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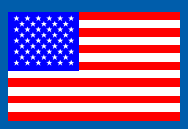
Clinical Laboratory Safety; Approved Guideline—Third Edition

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.



Clinical and Laboratory Standards Institute

Advancing Quality in Health Care Testing

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A document is published as a standard, guideline, or report.

Standard A document developed through the consensus process that clearly identifies specific, essential requirements for materials, methods, or practices for use in an unmodified form. A standard may, in addition, contain discretionary elements, which are clearly identified.

Guideline A document developed through the consensus process describing criteria for a general operating practice, procedure, or material for voluntary use. A guideline may be used as written or modified by the user to fit specific needs.

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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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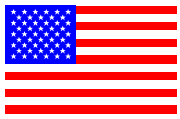

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Contents

Contents (Continued)

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

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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.