

# QMS11

## Nonconforming Event Management

Grounded in the principles of quality management, risk management, and patient safety, this guideline provides an outline and content for developing a program to manage a laboratory's nonconforming events.

.....

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

# Clinical and Laboratory Standards Institute

*Setting the standard for quality in medical laboratory testing around the world.*

The Clinical and Laboratory Standards Institute (CLSI) is a not-for-profit membership organization that brings together the varied perspectives and expertise of the worldwide laboratory community for the advancement of a common cause: to foster excellence in laboratory medicine by developing and implementing medical laboratory standards and guidelines that help laboratories fulfill their responsibilities with efficiency, effectiveness, and global applicability.

## **Consensus Process**

Consensus—the substantial agreement by materially affected, competent, and interested parties—is core to the development of all CLSI documents. It does not always connote unanimous agreement, but does mean that the participants in the development of a consensus document have considered and resolved all relevant objections and accept the resulting agreement.

## **Commenting on Documents**

CLSI documents undergo periodic evaluation and modification to keep pace with advancements in technologies, procedures, methods, and protocols affecting the laboratory or health care.

CLSI's consensus process depends on experts who volunteer to serve as contributing authors and/or as participants in the reviewing and commenting process. At the end of each comment period, the committee that developed the document is obligated to review all comments, respond in writing to all substantive comments, and revise the draft document as appropriate.

Comments on published CLSI documents are equally essential, and may be submitted by anyone, at any time, on any document. All comments are managed according to the consensus process by a committee of experts.

## **Appeals Process**

When it is believed that an objection has not been adequately considered and responded to, the process for appeals, documented in the CLSI Standards Development Policies and Processes, is followed.

All comments and responses submitted on draft and published documents are retained on file at CLSI and are available upon request.

## **Get Involved—Volunteer!**

Do you use CLSI documents in your workplace? Do you see room for improvement? Would you like to get involved in the revision process? Or maybe you see a need to develop a new document for an emerging technology? CLSI wants to hear from you. We are always looking for volunteers. By donating your time and talents to improve the standards that affect your own work, you will play an active role in improving public health across the globe.

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

Clinical and Laboratory Standards Institute  
950 West Valley Road, Suite 2500  
Wayne, PA 19087 USA  
P: +1.610.688.0100  
F: +1.610.688.0700  
[www.clsi.org](http://www.clsi.org)  
[standard@clsi.org](mailto:standard@clsi.org)

---

## Nonconforming Event Management

Anne T. Daley, MS, CMQOE(ASQ), CSSBB, CLC(AMT),  
MT(ASCP)DLM  
Laura McClannan, MS, MT(ASCP)SBB  
Kathryn Connolly, CQA (ASQ), MT(ASCP)  
Christine M. Gryko, MT(ASCP)  
Nichole Korpi-Steiner, PhD, DABCC, FACB  
Betty Lim

Coleen McAloney, RT, BGS  
Jennifer Nosbisch  
Renee Rosa, BSMT H(ASCP)  
Andreas Rothstein, MS  
Joe C. Rutledge, MD  
Ann F. Stankiewicz, PhD  
Kimberly Zohner, MT(ASCP)

### Abstract

---

Clinical and Laboratory Standards Institute document QMS11—*Nonconforming Event Management* provides a suggested outline and content for a program to manage a laboratory's nonconforming events. Such a program is a fundamental component of a QMS and patient safety.

Clinical and Laboratory Standards Institute (CLSI). *Nonconforming Event Management*. 2nd ed. CLSI guideline QMS11 (ISBN 1-56238-909-2 [Print]; ISBN 1-56238-910-6 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2015.

The Clinical and Laboratory Standards Institute consensus process, which is the mechanism for moving a document through two or more levels of review by the health care community, is an ongoing process. Users should expect revised editions of any given document. Because rapid changes in technology may affect the procedures, methods, and protocols in a standard or guideline, users should replace outdated editions with the current editions of CLSI documents. Current editions are listed in the CLSI catalog and posted on our website at [www.clsi.org](http://www.clsi.org).

**If you or your organization is not a member and would like to become one, and to request a copy of the catalog, contact us at:**

**P:** 610.688.0100 **F:** 610.688.0700 **E:** [customerservice@clsi.org](mailto:customerservice@clsi.org) **W:** [www.clsi.org](http://www.clsi.org)

Copyright ©2015 Clinical and Laboratory Standards Institute. Except as stated below, any reproduction of content from a CLSI copyrighted standard, guideline, companion product, or other material requires express written consent from CLSI. All rights reserved. Interested parties may send permission requests to [permissions@clsi.org](mailto:permissions@clsi.org).

CLSI hereby grants permission to each individual member or purchaser to make a single reproduction of this publication for use in its laboratory procedure manual at a single site. To request permission to use this publication in any other manner, e-mail [permissions@clsi.org](mailto:permissions@clsi.org).

## Suggested Citation

CLSI. *Nonconforming Event Management*. 2nd ed. CLSI guideline QMS11. Wayne, PA: Clinical and Laboratory Standards Institute; 2015.

### Previous Edition:

November 2007

### Reaffirmed:

September 2019

ISBN 1-56238-909-2 (Print)

ISBN 1-56238-910-6 (Electronic)

ISSN 1558-6502 (Print)

ISSN 2162-2914 (Electronic)

Volume 35, Number 13

.....

## Committee Membership

### Consensus Committee on Quality Management Systems and General Practices

**Tania Motschman, MS, MT(ASCP)SBB,  
CQA(ASQ)  
Chairholder  
Laboratory Corporation of America  
USA**

**Anne T. Daley, MS, CMQOE(ASQ),  
CSSBB, CLC(AMT), MT(ASCP)DLM  
Vice-Chairholder  
Chi Solutions, Inc.  
USA**

Deirdre Astin, MS, MT(ASCP)  
New York State Department of Health  
USA

Michael B. Cohen, MD  
ARUP Laboratories  
USA

Dennis J. Ernst, MT(ASCP)  
Center for Phlebotomy Education  
USA

Karen Heaton, MLT(CMLTA)  
Alberta Health Services  
Canada

Debra Kuehl, MS, M(ASCP)  
Centers for Disease Control and  
Prevention  
USA

Michelle Jenkins, MS, MT(AMT),  
CQE(ASQ), CMQ/OE  
Abbott  
USA

Michelle McLean, MS, MT(ASCP)  
Greiner Bio-One Inc.  
USA

Melissa Singer, MT(ASCP)  
Centers for Medicare & Medicaid  
Services  
USA

Janette Wassung  
PathCare Pathology Laboratory  
South Africa

Ginger Wooster, MBA, MT(ASCP)  
Orchard Software Corp  
USA

### Working Group on Nonconforming Event Management

**Anne T. Daley, MS, CMQOE(ASQ),  
CSSBB, CLC(AMT), MT(ASCP)DLM  
Chairholder  
Chi Solutions, Inc.  
USA**

**Laura McClannan, MS, MT(ASCP)SBB  
Vice-Chairholder  
Laboratory Corporation of America  
USA**

**Christine M. Gryko, MT(ASCP)  
Committee Secretary  
Roswell Park Cancer Institute  
USA**

Kathryn Connolly, CQA (ASQ),  
MT(ASCP)  
COLA  
USA

Betty Lim  
Spectra Laboratories  
USA

Coleen McAloney, RT, BGS  
PHSA Laboratories/BC Centre for  
Disease Control  
Canada

Joe C. Rutledge, MD  
College of American Pathologists  
USA

Ann F. Stankiewicz, PhD  
Roche Diagnostics  
USA

Kimberly Zohner, MT(ASCP)  
Barnes-Jewish Hospital  
USA

#### Staff

Clinical and Laboratory Standards  
Institute  
USA

Luann Ochs, MS  
*Senior Vice President – Operations*

Jennifer K. Adams, MT(ASCP), MSHA  
*Project Manager*

Megan L. Tertel, MA, ELS  
*Editorial Manager*

Joanne P. Christopher, MA  
*Editor*

Alexander B. Phucas  
*Editor*

## Acknowledgment

---

CLSI, the Consensus Committee on Quality Management Systems and General Practices, and the Working Group on Nonconforming Event Management gratefully acknowledge the following volunteers for their important contributions to the development of this document:

Nichole Korpi-Steiner, PhD, DABCC, FACB  
University of North Carolina  
USA

Renee Rosa, BSMT H(ASCP)  
BD  
USA

Jennifer Nosbisch  
Mayo Clinic  
USA

Andreas Rothstein, MS  
Colombia

# 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: Nonconforming Event Management</b>	<b>9</b>
2.1 Nonconforming Event Management Program Overview	12
2.2 Individual Nonconforming Event Process	17
2.3 Collective Nonconforming Event Data Assessment Process	37
2.4 Management Review Process	45
2.5 Continual Improvement Process	49
<b>Chapter 3: Path of Workflow and Quality System Essentials</b>	<b>53</b>
3.1 Path of Workflow	54
3.2 Quality System Essentials	56
3.3 Path of Workflow and Quality System Essentials Summary	59
<b>Chapter 4: Conclusion</b>	<b>61</b>
<b>Chapter 5: Supplemental Information</b>	<b>63</b>
<b>References</b>	64
<b>Appendix A1. Data Collection Tools</b>	67
<b>Appendix A2. Investigation and Data Reporting Tools</b>	68
<b>Appendix B. Potential Components of an Internal Nonconforming Event Report</b>	72
<b>Appendix C1. Nonconforming Event Report Form (Example 1)</b>	73
<b>Appendix C2. Nonconforming Event Report Form (Example 2)</b>	74
<b>Appendix C3. Nonconforming Event Report Form (Example 3)</b>	76
<b>Appendix C4. Nonconforming Event Report Form (Example 4)</b>	78
<b>Appendix D. Risk Classification Example</b>	81
<b>Appendix E. Information to Consider When Conducting Root Cause Analysis</b>	84
<b>Appendix F1. Root Cause Analysis Process (Example 1)</b>	85
<b>Appendix F2. Root Cause Analysis Process (Example 2)</b>	86

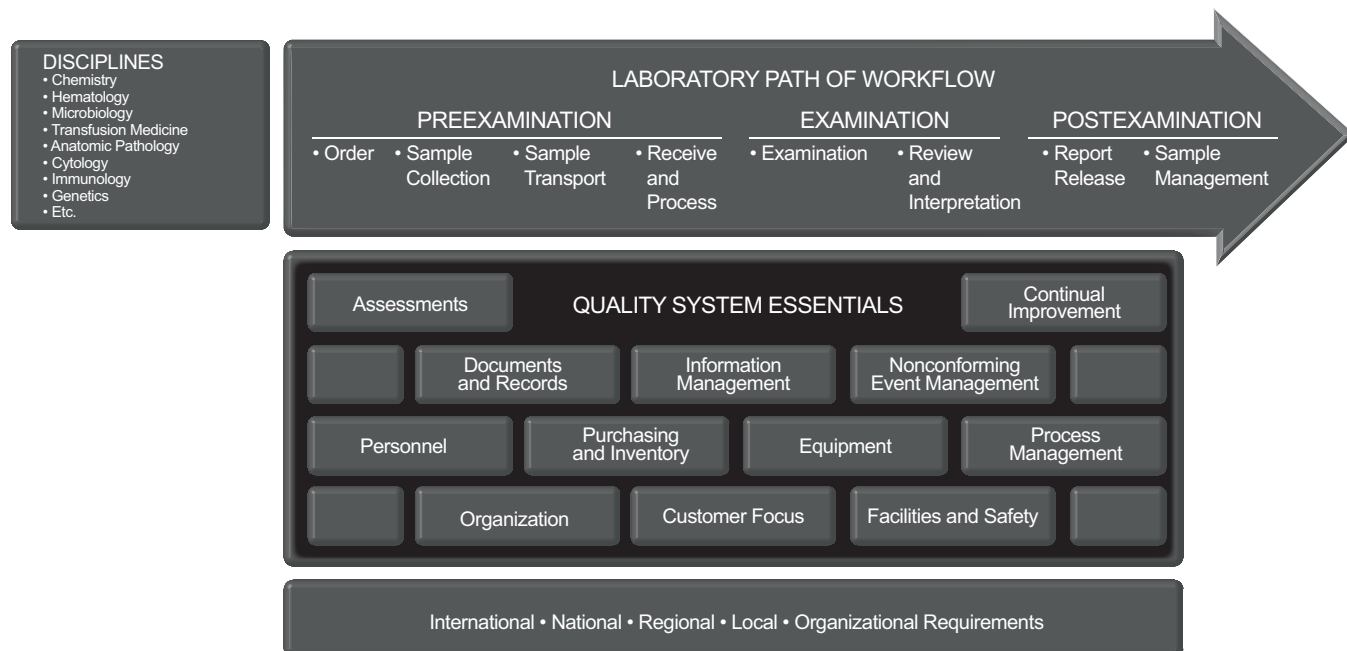
## Contents (Continued)

---

<b>Appendix G1.</b> Nonconforming Event Case Study Example – The Process .....	87
<b>Appendix G2.</b> Nonconforming Event Case Study Example – The Report .....	88
<b>Appendix G3.</b> Nonconforming Event Case Study Example – The Process Map .....	90
<b>Appendix G4.</b> Nonconforming Event Case Study Example – The Cause and Effect Diagram and 5 Whys Analysis .....	91
<b>Appendix H.</b> Nonconforming Event Log .....	92
<b>Appendix I.</b> Application of Data Analysis: A Laboratory Example .....	93
<b>Appendix J.</b> Management Review Agenda Template .....	102
<b>Appendix K1.</b> Quality Report Example .....	103
<b>Appendix K2.</b> Quality Report by Quality System Essential .....	108
<b>The Quality Management System Approach</b> .....	112
<b>Related CLSI Reference Materials</b> .....	114

## Foreword

Quality system essential (QSE) Nonconforming Event (NCE) Management is one of the 12 QSEs described in CLSI document QMS01,<sup>1</sup> which provides the necessary background information and guidance to develop and maintain a QMS. The QMS model depicted in Figure 1 demonstrates how each QSE, such as NCE Management, is a building block to quality and is necessary to support any laboratory's path of workflow from preexamination to examination to postexamination.



**Figure 1. The Quality Management System Model for Laboratory Services (see CLSI document QMS01<sup>1</sup>)**

QSEs are the foundational building blocks that function effectively to support the laboratory's path of workflow. If a QSE is missing or not well implemented, problems will occur in preexamination, examination, and postexamination laboratory activities. For example, when the laboratory lacks defined processes for properly installing, calibrating, and maintaining its analyzers so that they are working effectively, there will be problems in examination processes.

International guidance related to the QSEs and the laboratory's path of workflow is described in selected International Organization for Standardization (ISO) standards. ISO 9001<sup>2</sup> defines a process-based model for quality that any business should use to manage its operations—the information relates directly to the QSEs. ISO 17025<sup>3</sup> specifies requirements for both quality management and technical operations of testing and calibration laboratories. ISO 15189<sup>4</sup> defines standards for quality management and technical operations in the medical laboratory environment.

## Overview of Changes

This document replaces the previous edition of the guideline, QMS11-A (GP32-A in previous coding system), published in 2007. Several changes were made in this edition, including:

- ▶ Expansion of the connected processes that define the primary activities of an NCE program
- ▶ Alignment with new or changed international, national, and accreditation requirements for laboratories since the last edition of this guideline
- ▶ Additional examples of documents and forms that can be used or modified as needed for implementing an NCE program
- ▶ Addition of an example NCE investigation
- ▶ Information related to handling externally generated communications (ie, alerts and recalls) as NCEs

### KEY WORDS

**Adverse events**

**Errors**

**Incident reporting**

**Nonconformances**

**Nonconforming event**

**Nonconformities**

**Patient safety**

**Root cause**

**Root cause analysis**

# 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



# Nonconforming Event Management

## IMPORTANT NOTE:

This guideline is intended to **supplement, but not replace**, an organization's established risk management or patient safety program.

## NOTE:

An NCE management program is based on principles of quality management, risk management, and patient safety.

## NOTE:

Removal of root causes of NCEs leads to improved quality, which leads to improved patient safety.

## 1 Introduction

### 1.1 Scope

This guideline is intended for use by individuals in a laboratory to facilitate establishment and maintenance of an internal nonconforming event (NCE) management program that includes:

- ▶ Responding to an event that does not conform to the laboratory's established policies, processes, and/or procedures
- ▶ Responding to an event that does not follow established QMS policies, processes, and/or procedures
- ▶ Monitoring events through the data assessment, management review, and continual improvement (CI) connected processes

This guideline is intended to **supplement, but not replace**, an organization's established risk management or patient safety program.

The guidance provided herein is perhaps best used within a medical laboratory; however, other types of laboratories may also find value in the concepts presented.

### 1.2 Background

An NCE management program is based on principles of quality management, risk management, and patient safety. The purpose of a program to manage NCEs is to identify and characterize problem-prone processes in a laboratory's path of workflow and within the supporting processes of the QMS so CI initiatives can be prioritized, resources allocated, and improvements implemented.

An NCE management program identifies systematic problems and gains management's commitment to removing the causes. As the words suggest, NCEs do not conform with the organization's established policies, processes, or procedures, or to applicable regulatory or accreditation requirements. NCEs also have the potential to affect patient safety or the efficiency and effectiveness of work operations.

NCE management is linked to the laboratory's and health care organization's risk management program because it provides information on systemic service problems that could pose legal or financial risk issues for the organization.

NCE management is also linked to quality management. Removal of root causes of NCEs leads to improved quality, which leads to improved patient safety.