CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

QMS26

Managing Laboratory Records

This guideline presents recommendations for developing a records management program, including designing, creating, reviewing, retaining, and disposing of laboratory records.

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

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Managing Laboratory Records

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Abstract

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Foreword

Quality system essential (QSE) Documents and Records 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 that each QSE, such as Documents and Records Management, is a building block to quality and is necessary to support any laboratory's path of workflow from preexamination to examination to postexamination.

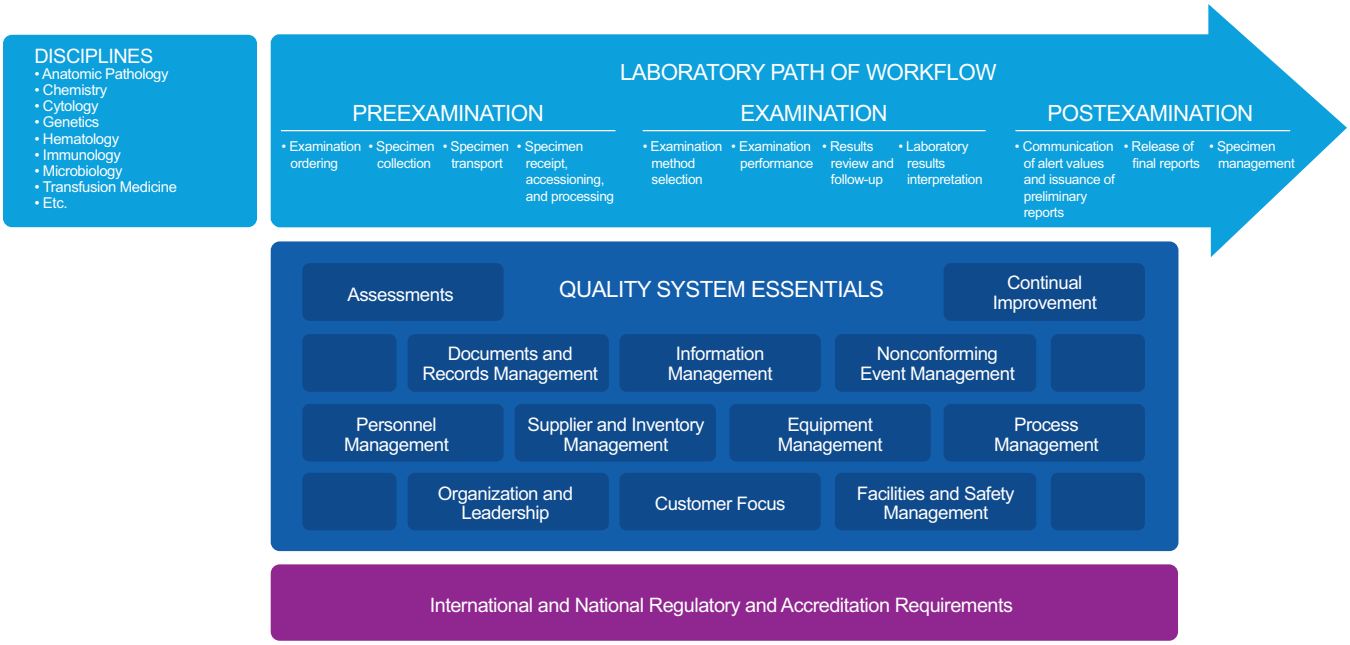

Figure 1. The QMS Model for Laboratory Services (see CLSI document QMS01[1]). The 12 QSEs are building blocks necessary to support any laboratory's path of workflow. This figure represents how the 12 QSEs support a medical laboratory's disciplines and stages of examination.

QSEs are the foundational building blocks that function effectively to support the laboratory's path of workflow. If a QSE is missing or poorly implemented, problems will occur in preexamination, examination, and postexamination processes. For example, when the laboratory lacks a defined process to manage its records, it could be unable to:

- Locate previous examination results needed for comparison with current results, adversely affecting patient care.
- Find previous QC records needed to investigate a supplier recall of a reagent or QC material so that the effects of the recalled reagent or QC material cannot be determined, including possible erroneous results.

International guidance related to the QSEs and the laboratory's path of workflow is available. Topics include:

- A process-based model for quality that any business should use to manage its operations, with information relating directly to the QSEs[2]
- Requirements for both quality management and technical operations of testing and calibration laboratories[3]
- Standards for quality management and technical operations in the medical laboratory environment[4]

QMS26 is a **guideline** that can help laboratories implement a laboratory records management program and meet international standards and regulatory and accreditation requirements.[2-13] **QMS26 is not a standard;** that is, this guideline **does not set requirements** for managing records. Rather, it provides suggestions and examples for fulfilling the requirements.

NOTE: The content of this guideline is supported by the CLSI consensus process and does not necessarily reflect the views of any single individual or organization.

KEY WORDS

Records **Records management**

Chapter 1

Introduction

This chapter includes:

- Guideline's scope and applicable exclusions
- Background information pertinent to the guideline's content
- Terminology information, including:
  - Terms and definitions used in the guideline
  - Abbreviations and acronyms used in the guideline

Managing Laboratory Records

1 Introduction

1.1 Scope

This guideline is intended to help laboratories meet QMS requirements for the records portion of quality system essential (QSE) Documents and Records Management. It presents recommendations for developing a records management program, including designing, creating, reviewing, retaining, and disposing of laboratory records. This guideline can be used in laboratories worldwide and is intended for use primarily by:

- Medical laboratories
- Blood gas laboratories
- Blood donor and pretransfusion testing laboratories
- Public health laboratories
- Clinical research laboratories

However, because the concepts of records management are generic, this guideline is also applicable to other types of laboratories, including but not limited to:

- Food laboratories
- Environmental laboratories
- Veterinary laboratories

This guideline does not specifically cover management of specimens and clinical materials (eg, pathology blocks and slides, blood and body fluid specimens), which also requires appropriate retention and disposal. However, many of the concepts contained in this guideline could be applied to management of these materials. Refer to CLSI document QMS01[1] for more information about specimen management. This guideline does not cover the documents portion of QSE Documents and Records Management. Refer to CLSI document QMS02[14] for more information on document management.

1.2 Background

All laboratories, regardless of size, generate important laboratory records. Records contain information about and evidence of laboratory activities and need to be managed to be useful. The records have to be accessible when needed and properly disposed of when no longer required. Medical laboratories have become very complex, and strategies to manage the types and volume of laboratory records have also become increasingly complex. Regardless of the record type or medium, a records management program provides a means to control each record throughout its lifespan. All personnel from the newest person to the laboratory director have a role in records management. The benefits of a records management program are presented in Table 1.