need to be at the very least tuberculocidal.

- The text has been revised as recommended.

Section 6.4.3, Spill Clean-Up Procedure

20. The statement that workers need to evacuate the area for at least 60 minutes if a BSL 3 agent is spilled outside of a BSC raises a number of questions. If you have respiratory protection and your PPE, couldn’t you begin to clean up the spill? If you’re suggesting that you’re relying on sufficient air changes per hour (ACH) to clean the air, then you need to develop this point more fully. You need to give some insight regarding how you came up with the 60 minutes and this strategy.

- The text has been revised as recommended and a reference provided.

Section 9.2.3, Skin Puncture

21. The first sentence in this subtopic doesn’t make sense. I suggest revising this sentence to read, “Skin puncture procedures may result in small amounts of blood to exude onto the patient’s skin, thereby posing a potential hazard to the laboratory worker.”

- The text has been revised as recommended.

Section 12.6.4.1, Assembled Devices

22. Include a statement that the manufacturer’s instructions should be followed. That ties in with the statement about flushing the device with a fluid “as specified.”

- The text has been revised as recommended.

Appendix D

23. When discussing cases subsequent to hormone therapy, it’s important to emphasize that hormone source material derived from infectious sources are implicated in transmission. Not all recipients of hormone therapy were at risk.

- The text has been revised as recommended.

24. Healthcare facilities must do more than simply “consider” the use of these prion inactivation strategies. Include the recent JCAHO Sentinel Event Alert #20 from June 2001. This indicates that facilities (including the laboratories) need to have policies and procedures in place to address the management of known and/or suspect cases.

- The JCAHO reference has been added.
The Quality Management System Approach

Clinical and Laboratory Standards Institute subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The approach is based on the model presented in the most current edition of CLSI/NCCLS document HS1—*A Quality Management System Model for Health Care*. The quality management system approach applies a core set of “quality system essentials” (QSEs), basic to any organization, to all operations in any healthcare service’s path of workflow (i.e., operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager’s guide. The quality system essentials (QSEs) are:

- Documents & Records
- Equipment
- Information Management
- Process Improvement
- Organization
- Personnel
- Purchasing & Inventory
- Occurrence Management
- Service & Satisfaction
- Process Control
- Assessment
- Facilities & Safety

M29-A3 addresses the quality system essentials (QSEs) indicated by an “X.” For a description of the other Clinical and Laboratory Standards Institute documents listed in the grid, please refer to the Related CLSI/NCCLS Publications section on the following page.

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Adapted from CLSI/NCCLS document HS1—*A Quality Management System Model for Health Care*.

Path of Workflow

A path of workflow is the description of the necessary steps to deliver the particular product or service that the organization or entity provides. For example, CLSI/NCCLS document GP26—*Application of a Quality Management System Model for Laboratory Services* defines a clinical laboratory path of workflow which consists of three sequential processes: preexamination, examination, and postexamination. All clinical laboratories follow these processes to deliver the laboratory’s services, namely quality laboratory information.

M29-A3 addresses the clinical laboratory path of workflow steps indicated by an “X.” For a description of the other Clinical and Laboratory Standards Institute documents listed in the grid, please refer to the Related CLSI/NCCLS Publications section on the following page.

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Adapted from CLSI/NCCLS document HS1—*A Quality Management System Model for Health Care*.
Related CLSI/NCCLS Publications

GP5-A2 Clinical Laboratory Waste Management; Approved Guideline—Second Edition (2002). Based on U.S. regulations, this document provides guidance on safe handling and disposal of chemical, infectious, radioactive, and multihazardous wastes generated in the clinical laboratory.

GP16-A2 Routine Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline—Second Edition (2001). This guideline describes routine urinalysis test procedures that address materials and equipment, macroscopic examinations, clinical analyses, and microscopic evaluations.

GP17-A2 Clinical Laboratory Safety; Approved Guideline—Second Edition (2004). This document provides general guidelines for implementing a high-quality laboratory safety program. The framework is adaptable to any laboratory.

H3-A5 Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard—Fifth Edition (2003). This document provides procedures for the collection of diagnostic specimens by venipuncture, including line draws, blood culture collection, and venipuncture in children. It includes recommendations on order of draw.

H4-A5 Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard—Fifth Edition (2004). This document provides a technique for the collection of diagnostic capillary blood specimens, including recommendations for collection sites and specimen handling and identification. Specifications for disposable devices used to collect, process and transfer diagnostic capillary blood specimens are also included.


H18-A3 Procedures for the Handling and Processing of Blood Specimens; Approved Guideline—Third Edition; (2004). This document includes criteria for preparing an optimal serum or plasma sample and for the devices used to process blood specimens.

H21-A4 Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays; Approved Guideline—Fourth Edition (2003). This guideline contains procedures for collecting, transporting, and storing blood; processing blood specimens; storing plasma for coagulation testing; and provides general recommendations for performing the tests.

LA4-A4 Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Fourth Edition (2003). This document addresses the issues associated with specimen collection, the filter paper collection device, and the transfer of blood onto filter paper, and provides uniform techniques for collecting the best possible specimen for use in newborn screening programs.

X3-R Implementing a Needlestick and Sharps Injury Prevention Program in the Clinical Laboratory; A Report (2002). This report presents a step-by-step approach for implementing safer medical devices that reduce or eliminate sharps injuries to laboratory personnel. X3-R is written in an expanded checklist format, outlines a process that goes beyond general recommendations, and specifically addresses the needs of professionals performing specimen collection and clinical laboratory procedures.

X4-R Planning for Challenges to Clinical Laboratory Operations During a Disaster; A Report (2003). This document provides guidance on steps to be taken by the clinical laboratory to be prepared in the event of an emergency. X4-R is written for use by laboratory managers, directors, and supervisors, and is intended to provide a checklist of considerations to be used to assess, preparedness and begin planning for continuance and redirection of clinical laboratory services during emergency situations.

* Proposed-level documents are being advanced through the Clinical and Laboratory Standards Institute consensus process; therefore, readers should refer to the most recent editions.