CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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# GP36-A

## Planning for Laboratory Operations During a Disaster; Approved Guideline

This document provides guidance for laboratory and health care leadership for development, implementation, and sustainment of effective emergency preparedness plans (all hazards) supporting nonanalytical components of clinical and public health laboratory services that may pertain to various natural and manmade disasters.

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

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

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# Planning for Laboratory Operations During a Disaster; Approved Guideline

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## Abstract

Clinical and Laboratory Standards Institute document GP36-A—*Planning for Laboratory Operations During a Disaster; Approved Guideline* provides guidance for clinical laboratory leadership to develop, implement, and sustain an effective emergency preparedness plan (all hazards) to minimize the effects of, respond to, and recover from likely natural and manmade disasters that may affect laboratory operational functions.

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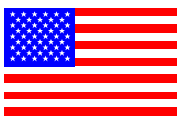

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## Foreword

In 2003, partly in response to the terrorist events that occurred in the United States on September 11, 2001, CLSI published GP46-R, *Planning for Challenges to Clinical Laboratory Operations During a Disaster; A Report*. That document sought to introduce laboratory professionals to considerations used to assess preparedness and begin planning for continuance and redirection of clinical laboratory services during emergency situations.

GP36 was created to provide a more comprehensive document that incorporates disaster planning by process and example. It presents information that will be useful to experienced laboratory leadership and to those for whom preparedness planning is a new endeavor. This document follows a preparedness planning process recommended by business continuity planning professionals,[1] which is intended to take the reader from early phases of preparedness planning through mitigation, preparedness, response, and recovery, while following the quality management approach for policies and procedures (see CLSI document QMS01[2]). The document provides information on policy development through Chapter 5. Chapters 6 through 8 encompass the educational components that lead to the development of emergency processes and procedures (an emergency operations plan [EOP]), while Chapter 9 addresses EOP implementation. The document concludes with a short review of the special issues relating to pandemic influenza.

This document is intended to lead the reader through a logical sequential approach to the emergency planning process. It is not intended to specify what the plan should look like. Plans should be adapted to the individual laboratory. Especially for hospital-based laboratories, a dominant theme should be integration of laboratory aspects of emergency operations with the larger hospital/facility EOPs.

This document also generically or specifically refers to emergency plans that operate at the personal, laboratory, facility, system, community, state, and national levels. Laboratory emergency plans should relate properly to national, state, and/or local regulations or organizational plans that derive from these sources, depending on the topic. Attempts have been made to denote such relationships where deemed appropriate.

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 health care services that address identified needs of both 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.

GP36 is one such consensus document. Although GP36 is a useful resource for a wider audience, it is intended primarily to help the user navigate the US requirements for disaster preparedness. Because relevant practices are widely country specific, the Consensus Committee on Quality Systems and Laboratory Practices determined that it would not be feasible to develop a comparable guideline intended for global application at this time. The consensus committee hopes 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 US flag (below the abstract, and throughout the document footer) and the unique tagline on the cover call attention to its national focus, and differentiate GP36 from our global consensus documents.

### Key Words

Communications, continuity of operation plan, disaster, emergency operations plan, laboratory, pandemic, preparedness, public health, terrorism

# Planning for Laboratory Operations During a Disaster; Approved Guideline

## 1 Scope

This document provides guidance for laboratory leadership and personnel to develop, implement, and sustain effective emergency operations plans (EOPs) that pertain to all hazards (eg, emerging public health threats, natural and manmade disasters, unexpected system failures) and support operations through the entire laboratory path of workflow (preexamination, examination, and postexamination). The discussion of the examination phase focuses on general principles and not on specific diagnostic tests.

General aspects of this document could pertain to hospital laboratories, independent referral laboratories, and public health laboratories (PHLs). Additional emphasis is given on how to interact with governmental Laboratory Response Networks (LRNs). This document should be used as a guideline to develop a local or site-specific EOP.

Laboratory analytical aspects involving biothreat incidents are not addressed. Although certain aspects of the guideline focus on emergency operational challenges confronting hospital-based laboratories, guidance for clinical laboratory preparedness for referral (independent) laboratories is also provided.

## 2 Introduction

International and national events have emphasized a need to expand laboratory, facility, community, state, and national preparedness to include realistic considerations of the types and magnitudes of emergency incidents heretofore thought impossible. This document seeks to recognize and address preparedness and operational challenges that are unique to the clinical laboratory.

There are many inducements for a laboratory to establish a comprehensive disaster recovery plan. Recent audits, new laws and regulations, increased market competitiveness, accreditation requirements, or recent disaster may trigger the onset of the planning process.

Disaster planning and preparedness requires dedicated people, time, and money. Of these three, dedicated people are the most important resource. A great deal of planning and work can be accomplished without expense through peer collaboration and volunteerism. Networking among the participants and potential stakeholders during disaster plan development is strongly encouraged in order to create a robust and flexible plan and to enhance other aspects of routine clinical laboratory practice, such as relationships with local public health personnel.

Additional funding will be needed at most facilities to achieve suitable preparedness. Funding for hospital and laboratory preparedness may be available through national, state, local, or organizational sources. Currently, most federal funding is available to hospitals through contracts or grants administered by state authorizing agencies. The future status of the Metropolitan Medical Response System (MMRS), which has provided funds for emergency medical response enhancements to many cities where weapons of mass destruction (WMD) could pose a threat, is uncertain at the time of publication.[3] Local community businesses and other resources may also be available to help communities prepare for emergency medical response. Laboratories may benefit directly or indirectly from these funding sources.