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

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

A guideline for national application developed through the Clinical and Laboratory Standards Institute consensus process.

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

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Abstract

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

This guideline contains detailed recommendations for the protection of workers from disease agents transmitted by aerosols, droplets, blood, and body substances; it focuses on hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV), because they pose a risk that is both common and grave. Other blood-borne viruses of concern to laboratory workers include hepatitis D virus (HDV); hepatitis E (HEV); hepatitis G (HGV); other possible parenterally transmitted non-A, non-B hepatitis viruses (NANB); human T cell 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. In addition, safety recommendations are provided for two emerging viruses, SARS-CoV and West Nile virus.

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

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

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

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Foreword

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

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

CLSI believes that a single source of authoritative, current, complete, and practical recommendations which addresses all areas of the healthcare facility laboratory (clinical, anatomical pathology, point-of-care testing, and medical clinics and offices) offers a useful guide to the current best practices for the protection of laboratory workers. This guideline is intended to be a bench document for those workers who are potentially exposed to infectious materials. Source material is included as appendixes so that the reader can easily access the reference material. The references are not comprehensive but include U.S. and other international standards on laboratory safety[1-4] and the most important documents that were used by the working group. Although this document draws heavily from the recommended and mandated guidelines and regulations applicable in the United States, the material contained in this document is useful for improving laboratory safety throughout the world. Changes in regulations and recommendations occur rapidly, and the reader is advised to consult authoritative publications and websites for the most current information.

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

Foreword (Continued)

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

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

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

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

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

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

Acknowledgment

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

Key Words

Aerosols, airborne transmission, biological safety cabinet, blood-borne pathogens, exposure control, infectious disease, instrument biohazards, laboratory workers, medical waste, personal protective equipment (barrier protection), standard precautions, universal precautions

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

1 Scope

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

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

2 Introduction

Clinical laboratory workers are a high-risk group for job-related exposure to blood-borne pathogens including HBV, HCV, and HIV, as are pathologists and other workers who handle tissue and body substances from infected patients. Exposures occur through needlesticks, cuts from sharp instruments, or contact of the eye, nose, mouth, and skin with infected patients' blood, body substances, or other potentially infectious materials. And though most exposures do not result in infection, the risk of healthcare workers acquiring HBV, HCV, or HIV following needlesticks or cuts via percutaneous exposure (the most frequently cited mode of transmission) is estimated to be 6 to 30%, 1.8%, and 0.3%, respectively.[5] Transmission of at least 20 different pathogens by needlestick and sharps injuries has been reported.[6] During the past decade, an estimated 100 to 200 U.S. healthcare personnel have died each year from occupationally acquired HBV infection.[7] From 1978 through December 2002, 57 healthcare workers have acquired HIV through occupational exposure, with 139 additional cases of undocumented, but possible, occupationally acquired HIV infection among healthcare workers in the United States (see Table 1). With the publication of the approved revision of CLSI guideline M29-A3, CLSI has consolidated the available information on the subject for the United States. Worldwide data are not currently available.