CLINICAL AND LABORATORY STANDARDS INSTITUTE®

2nd Edition

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.

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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.

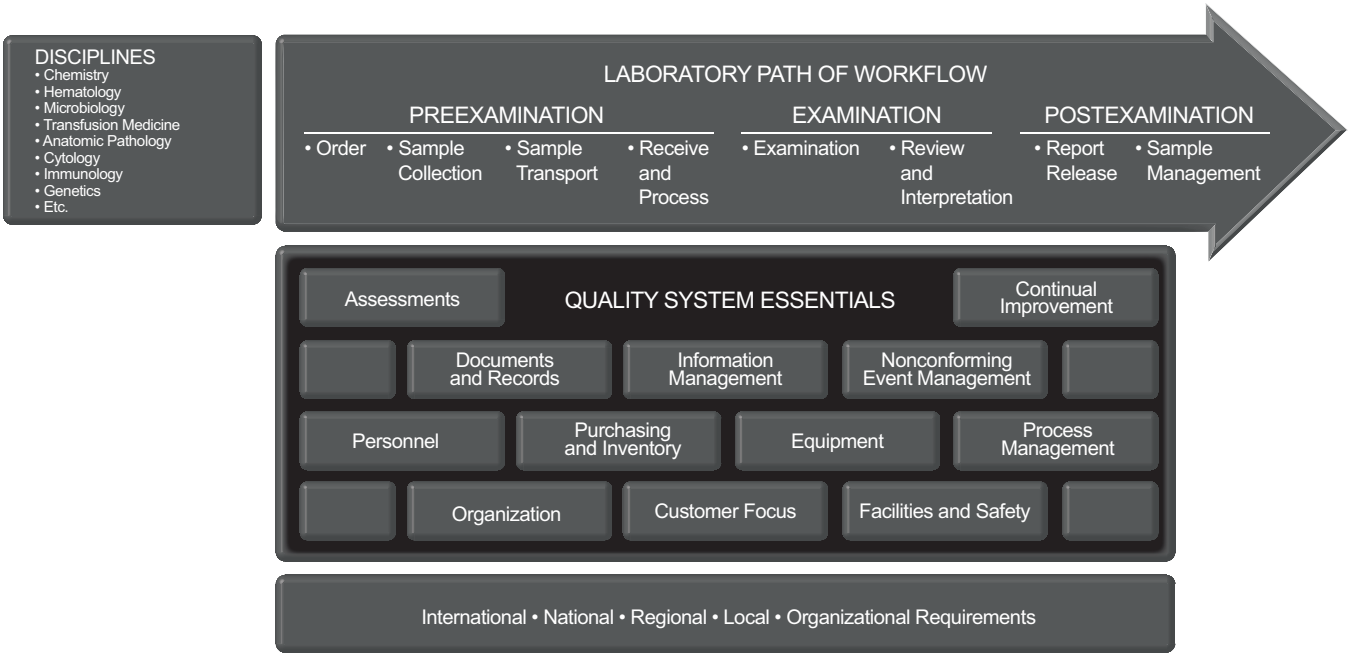

Figure 1. The Quality Management System Model for Laboratory Services (see CLSI document QMS01[1])

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.

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.

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.

NOTE:

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

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.

NOTE:

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