

# GP47

## Management of Critical- and Significant-Risk Results

This guideline provides current best practice recommendations for developing and implementing a policy and procedures for the identification, reporting, and management of critical- and significant-risk laboratory results. Emphasis is placed on management responsibilities such as development of the policy, the process, procedures, job descriptions, and monitoring systems that ensure effective reporting and compliance with regulatory requirements.

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

## Management of Critical- and Significant-Risk Results

Andrew N. Young, MD, PhD  
Anand Dighe, MD, PhD  
Graham Beastall, PhD, FRCPath  
Lydia C. Contis, MD  
Pilar Fernandez-Calle, MD, PhD  
Christine M. Gryko, MT(ASCP)  
Peter Heseltine, MD, FACP, FACB, FIDSA  
Andrea Rita Horvath, MD, PhD

Devery Howerton, PhD, MS, MT(ASCP)SI  
Neal Kachalia, MT(ASCP), DLM, MBA  
Michael J. Misialek, MD  
Raouf E. Nakhleh, MD  
Jennifer F. Rhamy, MBA, MA, MT(ASCP), SBB, HP  
Susan Shuptar, BS, MT(ASCP)  
Graham H. White, PhD, MAACB, FNACB, FFSc(RCPA)

### Abstract

Clinical and Laboratory Standards Institute document GP47—*Management of Critical- and Significant-Risk Results* describes systems for effective communication of laboratory results that need urgent clinical review. These laboratory results signify risk of major adverse patient outcomes. Therefore, mechanisms for their rapid identification and timely reporting are essential for patient safety. This guideline emphasizes management responsibilities for the development of the policy, the process, procedures, job descriptions, and monitoring systems that promote effective, timely reporting and compliance with regulatory requirements.

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# Contents

Abstract .....	i
Committee Membership .....	iii
Foreword .....	vii
<b>Chapter 1: Introduction .....</b>	<b>1</b>
1.1 Scope .....	2
1.2 Background .....	2
1.3 Terminology .....	3
<b>Chapter 2: Development of an Organizational Process for Managing Critical- and Significant-Risk Laboratory Results .....</b>	<b>9</b>
2.1 Developing Critical- and Significant-Risk Alert Lists and Thresholds .....	11
2.2 The Critical- and Significant-Risk Reporting Process .....	22
2.3 Critical- and Significant-Risk Process Is Implemented .....	33
2.4 Critical- and Significant-Risk Result Process Is Monitored .....	39
<b>Chapter 3: Quality System Essentials for Managing Critical- and Significant-Risk Laboratory Results .....</b>	<b>43</b>
3.1 Organization .....	44
3.2 Customer Focus .....	44
3.3 Personnel .....	45
3.4 Purchasing and Inventory .....	45
3.5 Equipment .....	45
3.6 Process Management .....	49
3.7 Documents and Records .....	49
3.8 Information Management .....	50
3.9 Nonconforming Event Management .....	51
3.10 Assessments .....	52
3.11 Continual Improvement .....	52
<b>Chapter 4: Conclusion .....</b>	<b>53</b>
<b>Chapter 5: Supplemental Information .....</b>	<b>55</b>
<b>References</b> .....	56
<b>Appendix A.</b> Different Terms Used for Critical- and Significant-Risk Laboratory Results .....	60
<b>Appendix B.</b> US Benchmark Data From the College of American Pathologists .....	61
<b>Appendix C.</b> Sample Documents Related to the Reporting of Critical- and Significant-Risk Results .....	65

## Contents (Continued)

<b>Appendix D.</b> Regulatory and Accreditation Requirements .....	68
<b>Appendix E.</b> Critical- and Significant-Risk Results in Infectious Disease, Hematology/Oncology, and Transplantation Medicine .....	74
<b>Appendix F.</b> Critical- and Significant-Risk Results in Transfusion Medicine .....	75
<b>Appendix G.</b> Critical- and Significant-Risk Results in Anatomic Pathology.....	76
<b>Appendix H.</b> Sample Escalation Protocol Process .....	80
<b>Appendix I.</b> Example of a Tool for Quality Monitoring of the Management of Critical- and Significant-Risk Results .....	82
<b>The Quality Management System Approach</b> .....	84
<b>Related CLSI Reference Materials</b> .....	86

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## Foreword

The timely reporting of results that need urgent clinical review is a fundamental responsibility of medical laboratories. This practice is essential for patient safety and is mandated by regulatory and accreditation requirements for laboratories and health care organizations. Laboratory and anatomic pathology results need urgent clinical review when they represent a high risk to patient health and safety. When the results indicate risk of immediately life-threatening conditions, they need to be communicated without delay to a responsible caregiver for urgent patient evaluation and management. GP47 recommends this result category be called “critical-risk” results. In addition, the concept of patient risk can be applied to a broader range of results that may not be immediately life-threatening, but still represent a risk to patients unless they are clinically evaluated and managed within a specific time frame sooner than would occur through routine reporting. GP47 recommends that this result category be called “significant-risk” results.

Due to the high risk to patient safety and the need for timely communication, the reporting of critical- and significant-risk results typically involves special procedures characterized by:

- ▶ Direct, person-to-person communication
- ▶ Verification of accurate receipt of information
- ▶ Occurrence within clinically appropriate time frames
- ▶ Documentation in the patient record

Many regulatory and accreditation organizations require processes for reporting results that need urgent clinical review as well as monitoring systems and quality goals to ensure reporting is timely and effective. Compliance with these regulatory and accreditation requirements is often a focal point during inspections of laboratories and health care organizations.

This guideline defines key processes in the reporting of critical- and significant-risk laboratory results. It recommends processes and procedures that are compliant with regulatory and accreditation requirements and consistent with patient safety best practices.

**NOTE:** The findings and conclusions in this document are those of the authors and do not necessarily reflect the views of the organizations they represent.

### KEY WORDS

Alert lists

Alert thresholds

Communication

Critical-risk results

Critical values

Patient safety

Quality management

Risk management

Significant-risk results

# Chapter 1

## Introduction

This chapter includes:

- ▶ Document scope and applicable exclusions
- ▶ Background information pertinent to the document content
- ▶ “Note on Terminology” that highlights particular use and/or variation in use of terms and/or definitions
- ▶ Terms and definitions used in the document
- ▶ Abbreviations and acronyms used in the document



# Management of Critical- and Significant-Risk Results

## 1 Introduction

### 1.1 Scope

This guideline is intended for laboratory directors, managers, and personnel who develop and implement policies and processes for reporting laboratory results that need urgent clinical review. This guideline is also intended for health care administrators who oversee compliance with regulatory and accreditation requirements and clinical practice standards related to patient safety. This information is aligned with standards existing at the time of publication. This guideline is appropriate for all health care environments that conduct laboratory examinations for patient care. Materials are appropriate for laboratories associated with hospitals, clinics, or physician offices as well as independent referral laboratories. The recommendations cover every laboratory discipline and pertain to medical laboratories of every size, scope, and complexity, including point-of-care testing sites.

The process for reporting critical- and significant-risk results is emphasized. The document also describes evidence-based quality metrics and methods to monitor the effectiveness of the reporting process. Common organizational challenges to reporting these laboratory results, and new approaches that apply informatics to make the process more effective and efficient are discussed. The appendixes include a sample policy, sample forms, specific information for specialty laboratories, and a sample flow chart for an escalation process. A summary of commonly reported critical- and significant-risk results, which are compliant with regulatory and accreditation requirements, is provided for organizations to consider for use. Because no single approach applies to every health care environment, organizations are encouraged to modify their policy and processes to reflect the clinical needs of their patient populations.

This guideline does not cover the reporting of results from other diagnostic services such as radiology or cardiology. However, the general recommendations may be relevant to these services. In addition, this document does not focus in depth on the reporting of routine laboratory results; however, organizations should recognize that a breakdown in the receipt and follow-up of all result categories may also be a source of patient harm and medicolegal actions.

### 1.2 Background

Reporting laboratory results needing urgent clinical review was originally highlighted by Lundberg, who defined a critical laboratory result as one suggesting imminent danger to a patient unless appropriate action was promptly initiated.<sup>1</sup> Since this initial description, hospitals and laboratories

# 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 using 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

GP47 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 page 86.

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					
						EP18			EP18	EP18	EP18
						EP23					
QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01
							QMS02				
											QMS06
									QMS11		
					QMS13						
										QMS15	
						QMS18					

## Related CLSI Reference Materials\*

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- EP18**     **Risk Management Techniques to Identify and Control Laboratory Error Sources. 2nd ed., 2009.** This guideline describes risk management techniques that will aid in identifying, understanding, and managing sources of failure (potential failure modes) and help to ensure correct results. Although intended primarily for *in vitro* diagnostics, this document will also serve as a reference for clinical laboratory managers and supervisors who wish to learn about risk management techniques and processes.
- EP23™**     **Laboratory Quality Control Based on Risk Management. 1st ed., 2011.** This document provides guidance based on risk management for laboratories to develop quality control plans tailored to the particular combination of measuring system, laboratory setting, and clinical application of the test.
- QMS01**     **Quality Management System: A Model for Laboratory Services. 4th ed., 2011.** This document provides a model for medical laboratories that will assist with implementation and maintenance of an effective quality management system.
- QMS02**     **Quality Management System: Development and Management of Laboratory Documents. 6th ed., 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.
- QMS06**     **Quality Management System: Continual Improvement. 3rd ed., 2011.** This guideline considers continual improvement as an ongoing, systematic effort that is an essential component of a quality management system. A continual improvement program may consist of fundamental processes and common supporting elements described in this guideline.
- QMS11**     **Management of Nonconforming Laboratory Events. 2nd ed., 2015.** Grounded in the principles of quality management, risk management, and patient safety, this guideline provides an outline and the content for developing a program to manage a laboratory's nonconforming events.
- QMS13**     **Quality Management System: Equipment. 1st ed., 2011.** This guideline provides recommendations for establishing equipment management processes from selection through decommission of equipment used in the provision of laboratory services.

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

## Related CLSI Reference Materials (Continued)

- QMS15**    **Assessments: Laboratory Internal Audit Program. 1st ed., 2013.** This document provides guidance for how a laboratory can establish an internal audit program to enhance the quality of its services through continual improvement. Whereas an audit program defines the “who,” “what,” “when,” “where,” and “how” of meeting requirements for internal auditing, the audit process describes the details of how to conduct individual laboratory internal audits.
- QMS18**    **Process Management. 1st ed., 2015.** This guideline describes four requirements for managing laboratory processes and provides suggestions for effectively meeting regulatory and accreditation requirements, optimizing efficient use of resources, and contributing to patient safety and positive outcomes.

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E: [customerservice@clsi.org](mailto:customerservice@clsi.org) [www.clsi.org](http://www.clsi.org)

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