

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.

ISBN 1-56238-981-5 (Print)
ISBN 1-56238-982-3 (Electronic)
ISSN 1558-6502 (Print)
ISSN 2162-2914 (Electronic)

GP36-A
Vol. 34 No. 19
Replaces GP46-R
Vol. 23 No. 29

Planning for Laboratory Operations During a Disaster; Approved Guideline

Volume 34 Number 19

Thomas L. Williams, MD, FACB, FASCP, FCAP
Gina Potenza, CBCP
Maria Paz Carlos, DVM, PhD, MBA
Raymond L. Kaplan, PhD
Chris N. Mangal, MPH
Elliot L. Rank, PhD, D(ABMM)
Anthony R. Sambol, MA, SV(ASCP), SM(NRM)
Richard S. Seaberg, MT(ASCP)
Andrew N. Young, MD, PhD

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.

Clinical and Laboratory Standards Institute (CLSI). *Planning for Laboratory Operations During a Disaster; Approved Guideline*. CLSI document GP36-A (ISBN 1-56238-981-5 [Print]; ISBN 1-56238-982-3 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2014.

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Suggested Citation

CLSI. *Planning for Laboratory Operations During a Disaster; Approved Guideline*. CLSI document GP36-A. Wayne, PA: Clinical and Laboratory Standards Institute; 2014.

Previous Edition:

October 2003

Reaffirmed:

September 2019

ISBN 1-56238-981-5 (Print)
ISBN 1-56238-982-3 (Electronic)
ISSN 1558-6502 (Print)
ISSN 2162-2914 (Electronic)

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SAMPLE

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 QMS01²). 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.

3 Terminology

3.1 A Note on Terminology

Terms used in this document are largely nonscientific, ordinary descriptors, favoring US readership. An effort has been made to ensure that terms and identifiers referring to public, accreditation, or professional organizations, or their technical documents and terminology, are current.

3.2 Definitions

all hazards planning – detailed guidelines worked out in advance for addressing emergency situations; **NOTE:** All hazards planning, as used by emergency planners, promotes developing one general emergency operations plan intended to cover many different types of incidents. It relies on the core concept that many planned response actions are the same, irrespective of the type of disaster inciting them.

alternate care facility (ACF) – nonhospital facility that assumes the function of outpatient, urgent, or inpatient care during an emergency to promote expansion of community bed capacity and care.

amateur radio – international hobby composed of volunteer operators, licensed (in the United States) under the Amateur Radio Service; **NOTE 1:** Amateur Radio Service is a communications service as defined by the Federal Communications Commission; **NOTE 2:** Also known as “ham radio”; **NOTE 3:** US and Canadian amateur operators often assist in emergencies, are usually organized through local clubs and organizations, and are often affiliated with the Amateur Radio Emergency Service.⁴

asset – any resource both available and useful during disaster response.

badge – familiar, externally visible identification device; **NOTE:** Badges may also be generated by emergency agencies during an incident, and may bear expiration dates and specific access restrictions.

biological safety level//biosafety level (BSL) – combinations of laboratory practices and techniques, safety equipment, and laboratory facilities. Each combination is specifically appropriate for the performed operations, the documented or suspected routes of transmission of the infectious agents, and the laboratory function or activity.⁴

biosafety level 2 (BSL-2) – practices, safety equipment, and facility design and construction that are applicable to clinical, diagnostic, teaching, and other laboratories in which work is done with the broad spectrum of indigenous moderate-risk agents that are present in the community and associated with human disease of varying severity.⁵

biosafety level 3 (BSL-3) – practices, safety equipment, and facility design and construction that are applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents with a potential for respiratory transmission, and which may cause serious and potentially lethal infection.⁵

biosafety level 4 (BSL-4) – practices, safety equipment, and facility design and construction that are required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening diseases that are frequently fatal and for which there are no vaccines or treatments or a related agent with unknown risk of transmission.⁵

capability – ability to deliver an intended outcome of an exercise with any combination of properly planned, organized, equipped, trained, and exercised personnel through the execution of plan documents.

The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system (QMS) 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 QMS 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

GP36-A 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
POCT07	POCT07	X GP05 GP17 M29	POCT07	POCT07	POCT07	POCT07	POCT07	POCT07	POCT07	POCT07	POCT07
QMS01	QMS01	QMS01	QMS01	POCT09 QMS01	POCT09 QMS01	POCT08 POCT09 QMS01	QMS01 QMS02	QMS01	QMS01	POCT09 QMS01	QMS01

Path of Workflow

A path of workflow is the description of the necessary processes to deliver the particular product or service that the organization or entity provides. A laboratory path of workflow consists of the sequential processes: preexamination, examination, and postexamination and their respective sequential subprocesses. All laboratories follow these processes to deliver the laboratory’s services, namely quality laboratory information.

GP36-A does not address any of the clinical laboratory path of workflow steps. For a description of the document listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Preexamination				Examination			Postexamination	
Examination ordering	Sample collection	Sample transport	Sample receipt/processing	Examination	Results review and follow-up	Interpretation	Results reporting and archiving	Sample management
QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01

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.
- GP17-A3** **Clinical Laboratory Safety; Approved Guideline—Third Edition (2012).** 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.
- M29-A4** **Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline—Fourth Edition (2014).** 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.
- POCT07-A** **Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline (2010).** This document presents the core infrastructure for a standardized error tracking system with the primary goals of reducing risk and increasing quality of point-of-care testing, while accumulating standardized data for benchmarking use.
- POCT08-A** **Quality Practices in Noninstrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers; Approved Guideline (2010).** This instructional guideline delivers laboratory science concepts and activities with the goal of increasing knowledge and quality of laboratory testing for testing personnel with no laboratory background.
- POCT09-A** **Selection Criteria for Point-of-Care Testing Devices; Approved Guideline (2010).** This document provides guidance on selection of point-of-care testing devices based on the patient care setting and clinical needs. It is designed as an aid to laboratory and facility management to simplify and facilitate the selection process but also allows evaluation of devices to identify those that are optimal to the patient care setting and population served.
- QMS01-A4** **Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition (2011).** This document provides a model for medical laboratories that will assist with implementation and maintenance of an effective quality management system.
- QMS02-A6** **Quality Management System: Development and Management of Laboratory Documents; Approved Guideline—Sixth Edition (2013).** This document provides guidance on the processes needed for document management, including creating, controlling, changing, and retiring a laboratory's policy, process, procedure, and form documents in both paper and electronic environments.

* 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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950 West Valley Road, Suite 2500, Wayne, PA 19087 USA

P: 610.688.0100 Toll Free (US): 877.447.1888 F: 610.688.0700

E: customerservice@clsi.org www.clsi.org

PRINT ISBN 1-56238-981-5

ELECTRONIC ISBN 1-56238-982-3