CLINICAL AND LABORATORY STANDARDS INSTITUTE®

2nd Edition

QMS11

Nonconforming Event Management

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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.

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Nonconforming Event Management

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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.

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Foreword

Quality system essential (QSE) Nonconforming Event (NCE) Management is one of the 12 QSEs described in CLSI document QMS01,[1] 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.

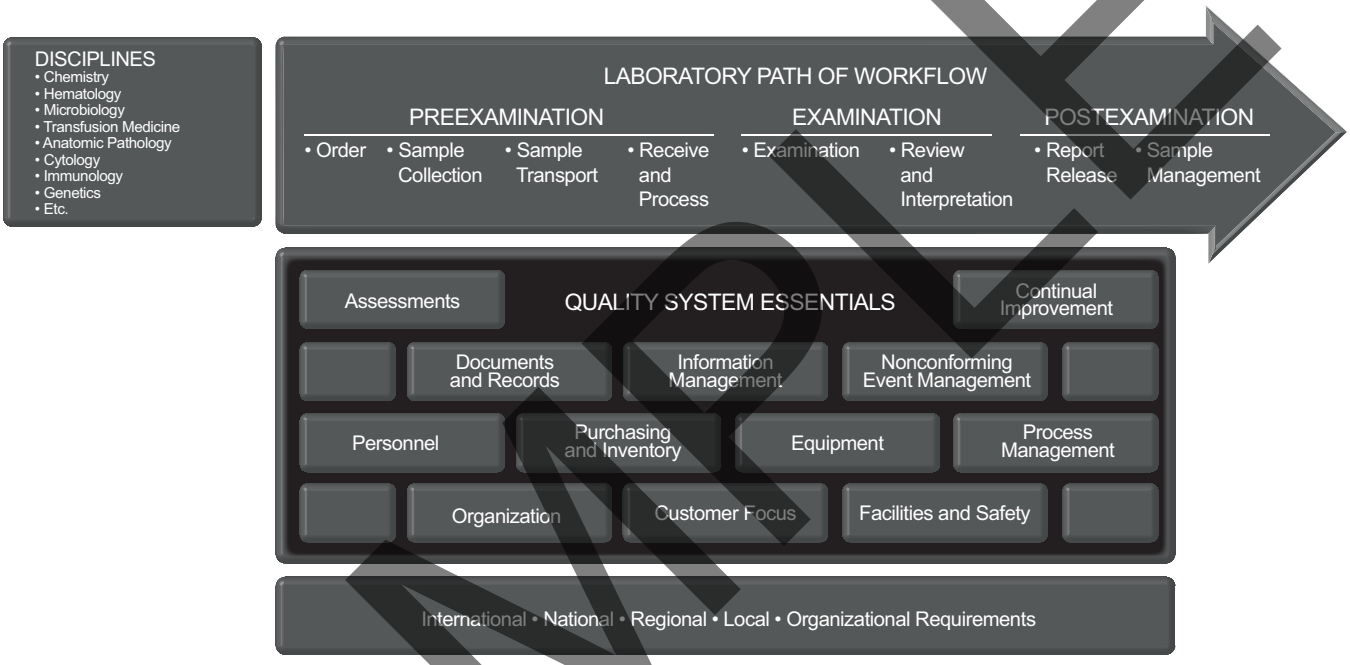

Figure 1. The Quality Management System Model for Laboratory Services (see CLSI document QMS01[1])

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[2] 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[3] specifies requirements for both quality management and technical operations of testing and calibration laboratories. ISO 15189[4] defines standards for quality management and technical operations in the medical laboratory environment.

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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

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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.

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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

QMS11 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 114.

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		
QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01
											QMS06
										QMS12	
QMS14											
QMS20											

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Related CLSI Reference Materials*

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.

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.

QMS12 **Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality. 1st ed., 2010.** This document provides guidance on development of quality indicators and their use in the medical laboratory.

QMS14 **Quality Management System: Leadership and Management Roles and Responsibilities. 1st ed., 2012.** This guideline presents concepts and information intended to assist a laboratory in meeting leadership requirements for its quality management system. Guidance is provided for leaders to effectively design, implement, and maintain the cultural, structural, and functional aspects of their laboratory's organization that are critical to managing and sustaining quality.

QMS20 **Understanding the Cost of Quality in the Laboratory. 1st ed., 2014.** This report provides guidance to a laboratory in understanding and managing the different types of quality costs that affect processes, services, and financial well-being.

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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.

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