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Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Second Edition

Based on U.S. regulations, this document provides guidance on the risk of transmission of hepatitis viruses and human immunodeficiency viruses in any laboratory setting; specific precautions for preventing the laboratory transmission of blood-borne infection from laboratory instruments and materials; and recommendations for the management of blood-borne exposure.

A guideline for national application developed through the NCCLS consensus process.

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Healthcare professionals in all specialties are urged to volunteer for participation in NCCLS projects. Please contact the NCCLS Executive Offices for additional information on committee participation.

Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Second Edition

Abstract

NCCLS document M29-A2 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 needles and sharps safety, prions, agents of Creutzfeldt-Jakob disease, and airborne transmission of potential agents of bioterrorism.

This guideline contains detailed recommendations for the protection of workers from disease agents transmitted by aerosols, 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 lymphotrophic 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.

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,* 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

Workers in the medical community are at risk 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. Laboratory workers, who are routinely exposed to potentially infectious material, have long been recognized as a high-risk group for occupationally related exposure to infectious agents. 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 committee has made significant changes in the document from the previous version. Importantly, the scope of the guideline was expanded to include not only blood-borne pathogens but also other agents associated with laboratory-acquired infections, acts of bioterrorism, and emerging infections. This change was necessitated by the potential for exposure to many different agents due to increased worldwide travel and trade. Other changes 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. Appendixes were added to provide in-depth information on 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 you to submit your comments to the NCCLS Executive Offices. We would deeply appreciate receiving your specific comments on the contents as well as any additional information that you possess that was not available to the working group. Each comment will be evaluated and addressed in the next edition of the guideline.

NCCLS felt that a single source of authoritative, current, complete, and practical recommendations which addressed all areas of the healthcare facility laboratory (clinical, anatomical pathology, point-of-care testing, and medical clinics and offices) would offer 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 other international standards on laboratory safety[1,2] and the most important documents that were used by the committee. 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.

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 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 "must" is used to indicate the lack of choice on the part of the user. In the United States, the 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.

Foreword (Continued)

The working group feels 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.

This guideline deals not only with issues concerning clinical laboratories but includes detailed discussion of common functions and practices that may affect many other healthcare workplaces or research facilities. Therefore, information may be extracted from this guideline for use in other areas that handle potentially infectious material.

The Area Committee on Microbiology and the Working Group on Protection of Laboratory Workers wish to acknowledge the following individuals for their invaluable contributions in preparing the approved-level, second edition of this guideline: Dr. Elise Beltrami, Centers for Disease Control and Prevention; Nancy Dubrowny, BD VACUTAINER Systems; and Joan D. Wiseman, BD VACUTAINER Systems.

NCCLS 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 NCCLS consensus documents are intended for global application. Under certain circumstances, however, an NCCLS standard or guideline may be intended for primary use in a specific country or region.

NCCLS document M29-A2—*Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline—Second Edition* is one such consensus document. While M29-A2 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-A2 from our global consensus documents.

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—Second Edition

1 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.[3] Transmission of at least 20 different pathogens by needlestick and sharps injuries has been reported.[4] During the past decade, an estimated 100 to 200 U.S. healthcare personnel have died each year from occupationally acquired HBV infection.[5] Between 1978 and June 2000, 56 healthcare workers have acquired HIV through occupational exposure, with 138 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 NCCLS guideline M29-A2, NCCLS 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.)

Group at Risk	Statistics	HBV	HCV	HIV
Healthcare Workers (8 - 9 million)	New cases per year*	800 - 1,000†	500 – 1,000‡	56 in 21 yrs (since 1978)
	Deaths per year*	100-200†	Unknown	Unknown
	Total Infected*	Unknown	80,000 – 180,000§	56 documented cases 138 possible cases
U.S. Population in General (250 – 300 million)	New cases per year	240,000#	28,000‡ – 36,000¶	21,048††
	Deaths per year	5,000 –7,000#	8,000 –10,000¶	16,273‡‡
	Total Infected	1 - 1.25 million**	3.9 - 4.5 million¶	1 – 1.5 million

* Occupationally acquired.

† Estimated from 1994. CDC guidelines for infection control in health care personnel, 1998. *Am J Infect Control.* 1998;26:302.

‡ Estimated from 1995, 28,000 for total US population of which 2 to 4% occurred in healthcare workers. CDC guidelines for infection control in health care personnel, 1998. *Am J Infect Control*. 1998;26:304.

§ 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. Recommendations for prevention and control of hepatitis C virus (HCV) infection and HCV-related chronic disease. *MMWR*. 1998;47(RR-19):1-39.

CDC. NCID Division of Viral and Rickettsial Diseases; 1996

**CDC. NCID Viral Hepatitis B-Fact Sheet; Feb 2000 (www.cdc.gov/ncidod/diseases/hepatitis/b).

†† From July 1999 to June 2000. CDC-HIV/AIDS Surveillance Report. Vol. 12; No. 1:Table 3. (www.cdc.gov/hiv/stats/hasrlink.htm).

‡‡ For 1999, estimated deaths due to AIDS. CDC-HIV/AIDS Surveillance Report. Vol. 12; No. 1:Table 28 (www.cdc.gov/hiv/stats/hasrlink.htm).

2 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-A2 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.

3 Definitions[a]

Aerosol, *n* - A system of respirable particles dispersed in a gas, smoke, or fog that can be retained in the lungs.

Airborne transmission, *n* – The spread of infection by inhalation of droplet nuclei containing infectious agents.

Antiseptic, *n* **-** A chemical germicide formulated to be used on skin or tissue; NOTE**:** Antiseptics should not be used as disinfectants. The FDA has regulatory authority over antiseptic compounds.

Blood-borne pathogens, *n* **–** Pathogenic microorganisms that are present in human blood and can cause disease in humans.

Contact transmission, *n* **-** Infectious agents are transmitted through direct (touching the infected or colonized individual) or indirect (touching contaminated objects) contact.

Contaminant, *n* - A microorganism, chemical, or other material that makes something impure by contact or mixture with it.

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

Contaminated sharps, *n* **-** 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, *n* - A procedure that eliminates or reduces microbial or toxic agents to a safe level with respect to the transmission of infection or other adverse affects; **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, *n* - An agent intended to destroy or irreversibly inactivate all microorganisms, but not necessarily their spores, on inanimate surfaces, e.g., work surfaces or medical devices. **NOTE:** Most disinfectants are not effective sterilizers.

Disinfection, *n* **-** A procedure that kills pathogenic microorganisms, but not necessarily their spores; NOTE**:** Chemical germicides that are formulated as disinfectants are used on inanimate surfaces (medical devices, etc.) and should not be used on skin or tissues.

[a] Some of these definitions are found in NCCLS document NRSCL8—*Terminology and Definitions for Use in NCCLS Documents.* For complete definitions and detailed source information, please refer to the most current edition of that document.

Droplets, *n* **-** Particles of moisture produced by aerosolization that may carry an infectious agent. Droplets larger than 150 μm generally fall to a surface; **NOTE:** Droplets smaller than 150 μm generally evaporate and may remain suspended in air.

Droplet nuclei, *n* **-** Droplets that evaporate before falling to a surface and range in size from 1 to 5 μm; **NOTE:** Droplet nuclei can remain airborne for extended periods of time.

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

Equipment, *n* **-** The articles or implements used or needed for a specific purpose or activity.

Germicide, *n* **-** A general term that indicates an agent that kills pathogenic microorganisms on inanimate surfaces.

Hospital disinfectant, *n* **-** An agent with demonstrated effectiveness against *Staphylococcus aureus*, *Salmonella choleraesuis*, and *Pseudomonas aeruginosa*; **NOTE:** A healthcare facility disinfectant may be effective against such organisms as *Mycobacterium tuberculosis*, pathogenic fungi, or certain specifically named viruses. All commercially available healthcare facility disinfectants contain a claim of effectiveness for specific agents in their labeling. All claims of effectiveness must be substantiated by data that are submitted to, and accepted by, the EPA prior to registration.

Infectious waste, *n* **-** Waste containing or assumed to contain pathogens of sufficient virulence and quantity, so that exposure to the waste by a susceptible host could result in a communicable disease.

Instrument, *n* **-** A device that will give analytical answers as a result of electrical or mechanical measurements on an element, compound, solution, etc.

Laboratory worker, *n* **-** 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, *n* **-** Materials generated as a result of diagnosis and treatment of patients.

Needleless system, *n* **-** 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, *n* **-** 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), *n* **-** 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, *adj* **–** Piercing mucous membranes or the skin through such events as needlesticks, human bites, cuts, and abrasions.

Percutaneous, *adj*– Parenteral inoculation of infectious material or transfusion of blood or blood products.

Personal protective equipment (PPE), *n* **-** Specialized clothing or equipment worn by an employee for protection against a hazard.

Primary container, *n* - A vessel, including its closure, that contains the specimen.

Prions, *n* – Infectious, abnormal host proteins that cause transmissible spongiform encephalopathies and are resistant to a number of standard disinfection and sterilization procedures.

Regulated waste, *n* **-** 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.

Secondary container, *n* - 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, *n* - A container approved for the containment of contaminated sharps for transport.

Sharps with engineered sharps injury protections, *n* **-** 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, *n* **-** 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, *n* **-** A procedure that effectively kills all microbial life, including bacterial spores on inanimate surfaces.

Sterilant, *n* **-** An agent intended to destroy all microorganisms (viruses, vegetative bacteria, fungi, and large numbers of highly resistant bacterial endospores) on inanimate surfaces.

Universal precautions, *n* **-** Set of precautions designed to reduce risk of transmission of HIV, hepatitis B virus, and other blood-borne pathogens in the healthcare setting; **NOTES:** a) 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; b) 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.

Wipe test, *n* - 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

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
EPA	U.S. Environmental Protection Agency
FDA	U.S. Food and Drug Administration
HAV	hepatitis A virus
HBIG	hepatitis B virus immune globulin
HBV	hepatitis B virus
HBsAg	hepatitis B surface antigen
HCV	hepatitis C virus
HDV	hepatitis D virus
HEPA filtration	high-efficiency particulate filtration
HEV	hepatitis E virus
HGV	hepatitis G virus
HHS	U.S. Department of Health and Human Services
HICPAC	Hospital Infection Control Practices Advisory Committee
HIV	human immunodeficiency virus
HTLV	human T cell lymphotrophic virus
JCAHO	Joint Commission on the Accreditation of Healthcare Organizations
NANB	non-A, non-B hepatitis virus
NIOSH	National Institute for Occupational Safety and Health
NSF	National Sanitation Foundation International
OSHA	Occupational Safety and Health Administration
PEP	postexposure prophylaxis

SOP standard operating procedure

TB tuberculosis

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 (CDC. 1999. Occupational exposure to HIV, Information for healthcare workers, www.cdc.gov/ncidod/hip/faq.htm). 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 (56 cases, as of June 2000). Notwithstanding, among U.S. healthcare workers with documented occupational HIV seroconversion, 89% (50/56) 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.[6] Indeed, following workplace exposure to HIV-infected materials, healthcare workers have seroconverted; developed the acute retroviral syndrome; and have developed AIDS.

Table 2. Healthcare Workers with Documented Occupationally Acquired AIDS/HIV Infection by Type of Occupation Exposure and Type of Fluid Involved, Reported from 1978 through June 2000, United States (Adapted from Centers for Disease Control and Prevention: *HIV/AIDS Surveillance Report.* Vol. 12, No. 1. [See www.cdc.gov/hiv/stats/hasrlink.htm])

Type of Occupational Exposure	Number
Percutaneous (needlestick or cuts)	48
Mucocutaneous (eye, nose, mouth, or skin)	5
Both (above)	2
Undetermined	1
TOTAL	**56**

Type of Fluid Involved in Exposure	Number
Blood	49
Concentrated virus in laboratory	3
Visibly bloody fluid	1
Unspecified fluid	3
TOTAL	**56**

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 1,000 cases occur each year, with 1.8% of the US population having evidence of infection. (CDC. 1998. Exposure to Blood. What health-care workers need to know. Department of Health & Human Services, p 1-8. www.cdc.gov/ncidod/hip/Blood/exp_blood.htm). Hepatitis C virus infection is the most common chronic blood-borne infection in the United States. During the 1980s, CDC estimates that 230,000 new infections occurred each year. After 1989, however, infections began to steadily decline and by 1996 a reduction in the infection rate of >80% was observed,

with approximately 36,000 cases/year. To date, at least 3.9 million Americans are thought to be infected with HCV.[7]

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). Appendix A contains source material of general interest and recommended measures for handling HAV, HBV, and HIV-containing specimens.

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.[8] 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 µL,[9] a quantity sufficient to contain up to 100 infectious doses of HBV.[10] The risk of transmission after a needlestick exposure to a nonimmune person is at least 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 10 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 which develop active liver disease. Of the patients with active liver disease, 10% to 20% develop cirrhosis, and 1% to 5% develop cancer.[7] 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 (CDC. *MMWR*. 1998;47(RR19):7.)

Type of Exposure	HBV	HCV	HIV
Percutaneous	18% (6% - 30%)	1.8% (0% - 7%)	0.3% (0% - 0.9%)
Mucous membrane (Eye, nose, mouth)	Unknown	— *	0.1%
Nonintact Skin	Unknown	— *	<0.1%
Concentration in blood (Particles per mL)	10^8 to 10^9	10^2 to 10^3	10^0 to 10^4

* 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 between 0% and 0.9%. 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 June 2000, United States* (Adapted from Centers for Disease Control and Prevention: *HIV/AIDS Surveillance Report*. Vol. 12, No. 1. [See www.cdc.gov/hiv/stats/hasrlink.htm])

Occupation	Documented Occupational Transmission†	Possible Occupational Transmission‡
	Number	Number
Dental worker, including dentist	—	6
Embalmer/morgue technician	1	2
Emergency medical personnel	—	12
Health aide/attendant	1	15
Housekeeper/maintenance worker	2	13
Laboratory technician, clinical	16	17
Laboratory technician, nonclinical	3	—
Nurse	23	35
Physician, nonsurgical	6	12
Physician, surgical	—	6
Respiratory therapist	1	2
Technician, dialysis	1	3
Technician, surgical	2	2
Technician/therapist, other than above	—	9
Other health occupations	—	4
Total	**56**	**138**

* Healthcare workers are defined as those persons, including students and trainees, who have worked in a health-care, clinical, or HIV laboratory setting at any time since 1978. (See *MMWR*. 1992;41:823-25.)

† Healthcare workers who had documented HIV seroconversion after occupational exposure or had other laboratory evidence of occupational infection. Twenty-five of these healthcare 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 56 healthcare workers with documented occupationally acquired HIV infection, almost 90% resulted from either a needlestick or cut, or both (see Table 2). Twenty-five 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% to 0.9% (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, splashing, or spattering of oral or nasal mucosa or conjunctiva. Approximately 13% (7/56) 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.[11]

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 9). 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.[11]

5.2.2 Indirect Contact

HBV can be transmitted indirectly from such common environmental surfaces as telephones, test tubes, laboratory devices, and other surfaces contaminated with infectious blood, plasma, serum, or body fluids that can be transferred to the skin or mucous membranes by hand contact. To date no environmentally mediated transmission of HIV has been documented. Indirect transmission of HCV and HTLV I/II has not 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 should not be worn in the laboratory, since caustic chemicals may accumulate under the lenses if there is a splash. If contact lenses are worn, proper eye protection should be used (e.g., goggles).

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. [See www.osha-slc.gov/Preamble/Blood_data/BLOOD5.html].)

HBV INFECTION OUTCOME	%
No or mild symptoms	65 –75
Clinical illness	25 - 33
Hospitalization	5 - 7
Chronic HBV carrier	5 – 10
Death (cirrhosis)	1.7
Death (liver cancer)	0.4
Death (fulminant hepatitis)	0.1
Death (all)	2.2

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. Routine precautions used in the handling of blood (gloves and hand washing) are adequate to prevent transmission of hepatitis and retroviruses from blood-contaminated feces.

5.2.4 Airborne Transmission

Aerosols are invisible particles—generally, less than 10 microns in diameter—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 ^{o}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 $TCID_{50}$/mL) were dried at room temperature (23 to 27 ^{o}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 ^{o}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 ^{o}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 be considered 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 high-level 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 11).

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. 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*.[12] 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 11.3.1). 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.

5.3.1 Airborne Transmission

Agents that can be transmitted by the aerosol route cause the most 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 *M. tuberculosis*, *B. pertussis*, *C. diphtheriae*, *N. meningitidis*, *B. anthracis,* and *Y. pestis*. *N. meningitidis* and other agents (e.g., *Brucella* spp., *F. tularensis*, and *B. pseudomallei*) that are transmitted via an airborne route will be discussed below because of the high mortality seen in laboratory-acquired infections[13] or their potential for use in acts of biological terrorism.

NEISSERIA MENINGITIDIS[b]

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*. (Editor's Note: Laboratorians who are likely to encounter meningococcal isolates from sterile sites may have increased risk of infection and should consider the use of PPEs (e.g., splashguards, masks) or BSC during manipulation of these isolates and vaccination as an adjunctive measure.[13] Vaccination does not eliminate the risk of infection.)

BACILLUS ANTHRACIS[b]

Numerous cases of laboratory-associated anthrax, occurring primarily at facilities conducting anthrax research, have been reported. No laboratory-associated cases of anthrax have been reported in the United States since the late 1950s when human anthrax vaccine was introduced. Any work with *B. anthracis* requires special security considerations due to its potential use for purposes of biological terrorism. 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 Centers for Disease Control and Prevention; 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.

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[b] 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).

Editor's 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. 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[b]

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.

FRANCISELLA TULARENSIS[b]

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 10 organisms by the respiratory route.

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[b] 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).

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 *Francisella 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 (APIC) published in the CDC Morbidity and Mortality Weekly Report (MMWR) for recommendation for vaccination against *F. tularensis*.

BURKHOLDERIA PSEUDOMALLEI[b]

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*.

Laboratory Hazards: The agent 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 agent has been demonstrated in blood, sputum, and abscess materials and 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: Pure cultures of agents that are known to be particularly pathogenic to those with an intact immune system should always be transferred within a biological safety cabinet, although many common bacterial and fungal pathogens may be safely manipulated on the open bench using BSL-2 procedures and practices. Agents transmitted by airborne droplets or aerosols that may pose a threat to laboratory workers or a secondary risk to close family contacts or the community include *Mycobacterium tuberculosis, Bordetella pertussis*, *Corynebacterium diphtheriae*, *Neisseria meningitidis*, and *Yersinia pestis*. 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 biological safety cabinet 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*. This is a partial list of infectious host agents that may cause laboratory-acquired infections and is not intended to be inclusive.

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[b] 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).

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. 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 *BMBL*.[14]

6 Protection Techniques

In the United States, OSHA has published a *Final Rule on Occupational Exposure to Bloodborne Pathogens* (29 CFR 1910.1030) 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 be used in all phases of laboratory work, which involve human specimens including specimen accessioning, preparation, analysis, and disposal. See Section 8.8.2 regarding special procedures for microbiology laboratories.

6.1 Hand Washing

Frequent hand washing is the most important safety precaution, which must be practiced after contact with patients and laboratory specimens.

Immediately after accidental skin contact with blood, body substances, or tissues, hands or other skin areas must be thoroughly washed. If the contact occurs through breaks in gloves, the gloves should immediately be removed and the hands should be thoroughly washed.

Hands should be washed:

- whenever there is visible contamination with blood or body substances;
- after the completion of work and before leaving the laboratory;
- after removing gloves (Gloves should be worn when performing phlebotomy and changed between patients. The hands should be washed when the gloves are removed and before donning new gloves);
- 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.

Washing with soap and running water is recommended; however, any standard detergent product acceptable to personnel may be used. In settings where water is not available, alcohol-based gels or liquids, hand-wipe towelettes, and cleansing foams can be used. (In the U.S., employees must wash their hands with soap and running water as soon as feasible thereafter.)

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.

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 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. Latex or vinyl gloves provide adequate barrier protection. Disposable nonsterile latex, nitrile, and vinyl gloves are available from healthcare suppliers. Gloves are available in wrist, elbow, and shoulder length. Regulatory agencies may require higher standards.

Gloves made of thin latex or vinyl are not intended to provide protection from puncture wounds caused by sharp devices. A single glove will protect the hands from contamination with blood and body substances (see Double Gloving in Section 6.2.1.5). In high-risk situations, puncture resistance is provided by heavyweight utility gloves such as those used for dishwashing. Stainless steel mesh gloves protect against injury caused by large, sharp edges (e.g., knife blades).

Disposable gloves should be changed frequently. Disposal of used gloves, especially consignment to biohazardous waste, should follow local regulatory protocol (see Section 8.10).

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

Gloves should be examined for visible defects after donning and before commencing work. Gloves should be changed if they accidentally become visibly contaminated with blood or body substances, or if physical (e.g., defects, tears) or chemical (e.g., organic solvent) damage occurs.

Gloves need not be changed during laboratory activities, which 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 environmental contamination from soiled gloves.

Laboratory workers should be taught aseptic technique for donning and removing gloves. 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.

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.

Because the use of powder-free gloves reduces the dissemination of latex proteins into the environment, powdered latex gloves should be 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.

6.2.1.2 CDC Recommendations

Although the Food and Drug Administration (FDA) has responsibility for regulating the medical glove industry, the CDC recommends these general guidelines for the laboratorian:

- The material from which the gloves are manufactured should be appropriate for the task being performed. There are no reported differences in barrier effectiveness between intact latex and intact vinyl used as starting material to manufacture gloves.

NOTE: Reports in the literature indicate that defect rate of holes in gloves made of either latex or vinyl vary greatly by manufacturer and conditions of use.

- Use sterile gloves for procedures involving contact with normally sterile areas of a patient's body.

- Use nonsterile examination gloves for procedures involving contact with mucous membranes, unless otherwise indicated, and for other procedures which do not require the use of sterile gloves (e.g., laboratory work).

- Change gloves between patient contacts or before touching surfaces that should not be contaminated (i.e., nonlaboratory equipment, office items, etc.). Gloves should be removed and hands washed prior to leaving the laboratory environment.

- Do not wash or disinfect gloves for reuse. Detergents may cause enhanced penetration of liquids through undetected holes, and disinfectants may cause deterioration. Organic solvents rapidly deteriorate latex gloves, and some solvents dissolve vinyl gloves.

- 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.

6.2.1.3 General Recommendations

Gloves should be worn by:

- all healthcare providers procuring specimens. Healthcare providers should change gloves as soon as possible if the gloves become visibly contaminated with blood or show evidence of perforation, tears, or leaks. Gloves worn by phlebotomists and other healthcare providers should be changed between each patient contact (see Section 6.2.1.2).

- 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 7.2 for further details.)

- all personnel when handling biohazardous bagged material and visibly contaminated items or linen (see Section 8.10).

6.2.1.4 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 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.

6.2.1.5 Double Gloving

Wearing two pairs of gloves is recommended during autopsies 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 8.11.

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.

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.[15]

6.2.3 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 8.11.7.

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

- Potential for **contaminating** and/or **soaking** shoes — wear **FLUID-PROOF** shoe covers.

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 should be changed immediately if visibly contaminated with blood or body substances to prevent blood seeping through and contaminating garments or skin. They should be changed at appropriate intervals to ensure cleanliness. 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.

6.2.4 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 IIA or IIB biological safety cabinet. (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 government agencies responsible for the regulation of disinfectants and sterilants has always been a confusing issue. Recently, the FDA and EPA clarified the types of compounds each agency would regulate. The FDA regulates chemical germicides formulated as antiseptics, preservatives, or drugs that are used on or in the human body. In the laboratory this would include the sterilants and high-level disinfectants. The EPA regulates the general-purpose disinfectants, such as those chemicals used for 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 bleach is often used as an intermediate-level disinfectant. Aluminum and stainless steel are corroded by sodium hypochlorite, and, therefore, other disinfectants may be preferred. The commercial product is usually a 5.25% solution of sodium hypochlorite (50,000 mg/L of free available chlorine). Table 6 lists commonly used aqueous dilutions of the commercial product.

NOTE: All dilutions should be made weekly with tap water to prevent the loss of germicidal action during storage.[16,17]

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 5,000 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.

Table 6. Dilutions of Household Bleach

Volume of Bleach	Volume of Water	Dilution Ratio	Sodium Hypochlorite (%)	Available Chlorine (mg/L)
Undiluted	0	1	5.25	50,000
1	9	1:10	0.5	5,000
1	99	1:100	0.05	500

If a surface or medical device is contaminated with dried blood or body fluid, remove all visible traces of it before decontamination. The dried blood should be wet and softened with diluted bleach or detergent disinfectant before being scraped off to prevent scattering potentially infectious material and to facilitate complete removal. After removal of the dried blood, decontaminate or sterilize the surface depending on the intended use of the device. If complete removal is not possible, expose the surface to diluted bleach for a longer time (20 to 30 minutes may be necessary; see Section 11).

For large spills of cultured or concentrated infectious agents, the spill should first be flooded and mixed with an EPA-approved hospital disinfectant or 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. Examples of effective product classes are:

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

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 for instrument or device decontamination.

- gluteraldehyde (2.4% to 3.4%);
- peroxyacetic acid (0.08%) and hydrogen peroxide (1%);
- ortho-phthalaldehyde (0.5%); and
- hydrogen peroxide (7.5%).

A listing of commercial disinfectants and sterilants is available on the following websites http://ace.orst.edu/info/nain/lists.htm; http://www.fda.gov/cdrh/index.html.

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

Germicidal activity is classified as high-level, intermediate-level, or low-level.

Sterilization and disinfection procedures generally used in healthcare facilities are able to sterilize or disinfect medical devices, including those contaminated with blood containing blood-borne pathogens (including HBV and HIV).

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). Medical devices that come into contact with mucous membranes should be sterilized or receive high-level disinfection before use.

HBV, HAV, HCV, and HIV can be inactivated by all classes of disinfectant chemicals (i.e., low-, intermediate- to high-level disinfectants).

Commercially available liquid chemical germicides that are tuberculocidal can be used to inactivate blood-borne viruses such as HBV, HCV, and HIV. Several commercial, quaternary, ammonium-based, housekeeping products have recently been approved by EPA to make claims of activity against HIV and HBV. However, it is the opinion of the committee that germicides of the intermediate-level category (i.e., have a tuberculocidal claim) be used for surface decontamination in laboratory areas as a safe minimum. Refer to the manufacturer's instructions for exposure times and conditions.

Table 7. Activity Levels of Selected Liquid Germicides* (Favero MS, Bond WW. Chemical disinfection of medical and surgical materials. In: Block SS, ed. *Disinfection, Sterilization, and Preservation.* 5th ed. Philadelphia: Lippincott Williams and Wilkins; 2001. Adapted with permission of the authors and Lippincott Williams and Wilkins.)

Procedure/Product	Aqueous Concentration†	Activity Level
Sterilization		
Glutaraldehyde	Variable‡	N/A
Hydrogen peroxide	6 – 30%	N/A
Formaldehyde	6 – 8%§	N/A
Chlorine dioxide	Variable	N/A
Peracetic acid	Variable	N/A

Table 7. (Continued)

Procedure/Product	Aqueous Concentration[†]	Activity Level
Disinfection[¶]		
Glutaraldehyde	Variable	High to intermediate
Hydrogen peroxide	3 – 6%	High to intermediate
Formaldehyde	1 – 8%	High to low
Chlorine dioxide	Variable	High
Peracetic acid	Variable	High
Chlorine compounds[#]	500 to 5,000 mg/L Free/available chlorine	Intermediate
Alcohols (ethyl, isopropyl)[**]	70%	Intermediate
Phenolic compounds	0.5 – 3%	Intermediate to low
Iodophor compounds[††]	40 – 50 mg/L free iodine; up to 10,000 mg/L available iodine	Intermediate to low
Quaternary ammonium compounds	0.1 – 0.2%	Low

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 1,000 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 clean (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 precleaned 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. The factors that influence decontamination procedures are: volume of spill; which body fluid is 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 11).

(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 material in decontamination is not known and, 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 to 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 8.10). 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 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, 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*,[18] 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.

The 1991 Occupational Safety and Health Administration (OSHA) Occupational Exposure to Bloodborne Pathogens Standard[19] incorporated the basic concepts of standard precautions. A 1999 OSHA Instruction[20] provided clarification and additional interpretations of the standard. Both 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.

Because the concept of standard precautions 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.

7.1 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 healthcare workers.

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 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.

7.2 Components

7.2.1 Hand Washing

- Wash hands after touching all potentially infectious material whether or not gloves are worn.

- Remove gloves promptly after the task is completed.

- Wash hands immediately after gloves are removed and when otherwise indicated to avoid transfer of microorganisms to other surfaces or environments.

7.2.2 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.

- Wear gloves when 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 wash hands immediately after removing gloves.

7.2.3 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.

7.2.4 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 wash hands to avoid transfer of microorganisms to other surfaces or environments.

7.2.5 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.

7.2.6 Environmental Control

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

Ensure that these procedures are being followed.

7.2.7 Usage of "Sharps"

Minimize use of needles in laboratories. Utilize a protective needle device to minimize the risk of a needlestick (see Section 8.2.1).

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 is as feasible to the immediate area where sharps are used or can reasonably be anticipated to be found.

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

7.2.8 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.

7.3 Warning Labels for All Potentially Infectious Material

Standard precautions eliminate the need for using specific biohazard warning labels 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 if infectious and capable of transmitting disease. It also counters the false sense of security that unlabelled specimens may generate among unwary laboratory workers.

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 also stipulate that any specimen potentially containing blood-borne pathogens must have a biohazard-warning label when transported from one facility to another.

8 Special Precautions for Laboratories

All clinical specimens should be treated as infective, 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.)

8.1 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).

- 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 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 NCCLS document H18—*Procedures for the Handling and Processing of Blood Specimens*.

8.2 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 self-inflicted needlesticks. For complete protection, gloves and a 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.

Collect blood specimens according to the manufacturer's instructions and institutional guidelines.

NOTE: Blood collection using a syringe and needle 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 puncturing the diaphragm of the rubber stopper and allowing 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.

8.2.1 Blood Collection Equipment and Safety Devices

Blood-borne pathogen exposures are estimated to be between 590,000 and 800,000 injuries annually. Most are preventable; 75% of all incidents are associated with disposable syringes and could be prevented by using safer equipment (engineering controls). In the United States, Congress passed the Federal Needlestick Safety and Prevention Act (HR5178) that mandates OSHA to revise the Bloodborne Pathogens Standard to strengthen the use of any sharps with engineered sharps injury protection. Some states have enacted stricter mandates regarding the use of needleless and safety engineered sharps devices.[c]

The FDA is responsible for clearing medical devices. When choosing safer equipment to minimize risk, the following features should be evident:

- provide a barrier between the hand and needle, with the worker's hand *always* remaining behind the needle;
- be an integral part of the collection device and not an accessory;
- be in effect *before* disassembly and remain in effect *after* disposal to protect others; and
- be simple and require little or no training.

To be in compliance with OSHA, any choice of safety device (engineering control) must:

- be evaluated for effectiveness;
- have employee acceptance;
- have thorough employee training; and
- be regularly maintained, examined, and repaired by the employer.

[c] Assistance for compliance with OSHA regulations can be found in the forthcoming NCCLS report *Implementing a Needlestick and Sharps Injury Prevention Protection in the Clinical Laboratory.* Additional information can be found at http://www.med.virginia.edu/medcntr/centers/epinet.

8.2.2 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 if there is a potential for spraying of blood. 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 Nov 99 and the most current editions of the following NCCLS documents:

- H3—*Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture;*
- H21—*Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays;* and
- H11—*Procedures for the Collection of Arterial Blood Specimens*.

8.2.3 Skin Puncture

Skin puncture, of necessity, causes the contamination of the skin surface and poses a hazard to the laboratory worker. Therefore, gloves should be worn when performing skin punctures. 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 8.2.2). Local and regional regulatory policy should be followed.

8.3 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 NCCLS document LA4—*Blood Collection on Filter Paper for Neonatal Screening Programs.* For additional information, see the most recent edition of NCCLS document H4—*Procedures for the Collection of Diagnostic Blood Specimens by Skin Puncture*.

The laboratory should evaluate performance of containers prior to purchase. (For detailed recommendations regarding urine specimens, see the most recent edition of NCCLS document GP16—*Routine 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.

8.3.1 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 may be 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.

8.3.2 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.

8.3.3 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.

8.4 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.

8.5 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.

8.6 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.

8.7 Shipping Specimens

For shipping specimens out of the laboratory, please refer to current U.S. Department of Transportation regulations or to the International Air Transport Association (IATA) guidelines for specific details.[21]

8.8 Areas Needing Special Attention

8.8.1 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.

8.8.2 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.

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.

When inoculating a blood culture bottle with a needle and syringe the bottle should not be hand-held. The bottle may be secured in a device that stabilizes the bottle. The device should hold the bottle securely to permit easy entry and removal of the needle. After use, the entire needle and syringe assembly should be discarded without removing or resheathing the needle. Safety devices should be used whenever possible.

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.

Unfixed slides may contain infectious material.

8.8.3 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 8.9.3), removed, and discarded in 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.

8.9 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.

8.9.1 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.

8.9.2 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 8.9.3).

8.9.3 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 8.8.2 and 8.8.3 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.

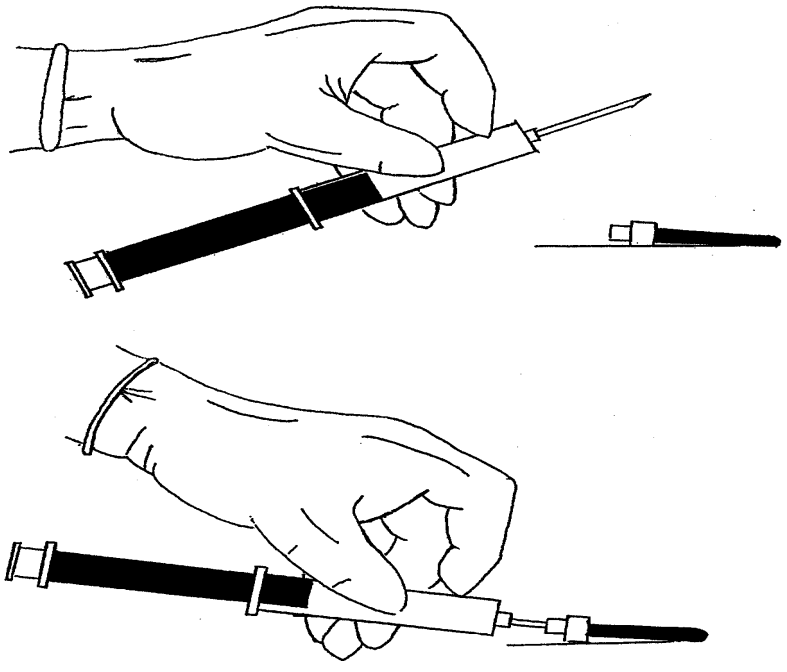

Figure 1. One-handed Technique for Resheathing Needles

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 needles. Their use is preferred and recommended, and is required in the U.S.

8.10 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;
- 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 NCCLS document GP5—*Clinical Laboratory Waste Management* should be consulted for additional detailed information.

8.10.1 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*.[19]

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.

8.10.2 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.

8.10.3 Packaging

Designated waste must be packaged so as to protect 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.

8.10.4 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.

8.10.5 Transport

Wastes should be transported in clearly labeled, dedicated, leakproof containers or carts. In the U.S., containers should meet the specifications established by the Department of Transportation.

8.10.6 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.

8.10.7 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.

8.11 The Autopsy

8.11.1 General Considerations

The autopsy should be carried out with adequate assistance. **Written consent authorizing the autopsy must be obtained from the next of kin.** 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.

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.

8.11.2 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. Standard precautions are adequate to protect against occupationally acquired infection with the CJD agent with other tissues and fluids. 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. tuberculosis.*

8.11.3 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, cutdowns, 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.

8.11.4 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 9).

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 for the employee to work in the morgue. If the risk of infection is deemed acceptable, the worker should scrupulously follow standard precautions.

Immunosuppressed workers should not be permitted to participate in autopsies on bodies known to be HIV infected, since communicable, opportunistic, pathogenic agents are frequently present in these bodies (e.g., fungi and *Mycobacteria)*, which may pose a hazard to such individuals.

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.

8.11.4.1 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.

8.11.5 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. N95 particulate or powered HEPA respirator (see Section 10.4) should be worn under the shield while performing autopsies on deceased persons who may have tuberculosis at the time of death to prevent inhalation of airborne organisms, e.g., *M. tuberculosis* (which is commonly present in HIV-infected bodies). (See Section 10 regarding laboratory exposure to *M. tuberculosis*.)

  N95 particulate respirator (see Section 10.4) and goggles to cover the mouth, nose, and eyes may be worn if a plastic face shield is not worn. Safety goggles should have a cushion seal.

  Wrap-around safety glasses, which fit over ordinary prescription glasses, may be worn, but do not fully protect the eyes. Ordinary glasses do not offer adequate protection.

  Contact lenses should not be manipulated in the autopsy room.

- 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 6.2.1.5) 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 rib cage, vertebrae, or calvarium; or other times when saws, chisels, or bone cutters are used. 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.

8.11.6 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 that 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 (as 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 Section 10). 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.

- 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 should be taken by crushing the cut end of a rib and expressing the marrow contents. Vertebral marrow should not be obtained unless the clinical information warrants it, since significant spattering of blood may occur. 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, because cuts of the hands are common and adequate decontamination of the cryostat is dif-

ficult. If frozen sections are cut, gloves should be worn. Freezing propellants under pressure should not be used, as they may cause the spattering of droplets of infectious material. If the autopsy has revealed pathologic findings consistent with an HIV, HBV, or other blood-borne infection, or if tissue containing *M. tuberculosis* has been cut, the cryostat should be defrosted and decontaminated immediately with a tuberculocidal hospital disinfectant. Otherwise, the cryostat should be decontaminated immediately after use with 70% alcohol. This should include removal of all tissue sections and trimmings. Stainless steel mesh gloves should be worn when handling the microtome blade or cleaning the cryostat.

- 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.

8.11.7 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.

8.12 Surgical Specimens

8.12.1 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. When large or bloody specimens are handled, facial barrier precautions should be followed, or the specimen should be processed in a BSC.

8.12.2 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 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 used to prepare smears or cell blocks are extremely hazardous. 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.

8.12.3 Decontamination

The surgical dissecting area should be decontaminated in the same manner as the autopsy area (see Section 6.4 and Section 8.11.7). 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.

9 Management of Laboratory Accidents

9.1 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) and 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 exposure reporting, wound management, evaluation of transmission risk, and consideration of postexposure prophylaxis (PEP). For a comprehensive review of the risk and management of blood-borne infections, the reader should refer to recent publications[22, 23] and Appendix A.

9.1.1 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 (see Section 8.2.1) should include:

- 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, and the viral load status, if known; and
- details about counseling, postexposure management, and follow-up.

9.1.2 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.

9.1.3 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).

9.1.4 Postexposure Prophylaxis (PEP)

The routine practices of the institution regarding HBV and HIV prophylaxis should be considered as outlined below.

Table 8. Recommended Serologic Testing for HCWs Following Occupational Exposures to HIV, HBV, and HCV (Adapted from Beltrami, et al. Risk and management of blood-borne infections in HCWs. *Clin Microbiol Rev*. 2000;13:385-407. Used with permission from the American Society for Microbiology.)

Infection status of source patient	Recommended serologic test at:			
	Baseline	6 wk	12 wk	6 mo
HIV-positive	HIV antibody testing using EIA*	HIV antibody testing using EIA	HIV antibody testing using EIA	HIV antibody testing using EIA
HbsAg-positive	Anti-HBs if previously vaccinated against HBV and response to vaccination unknown			
Anti-HCV-positive	HCV antibody testing using EIA†; ALT measurement	HVC RNA (optional)‡		HCV antibody testing (using EIA); ALT measurement at 4 to 6 mo‡
Unknown	HIV antibody testing using EIA; anti-HBs if previously vaccinated to HBV and response to vaccination unknown; HCV antibody testing using EIA; ALT measurement	HIV antibody testing using EIA	HIV antibody testing using EIA	HIV antibody testing using EIA; HCV antibody testing using EIA; ALT measurement

* 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.

9.2 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. The dosage recommended by the manufacturer should be administered by the intramuscular route in the deltoid muscle in adults with a needle 1 to 1.5 inches long. 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.[19]

9.2.1 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.[24]

The use of immunoprophylaxis is conditioned by the hepatitis B surface antigen (HBsAg) status of the source 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. The procedures outlined below should be followed.

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. See Table 9 below for a summary of the recommendations.

Table 9. Recommended Postexposure Prophylaxis for Exposure to Hepatitis B Virus (CDC. *MMWR*. June 29, 2001;50(RR-11):1-42.)

Vaccination and antibody response of exposed worker[*]	Treatment when source is found to be:		
	HbsAg[†]-positive	HbsAg-negative	Source unknown or not available for testing
Unvaccinated	HBIG[‡] x 1 and initiate HB vaccine series[§]	Initiate HB vaccine series	Initiate HB vaccine series
Previously vaccinated: known responder[¶]	No treatment	No treatment	No treatment
Known nonresponder[**]	HBIG x 1 and initiate re-vaccination or HBIG x 2[#]	No treatment	If known high-risk source, treat as if source were HBsAg-positive
Antibody response unknown	Test exposed person for anti-HBs[**] 1. If adequate,[¶] no treatment 2. If inadequate,[¶] HBIG x 1 and vaccine booster	No treatment	Test exposed person for anti-HBs 1. If adequate, [§] no treatment 2. If inadequate, [§] vaccine booster and recheck titer in 1 to 2 months

[*]Persons who have previously been infected with HBV are immune to reinfection and do not require postexposure prophylaxis.
[†] Hepatitis B surface antigen.
[‡]Hepatitis B immune globulin; dose 0.06 mL/kg intramuscularly.
[§] Hepatitis B vaccine series.
[¶]A responder is a person with adequate levels of serum antibody to HBsAg (i.e., anti-HBs ≥ 10 mIU/mL); a nonresponder is a person with inadequate response to vaccination (i.e., serum anti-HBS < 10 mIU/mL.
[#]The option of giving one dose of HBIG and reinitiating the vaccine series is preferred for nonresponders who have not completed a second three-dose vaccine series. For those who previously completed a second vaccine series but failed to respond, two doses of HBIG are preferred.
[**]Antibody to HBsAg.

9.2.1.1 Source of Exposure HbsAg-positive

- **The exposed worker is not vaccinated or partially vaccinated against HBV.**

  — For unvaccinated workers, a single dose of hepatitis B immune globulin (HBIG) (0.06 mL/kg) should be given as soon as possible (within 24 hours if practicable), and the first dose of HB vaccine should be given intramuscularly (IM) in the deltoid (at a separate site) simultaneously with HBIG or within seven days of exposure. The second and third doses of HB vaccine should be given one and six months later.

  — If the exposed worker has not completed vaccination as scheduled and HBIG as indicated, he/she is considered only partially vaccinated.

- **The exposed worker is vaccinated, and anti-HBs status is known to have responded.**

  — An adequate response has not been demonstrated in the past 24 months. **The worker should be tested for antibody level.** An adequate antibody level is ≥ ten milli-international units (mIU/mL, approximately equivalent to ten sample ratio units (SRU) by radioimmunoassay or by a positive enzyme immunoassay test).

  — If anti-HBs is adequate, no treatment is necessary.

  — If anti-HBs antibody is inadequate, a booster dose of HB vaccine should be given.

- **The exposed worker is known NOT to have responded to the primary vaccination.**

  — A single dose of HBIG and a dose of HB vaccine should be given as soon as possible after exposure, or

  — Two doses of HBIG should be given, one as soon as possible after exposure and one a month later. This option is preferred for those who have failed to respond to at least four doses of vaccine.

- **The exposed worker has been vaccinated, and the anti-HBs response is unknown. The exposed person should be tested for anti-HBs.**

  — If antibodies are adequate, no additional treatment is necessary.

  — If antibodies are inadequate, one dose of HBIG should be given immediately and a booster dose of HB vaccine should be given.

9.2.1.2 Source of Exposure Known and HBsAg Negative

- If the exposed worker is unvaccinated, vaccination should be started within seven days.

- If the exposed worker has not completed vaccination, vaccination should be completed as scheduled.

- If the exposed worker has been vaccinated, no treatment is necessary.

9.2.1.3 Source of Exposure Unknown or Not Available for Testing

- **The exposed worker has not been vaccinated or has not completed vaccination.**

  — The exposed worker has not been vaccinated; vaccination should be started within seven days.

  — The exposed worker has not completed vaccination; vaccination should be completed within seven days.

- **The exposed worker has been vaccinated, and the anti-HBs response is known.**

  — If the response is adequate, no treatment is necessary.

— If the worker is known NOT to have responded, the following may be considered if the source is known to be at high risk for HBV infection.

  - A single dose of HBIG and a dose of HB vaccine should be given as soon as possible after exposure, or

  - Two doses of HBIG should be given, one as soon as possible after exposure and one a month later. This option is preferred for those who have failed to respond to at least four doses of vaccine.

— The exposed person has been vaccinated, and the anti-HBs response is unknown. Test the exposed person for anti-HBs antibody.

  - If anti-HBs is adequate, no treatment is necessary.

  - If anti-HBs is inadequate, a booster dose of vaccine should be given.

9.3 Postexposure to Parenterally Transmitted HCV

The ACIP and HICPAC currently do not recommend postexposure prophylaxis after percutaneous exposure to blood of a patient infected with HCV.[24] There are no data on the efficacy of immune globulin and use of antiviral agents (e.g., interferon) to prevent HCV infection.

Occupational HCV postexposure follow-up should include the following recommendations[7]:

- 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 four to six weeks.); and

- confirmation by supplemental anti-HCV testing of all anti-HCV results reported as positive by EIA.

9.4 Potential 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.

Updated recommendations for the management of HCWs who have occupational exposure to blood and other body fluids that may contain HIV appear in Tables 10 and 11.

9.4.1 Evaluation of Occupational Exposure and Need for PEP

9.4.1.1 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 mucus 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.

    — Less severe risk for transmission (e.g., solid needle, superficial scratch).

    — More severe risk for transmission (e.g. large-bore hollow needle, deep puncture, visible blood on device).

Table 10. HIV PEP Recommendations for Percutaneous Injuries (CDC. *MMWR*. June 29, 2001;50 (RR-11):1-42.)

	Infection Status of Source				
Exposure Type	**HIV-Positive Class 1*** Asymptomatic HIV infection or known low viral load (e.g., < 1,500)	**HIV-Positive Class 2*** Symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load	**Source of Unknown HIV Status** (e.g., the source person refuses HIV testing)	**Unknown Source** (e.g., a needle from a sharps disposal container)	**HIV-Negative**
Less severe e.g., solid needle, superficial injury	Recommend basic 2-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP† for source with HIV risk factors‡	Generally, no PEP warranted; however, consider basic 2-drug PEP† in settings where exposure to HIV-infected persons is likely	No PEP warranted
More severe e.g., large-bore hollow needle, deep puncture, visible blood on device, or needle used in patient's artery or vein.	Recommend expanded 3-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP† for source with HIV risk factors‡	Generally, no PEP warranted; however, consider basic 2-drug PEP† in settings where exposure to HIV-infected persons is likely	No PEP warranted

* If drug resistance is a concern, obtain expert consultation. Initiation of PEP should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

† The designation, "consider PEP," indicates that PEP is optional and should be based on an individualized decision between the exposed person and the treating clinician.

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

Table 11. HIV PEP Recommendations for Mucous Membrane Exposure and Nonintact Skin[*] Exposures (CDC. *MMWR*. June 29, 2001;50(RR-11):1-42.)

	Infection Status of Source				
Exposure Type	**HIV-Positive Class 1**[†] Asymptomatic HIV infection or known low viral load (e.g., < 1,500)	**HIV-Positive Class 2**[†] Symptomatic HIV infection, AIDS, acute seroconversion, or known high viral load	**Source of Unknown HIV Status** (e.g., the source person refuses HIV testing)	**Unknown Source** (e.g., a needle from a sharps disposal container)	**HIV-Negative**
Small volume e.g., few drops	Consider basic 2-drug PEP[‡]	Recommend basic 2-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP[‡] for source with HIV risk factors[¶]	Generally, no PEP warranted; however, consider basic 2-drug PEP[‡] in settings where exposure to HIV-infected persons is likely	No PEP warranted
Large volume e.g., major blood splash	Recommend basic 2-drug PEP	Recommend expanded 3-drug PEP	Generally, no PEP warranted; however, consider basic 2-drug PEP[‡] for source with HIV risk factors[§]	Generally, no PEP warranted; however, consider basic 2-drug PEP[‡] in settings where exposure to HIV-infected persons is likely	No PEP warranted

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

[†]If drug resistance is a concern, obtain expert consultation. Initiation of PEP should not be delayed pending expert consultation, and, because expert consultation alone cannot substitute for face-to-face counseling, resources should be available to provide immediate evaluation and follow-up care for all exposures.

[‡]The designation, "consider PEP," indicates that PEP is optional and should be based on an individualized decision between the exposed person and the treating clinician.

[§]If PEP is offered and taken, and the source is later determined to be HIV-negative, PEP should be discontinued.

9.4.1.2 Evaluation and Testing of an Exposure Source: Determination of HIV Status Code (HIV SC)

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

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

— HIV antibody testing (EIA) of an exposed 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 should be considered.

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

9.4.1.3 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, 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.

9.4.2 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. The following recommendations apply to situations where an HCW has been exposed to a source person with HIV or sufficient information suggests that there is likelihood that the source person is HIV-infected. 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.

9.4.2.1 Source of Exposure is HIV-positive—Class 1

- If the exposure type poses a low risk for transmission (skin and mucus membrane), the basic PEP regimen may be considered.

  — A large-volume exposure may justify PEP.

  — The exposed HCW and treating clinician should decide whether the risk for drug toxicity outweighs the benefit of PEP.

- If the exposure type poses a low risk for HIV transmission (percutaneous injury), the basic PEP regimen is recommended with counseling.

  — PEP should be initiated as soon as possible (within hours rather than days).

  — No increased risk for HIV transmission has been observed, but PEP is appropriate.

- If the exposure type poses a high risk for HIV transmission (percutaneous injury), the expanded PEP regimen is recommended with counseling.

  — A third antiretroviral agent should be added for exposures that pose an increased risk for HIV transmission or where resistance to one or more antiretroviral agents is known or suspected.

  — PEP should be implemented in consultation with experts in antiretroviral treatment and HIV transmission (e.g., PEP line).

9.4.2.2 Source of Exposure is HIV-positive—Class 2

- If the exposure type poses a low risk for HIV transmission (skin and mucus membrane), the basic PEP regimen is recommended with counseling.

- If the exposure type poses a high risk for HIV transmission (percutaneous injury), the expanded PEP regimen is recommended with counseling.

  — A three-drug regimen should be used for exposures that pose an increased risk for HIV transmission or where resistance to one or more antiretroviral agents is known or suspected.

  — PEP should be implemented in consultation with experts in antiretroviral treatment and HIV transmission.

9.4.2.3 Source Status Unknown or Source Unknown

- If the source person's HIV serostatus is unknown, initiating PEP should be made on a case-by-case basis, after considering the type of exposure and the clinical and/or epidemiologic likelihood of HIV infection in the source.

  — If these considerations suggest a possible risk for HIV transmission and HIV testing of the source is pending, consider the basic PEP regimen until laboratory results are available.

- If the exposure source is unknown, initiating PEP should be addressed on a case-by-case basis.

  — If the setting where the exposure occurred suggests a possible risk for HIV exposure, the basic PEP regimen should be considered.

9.4.3 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.

9.4.3.1 Antibody Testing (Table 8)

- HIV antibody testing should be performed for at least six months postexposure (e.g., at 6 weeks, 12 weeks, and 6 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.

9.4.3.2 Toxicity

- If PEP is used, drug-toxicity monitoring should be performed at baseline and two weeks after starting PEP.

    — Baseline tests should include a complete blood count and renal and hepatic profiles.

    — If the HCW is receiving protease inhibitor (PI), monitoring for hyperglycemia should be included.

    — If the HCW is receiving indinavir (IDV), monitoring for crystalluria, hematuria, hemolytic anemia, and hepatitis should be included.

    — If toxicity is noted, modification of the regimen should be considered with expert consultation; further diagnostic studies may be indicated.

9.4.3.3 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 6 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.

9.4.4 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, the National Clinicians' Postexposure Prophylaxis Hotline (PEPline: 888-448-4911) has been created to assist clinicians with these issues.

Table 12. HIV Postexposure Prophylaxis Resources and Registries

Resources or registry	Contact information
National Clinicians' Postexposure Hotline (PEPline)	Ph: (888) 448-4911
Antiretroviral Pregnancy Registry	Ph. (800) 258-4263 Fax: (800) 800-1052 Write: 1410 Commonwealth Drive Suite 215 Wilmington, NC 28405
Food and Drug Administration (for reporting unusual or severe toxicity to antiretroviral agents)	Ph. (800) 332-1088
CDC (for reporting HIV seroconversions in HCWs who received PEP)	Ph. (800) 893-0485
Hospital Infections Program Home Page	http://www.cdc.gov/ncidod/hip/faq.htm

9.5 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. Recent cases of fatal meningococcemia in clinical laboratory workers underscore the potential risks of handling clinical samples and cultures.[13] In addition to percutaneous inoculation, other routes of acquiring infection include aerosolization, direct skin contract, splash to mucus 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.[25]

9.5.1 Prevention

The current CDC guidelines on immunization of healthcare workers provide recommended practices for hospital workers, including laboratory personnel.[24] Specific recommendations for vaccination of laboratory workers in high-risk situations are listed in Table 13. Vaccination, however, should not be an alternative to good laboratory practices when handling specimens and cultures.

9.5.2 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 institute 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.[13,26]

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

Generic name	Primary/booster dose schedule	Indications	Major precautions/contraindications
BCG vaccine (tuberculosis)	One percutaneous dose of 0.3 mL; no booster recommended	Not routinely indicated. Laboratory personnel who process large volumes of specimens which *M. tuberculosis* is isolated or high proportion of *M. tuberculosis* resistant to isoniazid and rifampin	Immunocompromised state and pregnancy
Hepatitis A Vaccine	Two doses IM, either 6-12 mo apart or 6 mo apart	Not routinely indicated. Laboratory personnel who work with HAV-infected primates or with HAV in a research setting	History of anaphylactic reaction to alum or the preservative 2-phenoxyethanol; 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
Meningococcal polysaccharide vaccine (quadrivalent A, C, W135, and Y)	One dose in volume and by route specified by manufacturer; need for boosters is unknown	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.	Vaccine safety in pregnant women has not been evaluated; vaccine should not be given during pregnancy unless risk of infection is high
Polio vaccine	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	Laboratory personnel handling specimens that may contain wild poliovirus	History of anaphylactic reaction after receipt of streptomycin or neomycin; safety in pregnant women has not been evaluated.
Rabies vaccine	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.	Laboratory personnel who work with rabies or infected animals in diagnostic or research activities	The frequency of booster doses should be based on frequency of exposure.

Table 13. (Continued)

Generic name	Primary/booster dose schedule	Indications	Major precautions/contraindications
Tetanus and diphtheria (Td) vaccine	Two doses IM 4 wk apart; 3rd dose 6-12 mo after 2nd dose; booster every 10 yr	All adults; tetanus prophylaxis in wound management	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
Typhoid vaccine (IM, SC, and oral)	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 weeks 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.	Personnel in microbiology laboratories who frequently work with *Salmonella typhi*	Severe local or systemic reaction to a previous dose of typhoid vaccine; Ty21a vaccine should not be given to immunocompromised personnel or individual receiving antimicrobial agents
Vaccinia vaccine (smallpox)	One dose administered with a bifurcated needle; boosters every 10 yr.	Laboratory personnel who directly handle cultures of or animals contaminated with recombinant vaccinia viruses or orthopox viruses that infect humans	Pregnancy, presence or history of eczema, or immunocompromised status in potential vaccines or in their household contacts

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

10 *Mycobacterium tuberculosis* in the Healthcare Setting

The Centers for Disease Control and Prevention (CDC) issued final guidelines for preventing the transmission of *M. tuberculosis* in healthcare facilities in October 1994[15] and guidelines for laboratories that work with *M. tuberculosis*.[27] The Occupational Safety and Health Administration (OSHA) issued a proposed rule on the Occupational Exposure to Tuberculosis in October 1997.[28]

These CDC guidelines and OSHA-proposed rule are targeted to all aspects of healthcare delivery and primarily to the care of patients who are infected with *M. tuberculosis.* The NCCLS guidelines, on the other hand, focus only 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.

10.1 Epidemiology, Transmission, and Pathogenesis of *M. tuberculosis*

10.1.1 Epidemiology

Tuberculosis is an old disease but one that has been decreasing in incidence in the United States and other developed countries. In the mid-1980s there was a significant resurgence of tuberculosis in the United

States, which was primarily 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. Since 1992 the number of tuberculosis cases has decreased each year and reached a record low in 1998.

10.1.2 Transmission and Pathogenesis

M. tuberculosis is carried in airborne-viable particles referred to as "droplet nuclei." These particles can be generated when persons who have active pulmonary or laryngeal TB cough, speak, or sneeze. The particles generated by these actions are relatively large, but by evaporation small particles in the size range of one to five microns are formed. These particles can remain airborne for extended periods of time and be carried throughout a room or building by air currents. Infection occurs when a person inhales droplet nuclei containing *M. tuberculosis,* and these particles pass through the mouth or nasal passages, upper respiratory tract, and bronchi to reach the alveoli of the lung. Usually within two to ten weeks after initial infection, the immune system limits the reproduction and spread of the organism, but some of the bacilli remain dormant for many years. This condition is known as "latent TB infection."

In general, persons who become infected have about a ten percent 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.

10.2 Risk for Transmission of *M. tuberculosis* in Healthcare Facilities

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; occupations of those working within the healthcare facility; specific areas within the healthcare facility; and the effectiveness of TB infection control interventions.

Transmission in healthcare facilities has been associated with close contact with persons who have infectious TB and with the performance of certain procedures, e.g., bronchoscopy, endotracheal intubation and suctioning, sputum induction, and aerosol treatments that induce coughing. In addition, laboratory workers who process specimens from patients infected with *M. tuberculosis* can be at risk of infection when aerosols are produced and containment or respiratory protection is inadequate.

10.3 Fundamentals of Infection Control

An effective TB control program requires early identification, isolation, and effective treatment of persons who have active TB. The program should be based on a hierarchy of controls, which include the following measures:

- Administrative measures that are intended to reduce the risk of exposing individuals to persons who have infectious TB. These steps include:

    — written policies and protocols to ensure rapid identification, isolation, and treatment of persons who have TB;

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

    — if necessary, wearing adequate respiratory protection;

— educating, training, and counseling healthcare workers about TB; and

— screening healthcare workers for TB infection.

- Engineering controls to prevent the spread and reduce the concentration of infectious droplet nuclei. 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 to TB in those few areas that remain. The third level of control includes airborne precautions, i.e., wearing adequate personal respiratory protective equipment when, despite all other control measures, the risk for infection with *M. tuberculosis* remains relatively high.

In general, laboratory procedures for culturing *M. tuberculosis* and for examining certain specimens from infected patients make use of existing guidelines for biosafety[14] where engineering controls are used to eliminate the risk. Procedures are conducted using Class II biological safety cabinets and in accordance with the latest recommendations on working safely with *M. tuberculosis* published by the CDC. If these requirements cannot be met, laboratory work should not be done.

10.4 Respiratory Protection

According to CDC, NIOSH, and OSHA recommendations,[28,29,30] respiratory protective devices used in healthcare settings for protection against *M. tuberculosis* should meet the following performance criteria:

- the ability to filter particles 1 μm in size in the unloaded state with a filter efficiency of ≥95% (i.e., filter leakage of less than 5%), given flow rates of up to 50 L per minute, e.g., N95 particulate respirator;

- the ability to be qualitatively or quantitatively fit tested in a reliable way to obtain a face-seal leakage of less than ten percent;

- the ability to fit the different facial sizes and characteristics of healthcare workers that can usually be met by making respirators available in at least three sizes; and

- the ability to be checked for face piece fit in accordance with standards established by OSHA and good industrial hygiene practice, by healthcare workers each time they put on their respirators.

It is emphasized that microbiologic procedures practiced in laboratories on specimens from patients infected with TB should use biosafety precautions described in the CDC/NIH manual.[14]

10.5 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.

Respiratory protective devices should be worn by personnel while performing autopsies on individuals who may have infectious TB at the time of death.

11 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.

11.1 Accidental Injury Prevention

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.

11.2 Equipment Type

This section is applicable to the infectious hazards encountered in the operation of any device used for *in vitro* diagnostic testing in the clinical laboratory.

11.3 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.

11.3.1 Centrifugation

All centrifuges should have lockable lids that should not be opened 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.

Concentrating infectious agents is a potentially hazardous procedure, as the inoculum size will be increased if an exposure occurs. If aerosolization is likely to occur during the process of concentration, Class II biological safety cabinets should be used. Ensure that the function of the safety cabinet is not

compromised as a result of excessive equipment or poor placement of equipment interfering with airflow dynamics. Centrifuges should not be placed in a biological safety cabinet unless specifically designed for this use, since the motor may produce strong air currents and turbulence that may disrupt the laminar airflow. (See Appendix B for exceptions.)

The use of special containment vessels, such as sealed rotors or safety cups, is strongly recommended, especially for processing highly concentrated or large volumes of infectious agents and specimens that may contain agents that are spread by airborne transmission, e.g., *M. tuberculosis*. Sealed rotors or safety cups should be opened inside a biosafety cabinet when centrifuging is complete.

11.3.1.1 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.

11.3.1.2 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.

11.3.1.3 Overflow

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

11.3.1.4 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.

11.3.2 Sedimentation and Filtration Equipment

Sedimentation and filtration equipment should be 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.

11.3.3 Vacuum Pumps

If a mechanical vacuum apparatus with an in-line, liquid disinfectant trap and a hydrophobic filter is used to collect contaminated filtrate, all components should be decontaminated after disposing of the contents.

11.3.4 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.

11.4 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 face when removing caps, or remove caps behind splashguards.

11.4.1 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 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 designated contaminated waste container.

11.5 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.

11.5.1 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.

11.5.2 Refrigerator Storage

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.

11.5.3 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 45^0 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.

11.5.4 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.

11.6 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.

11.7 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.

11.7.1 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.

11.7.2 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.

11.7.3 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.

11.7.4 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. NCCLS 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.

11.7.4.1 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.

(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.

11.7.4.2 Disassembled Devices

Contaminated device components should be decontaminated 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.

11.7.4.3 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 NCCLS document GP5—*Clinical Laboratory Waste Management*.

11.7.5 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.

11.8 Selected Device Biohazards

11.8.1 Automated Analyzer

11.8.1.1 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.

11.8.2 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 8.9). 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 ten percent household bleach.

11.8.3 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 10). The device and the work area should be decontaminated after use.

11.8.4 Hematology

Hematology laboratories should use special caution with microhematocrit tubes. These tubes are prone to breakage, and finger-sticks 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).[31] 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.

11.8.5 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.

11.9 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.

11.9.1 Sample and Liquid-Level Sensor Probes

Sample and liquid-level sensor probes are generally sharp and 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.

11.10 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.

11.11 Maintenance

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

12 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 includes occupational hazards associated with blood and other potentially infectious materials.

12.1 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:

- The Occupational Exposure to Bloodborne Pathogens; Needlestick and Other Sharps Injuries; Final Rule.-66:5317-5325 [www.osha-slc.gov/FedReg_osha_data/FED20010118A.html];

- OSHA Instruction, Subject: Enforcement Procedures for the Occupational Exposure to Bloodborne Pathogens (29 CFR 1910.1030) Directives Numbers: CPL 2-2.44D; Effective: November 5, 1999;

- DHHS (NIOSH) Publication No. 2000-108; Preventing Needlestick Injuries in Health Care Settings. November 5, 1999; and

- Federal Register: January 18, 2001. Volume 66, Number 12, pages 5317-5325, Revisions to OSHA's BBP Standard as required under the Needlestick Safety and Prevention Act (November 6, 2000, Pub.L. 106-430).

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.

- 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.

12.2 Monitoring

OSHA requires that a written exposure control plan be developed and enforced. OSHA will accept locally developed exposure-control policies so 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 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.

12.3 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 (November 5, 1999) directives (CPL 2-2.44.D) to further clarify enforcement guidelines and interpretations of the original Occupational Exposure to Bloodborne Pathogens Standard (29 CFR 19910.1030) published in 1992.

The DOL and HHS documents establish national standards. OSHA regulates healthcare facilities, among many others. 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

13 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 from CDC 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.

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Appendix A. Agent Summary Statements and Criteria for Biosafety Level 2

A1. Criteria For Biosafety Level 2 (From *Biosafety in Microbiological and Biomedical Laboratories.* USDHHS/CDC/NIH. 4th ed. HHS Publication No. (CDC) 93-8395. Washington, DC: U.S. Government Printing Office; 1999:19-26.)

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. Work surfaces are decontaminated on completion of work or at the end of the day and after any spill or splash of viable material 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.

Appendix A. (Continued)

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.

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. Plasticware 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.

Appendix A. (Continued)

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.

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 lab. [Editorial Note: Please refer to the animal section in *Biosafety in Microbiological and Biomedical Laboratories*.]

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. Editorial note: See Section 11.3.1.1 on 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 lab 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.

Appendix A. (Continued)

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 lab. Alternatives to powdered latex gloves should be available. Hands are washed following removal of gloves.

A1.4 Laboratory Facilities (Secondary Barriers)

1. Provide lockable doors for facilities that house restricted agents (as defined in 42 CFR 72.6).

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 so as 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.

A2. Hepatitis A Virus, Hepatitis E Virus (From *Biosafety in Microbiological and Biomedical Laboratories*. USDHHS/CDC/NIH. 4th ed. HHS Publication No. [CDC] 93-8395. Washington, DC: U.S. Government Printing Office; 1999:19-26.)

Laboratory-associated infections with hepatitis A or E viruses do not appear to be an important occupational risk among laboratory personnel. However, the disease is a documented hazard in animal handlers and others working with chimpanzees and other nonhuman primates which are naturally or experimentally infected. Hepatitis E virus appears to be less of a risk to personnel than hepatitis A virus, except during pregnancy, when infection can result in severe or fatal disease. Workers handling other recently captured, susceptible primates (owl monkeys, marmosets) may also be at risk.

Appendix A. (Continued)

Laboratory Hazards: The agents may be present in feces, saliva, and blood of infected humans and nonhuman primates. Ingestion of feces, stool suspensions, and other contaminated materials is the primary hazard to laboratory personnel. The importance of aerosol exposure has not been demonstrated. Attenuated or avirulent strains of hepatitis A viruses resulting from serial passage in cell culture have been described.

Recommended Precautions: Biosafety Level 2 practices, safety equipment, and facilities are recommended for activities with known or potentially infected feces from humans or nonhuman primates. Animal Biosafety Level 2 practices and facilities are recommended for activities using naturally or experimentally infected nonhuman primates. Animal care personnel should wear gloves and take other appropriate precautions to avoid possible fecal-oral exposure. A licensed inactivated vaccine against hepatitis A is available in Europe; it is available as an investigational vaccine in the U.S., and is recommended for laboratory personnel. Vaccines against hepatitis E are not available for use in humans. (Editorial Note: The hepatitis A vaccine is available in the U.S. Vaccination of laboratory workers is not recommended unless their work involves hepatitis A-infected primates or HAV research. CDC: Guidelines for infection control in healthcare personnel. *Am J Infect Contr*. 1998;26:289-354.)

Transfer of Agent: For a permit to import these agents, contact CDC.

A3. Hepatitis B Virus, Hepatitis C Virus (formerly known as nonA nonB Virus), Hepatitis D Virus (From *Biosafety in Microbiological and Biomedical Laboratories*. USDHHS/CDC/NIH. 4th ed. HHS Publication No. [CDC] 93-8395. Washington, DC: U.S. Government Printing Office; 1999:19-26.)

Hepatitis B has been one of the most frequently occurring laboratory-associated infections, and laboratory workers are recognized as a high-risk group for acquiring such infections. Individuals who are infected with hepatitis B virus are at risk of infection with hepatitis D (delta) virus, which is defective and requires the presence of hepatitis B virus for replication.

Hepatitis C infection can occur in the laboratory situation. The prevalence of antibody to hepatitis C is slightly higher in medical care workers than in the general population. Epidemiologic evidence indicates that hepatitis C is spread predominantly by the parenteral route.

Laboratory Hazards: Hepatitis B virus may be present in blood and blood products of human origin, in urine, semen, cerebrospinal fluid, and saliva. Parenteral inoculation, droplet exposure of mucous membranes, and contact exposure of broken skin are the primary laboratory hazards. The virus may be stable in dried blood or blood components for several days. Attenuated or avirulent strains have not been identified.

Hepatitis C virus has been detected primarily in blood and serum, less frequently in saliva and rarely or not at all in urine or semen. It appears to be relatively unstable to storage at room temperature, repeated freezing and thawing, etc.

Recommended Precautions: Biosafety Level 2 practices; containment equipment and facilities are recommended for all activities utilizing known or potentially infectious body fluids and tissues. Additional primary containment and personnel precautions, such as those described for Biosafety Level 3, may be indicated for activities with potential for droplet or aerosol production and for activities involving production quantities or concentrations of infectious materials. Animal Biosafety Level 2 practices; containment equipment and facilities are recommended for activities utilizing naturally or experimentally infected chimpanzees or other nonhuman primates. Gloves should be worn when working with infected animals and when there is the likelihood of skin contact with infectious materials. Licensed recombinant

Appendix A. (Continued)

vaccines against hepatitis B are available and are highly recommended for and offered to laboratory personnel. Vaccines against hepatitis C and D are not yet available for use in humans.

In addition to these recommended precautions, persons working with HBV, HCV, or other blood-borne pathogens should consult the OSHA Bloodborne Pathogen Standard. Questions related to interpretation of this standard should be directed to Federal, regional, or state OSHA offices.

Transfer of Agent: For a permit to import these agents, contact CDC.

A4. Retroviruses, including Human and Simian Immunodeficiency Viruses (HIV and SIV)

(From *Biosafety in Microbiological and Biomedical Laboratories*. USDHHS/CDC/NIH. 4th ed. HHS Publication No. [CDC] 93-8395. Washington, DC: U.S. Government Printing Office; 1999:19-26.)

Data on occupational HIV transmission in laboratory workers are collected through two CDC-supported national surveillance systems: surveillance for 1) AIDS; and 2) HIV-infected persons who may have acquired their infection through occupational exposures. For surveillance purposes, laboratory workers are defined as those persons, including students and trainees, who have worked in a clinical or HIV laboratory setting anytime since 1978. Cases reported in these two systems are classified as either documented or possible occupational transmission. Those classified as documented occupational transmission had evidence of HIV seroconversion (a negative HIV-antibody test at the time of the exposure which converted to positive) following a discrete percutaneous or mucocutaneous occupational exposure to blood, body fluids, or other clinical or laboratory specimens. As of June 1998, CDC had reports of 16 laboratory workers (all clinical) in the United States with documented occupational transmission.

In 1992, two workers in different laboratories were reported to have developed antibodies to simian immunodeficiency virus (SIV) following exposures. One was associated with a needlestick that occurred while the worker was manipulating a blood-contaminated needle after bleeding an SIV-infected macaque monkey. The other involved a laboratory worker who handled macaque SIV-infected blood specimens without gloves. Though no specific incident was recalled, this worker had dermatitis on the forearms and hands while working with the infected blood specimens. The first worker seroconverted and has no evidence of persistent SIV infection. The second worker has been seropositive for at least nine years with no evidence of illness or immunological incompetence.

Recent publications have identified the prevalence (4/231, 1.8%) of infection with simian foamy viruses (SFV) among humans occupationally exposed to nonhuman primates. Evidence of SFV infections included seropositivity, proviral DNA detection, and isolation of foamy virus. The infecting SFV originated from an African green monkey (one person) and baboons (three people). These infections have not as yet resulted in either disease or sexual transmission, and may represent benign endpoint infections.

Laboratory Hazards: HIV has been isolated from blood, semen, saliva, tears, urine, cerebrospinal fluid, amniotic fluid, breast milk, cervical secretion, and tissue of infected persons and experimentally infected nonhuman primates. CDC has recommended that blood and body fluid precautions be used consistently when handling any blood-contaminated specimens. This approach, referred to as "universal precautions," precludes the need to identify clinical specimens obtained from HIV-positive patients or to speculate as to the HIV status of a specimen.

Although the risk of occupationally acquired HIV is primarily through exposure to infected blood, it is also prudent to wear gloves when manipulating other body fluids such as feces, saliva, urine, tears, sweat, vomitus, and human breast milk. This also reduces the potential for exposure to other microorganisms that may cause other types of infections.

Appendix A. (Continued)

In the laboratory, virus should be presumed to be present in all blood or clinical specimens contaminated with blood, in any unfixed tissue or organ (other than intact skin) from a human (living or dead), in HIV cultures, in all materials derived from HIV cultures, and in/on all equipment and devices coming into direct contact with any of these materials.

SIV has been isolated from blood, cerebrospinal fluid, and a variety of tissues of infected nonhuman primates. Limited data exist on the concentration of virus in semen, saliva, cervical secretions, urine, breast milk, and amniotic fluid. In the laboratory, virus should be presumed to be present in all SIV cultures, in animals experimentally infected or inoculated with SIV, in all materials derived from HIV or SIV cultures, and in/on all equipment and devices coming into direct contact with any of these materials.

In the laboratory, the skin (especially when scratches, cuts, abrasions, dermatitis, or other lesions are present) and mucous membranes of the eye, nose, and mouth should be considered as potential pathways for entry of these retroviruses. Whether infection can occur via the respiratory tract is unknown. The need for using sharps in the laboratory should be evaluated. Needles, sharp instruments, broken glass, and other sharp objects must be carefully handled and properly discarded. Care must be taken to avoid spilling and splashing infected cell-culture liquid and other virus-containing or potentially infected materials.

Recommended Precautions:

In addition to the following recommended precautions, persons working with HIV, SIV, or other blood-borne pathogens should consult the OSHA Bloodborne Pathogen Standard. Questions related to interpretation of this Standard should be directed to Federal, regional, or state OSHA offices.

1. BSL-2 standard and special practices, containment equipment, and facilities are recommended for activities involving **all** blood-contaminated clinical specimens, body fluids, and tissues from **all** humans, or from HIV- or SIV-infected or inoculated laboratory animals.

2. Activities such as producing research-laboratory-scale quantities of HIV or SIV, manipulating concentrated virus preparations, and conducting procedures that may produce droplets or aerosols, are performed in a BSL-2 facility, but using the additional practices and containment equipment recommended for BSL-3.

3. Activities involving industrial-scale volumes or preparation of concentrated HIV or SIV are conducted in a BSL-3 facility, using BSL-3 practices and containment equipment.

4. Nonhuman primates or other animals infected with HIV or SIV are housed in ABSL-2 facilities using ABSL-2 special practices and containment equipment.

Additional Comments:

1. There is no evidence that laboratory clothing poses a risk for retrovirus transmission; however, clothing that becomes contaminated with HIV or SIV should be decontaminated before being laundered or discarded. Laboratory personnel must remove laboratory clothing before going to non-laboratory areas.

2. Work surfaces are decontaminated with an appropriate chemical germicide after procedures are completed, when surfaces are overtly contaminated, and at the end of each workday. Many commercially available chemical disinfectants can be used for decontaminating laboratory work surfaces and some laboratory instruments, for spot cleaning of contaminated laboratory clothing, and for spills of infectious materials. Prompt decontamination of spills should be standard practice.

Appendix A. (Continued)

3. Human serum from any source that is used as a control or reagent in a test procedure should be handled at BSL-2.

4. It is recommended that all institutions establish written policies regarding the management of laboratory exposure to HIV and SIV in conjunction with applicable federal, state and local laws. Such policies should consider confidentiality, consent for testing, administration of appropriate prophylactic drug therapy, counseling, and other related issues. If a laboratory worker has a parenteral or mucous membrane exposure to blood, body fluid, or viral-culture material, the source material should be identified and, if possible, tested for the presence of virus. If the source material is positive for HIV antibody, virus, or antigen, or is not available for examination, the worker should be counseled regarding the risk of infection and should be evaluated clinically and serologically for evidence of HIV infection. Post-exposure prophylaxis should be offered according to the latest guidelines. The worker should be advised to report and seek medical evaluation of any acute febrile illness that occurs within 12 weeks after the exposure. Such an illness particularly one characterized by fever, rash, or lymphadenopathy may indicate recent HIV infection. If the initial (at time of exposure) test is negative, the worker should be retested 6 weeks after the exposure and periodically thereafter (i.e., at 12 weeks and 6, 9 and 12 months after exposure). During this follow-up period exposed workers should be counseled to follow Public Health Service recommendations for preventing transmission of HIV.

5. Other primary and opportunistic pathogenic agents may be present in the body fluids and tissues of persons infected with HIV. Laboratory workers should follow accepted biosafety practices to ensure maximum protection against inadvertent laboratory exposure to agents that may also be present in clinical specimens or in specimens obtained from nonhuman primates.

   Research involving other human (i.e., human T-lymphotrophic virus types I and II) and simian retroviruses occurs in many laboratories. Recently, surveillance for such infections revealed occupational exposure and infection by simian foamy virus among animal caretakers at laboratory research facilities. The precautions outlined above are sufficient while working with these agents.

   Laboratory work with retroviral vectors, especially those containing full-length infectious molecular genomes (HIV-1), should be handled in BSL-2 facilities under BSL-2/3 practice. This includes infectious clones derived from nonhuman viruses, but possessing xenotropic (especially for human cells) host ranges.

Transfer of Agent: For a permit to import these agents, contact CDC.

A5. Transmissible Spongiform Encephalopathies (Creutzfeldt-Jakob, Kuru, and Related Agents)

(From *Biosafety in Microbiological and Biomedical Laboratories*. USDHHS/CDC/NIH. 4th ed. HHS Publication No. [CDC] 93-8395. Washington, DC: U.S. Government Printing Office; 1999:19-26.)

Laboratory-associated infections with the transmissible spongiform encephalopathies (prion diseases) have not been documented. However, there is evidence that Creutzfeldt-Jakob disease (CJD) has been transmitted iatrogenically to patients by corneal transplants, dura mater grafts and growth hormone extracted from human pituitary glands, and by exposure to contaminated electroencephalographic electrodes. Infection is always fatal. There is no known nonhuman reservoir for CJD or kuru. Nonhuman primates and other laboratory animals have been infected by inoculation, but there is no evidence of secondary transmission. Scrapie of sheep and goats, bovine spongiform encephalopathy, and mink encephalopathy are transmissible spongiform encephalopathies of animals that are similar to the human transmissible diseases. However, there is no evidence that the animal diseases can be transmitted to man.

Appendix A. (Continued)

[Editor's Note: There is evidence that bovine spongiform encephalopathy and nvCJD are the same condition, in cattle and humans, respectively, and transmission is related to consumption of contaminated beef.]

Laboratory Hazards: High titers of a transmissible agent have been demonstrated in the brain and spinal cord of persons with kuru. In persons with Creutzfeldt-Jakob disease and its Gerstmann-Sträussler-Schenker Syndrome variants, a similar transmissible agent has been demonstrated in the brain, spleen, liver, lymph nodes, lungs, spinal cord, kidneys, cornea and lens, and in spinal fluid and blood. Accidental parenteral inoculation, especially of nerve tissues, including formalin-fixed specimens, is extremely hazardous. Although non-nerve tissues are less often infectious, all tissues of humans and animals infected with these agents should be considered potentially hazardous. The risk of infection from aerosols, droplets, and exposure to intact skin, gastric and mucous membranes is not known; however, there is no evidence of contact or aerosol transmission. These agents are characterized by extreme resistance to conventional inactivation procedures including irradiation, boiling, dry heat, and chemicals (formalin, betapropiolactone, alcohols); however, they are inactivated by 1 N NaOH, sodium hypochlorite (2% free chlorine concentration) and steam autoclaving at 132 ^{o}C for 4.5 hours. **[Editor's Note: The standard recommendation for steam autoclaving is now 132 to 134 ºC for 18 minutes.]**

Recommended Precautions: Biosafety Level 2 practices and facilities are recommended for all activities utilizing known or potentially infectious tissues and fluids from naturally infected humans and from experimentally infected animals. Extreme care must be taken to avoid accidental autoinoculation or other traumatic parenteral inoculations of infectious tissues and fluids. Although there is no evidence to suggest that aerosol transmission occurs in the natural disease, it is prudent to avoid the generation of aerosols or droplets during the manipulation of tissues or fluids, and during the necropsy of experimental animals. It is further strongly recommended that gloves be worn for activities that provide the opportunity for skin contact with infectious tissues and fluids. Formaldehyde-fixed and paraffin-embedded tissues, especially of the brain, remain infectious. It is recommended that formalin-fixed tissues from suspected cases of transmissible encephalopathy be immersed in 96% formic acid for 30 minutes before histopathologic processing. Vaccines are not available for use in humans.

Transfer of Agent: For a permit to import these agents, contact CDC. An importation or domestic transfer permit for bovine spongiform encephalopathy can be obtained from USDA/APHIS/VS.

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 BMBL4.[1] 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 Biological Safety Cabinet is designed with inward airflow at a velocity to protect personnel (75 to 100 lfpm), 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.

Appendix B. (Continued)

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

Type B cabinets are further subtyped into types B1, B2, and B3. Type B cabinets are hard-ducted to the building exhaust system and contain negative pressure plena. These features, plus a face velocity of 100 lfpm, allow work to be done with toxic chemicals 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.

The U.S. Department of Health and Human Services publication *Primary Containment of Biohazards: Selection, Installation, and Use of Biological Safety Cabinets* (2nd ed. Washington: GPO; 2001) is an excellent source of detailed information on this subject (http://www.cdc.gov/od/ohs/biosfty/bsc/bsc.htm).

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. When 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.

Appendix B. (Continued)

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).

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.

Appendix B. (Continued)

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 4 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.

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.

Appendix B. (Continued)

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.

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.

Appendix B. (Continued)

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 thirty 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.

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. Currently, the NSF recognizes only gaseous formaldehyde as a decontamination agent.

Reference for Appendix B

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

Additional Reference for Appendix B

Primary Containment of Biohazards: Selection, Installation and Use of Biological Safety Cabinets. U.S. Department of Health and Human Services. Washington, DC; 1995.

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 Spaulding[1] 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, 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, the Hospital Infections Program of CDC has published a guideline containing general considerations for methods and indications for hand washing, as well as strategies for sterilizing or disinfecting medical instruments and environmental surfaces.[2] (Garner and Favero, 1985 Food and Drug Administration). This guideline, which is currently scheduled for updating, is provided to all hospitals in the United States and should be consulted for current information. CDC recommendations for disinfection and sterilization strategies, environmental microbiologic control, and hand washing strategies will be addressed in separate guideline updates.

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/opp00001/citizens/antimic.htm
http://www.epa.gov/epahome/search.html

CDC http://www.cdc.gov/ncidod/hip/DEFAULT.HTM

http://ace.orst.edu/info/nain/lists.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.

References for Appendix C

1. Spaulding EH. Role of chemical disinfection in the prevention of nosocomial infections. In Brachman PS, Eickhoff TC, eds. *Proceedings of the International Conference on Nosocomial Infections* (1970). Chicago, IL: American Hospital Association. 1971:247-254.

2. Federal Register 59(No 116). Topical Antimicrobial Drug Products for Over-the Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products. Food and Drug Administration; 1994:31402-31452.

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

The major exception to the rule in the previous discussion of microbial inactivation is the causative agent of Creutzfeldt-Jakob disease (CJD) or other related infectious agents responsible for certain fatal degenerative diseases of the central nervous system in humans or animals. Recommendations for the sterilization of instruments and medical devices exposed to patients with prion disease (CJD) are based on studies that show prions are resistant to heat and chemical germicides. However, these studies use prion challenges that are enormous and unrealistic, because materials subjected to the inactivation processes are slurries and bits of tissue. Also, in virtually every reported study, the post-treatment recovery of active

Accordingly, it can be argued that the experimental portal of entry in these studies may not accurately reflect downstream transmission risks for any surface exclusive of neurosurgical instruments. Further, because the empiric principles of instrument cleaning are not taken into consideration in these studies, most recommendations are extraordinarily, and unjustifiably, conservative. The invariably fatal outcome of CJD infection also influences the ultraconservative nature of many current recommendations.

A family of diseases, collectively referred to in the past as "slow viral infections" (e.g., CJD or kuru in humans or scrapie in sheep or goats), appear to be caused by agents commonly referred to as "unconventional viruses."[1] CJD and several other transmissible spongiform encephalopathies (TSEs) currently are believed to be caused by prions.[2,3] These are small, proteinaceous unconventional agents referred to in the scientific literature as "PrP^{res} or *PrP^{sc}*." These proteins resist inactivation by procedures known to modify nucleic acids. Currently, there is no known immunologic response to the CJD agent. Traditional virologic methods have not been successful as tools to characterize the etiologic agent. PrP^{res} is an *abnormal* isoform of a normal protein (PrP^{c}) concentrated in brain tissue; the normal protein in uninfected individuals is sensitive to the action of proteinase K, whereas the CJD protein is resistant to this enzyme. The two isoforms, while identical in amino acid sequence, differ in their three-dimensional conformation and glycosylation patterns. PrP^{c} is converted to PrP^{res} in a process as yet undetermined, but the conversion is thought to involve posttranslation modification of the protein.[4]

Prion proteins are concentrated in the tissues of the central nervous system (CNS); these are considered the "high-risk" tissues for CJD. Tissues identified as "medium-risk" are cerebrospinal fluid (CSF), lymph node, spleen, pituitary gland, and tonsil. "Low-risk" tissues include bone marrow, liver, lung, thymus, and kidney. Tissues and body substances that carry little or no risk of transmitting CJD include blood,[5-8] feces, urine, skin, peripheral nerves, saliva, gingiva, and other organ systems.

The transmissibility of the CJD agent has been demonstrated in that disease can be induced in laboratory animals by intracerebral inoculation of infective material (i.e., brain tissue or CSF), but not by simple direct contact. Transmission of CJD has not been associated with environmental contamination or fomites. There are several categories of CJD cases classified on the basis of transmission and/or pattern of occurrence. These are sporadic, familial, iatrogenic, occupational, and the new variant form of CJD (nVCJD or "Mad Cow" agent).

Sporadic cases of CJD account for approximately 90% of the disease in North America. The exact mode of acquisition or transmission of sporadic CJD in humans is not known. Person-to-person transmission via skin contact has not been documented.

* 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)

Iatrogenic episodes of CJD have been recognized, and transmission has occurred via percutaneous exposure (into brain or other CNS tissue) to medical instruments contaminated with prion/tissue residues[9-14] by transplantation of CNS (dura mater or corneas) tissue,[15-22] or by repeated injections of CNS organ tissue (pituitary hormone) extracts.[23-25] Instrument-mediated spread from person-to-person is exceedingly rare, but it has apparently occurred after the use of contaminated neurosurgical instruments or stereotactic depth electrodes previously used on infected individuals. In the instance of the electrodes, in particular, brain tissue remained on the instruments due to insufficient or inappropriate cleaning, which precluded effective treatment (i.e., sterilization) of the instrument for reuse.[11]

Historically, methods for inactivating the agent of CJD have been based on studies using infected tissues and injecting animals known to be susceptible to CJD. In addition, other prions, such as the agent that causes scrapie in sheep and goats, are used as surrogates to determine inactivation characteristics of various chemical and physical agents. Prions in general are resistant to a number of standard disinfection and sterilization procedures, including steam autoclaving, dry heat, ethylene oxide gas, and chemical disinfection using either formaldehyde or glutaraldehyde. Sodium hypochlorite (NaOCl) derived from household bleach and having at least 2.5% available chlorine, 1 N sodium hydroxide (NaOH), extended steam sterilization or dry-heat sterilizer procedures has been shown to be effective in reducing the levels of prions in tissue by 4 to 7 logs.[26,27] Because of the agent's intrinsic resistance to physical and chemical inactivation methods and the invariably fatal outcome of CJD, most recommendations for processing medical devices known to have been used on patients diagnosed with CJD are extraordinarily conservative.[28-31]

The following protocols are examples of the extreme and unwarranted protocols that have been suggested:

Standard autoclave cycles (121 ºC for 15 minutes) are extended to one to two hours; or
Autoclave cycle of 134 ºC for 18 minutes (France); or
Autoclave cycle of 134 ºC for three minutes for six consecutive cycles (Netherlands); or
Exposure of surfaces to 1 N NaOH (which is caustic and corrosive) for 30 to 60 minutes;
Exposure to and washing of skin with NaOH solutions easily capable of breaching the skin barrier; [30] or
Exposure of surfaces to 2.5 to 5.25% NaOCl (chlorine bleach) for 30 to 60 minutes.

Many of the above recommendations are meant for any device used on a patient with suspected CJD, while others are meant for any device that is exposed to brain or CNS tissue of any patient.

In addition, manufacturers of some types of reusable medical devices recommend that the devices be decontaminated by exposure to NaOH or NaOCl, autoclaved, and then discarded (*incinerated*). Two US manufacturers of flexible fiber optic endoscopes have recommended that if the devices are used on patients with diagnosed or suspected CJD, these should be decontaminated by soaking in chlorine bleach, autoclaved for an extended period of time, and then either incinerated or returned to the manufacturer for disposal.

This degree of conservatism is not warranted for a number of reasons, all of which take into account the epidemiology of the CJD agent, including the specific source materials (CNS tissue) containing the prion and the modes of prion transmission.

Appendix D. (Continued)

Source Materials Containing the CJD Agent

In the reprocessing schemes mentioned above, the principles of infection transmission by medical devices or fomites are largely ignored, and it is assumed that all situations include worst-case scenarios. As mentioned above, tissues vary in their degrees of infectivity based on the concentration of CJD agent; some of the tissue tropism studies were based on animal TSE models (e.g., scrapie in sheep and goats). Most, if not all, reprocessing recommendations are based *solely* 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 instrument 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 episodes of CJD, it is clear that the only instrument-related exposures in patient care settings which may have resulted in infection are those instances involving devices which cannot be cleaned and which are contaminated with high-risk tissue from the CNS (e.g., brain, dura mater, corneas); or, in the case of transplants, exposures due to direct and intimate contact with CJD-laden CNS tissue; or from receiving one of the two implicated hormones—a growth hormone or gonadotropin.

Mode of Transmission

The transmission of CJD infections in patient-care settings invariably involves the use of prion-contaminated medical devices. Transmission of any infectious agent by means of a device or fomite is dependent on the concentration of the agent on the device or in and on the fomite, and the presence of a mechanism to introduce the agent into a patient's body in an efficient manner. A variety of iatrogenic episodes of CJD have been reported. In these instances, the CJD agent is tissue-associated, and transmission is linked with unintentional exposure to high-risk tissues. When tissue is entrapped in a device and cannot be removed by cleaning, or in transplant instances where the tissue per se becomes the device, there is an increased risk of transmission. The only reported instances (over 20 years ago) of patient-to-patient transmission involve devices such as depth electrodes which are composed of wires that are directly exposed to high-risk brain tissue and which are difficult to clean. These instruments contained a high prion/tissue load which were then implanted into an optimal tissue site (brain).

When a device is contaminated with tissues or body substances that are not deemed as high-risk, and the device is cleanable, the probability of infection transmission appears to be so low that it would not be measurable.

The Basis for a Rational Strategy for Preventing CJD Agent Transmission

Inactivation studies on prions, including the agents of CJD and scrapie, have been done by a number of research groups, each using different protocols for preparation of challenge material, inactivation methods, and assay techniques.[32-36] Therefore, it is not surprising the protocols and results differ greatly. Virtually all inactivation tests were done using tissue homogenates that would severely challenge any liquid or gas germicidal procedure, and are not consistent with the usual disinfection or sterilization challenge in the clinical setting. In addition, the liquid chemical germicides tested have been primarily aldehyde-based. Both glutaraldehyde and formaldehyde are fixative chemicals and would render prion/tissue more stable.

Alternatively, when a potentially contaminated device is able to be cleaned, and the prion/tissue load decreased or removed physically, the probability of infection transmission is significantly reduced, even if the tissue in question is a high-risk tissue. Appropriate cleaning and reprocessing procedures should be

Appendix D. (Continued)

carried out, however, in accordance with standard principles of disinfection and sterilization. In the instances of patient-to-patient transmission of CJD, described above, it should be noted that the depth electrodes were "sterilized" by soaking in 70% isopropanol and formalin. This procedure was referred to as a "conventional sterilization procedure." This procedure is not a sterilization procedure in any sense of the word and would be classified, at best, as an intermediate-level disinfection procedure that would never be recommended for a device that was exposed to human tissue. More appropriately, the leads should have been cleaned and subjected to a true sterilization procedure such as steam autoclaving. It should be noted, however, that it may not be possible to accomplish sufficient cleaning to adequately remove the prion/tissue load on such a device, and as such, it may be prudent to discard these devices if they have been exposed to high-risk tissues of patients with CJD.

Two major factors significantly affect the sterilization strategy for CJD-contaminated instruments and devices. One is the type of tissue to which the instrument has been exposed and the other is the cleanability of the device. If the item is exposed to high-risk tissue that contains a high prion burden and cannot be cleaned effectively, the instrument should be processed using one of the extended or specialized sterilization methods, or discarded. If the item is not exposed to high-risk tissue or can be cleaned effectively, then conventional processing and sterilization and disinfection protocols can be used. These recommendations are expanded below and in part are based on a current draft of a CDC guideline.[37-39]

Recommendations for Decontamination, Disinfection, and Sterilization of Reusable Devices Potentially Contaminated with the CJD Agent

Devices Contaminated with High-Risk Tissues:

Those devices that are impossible or difficult to clean should be discarded, or decontaminated initially by autoclaving at 132 to 134 ºC for 18 minutes in a prevacuum sterilizer, or 121 º for one hour in a gravity displacement sterilizer, or soaked in 1 N NaOH for one hour before terminal cleaning, wrapping, and sterilization by conventional means.

Those devices that are constructed such that cleaning procedures result in effective tissue removal can be cleaned and then sterilized by autoclaving at 132 to 134 ºC for 18 minutes in a prevacuum sterilizer, or 121 ºC for one hour in a gravity-displacement sterilizer.

Devices Contaminated with Medium- or Low-Risk Tissues:

These devices can be cleaned and disinfected or sterilized using conventional protocols of heat or chemical/*gas* sterilization, or high-level disinfection.

Among the most frequently asked questions are those regarding appropriate reprocessing protocols for flexible endoscopes after use on a patient with CJD. The current guidelines for cleaning and disinfection of these instruments need not be changed. To further minimize the risk of transmission of infection in general for any disease when an invasive procedure (i.e., biopsy) is done during endoscopy, several options may be considered. If the device accessory (e.g., biopsy forceps) is difficult to clean, the accessory may be discarded as a single-use item. If the accessory is heat-stable, it should be cleaned thoroughly with an ultrasonic cleaner and reprocessed in the normally accepted manner by steam autoclaving. Instruments designed and manufactured for a single use should always be used as intended, i.e., discarded after a single use.

Appendix D. (Continued)

Environmental (Housekeeping) Surfaces:

Environmental surfaces would not be expected to be associated with transmission of CJD to healthcare workers or patients. Floors, walls, counter tops, or other housekeeping surfaces in medical wards, autopsy rooms, and laboratories that are contaminated with high-risk tissues should be cleaned with a suitable detergent in the conventional fashion. A 1:10 dilution of chlorine bleach can be used to spot decontaminate visible residues of tissue before cleaning.

Table D1. Reported Mechanisms of Iatrogenic or Occupationally Acquired Episodes of CJD

Source of CJD Agent	Number of Cases
Depth electrodes / neurosurgical instruments	2 / 4
Corneal transplants	3
Dura mater transplants	66
Human cadaveric growth hormone	76 (worldwide), 15 (US)
Human cadaveric pituitary gonadotropin	4

References for Appendix D

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

OSHA Instruction CPL2-2.44 (November 5, 1999) 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 blood-borne 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, PA 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, TX 75202
(214) 767-4731
FAX (214) 767-4137
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, Guam, Hawaii, Nevada

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 Compliance Assistance
U.S. Department of Labor
Office of Health Compliance Assistance (OSHA)-Room N3467
200 Constitution Avenue
Washington, D.C. 20210
(202) 693-2190

NCCLS consensus procedures include an appeals process that is described in detail in Section 9.0 of the Administrative Procedures. For further information contact the Executive Offices or visit our website at www.nccls.org.

Summary of Comments and Subcommittee Responses

M29-A: *Protection of Laboratory Workers from Instrument Biohazards and Infectious Disease Transmitted by Blood, Body Fluids, and Tissue; Approved Guideline*

Section 6.2.1.1 (formerly Section 4.2.1.1)

1. This section should clearly distinguish IgE antibody-mediated hypersensitivity (Type I) to allergenic proteins as distinct from contact dermatitis (Type IV), which is cell-mediated immune response to chemicals added to latex.

- **The text has been modified to distinguish between antibody-mediated hypersensitivity and cell-mediated immune response to latex.**

2. Powdered latex gloves should be discouraged, at the minimum, as they represent the single, most important risk factor for the induction of latex-allergic reactions in healthcare workers due to occupational exposure.

- **The following text has been incorporated into Section 6.2.1.1 to address the commenter's concern:**

  "Because the use of powder-free gloves reduces the dissemination of latex proteins into the environment, powdered latex gloves should be 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."

Section 8.8.1 (formerly Section 6.7.1)

3. The document states, "Blood bank 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." What type of gown or laboratory coat is being referred to here (e.g., impermeable coat, uniform-style laboratory coat)?

- **Section 8.8.1 also recommends that blood banks follow standard precautions when processing blood. Section 7.2.4 on *Gown* recommends that workers "select a gown, apron, or laboratory coat appropriate for the activity and the amount of fluid likely to be encountered." Section 6.2.3 on *Protective Body Clothing* provides guidance for task-appropriate protective clothing.**

Summary of Delegate Comments and Working Group Responses

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

General

1. Your practice of keeping these documents active through a three-year review process is evident with the inclusion of current information on prions and latex allergy issues.

   The Occupational Safety and Health Administration (OSHA) issued a number of new requirements regarding needles and sharps safety earlier this year. The Centers for Disease Control and Prevention (CDC) also issued a safety alert on this subject in 1999. These changes are reflected in sections in your document. In order to provide proper focus to these major changes, it may be helpful to describe them in a section or preamble early on in the document with a note that further details are to follow in the text of the document.

- **The Abstract has been revised to highlight needles and sharps safety as new information included in this revised edition of the guideline.**

2. There are a number of references for the need to post items with the universal biohazard symbol. These references should also reference the need to include the word, "Biohazard" in order to provide full communication of the hazard present and to better address the applicable labeling requirements.

- **The universal biohazard symbol communicates the type of hazard.**

3. I strongly suggest NCCLS contact CDC to determine the expected publication of the MMWR article on recommendations of handling *Neisseria meninigiditis*. This article is close to publication and will probably suggest new guidelines on handling this important agent of laboratory-acquired infections.

- **NCCLS has contacted the Centers for Disease Control and Prevention regarding the expected publication of the MMWR article. Reference to this article has been made in Section 5.3.1 of the guideline.**

Section 3

4. You provide definitions of an "aerosol" and "airborne transmission" in this section. You note that an aerosol is, "a system of particles dispersed in a gas, smoke, or fog." *Mycobacterium tuberculosis* (TB) cultures are tested in clinical laboratories, and they pose the risk of airborne infections through the inhalation of respirable aerosols. In this context, the aerosol definition should be reflective that aerosols are respirable particles that can be retained in the lungs.

- **The definition of "aerosol" has been revised as recommended.**

5. You note that airborne transmission is "infectious agents are carried by, or through the air, usually in small droplets." However, later in section 5.2.4, you note that aerosols are invisible particles, which are typically less than 10 microns in diameter. Small droplets are generally not considered to be respirable. The airborne transmission definition should be reflective of infectious agents that can be transmitted through retention in the lungs of a respirable infectious aerosol. May we suggest rewording this definition to define airborne transmission as the spread *of* infection by inhalation *of* respirable size particles containing infectious agents. This would provide consistency and clarity needed for the development of information to follow in the document.

- **The definition of "airborne transmission" has been revised as recommended.**

6. The definition of "medical waste" is inclusive of "infectious waste" (well defined in these definitions) and of "non-medical waste". In order to better make this distinction, the use of the term "regulated medical waste" is suggested. It would be defined as "Materials generated as a result of diagnosis and treatment of patients that requires special handling. This may include `Infectious Wastes'."

- **The OSHA definition of Regulated Waste found in CPL 2-2.44D is used in the text.**

Section 4

7. Please correct the interpretation of the acronym/initialism for ASHRAE. It should read, "American Society of Heating, Refrigeration, and Air Conditioning Engineers."

- **The correction has been made.**

8. Please correct the acronym/initialism and interpretation for HEPA filtration. It should read, "HEPA filters—high energy particulate air filter."

- **The acronym/initialism and its interpretation as they appear in the guideline are accurate and have been maintained.**

Section 5.2

9. There is a statement regarding the types of fluids from which HIV has been isolated. We recommend adding to the next statement, "Only blood, bloody body fluids, or concentrated virus solutions have been implicated in the laboratory transmission of HIV to date."

- **The text has been modified to include "concentrated virus solutions," as body fluids may contain blood that is not visible.**

10. You also may want to mention that although the OSHA Bloodborne Pathogen Standard identifies only certain fluids that have been epidemiologically linked to HIV transmission, it also includes any body fluid that contains blood. The CDC Standard Precautions recommend precautions with all body fluids except sweat.

- **Universal and Standard Precautions are addressed in Section 7.**

11. Tables 2 and 4: the data is that recorded through June 2000, not June 1999.

- **The date has been revised as indicated.**

Section 5.3

12. The sentence that begins "Such practices should include…" is unclear. We suggest: "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 11.3.1)." This paragraph should also reference the process of removing samples from potentially positive blood cultures as a procedure with high potential for generating infectious aerosols.

- **The text has been revised as recommended.**

Section 5.3.1

13. *Neisseria meninigitidis*: Laboratory hazards: The agent may be present in genital cultures as well as sputum cultures. While these are generally not pure cultures, nor representative of "invasive infections," they are documented as infectious processes at these sites. Recommended precautions: This paragraph should specify the additional primary containment and personal precautions which might bee indicated for activities with a high potential for droplet or aerosol production, as well as those activities. If use of a BSC is meant, so state. BSL3 is referenced, but the document does not specify what procedures. Be specific. Not on vaccines: It should be noted that vaccines, if used, should be in addition to engineering and personal protective equipment. The current vaccine would not have been protective against a significant portion of the documented nosocomial strains.

- **The text has been revised to reflect the current CDC recommendations.**

Section 5.3.2

14. In the first sentence, replace "your" with "the," i.e., …a contaminated article (e.g., contaminated fingers or pencils) being placed in the mouth.

- **The text has been revised as suggested.**

Section 6

15. In the text following this heading, there is a listing of the hierarchy of controls identified in the original OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030). The listing includes standard precautions. The reference should be to "universal precautions". In the text of the OSHA Bloodborne Pathogens Standard, there is no definition for standard precautions. There is no reference to it in the text of the standard itself that follows the definitions section. We appreciate the later definitions of both Universal Precautions and Standard Precautions.

- **The text has been revised to reflect the content of the referenced OSHA standard.**

Section 6.1

16. When water is not available, proper guidance is given regarding alternative means of cleaning hands on an interim basis. It needs to be clear that these interim measures do not substitute for washing of hands in soap and water. This must still be done as soon as possible in these situations when soap and water becomes available.

- **The text has been revised as recommended.**

17. Many questions arise as to the appropriateness of, or need for, antibacterial soap products. Given the growing concern with resistant bacteria and the documented ability of the common antibacterial compounds (e.g., triclosan) to enhance antibiotic resistance, this is a question that is appropriate to raise for laboratorians.

- **The working group does not endorse soap products containing antibacterial agents as significantly superior to any standard detergent when used with running water. The relationship between the use of antibacterial soaps and emerging antimicrobial resistance in the healthcare environment remains controversial.**

Section 6.2.1

18. Your document indicates that gloves are meant to help prevent exposures to healthcare providers who procure specimens. Employees who are to collect blood specimens from patients are to wear gloves that are recognized as medical devices by the Food and Drug Administration (FDA). FDA issues a 510(k) number to the glove manufacturer, which enables them to label their product, "patient examination gloves." Gloves, which meet this requirement, would be the appropriate standard of care for the gloves used by employees who would handle and test specimens from patients. This should be noted in your document.

- **The document has been revised as recommended.**

19. The NCCLS draft document states, "It is the opinion of this working group that used gloves should be discarded as biohazardous wastes." Minimally contaminated materials such as gloves, gauze, or band-aids are not always designated as regulated medical wastes by state regulations or by OSHA, and pose almost no risk of blood-borne pathogen transmission. We would ask that a general statement about proper disposal of all disposables in laboratories be referred to the local state medical waste regulations.

- **The text has been revised as recommended.**

Section 6.2.1.1

20. The American Society of Testing and Materials (ASTM) in ASTM D 3578-00a recommends that latex gloves should contain no more than 200 micrograms/decimeter squared of water extractable protein in order to be considered low protein. This limit should be noted in the recommendation for the selection of low protein gloves.

- **A statement has been added in Section 6.2.1 to endorse the use of gloves cleared for medical use by the FDA in the U.S.**

Section 6.2.1.3

21. Consider adding to the list of appropriate glove use, the correct protective measures to be taken for ensuring that a healthcare provider's hands are adequately protected if they have a cut or if their skin is otherwise compromised, such as with dermatitis. The cut or broken skin should be covered with a water resistant bandage and gloves worn while handling clinical specimens.

- **The use of occlusive dressings is addressed in Section 6.2.4.**

Section 6.2.2.

22. The first paragraph states, "Facial barrier protection should be used if there is a reasonably anticipated potential for spattering or splashing blood or body substances." We would suggest that a biological safety cabinet, splashguard, or other engineering control be the preferred method of facial protection. If these are not available, then a full "plastic face shield best provides facial protection unless there is the potential for respirable aerosols containing airborne pathogens." Then the statement, "Splashguards may serve as an acceptable alternative to plastic face shields" can be deleted.

- **The working group recommends that one of the following three options is adequate protection for anticipated routine splattering or splashing of blood or body fluids: a full-face shield, a mask and eye protection, or a splashguard. However, these facial barriers do not provide protection against respirable aerosols.**

23. Paragraph 3 states, "If face shields are not used, a personal respirator and eye protection should be used." The preceding commentary in this section deals with protection against splashes and spattering of facial mucous membrane surfaces. A personal respirator is meant to primarily provide protection against respirable infectious aerosols. Its reference here could cause some confusion, especially since readers are being referred to section 10 for further information regarding protection against airborne pathogens such as TB. The sentence should reference the use of a face covering that protects the facial mucous membrane surfaces, such as a fluid-resistant surgeon's mask.

- **The text has been revised as recommended.**

24. The last statement, "The prevention of transmission of *Mycobacterium* tuberculosis is discussed in detail in Section 10" is an unnecessary statement under the facial protection section.

- **The sentence has been deleted.**

25. The discussion centers on splashes and splatters. Should the issue of aerosol production and protection appropriate to that danger be raised? The discussion might include assessment of the hazard created and the need for respirator protection or use of a BSC when needed. Revisiting this issue in a discussion of splatters and splashes may be repetitive, but useful to increase laboratory safety.

- **The issue of aerosols and appropriate protective measures is addressed elsewhere in the document.**

Section 6.4.1.1

26. A useful example under the FDA approved chemicals for the laboratory would be the antiseptics or antimicrobial hand washing agents.

- **This recommendation will be considered in the next revision of M29.**

Section 6.4.2

27. In paragraph 5 of this section, there is the statement, "…It is the opinion of the committee that germicides of the intermediate-level category (i.e., have a tuberculocidal claim) be used for surface decontamination in laboratory areas as a safe minimum." We would suggest adding a statement regarding attention to the contact time recommended by the manufacturer in order to achieve tuberculocidal activity.

- **The text has been revised as recommended.**

28. Footnote "g" in Table 7 makes some statements regarding the efficacy of alcohols as intermediate-level germicides. It would be helpful to also note that alcohol solutions are not sporicidal.

- **Footnote "g" has been revised.**

29. Table 7. Please complete the right hand side of the table ("Activity Level") for the sterilants, or fill in as N/A.

- **Table 7 has been revised as recommended.**

Section 6.4.3

30. We suggest adding a statement about biological spills outside biological safety cabinets that will generate aerosols (e.g., *Coccidiodes immitis*). Occupants should hold their breath and leave the laboratory immediately.

- **The text has been revised.**

Section 7.2.3

31. A short statement indicating that respirators should only be worn when there is a risk of exposure to a respirable, infectious aerosol or droplet nuclei (such as cleaning a spill of TB cultures or drawing blood from TB patients) should be added.

- **The use of respirators is addressed in Sections 8.11 and 10.**

32. Again, we would suggest adding a statement that biological safety cabinets or splashguards are the preferred methods for protection when splashes are anticipated.

- **See the response to Comment 22.**

33. This discussion is too narrowly focused. Should the issue of aerosol production and protection appropriate to that danger be raised? The discussion might include assessment of the hazard created and the need for respirator protection or use of a BSC when needed.

- **See the response to Comment 25.**

Section 8

34. Is the use of a face shield recommended when removing stoppers from "Hemogard" tubes since they are designed to reduce splatter/aerosols?

- **This issue is addressed in Section 8.3.1.**

Section 8.1

35. Facilities for hand washing are described in this section. We would recommend that foot-, knee-, or other automatic faucets be used in laboratories for washing hands to avoid contamination of handles.

- **The text has been revised.**

36. 7th bullet: should read PPE, not PEP.

- **This correction has been made.**

37. If engineering and work practice controls do not eliminate exposure, the PPEs are required.

- **See the response to Comment 36.**

Section 8.2

38. When using a hypodermic needle and syringe for transferring blood, consider using a safer blood transfer device to avoid the need for attaching a needle to puncture the vacuum tube stopper.

- **This issue has been addressed in Section 11.4.1.**

Section 8.2.1

39. The second sentence in the first paragraph indicates that Federal Needlestick Safety and Prevention Act authorized OSHA to revise its Bloodborne Pathogens standard. Under this act, OSHA was *required* to amend the standard; it was not an optional action that could be considered by OSHA. The use of the word, "mandated" would be more appropriate.

- **The text has been revised as recommended.**

40. An important point is that the revised OSHA Bloodborne Pathogens standard requirements are applicable to any sharps that may be contaminated with blood and other potentially infectious materials. There has much discussion in many forums about needle safety, but scalpels are also covered under the revised standard if they are used in procedures such as autopsies. A reference should be made here to this extent. Or, this should be noted as part of section 8.11 that deals with autopsies.

- **The text in Section 8.2.1 has been revised to indicate that the OSHA requirements apply to any sharps.**

41. It was good to see that you have referenced the state-specific needle safety requirements. At the time of the preparation of these comments, at least 20 states have passed such laws. You have referenced web sites earlier for information regarding disinfectants and germicides. The University of Virginia Health Care Worker Safety Center has a web site that tracks these state needle safety laws, and it provides a wealth of information that would be of value to someone performing a risk assessment for their needle safety program. That address is as follows:

    http://www.med.virginia.edu/medcntr/centers/epinet/

- **The web site has been added to the document.**

Section 8.2.3

42. OSHA may allow gauze pads with minimal blood to be discarded with the hospital waste stream as long as it is properly handled (Although OSHA designates regulated wastes by definition to minimize employee handling or exposure, it does not regulate the disposal of state-regulated medical waste). As with gloves above, the disposal of items minimally contaminated with blood and other potentially infectious materials is an environmental issue that is regulated in many states. Their proper disposition as per any applicable state environmental agency requirements also needs to be referenced, and consideration of moving the edited sentence to Section 8.10 should be given.

- **The text has been revised. See also the response to Comment 19.**

43. The last paragraph regarding packaging of specimens belongs under Section 8.3, Specimen Collection, Handling, and Transportation.

- **The text has been revised as recommended.**

44. The last paragraph is very confusing. The collection device is..."frequently contaminated on the outside." Is this a capillary tube? The example of a secondary, leakproof container (e.g., screw-top test tube) seems to indicate this. OSHA does not require labeling of secondary containers with "biohazard" symbol and verbiage if the specimen is visible and recognizable as a blood or body fluid container, and if the exposure control plan indicates that ALL blood and body fluids are handled with Universal Precautions.

- **See the response to Comment 43.**

45. The wording in the second sentence should be stronger, i.e., …gloves must be worn when performing skin punctures.

- **Section 8.2.2 cites the U.S. requirement that gloves must be worn when performing vascular access procedures.**

46. As stated in the last sentence, "the skin surface may be cleansed with an antiseptic such as alcohol…" Application of alcohol or povidone-iodine will cause the site to begin bleeding. The working group should consider rewording this sentence.

- **The last sentence has been deleted.**

Section 8.3.2

47. The best practices indicated in the document are good. However, there can be a lot of variability in the way contaminated requisitions are managed. This can be due to the testing performed at the site. For example, a facility that is accredited by the Substance Abuse and Mental Health Administration (SAMSHA) must retain original test requisitions as part of their accredited procedures. Contaminated requisitions may need to be placed into biohazard bags, photocopied, and then archived with a requisition photocopy being processed with the specimen.

- **The text has been revised as recommended.**

48. Institutions need to establish internal procedures to be followed for the proper management of contaminated requisitions. They need to be communicated to employees and followed by these workers.

- **See the response to Comment 47.**

Section 8.7

49. In order to provide more complete guidance for a laboratory that may have to ship specimens off-site for testing, they should be referred to the CDC requirements for ground shipment of the specimens, or the most current version of the Dangerous Goods Regulations of the International Air Transport Association (IATA) for air shipment of specimens.

- **The reader is referred to the U.S. Department of Transportation or IATA guidelines for details.**

Section 8.8.2

50. There is a reference to the need to perform some procedures in 'a biological safety cabinet (BSC) or behind a shield. More specific guidance needs to be provided as to which tasks need to be done in the BSC and which need to be done behind the shield. If specific tasks are not to be given, then criteria for making this determination needs to be provided.

- **The working group recommends that cultures or specimens suspected of containing highly infectious agents be handled in a BSC and tasks associated with splatter and splashes are performed behind a shield. The reader is referred to *Biosafety in Microbiological and Biochemical Laboratories*, 4th edition for details.**

Section 8.9.3

51. "A one-handed technique may be used to remove the needle..." needs to be changed to "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. Alternatively, a holder with a button-release for one-handed needle removal may be used for needle removal."

- **The text has been revised as recommended.**

52. A procedure is referenced for resheathing needles. However, in Section 8.9.2, the comment is made that needles should not be resheathed. This is a conflict. These sections should be rewritten. Also, there is a "mixing" of procedures between the two; one should deal with resheathing, and the other with removing the needle.

- **The text has been revised.**

53. The picture shown properly demonstrates this procedure when a vacutainer needle and standard needle holder are in use. Currently, there is no shortage of needle safety devices which can be used to collect specimens in vacuum tubes using a needle holder. For most employers, the situation demonstrated will not be occurring with these specific materials. There are some specimen collections, such as for arterial blood gases, where it may be needed to use the technique demonstrated, since the collected specimen needs to be injected into a test instrument after collection. If you have a sketch that shows this technique with a standard needle and syringe, then it may be more representative of an actual situation to be encountered by the users of your document.

- **The working group agrees with this comment. The figure has been modified as suggested.**

54. Resheathing needles is prohibited in the United States. This procedure should be removed from the guideline.

- **The document strongly states that needles should not be resheathed; however, occasionally resheathing is necessary.**

55. Last paragraph, last sentence. The sentence should be modified to read, "Their use is preferred and recommended, and is required in the U.S.

- **The text has been revised as recommended.**

Section 8.9.1

56. Sharps containers should not be filled above the fill lines on the sides of the container. The container must not need to be shaken in order to seal the container.

- **The text has been revised.**

Section 8.10

57. Throughout this section, attention needs to be given to the distinction between medical waste and regulated medical waste (i.e., infectious waste).

- **The text recommends consulting NCCLS document GP5—*Clinical Laboratory Waste Management* and OSHA regulations for detailed information on medical waste management.**

58. The implementation of a medical waste volume reduction program should be a recommended best practice. This program is an environmentally favorable practice, some state environmental agencies mandate this activity, and it reduces the risk of infection to employees and the public. (We have not reviewed GP5, the NCCLS document on the management of medical waste, so it is possible that you may have addressed this in that guide.)

- **The text has been revised to include waste reduction as a key element of a waste management plan. Users should consult NCCLS document GP5—*Clinical Laboratory Waste Management* for detailed information.**

Section 8.10.5

59. Regulated Medical waste is a hazardous material regulated by the U.S Department of Transportation (DOT). Containers used to ship medical waste to off-site treatment facilities need to meet the (DOT) performance testing requirements and meet specific state regulations.

- **The text has been revised as recommended.**

Section 8.10.6

60. Generators of regulated medical waste are responsible for its proper treatment. On-site treatment by the generator affords the best opportunity for addressing this concern. In many cases, treatment by an off-site medical waste contractor is needed. In these situations, it is strongly suggested that the medical waste treatment site be audited to ensure that treatment is done effectively and in accordance with the terms of the site's operating permit(s).

- **See the response to Comment 57.**

Section 8.10.7

61. We recommend changing the term "sterilization" to "decontamination" when discussing treatment of wastes.

- **NCCLS document GP5—*Clinical Laboratory Waste Management* recommends that radioactive waste be sterilized.**

Section 8.11.1

62. There are conflicting statements in this section: "The guidelines that follow should be used for all cases and are considered suitable for autopsies on individuals infected with HIV, HCV, or HBV." versus, "In established or suspected cases of serious blood-borne infections such as HIV, HCV, or HBV, the prosector may wish to apply more stringent precautions than those recommended herein." Using Standard Precautions as listed in the following sections is appropriate, and no more stringent precautions are necessary, unless you mean to address CJD instead of HIV, HCV, or HBV.

- **The text has been revised.**

63. In the recommendation of "airflow of 12 air changes per hour," should read "at least 12 air changes per hour."

- **The text has been revised as recommended.**

Section 8.11.5

64. In the NCCLS draft document, the use of a N95 respirator or a HEPA-filtered respirator is recommended to be worn under the face shields of persons participating in an autopsy. Some pathologists will balk at wearing a respirator because they claim it interferes with their ability to accurately have their descriptions recorded on the autopsy audio recording. The document, as written, could be interpreted as requiring the use of a respirator during any autopsy. The October 28, 1994 CDC Recommendations, "Guidelines for Preventing the Transmission *of Mycobacterium* Tuberculosis in Health Care Facilities" indicate that these respirators are to be worn by personnel while performing autopsies on deceased persons who may have TB at the time *of death.* This qualification should be placed with the respirator recommendation in the document. Providing this focus will make it more likely that employees will wear face shields during any autopsy and respirators when a determination has been made that their use is warranted. See also 10.5 Autopsy Rooms.

- **The text has been revised as recommended.**

Section 8.11.6

65. The discussion of scalpel and/or needle and syringe use should include the requirement to evaluate and implement safer devices such as sheathing scalpel blades or safety needles.

- **See Section 8.2.1.**

66. There is also a respirator use issue in the section dealing with bone cutting. The N95 respirator is only needed with suspected *M. tuberculosis* cases.

- **See the response to Comment 64.**

Section 8.11.7

67. Emphasize the use of safety scalpels, and discourage the removal of scalpel blades from the holders for disposal.

- **The text has been revised.**

Section 8.12.1

68. Emphasize the use of biological safety cabinets (BSCs) or splash shields when processing unfixed, large specimens where splatter would be expected.

- **The text has been revised.**

Section 9

69. Information on postexposure prophylaxis of laboratory accidents/exposures to *Brucella*, *Francisella*, *P. pseudomallei*, and other fastidious, virulent bacteria, viruses, and fungi is lacking.

- **A reference is provided for the postexposure treatment and prophylaxis of agents not specifically addressed in the text.**

Section 9.1

70. The first paragraph should include a mention of other infectious agents handled in the lab, not just blood-borne pathogens.

- **The text has been revised.**

Section 9.1.1

71. The investigation of blood-borne pathogens exposures has been an OSHA mandate for years. The 2001 OSHA Bloodborne Pathogen Standard revision now requires that a sharps injury log be prepared to record the circumstances of these types of exposures that involve a sharp. The second bullet implies that a medical device is involved in any blood-borne pathogen exposure. It should note that prompt identification of any sharps involved in the injury is needed and that the name, type, and brand of any sharp involved needs to be recorded.

- **The text has been revised to refer to Section 8.2.1.**

Section 9.1.4

72. On June 29, 2001, the CDC released its consolidated PEP recommendations for exposure to HIV, HBV, and HCV. This document should be specifically referenced.

- **The CDC document has been referenced.**

Section 9.5.1

73. Prevention recommendations may change as a result of the MMWR article on nosocomial *N. meningitidis* infection.

- **The Morbidity and Mortality Weekly Report (MMWR) article has been referenced.**

Section 9.5.2

74. Postexposure treatment recommendations may change as a result of the MMWR article on nosocomial *N. meningitidis* infection.

- **See the response to Comment 73.**

Section 10

75. Who needs a TB skin test (e.g., all laboratory workers or just phlebotomists and microbiology laboratory personnel)?

- **The working group believes that local committees for each facility should identify individuals that require TB skin testing based on risk exposure and applicable regional laws and regulations.**

76. The tasks that need to be performed at Biosafety Level (BSL) 3 should be identified. The tasks that are to be performed at BSL-2 need to be identified. If these tasks are not detailed here, then readers should be referred to the most current version of "Biosafety in Microbiological and Biomedical Laboratories" (BMBL) or the CDC Guidelines for working with TB in Laboratories for guidance.

- **Section 10.3 recommends consulting the BMBL 4th edition for detailed information.**

Section 10.1.2

77. There is a statement in the first paragraph that states, "Infection occurs when a susceptible person inhales droplet nuclei....". Please delete the word "susceptible" since all people are susceptible.

- **The word "susceptible" has been deleted.**

Section 10.2

78. You are correct in characterizing droplet nuclei as being potential sources of airborne TB from TB patients. The risk of infections from respirable aerosols generated during the testing of specimens and cultures from TB patients is less clear and needs to be more distinct. Although TB can be present in many body fluids from TB patients, it should be noted that it is primarily found in sputum and other respiratory specimens so special care can be taken when testing these types of specimens.

- **The greatest risk of acquiring tuberculosis in the laboratory is from respirable aerosols generated during specimen processing and handling of culture isolates. The detailed biosafety precautions to minimize this risk are found in the references.**

Section 10.3

79. In the first bullet, "...intended to reduce the risk of exposing susceptible individuals..." Please delete the word "susceptible" since all people are susceptible.

- **See the response to Comment 77.**

80. When engineering controls are described, it should be noted that a written preventative maintenance program needs to be prepared and implemented in order to verify these controls are providing their intended protection (i.e., work within a routinely-certified biological safety cabinet). In addition, a written plan needs to be prepared, posted, and implemented for dealing with spills of TB specimens and TB cultures. UV light is recognized as an engineering control, but should only be used as a secondary engineering control to augment other engineering controls. This should be noted in this section.

- **The text has been revised to address the need for a preventive program and that UV light augments other engineering controls. Spills are addressed in Section 6.4.3.**

Section 10.4

81. The scope of your document includes workers who procure specimens, and respirators are required for the collection of specimens from TB patients in respiratory isolation. Respirators are also needed for TB spill responders, and laboratory workers in TB labs at the BSL-3 level. Also note that a Respiratory Protection Program is required per the OSHA Respiratory Protection Standard, and lab workers need to be medically cleared and fit-tested to wear the N95 respirators.

- **The document recommends consultation with the identified references for detailed information.**

Section 11.3.1

82. The second paragraph that begins, "Centrifuges should not be placed…" should be placed at the end of the section.

- **The text has been revised.**

Section 11.5

83. The sentence that indicates that food should not be stored with specimens in refrigeration units should also indicate that beverages should not be stored in this manner.

- **The working group believes that beverages are included in the "food" category.**

Section 11.8.3

84. There is a reference to the generation of aerosols from cell sorters in this section. Please revise to read, "if the fluid being sorted potentially contains organisms that are transmitted by the airborne route, and the cell sorter produces respirable size aerosols, a personal respirator should be worn."

- **The text has been revised as recommended.**

Section 11.10

85. "Dirty" work surfaces and items where the use of gloves is mandatory must also be posted with the universal biohazard symbol and the word, "Biohazard". Labeling alone and noting this practice in a policy manual is not sufficient. Employees must be trained to recognize and understand this posting in their work areas.

- **This issue is addressed in Section 6.2.1.4.**

Section 12.1

86. Please include in the list of references the January 18, 2001 issue of the Federal Register (Volume 66, Number 12) that announced the revisions to the OSHA Bloodborne Pathogen Standard Revision.

- **The reference is included in Section 12.1.**

87. On page 73, there is a statement, “Employees must be trained to report and carefully log each sharps injury with a minimum of information including 1) the identification of the device...” please include not only the identification of the type of device, but the brand of the device as well (required by the OSHA Bloodborne Pathogen Standard for the sharps injury log).

- **The text has been revised as recommended.**

88. The statement, “The training program should be developed in cooperation with the infection control department of the institution.” Please add “...safety office, or other professional group knowledgeable in blood-borne pathogens and other biological safety issues.”

- **The text has been revised as recommended.**

Appendix B

89. There should be a statement noting that horizontal laminar flow cabinets are not recommended for use with infectious agents. This containment device was designed for work protection, not employee protection. BSCs should also be placed away from high traffic areas in order to minimize airflow disruption inside of the BSC. The need for at least annual certification of the BSC as per the most recent version of National Sanitation Foundation (NSF) Standard No. 49 or manufacturer’s specifications needs to be noted.

- **Appendix B describes the BSCs that are appropriate for work with infectious agents and notes the other issues identified.**

90. B.2.1: Third paragraph. The recommendations are not clear. Be specific. BSL3 procedures are not listed, so is the intent that a respirator should be used in addition to a BSC when high-risk procedures are being performed?

- **The text has been revised.**

91. In B.2.2 on Preparation of Work Space: It was good to see the recommendation of a post disinfection wipe of the BSC work surfaces with sterile water after decontamination with diluted bleach. It should be noted that 70% ethanol solutions are not sporicidal and may or may not be effective against fungal or bacterial spores. The reference to the "reduction in mold spores and thereby minimizing contamination of cultures" should be dropped.

- **The text has been revised.**

92. In B.2.3 on Material Placement: Work materials should be manipulated at least four inches away from the air intake grille in order to take optimal advantage of the laminar sterile airflow within the BSC.

- **The text has been revised.**

93. In B.4.3 on Gas Decontamination: The NSF currently recognizes only gaseous formaldehyde as a decontamination agent. NSF is still reviewing efficacy data regarding the use of gaseous hydrogen peroxide.

- **The text has been revised as recommended.**

Related NCCLS Publications*

GP5-A **Clinical Laboratory Waste Management; Approved Guideline (1993)**. This document provides guidance on safe handling and disposal of chemical, infectious, radioactive, and physical waste generated in the clinical laboratory.

GP16-A **Routine Urinalysis and Collection, Transportation, and Preservation of Urine Specimens; Approved Guideline (1995).** This guideline describes routine urinalysis test procedures that address materials and equipment, macroscopic examinations, clinical analyses, and microscopic evaluations.

H3-A4 **Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard — Fourth Edition (1998).** 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-A4 **Procedures for the Collection of Diagnostic Blood Specimens by Skin Puncture; Approved Standard—Fourth Edition (1999).** This standard provides detailed descriptions and explanations of proper collection techniques, as well as hazards to patients from inappropriate specimen collection by skin puncture procedures.

H11-A3 **Procedures for the Collection of Arterial Blood Specimens; Approved Standard—Third Edition (1999).** This standard describes principles for collecting, handling, and transporting arterial blood specimens. The document is aimed at reducing collection hazards and ensuring integrity of the arterial specimen.

H18-A2 **Procedures for the Handling and Processing of Blood Specimens; Approved Guideline—Second Edition; (1999).** This guideline addresses multiple factors associated with handling and processing specimens, as well as factors that can introduce imprecision or systematic bias into results.

H21-A3 **Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays; Approved Guideline—Third Edition (1998).** 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-A3 **Blood Collection on Filter Paper for Neonatal Screening Programs; Approved Standard—Third Edition (1997).** This document provides techniques for specimen collection; specifications for specimen matrix and shipment; and requirements for the specimen collection kit.

NRSCL8-A **Terminology and Definitions For Use in NCCLS Documents; Approved Standard (1998).** This document provides standard definitions for use in NCCLS standards and guidelines, and for submitting candidate reference methods and materials to the National Reference System for the Clinical Laboratory (NRSCL).

* Proposed- and tentative-level documents are being advanced through the NCCLS consensus process; therefore, readers should refer to the most recent editions.

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