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M29-A4

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

Based on US 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 US application developed through the Clinical and Laboratory Standards Institute consensus process.

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Clinical and Laboratory Standards Institute
950 West Valley Road, Suite 2500
Wayne, PA 19087 USA
P: 610.688.0100
F: 610.688.0700
www.clsi.org
standard@clsi.org

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

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Donald R. Callihan, PhD, D(ABMM)
Terry Jo Gile, MT(ASCP), MA Ed
Kathleen G. Beavis, MD
Mary L. Cipriano, MBA, RBP, CBSP
Barry D. Cohen, MPH, CBSP
Mary DeMartino, BS, MT, SM(ASCP)
Gerald A. Denys, PhD, D(ABMM)

Marcia Finucane, MS, CBSP, MT(ASCP)
Larry D. Gray, PhD
William E. Homovec, CBSP, MPH
Steven J. LaCroix, MS, CBSP
Marcia Pindling-Watkins, MS, MT, M(ASCP)
Jonathan Richmond
Elizabeth G. Weirich, MS, SM(NRCM), CBSP

Abstract

Clinical and Laboratory Standards Institute document M29-A4—*Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition* is intended to be a practical tool to aid in the development of an effective biosafety program for laboratory workers. It promotes best laboratory practices to protect workers from exposure to infectious diseases encountered in the clinical laboratory and to minimize the potential transfer of infectious organisms outside of the laboratory. These practices include but are not limited to use of standard precautions, good laboratory practices (eg, disinfection of contaminated work surfaces), safety devices, personal protective equipment, and appropriate decontamination and disposal of biological hazards. It emphasizes that specific policies and procedures, along with appropriate training of personnel on consistent application of laboratory precautions during the performance of work tasks, are essential administrative controls for the prevention of laboratory-acquired infections. Information is provided on safe transport of infectious substances, laboratory equipment hazards, occupational health and incident response, planning for public health emergencies, and best practices for biosafety training and competency assessment. Guidelines for the development of an effective biological risk assessment are also provided.

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Committee Membership

Consensus Committee on Microbiology

**Richard B. Thomson, Jr., PhD,
D(ABMM), FAAM
Chairholder**
Evanston Hospital, North Shore
University Health System
Evanston, Illinois, USA

**John H. Rex, MD, FACP
Vice-Chairholder**
AstraZeneca Pharmaceuticals
Waltham, Massachusetts, USA

Thomas R. Fritsche, MD, PhD
Marshfield Clinic
Marshfield, Wisconsin, USA

Patrick R. Murray, PhD
BD Diagnostic Systems
Sparks, Maryland, USA

Jean B. Patel, PhD, D(ABMM)
Centers for Disease Control and
Prevention
Atlanta, Georgia, USA

Kerry Snow, MS, MT(ASCP)
FDA Center for Drug Evaluation
and Research
Silver Spring, Maryland, USA

John D. Turnidge, MD
SA Pathology at Women's and
Children's Hospital
North Adelaide, Australia

Jeffrey L. Watts, PhD,
RM(NRCM)
Zoetis, Inc.
Kalamazoo, Michigan, USA

Nancy L. Wengenack, PhD,
D(ABMM), FIDSA
Mayo Clinic
Rochester, Minnesota, USA

Barbara L. Zimmer, PhD
Siemens Healthcare Diagnostics
Inc.
West Sacramento, California, USA

Document Development Committee on the Protection of Laboratory Workers

**Donald R. Callihan, PhD, D(ABMM)
Chairholder**
Alliance Biosciences
Elkridge, Maryland, USA

**Terry Jo Gile, MT(ASCP), MA Ed
Vice-Chairholder**
Safety Lady LLC
North Ft. Myers, Florida, USA

Kathleen G. Beavis, MD
College of American Pathologists
Northfield, Illinois, USA

Mary L. Cipriano, MBA, RBP, CBSP
Wilmette, Illinois, USA

Mary DeMartino, BS, MT, SM(ASCP)
William A. Hinton State Laboratory
Institute
Jamaica Plain, Massachusetts, USA

Gerald A. Denys, PhD, D(ABMM)
Indiana University School of Medicine
Indianapolis, Indiana, USA

Larry D. Gray, PhD
Clinical Microbiology Laboratory
Consultants, LLC
Cincinnati, Ohio, USA

William E. Homovec, CBSP, MPH
Laboratory Corporation of America
Burlington, North Carolina, USA

Elizabeth G. Weirich, MS, SM(NRCM),
CBSP
Centers for Disease Control and
Prevention
Atlanta, Georgia, USA

Staff

Clinical and Laboratory Standards
Institute
Wayne, Pennsylvania, USA

Luann Ochs, MS
Senior Vice President – Operations

Tracy A. Dooley, MLT(ASCP)
Staff Liaison

Marcy L. Hackenbrack, MCM,
M(ASCP)
Project Manager

Megan L. Tertel, MA
Editorial Manager

Joanne P. Christopher, MA
Editor

Patrice E. Polgar
Editor

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Barry D. Cohen, MPH, CBSP
Novartis Institutes for BioMedical Research
Cambridge, Massachusetts, USA

Marcia Finucane, MS, CBSP, MT(ASCP)
University of Kentucky Medical Center Hospital
Lexington, Kentucky, USA

Steven J. LaCroix, MS, CBSP
State of Washington Public Health Laboratories
Shoreline, Washington, USA

Marcia Pindling-Watkins, MS, MT, M(ASCP)
Virtua – West Jersey Hospital
Voorhees, New Jersey, USA

Jonathan Richmond
Jonathan Richmond & Associates
Southport, North Carolina, USA

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Representing the Association for Professionals in Infection Control and Epidemiology, Washington, District of Columbia, USA

Dee Pettit, PhD
Michael Anne Preas, RN, BSN, CIC

The American Biological Safety Association, Mundelein, Illinois, USA

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Foreword

Upsurges in global population, together with the free movement of goods and people across national borders, have increased the likelihood for rapid worldwide transmission of infectious agents. This potential for the rapid transmission of novel agents also increases the risk of laboratory workers acquiring infections as a result of their occupational exposure to potentially infectious patient material. 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 all health care workers—including laboratorians.

The risk to these workers increases with the heightened exposure to these potentially infectious materials and is present during all three phases of the laboratory path of workflow. In the preexamination phase, there is an increased risk of percutaneous injury during blood specimen collection through exposure to infectious aerosols or through direct contact with patients or specimens during transport. In the examination phase, specimen and culture manipulations expose the laboratory worker to numerous risks, including laboratory accidents and equipment. Management of biohazardous waste presents the primary risk associated with the postexamination phase.

Laboratory workers, who are routinely exposed to potentially infectious materials, have long been recognized as a high-risk group for occupationally related infections. Experience has demonstrated that implementing practices that decrease the worker's exposure to potentially infectious materials can minimize the risk of infection. These practices include designing facilities appropriately, effective training and consistent application of safe laboratory practices, following standard precautions, using personal protective equipment and safety devices, and the appropriate handling and disposal of biohazardous waste.

Because they pose a risk that is common and grave, diseases transmitted by blood and body substances (primarily hepatitis B virus [HBV], hepatitis C virus [HCV], and HIV) have been the focus of previous editions of M29. Many other infectious agents may be transmitted in blood; however, the consistent use of standard precautions recommended for HBV, HCV, and HIV has proven to be an effective means to protect workers from exposure to any bloodborne pathogen.

A single source of current, authoritative, practical recommendations addressing all laboratory areas (eg, clinical, anatomical pathology, and veterinary diagnostic laboratories; point-of-care testing sites; medical clinics; physician offices), M29 has been developed to provide a useful guide to best practices for the protection of laboratory workers, the local community, and the surrounding environment from exposure. This guideline is intended as a reference document for managers and supervisors of laboratory workers who have the potential for exposure to infectious materials.

The recommendations in this guideline are based on current knowledge and can be used to assist in the establishment of local institutional policy. However, each institution should be aware of and follow the laws and regulations applicable to its location.

Although this document draws heavily from the recommended and mandated guidelines and regulations applicable to the United States, the material contained in this document may be useful for improving laboratory safety throughout the world. Changes in regulations and recommendations occur rapidly, and it is advised that users consult authoritative publications and websites for the most current information. Although M29 may be a useful resource for a wider audience, it is intended primarily to help the US user navigate through US regulations. Because occupational exposure practices are heavily regulated and widely country specific, it has been determined that development of a comparable guideline intended for global application may not be feasible. It is anticipated 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 unique tagline on the cover and the imprint of the US flag on the Abstract page and throughout the document footers call attention to M29's national focus and differentiate it from CLSI's global consensus documents.

Overview of Changes From M29-A3

- The entire document was reorganized and updated with the focus on providing those responsible for providing a safe workplace with best practices for designing, implementing, and continuously improving the biosafety program for a clinical laboratory.
- Information on safe practices for the autopsy suite is no longer within the scope of M29. For reference purposes, the text from the previous edition was moved to Appendix A but was not revised. The most current guidelines for autopsy/necropsy and surgical pathology are contained in *Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories*.¹
- Information on standard laboratory practices that all clinical laboratories should follow when working with materials that could contain infectious agents, including bloodborne pathogens, was consolidated into a single section. Additional precautions to follow when working with agents known or suspected to cause laboratory-acquired infections (LAIs) are provided.
- Discussion of engineering controls and good housekeeping practices applicable to all clinical laboratories was updated.
- The section on shipping biohazardous material was updated to reflect current national and international regulations and has been supplemented with guidance on safe transport between laboratory sections as well as between laboratory facilities within a single institution.
- Current information on safe handling of material that might contain proteinaceous infectious particles was added to the section on medical waste management (see Section 12).
- Information on mitigating risks posed by laboratory equipment that may be exposed to biological agents was added, including recommendations for routine cleaning and decontamination. Best practices for preparing equipment for onsite repair and for return to the manufacturer for repair, refurbishing, or disposal were updated.
- The section on incident response to release, exposure, or injury involving potentially infectious materials was updated. Information on best practices for occupational health programs and their role in preventing and treating LAIs was updated. A new section on preparedness for public health emergencies was added.
- The section on biosafety training was extensively rewritten. Additional information was included on design and implementation of a biosafety training program based on recent guidance from the Centers for Disease Control and Prevention and Association of Public Health Laboratories on biosafety laboratory competencies.

Key Words

Aerosols, airborne transmission, biological risk assessment, biological safety cabinet, biosafety levels, bloodborne pathogens, exposure control, health care workers, infectious disease, instrument biohazards, laboratory biosafety, laboratory biosecurity, laboratory workers, medical waste, personal protective equipment, standard precautions, universal precautions

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

1 Scope

This guideline is intended to describe best laboratory practices for the protection of clinical laboratory workers from exposure to infectious pathogens. M29 was revised to provide guidance for clinical laboratory directors, managers, and supervisors in developing an effective laboratory-specific biosafety program according to the risks associated within the scope of services offered by the laboratory. The focus of this document is to provide guidance for laboratory management on the integration of appropriate biosafety practices within the overall laboratory safety program. The implementation of effective administrative controls as described herein is intended to provide the safest possible laboratory workplace where potentially infectious materials are present.

This guideline directly addresses issues concerning the biological risks present in clinical laboratories, in hospitals, and in other patient care settings. The same risk mitigation and exposure avoidance practices are also appropriate for many other diagnostic laboratory settings such as physician's office laboratories; reference laboratories; or local, regional, or state public health laboratories. Even workers in a clinical veterinary diagnostic laboratory are at risk for exposure to many common and uncommon infectious agents present in their patients' specimens. Although this document does not specifically address medical or animal research laboratories, information may be applicable to research settings in which specimens containing potentially infectious materials are tested.

2 Introduction

Clinical laboratory workers as well as pathologists and other health care workers (HCWs) who handle tissue, body fluids, and other specimens from infected patients are at high risk for work-related exposures to infectious material. The laboratory-associated hazards of working with microorganisms have been well documented by Pike from 1952 to 1979.² Accidental or unrecognized exposure to specimens or cultures of highly transmissible microorganisms, notably *Brucella* species, *Clostridium difficile*, *Coccidioides immitis/posadasii*, *Francisella tularensis*, *Mycobacterium tuberculosis*, *Neisseria meningitidis*, *Salmonella*, *Shigella*, and Shiga toxin-producing *Escherichia coli* has resulted in either life-threatening infection or death of clinical laboratory workers. For some of these organisms, laboratory workers are at greater risk of acquiring such infections than the general population (see Table 1).³ Laboratory-acquired infections (LAIs) may occur through inhalation; ingestion; direct contact of the eye, nose, mouth, or skin; or parenteral inoculation.

Prevention of exposure to bloodborne pathogens such as hepatitis B virus (HBV), hepatitis C virus (HCV), and HIV has been regulated by the Occupational Safety and Health Administration's (OSHA's) Bloodborne Pathogens Standard since the final rule was published in 1991.⁴ CLSI has been on the forefront of providing guidance for laboratory workers since publication of the proposed-level edition of M29 in 1987. Exposure includes accidental needlesticks; cuts from contaminated sharp instruments; and contact of the eye, nose, mouth, and skin with infected patients' blood, body substances, or other potentially infectious materials (OPIM). Although most known exposures do not result in infection, the risk of HCWs acquiring HBV, HCV, or HIV following needlesticks or cuts via percutaneous exposure (the most frequently cited mode of percutaneous 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 In each year from 1985 to 1995 in the United States, an estimated 100 to 200 health care personnel have died from occupationally acquired HBV infection.⁷ From 1978 to 2002, 57 HCWs acquired HIV through occupational exposure, with additional cases documented as probable cases of occupationally acquired HIV infection among HCWs in the United States (see Table 2).