CLINICAL AND LABORATORY STANDARDS INSTITUTE®

June 2012

GP17-A3

Clinical Laboratory Safety; Approved Guideline—Third Edition

This document contains general recommendations for implementing a high-quality laboratory safety program, which are provided in a framework that is adaptable within any laboratory.

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

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For additional information on committee participation or to submit comments, contact CLSI.

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Clinical Laboratory Safety; Approved Guideline—Third Edition

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Abstract

Clinical and Laboratory Standards Institute document GP17-A3—*Clinical Laboratory Safety; Approved Guideline—Third Edition* is written for laboratorians who are responsible for developing and implementing a safety program. Aspects of a safety program addressed in this guideline include maintenance and inspection, personal safety, and warning signs and labels. The guideline also addresses fire prevention, electrical and radiation safety, and other potential laboratory hazards.

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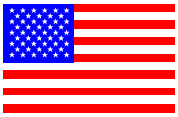

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Foreword

This document constitutes a guide to quality clinical laboratory practices. However, other types of laboratories might find this guideline useful. Based on the cumulative experience of contributors and reviewers, it is expected that the recommendations will result in the best outcomes for laboratory personnel and patients. Within this framework, reference is made to requirements that are mandated by United States (US) federal and state regulations governing laboratory and clinical practices. All laboratories (including those dependent on US federal funds) should adhere to these requirements. These recommendations can also form the basis for standards developed by accreditation organizations for laboratory accreditation. Laboratory personnel outside US jurisdiction should consult, when necessary, their own government or accreditation authorities to determine if the requirements must or should apply.

This document replaces the second edition of the approved guideline, GP17-A2, which was published in 2004. Several changes were made in this edition; chief among them is alignment with CLSI's QMS approach and alignment with new or changed national and accreditation requirements for laboratories since the last version of this guideline. In addition, this version of GP17 is aligned with the United Nations' Globally Harmonized System of Classification and Labelling of Chemicals (GHS). GHS is a system that defines and classifies the hazards of chemical products, and communicates health and safety information on labels and material safety data sheets (called Safety Data Sheets, or SDSs, in GHS). The goal is that the same set of rules for classifying hazards, and the same format and content for labels and SDSs, will be adopted and used around the world. An international team of hazard communication experts developed GHS.[1]

Key Words

Carcinogens, chemical hazards, compressed gases, electrical safety, hazardous waste disposal, laboratory safety, microbiological hazards, radiation safety, warning labels, warning signs

Clinical Laboratory Safety; Approved Guideline—Third Edition

1 Scope

Aspects of a safety program addressed in this guideline include maintenance and inspection, personal safety, and warning signs and labels. In addition, the guideline addresses fire prevention, electrical and radiation safety, and other potential laboratory hazards. Special considerations for anatomic pathology laboratories are also included. This guideline is written for laboratorians who are responsible for developing and implementing a safety program in medical laboratories. However, other types of laboratories will also find this guideline useful.

2 Terminology

2.1 A Note on Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization wherever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. CLSI recognizes that medical conventions in the global metrological community have evolved differently in the United States, Europe, and elsewhere; that these differences are reflected in CLSI, International Organization for Standardization (ISO), and European Committee for Standardization (CEN) documents; and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. In light of this, CLSI's consensus process for development and revision of standards and guidelines focuses on harmonization of terms to facilitate the global application of standards and guidelines.

Additional important note:

Throughout this guideline, the phrase "the laboratory needs to" explains an action directly related to fulfilling requirements of international, national, and accreditation organizations. By taking the actions described in this guideline, the laboratory will fulfill requirements; means by which the requirements are met are left to the discretion of the laboratory unless otherwise specified.

The phrase "the laboratory should" describes a recommendation provided in laboratory literature, a statement of good laboratory practice, or a suggestion for how to meet a requirement.

2.2 Definitions

effluent – outflow or discharge of liquid waste, as from a sewage system, factory, or nuclear plant.

hazard statement – phrase assigned to a hazard class and category that describes the nature of the hazard or hazards.[1]

major spill – spill that spreads rapidly, presents an inhalation hazard, endangers people or the environment, and/or involves personal injury or rescue and should be handled as an emergency by the department of public safety, fire department, or hazmat team.

pictogram – symbol plus other graphic elements intended to convey specific information about the hazards of the chemical[1]; **NOTE:** Each pictogram consists of a different black symbol on a white background within a red diamond border.

 

precautionary statement – phrase that describes recommended measure to be taken to minimize or prevent adverse effects resulting from exposure to a hazardous chemical or improper storage or handling of a hazardous chemical.[1]

signal word – indicates the relative level of severity of hazard and alerts the reader to a potential hazard on the label. The signal words used are "danger" and "warning[1];" **EXAMPLE:** Danger is used for the more severe hazards, while warning is used for less severe hazards.

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

universal precautions – set of precautions designed to reduce risk of transmission of HIV, hepatitis B virus, and other blood-borne pathogens in the health care setting; **NOTE 1:** All human blood; other body fluids containing visible blood; semen; vaginal secretions; tissue; and cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluid are considered potentially infectious under standard precautions; **NOTE 2:** Universal precautions do not apply to feces, nasal secretions, saliva (except in a dental setting), sputum, sweat, tears, urine, and vomitus unless they contain visible blood.

2.3 Abbreviations and Acronyms

AATCC	American Association of Textile Chemists and Colorists
AED	automatic external defibrillator
ALARA	as low as reasonably achievable
ANSI	American National Standards Institute
ASTM	ASTM International (formerly American Society for Testing and Materials)
BSC	biological safety cabinet
BMBL	*Biosafety in Microbiological and Biomedical Laboratories*
BSL	biosafety level
CAP	College of American Pathologists
CAS	Chemical Abstracts Service
CD	cytotoxic drug
CEN	Comité Européen de Normalisation (European Committee for Standardization)
CFH	chemical fume hood
CJD	Creutzfeldt-Jakob disease
CPR	cardiopulmonary resuscitation
dBA	decibels
EPA	US Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HAZWOPER	hazardous waste operations and emergency response
HBV	hepatitis B virus
HCV	hepatitis C virus
HEPA	high efficiency particulate air
HIV	human immunodeficiency virus
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IgE	immunoglobulin E
KI	potassium iodide
LC	lethal concentration
LD	lethal dose
lfm	linear feet per minute
LN	liquid nitrogen
LVMP	laboratory ventilation management program

The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The quality management system approach applies a core set of "quality system essentials" (QSEs), basic to any organization, to all operations in any health care service's path of workflow (ie, operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The QSEs are as follows:

Organization	Personnel	Process Management	Nonconforming Event Management
Customer Focus	Purchasing and Inventory	Documents and Records	Assessments
Facilities and Safety	Equipment	Information Management	Continual Improvement

GP17-A3 addresses the QSE indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Organization	Customer Focus	Facilities and Safety	Personnel	Purchasing and Inventory	Equipment	Process Management	Documents and Records	Information Management	Nonconforming Event Management	Assessments	Continual Improvement
		X GP05 M29	GP21								

Related CLSI Reference Materials*

GP05-A3 **Clinical Laboratory Waste Management; Approved Guideline—Third Edition (2011).** Based on US regulations, this document provides guidance on the safe handling and disposal of chemical, infectious, radioactive, and multihazardous wastes generated in the clinical laboratory. Although this document is a valuable resource for a wider audience, it is intended for use primarily in the United States.

GP21-A3 **Training and Competence Assessment; Approved Guideline—Third Edition (2009).** This document provides background information and recommended processes for the development of training and competence assessment programs that meet quality and regulatory objectives.

M29-A3 **Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Third Edition (2005).** 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.

* CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.

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