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

Clinical and Laboratory Standards Institute guideline QMS26—*Managing Laboratory Records* presents recommendations for developing a records management program, including designing, creating, reviewing, retaining, and disposing of laboratory records.

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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.

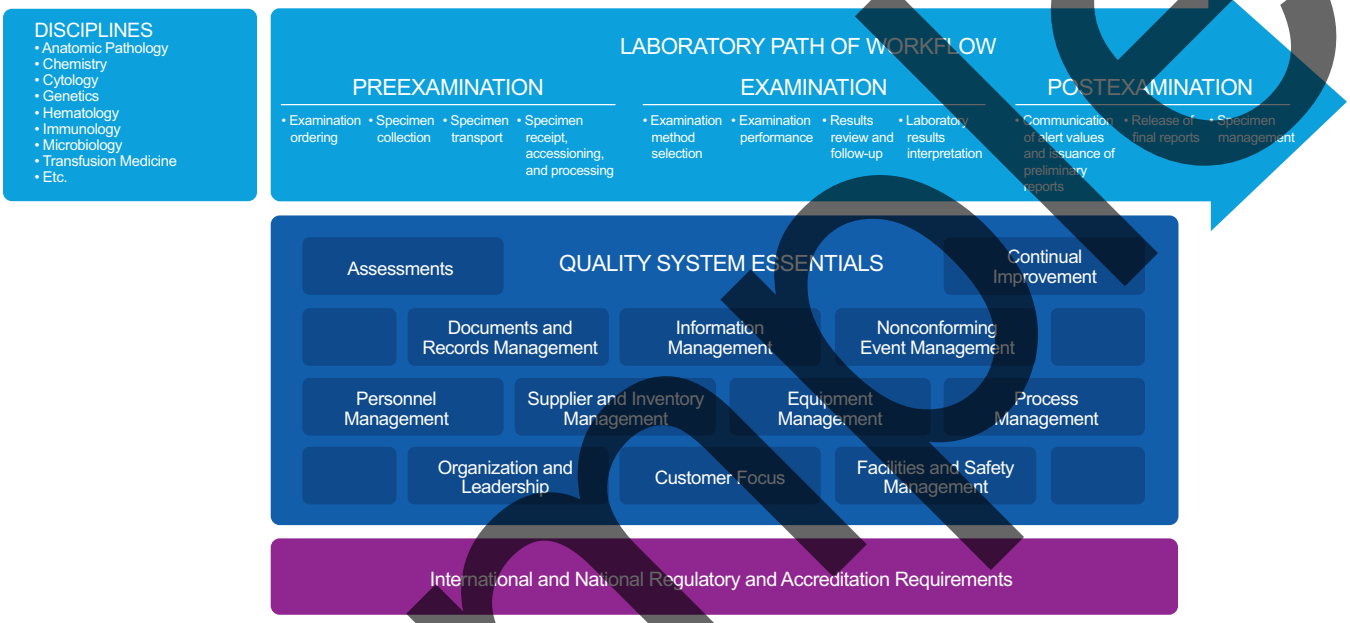

Figure 1. The QMS Model for Laboratory Services (see CLSI document QMS01[1]). The 12 QSEs are building blocks necessary to support any laboratory's path of workflow. This figure represents how the 12 QSEs support a medical laboratory's disciplines and stages of examination.

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.

Table 5. (Continued)

QSE	Record Example(s)	Related CLSI Document(s)
Nonconforming Event Management	NCE reports and action taken	QMS11[24]
Assessments	• Internal and external audit reports and corrective action records • Accreditation certificates • PT program results, alternative assessment results, and follow-up, when applicable • Quality indicators results and follow-up	QMS17[41] QMS15[42] QMS24[43] QMS12[44]
Continual Improvement	Continual improvement plans, reports, and results	QMS06[45]

Abbreviations: IQ, installation qualification; LIS, laboratory information system; NCE, nonconforming event; OQ, operational qualification; PQ, performance qualification; PT, proficiency testing; QC, quality control; QMS, quality management system; QSE, quality system essential.

2.3 Maintaining Records

Integral components of a records management program include processes to maintain records, including retention and storage of records, as well as transport records, when applicable. Proper records maintenance includes requirements that both physically and electronically stored records remain retrievable and useable during the time they are retained and that confidentiality is protected. Records maintenance processes also need to ensure that there is a plan for recovery of critical records in the event of a disaster. Records maintenance policies and processes need to include the following elements:

- Official record medium
- Retention period
- Storage location and conditions
- Records security classification
- Records indexing system
- Disaster recovery

2.3.1 Official Record Medium

The laboratory needs to determine the medium for the official record. Records can exist in many different media types, and the best medium for long-term records retention might not always be the original one. Examples of records media can be found in Subchapter 2.1.1. Some records might be available in multiple media, such as in both electronic and paper-based forms, but in most cases only one form is selected as the official record, and retention of other versions or copies is not required. For example, a laboratory could have a copy of an accreditation certificate posted in the laboratory, but the designated official record, which is subject to records maintenance processes, would be the original certificate retained by the laboratory director or a designated function or individual. Although the records maintenance processes discussed in this subchapter apply only to the official record, when there are multiple versions or copies, they should not be retained longer than the official record. Table 6 lists considerations related to records media.

5 Key Features of Electronic Records Management Systems

An ERMS uses automated techniques to manage records regardless of the record's medium. The "electronic" in ERMS refers to automating the records management **process,** not to the medium type. An ERMS is designed to manage the laboratory's electronic records on various media as well as paper records and those on other media types. An ERMS maintains a list of all the records in the laboratory, including information about how and where they are stored. ERMS can include[17,46]:

- Listing of records using the established laboratory (or organizational) records indexing system and any other relevant metadata
- Identification of records subject to records holds
- Function for users to search for specific records
- Identification of records that reach the end of their retention period. **NOTE:** Some ERMS can automatically delete specified electronic records when they are no longer needed.
- Listing of records that have been disposed, as well as related information (eg, authorization, date of disposal)

Some laboratories have an electronic QMS, in which records management is a specific module, along with document management, assessment management, nonconforming event management, training and competence assessments, etc. This system is not the same as an ERMS. Other laboratories (or the larger organization, when applicable) could have a stand-alone ERMS. An ERMS is beneficial because it:

- Ensures the authenticity and reliability of laboratory records by protecting them from unauthorized alteration
- Simplifies records access and makes it easier to search for records
- Supports collaboration between multiple users
- Allows for direct incorporation of data from instruments
- Provides security and confidentiality of records through user permission groups and access controls
- Facilitates consistent records management processes
- Improves efficiency and productivity by sorting records easily and automatically organizing records and generating disposal approval notifications

In addition to the records management program requirements already discussed in previous chapters, the laboratory should consider the guidelines presented in Table 15 before purchasing or building an ERMS.

Appendix H. Auditing the Records Management Program

The laboratory should include internal audits of records management in its internal audit program. The nature of a records audit varies depending on the type of records retained by the laboratory (electronic vs physical) and whether records are stored on- or off-site. Refer to CLSI document QMS15[1] for more information about laboratory internal audits. See Table H1 for examples of audits that can be conducted for the various processes in the records management program.

Table H1. Examples of Audits

Requirements	Notes
Reviewing	Ensure reviews occur according to the designated schedule and are recorded.
Maintaining	• Visit records storage locations, either on-site or off-site, to ensure: – Specific environmental conditions such as humidity and temperature are maintained, pest control means are in place, etc. – The storage area(s) is free from fire and water hazards, fire and flood response means are in place, and records are not stored directly on the floor, whenever possible. – The area is secure and access is limited to authorized persons. – Records are stored and maintained according to the retention schedule and the indexing system. – Records are accessible and information is readable and uncorrupted.
Accessing	• Measurement of timeliness of receipt of requested off-site records • Measurement of ease of and timeliness of access to on-site records • Verification of access to records after updates to or downtime in the ERMS
Making changes	Audit of a number of changed records to ensure both the original and new information are accessible and any applicable documentation or notification processes have been followed
Disposing	• Audit of selected number of records to ensure disposal took place as scheduled and is documented as required • Audit of laboratory workspace records to ensure only the required records are retained and unneeded records have been disposed of or moved to other storage location per the laboratory's process

Abbreviation: ERMS, electronic records management system.

Reference for Appendix H

1 CLSI. *Assessments: Laboratory Internal Audit Program; Approved Guideline*. CLSI document QMS15-A. Clinical and Laboratory Standards Institute; 2013.

Related CLSI Reference Materials[a]

AUTO03 **Laboratory Automation: Communications With Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems. 2nd ed., 2009.** This document provides standards to facilitate accurate and timely electronic exchange of data and information between the automated laboratory elements.

C24 **Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions. 4th ed., 2016.** This guideline provides definitions, principles, and approaches to laboratory quality control design, implementation, and assessment.

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.

GP05 **Clinical Laboratory Waste Management. 3rd ed., 2011.** Based on US regulations, this document provides guidance on the safe handling and disposal of chemical, infectious, radioactive, and multihazardous wastes generated in the clinical laboratory. Although this document is a valuable resource for a wider audience, it is intended for use primarily in the United States.

GP17 **Clinical Laboratory Safety. 3rd ed., 2012.** This document contains general recommendations for implementing a high-quality laboratory safety program, which are provided in a framework that is adaptable within any laboratory.

QMS01 **A Quality Management System Model for Laboratory Services. 5th ed., 2019.** This guideline provides a model for medical laboratories to organize the 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.

QMS03 **Training and Competence Assessment. 4th ed., 2016.** This guideline provides a structured approach for developing effective laboratory personnel training and competence assessment programs.

QMS04 **Laboratory Design. 3rd ed., 2016.** This guideline provides a foundation of information about laboratory design elements and guidance to help define issues to consider when designing a medical laboratory.

QMS05 **Qualifying, Selecting, and Evaluating a Referral Laboratory. 3rd ed., 2020.** This guideline provides recommended criteria and easily implemented processes to qualify, select, and evaluate a referral laboratory.

[a] 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)

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 **Nonconforming Event Management. 2nd ed., 2015.** 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.

QMS12 **Developing and Using Quality Indicators for Laboratory Improvement. 2nd ed., 2019.** This guideline describes how laboratories can develop and use quality indicators to measure and monitor performance of laboratory processes and identify opportunities for improvement.

QMS13 **Quality Management System: Equipment. 1st ed., 2011.** This guideline provides recommendations for establishing equipment management processes from selection through decommission of all items of equipment used in the provision of laboratory services.

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.

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.

QMS16 **Laboratory Personnel Management. 1st ed., 2015.** This guideline describes the process for meeting the regulatory and accreditation requirements of personnel management in the laboratory environment. This guideline offers suggestions and examples on managing the processes required for laboratory personnel to fully achieve laboratory management's operational and quality goals.

QMS17 **External Assessments, Audits, and Inspections of the Laboratory. 1st ed., 2017.** This guideline provides recommendations for establishing and maintaining a process to assist the laboratory in achieving a continuous state of readiness for assessment by an external organization. This includes selecting and evaluating an external assessment organization, preparing for and undergoing a successful assessment, and sustaining ongoing readiness for assessment.

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.

Related CLSI Reference Materials (Continued)

QMS19 **Customer Focus in a Quality Management System. 1st ed., 2017.** This guideline provides useful information for how laboratories can develop and maintain a customer focus and meet the regulatory and accreditation requirements for managing external and internal customers.

QMS21 **Purchasing and Inventory Management. 1st ed., 2016.** This guideline describes effective purchasing and inventory management processes, which ensure availability of the appropriate equipment, instruments, reagents, consumable materials, other products, and services procured from external sources needed for providing quality laboratory services.

QMS22 **Management of Paper-based and Electronic Laboratory Information. 1st ed., 2018.** This guideline includes recommendations for managing the data and information generated and entered into paper-based or electronic recordkeeping systems and disseminated electronically or otherwise to end users or other computer systems.

QMS23 **General Laboratory Equipment Performance Qualification, Use, and Maintenance. 2nd ed., 2019.** This guideline reflects requirements and provides recommendations for use in planning, recording, and monitoring performance qualification, function checks, calibration verification, and preventive maintenance activities for general laboratory equipment. Examples are included to provide insight and enhance comprehension.

QMS24 **Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality. 3rd ed., 2016.** This guideline describes a complete proficiency testing (PT) process to assist laboratories in using PT as a quality improvement tool.

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