CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

QMS22

Management of Paper-based and Electronic Laboratory Information

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.

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

Management of Paper-based and Electronic Laboratory Information

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Abstract

Clinical and Laboratory Standards Institute guideline QMS22—*Management of Paper-based and Electronic Laboratory Information* provides guidance for managing the data and information generated and entered into paper-based or electronic recordkeeping systems (eg, patient demographics, examination results and reports, interpretations) and disseminated electronically or otherwise to users or other computer systems (eg, verbal requests, printing, automatic faxing, e-mail, interfaces).

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Contents

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Foreword

Quality system essential (QSE) Information Management is one of the 12 QSEs described in CLSI document QMS01[1] and CLSI product *The Key to Quality*™,[2] which provide 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 Information Management, is a building block to quality and is necessary to support any laboratory's path of workflow from preexamination to examination to postexamination.
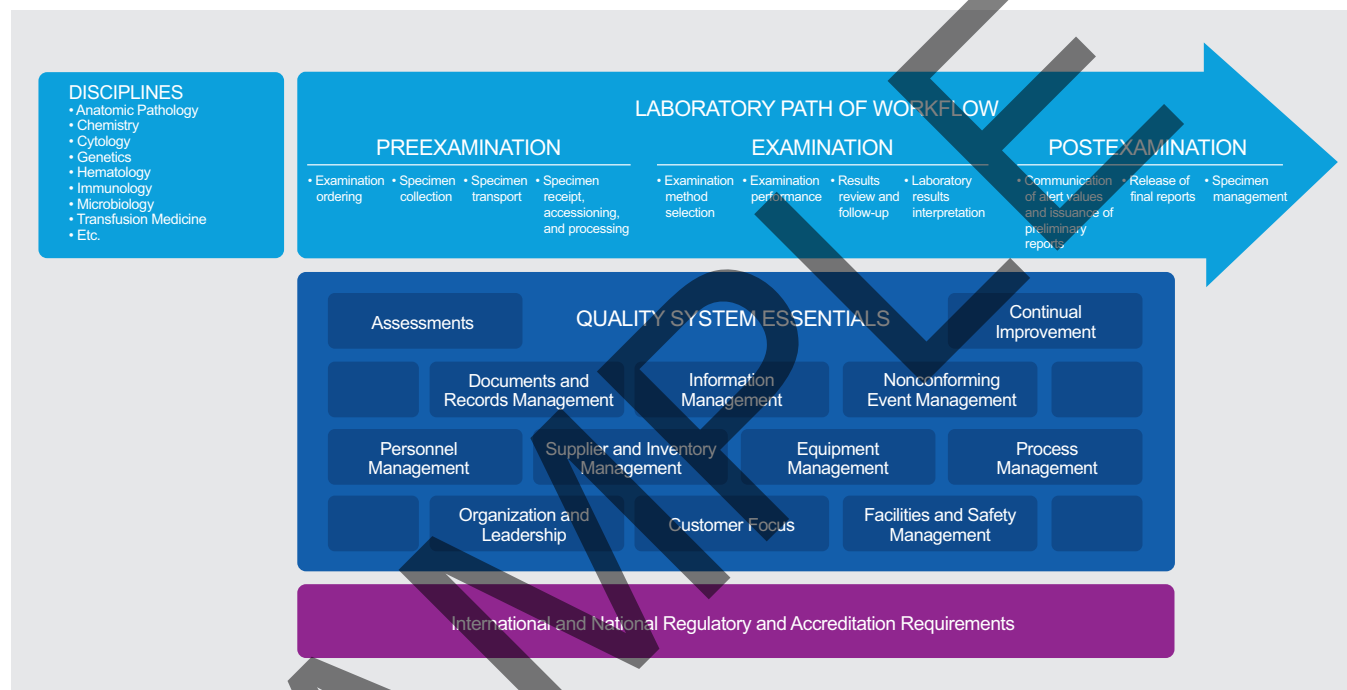
Abbreviation: QMS, quality management system.

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 and laboratory disciplines. 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 laboratory processes. For example, when the laboratory lacks defined processes and procedures for managing the information it generates and disseminates, problems in postexamination processes could result in improper patient treatment.

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[3]
- Requirements for both quality management and technical operations of testing and calibration laboratories[4]
- Standards for quality management and technical operations in the medical laboratory environment[5]

QMS22 is a **guideline** that can help laboratories implement processes that comply with regulatory and accreditation requirements for managing the data and information generated and entered into paper-based or electronic recordkeeping systems.[3-14] **QMS22 is not a standard,** ie, this guideline **does not set requirements** 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. Instead, this guideline describes what laboratories need to do to meet applicable regulatory and accreditation requirements for managing laboratory information and 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

Confidentiality	**Encryption**	**Integrity**
Data	**Information**	**Records**
Data management	**Information management**	
Documents	**Information systems**	

Chapter ❶

Introduction

This chapter includes:

- Guideline's scope and applicable exclusions

- Background information pertinent to the guideline's content

- "Note on Terminology" that highlights particular use and/or variation in use of terms and/or definitions

- Terms and definitions used in the guideline

- Abbreviations and acronyms used in the guideline
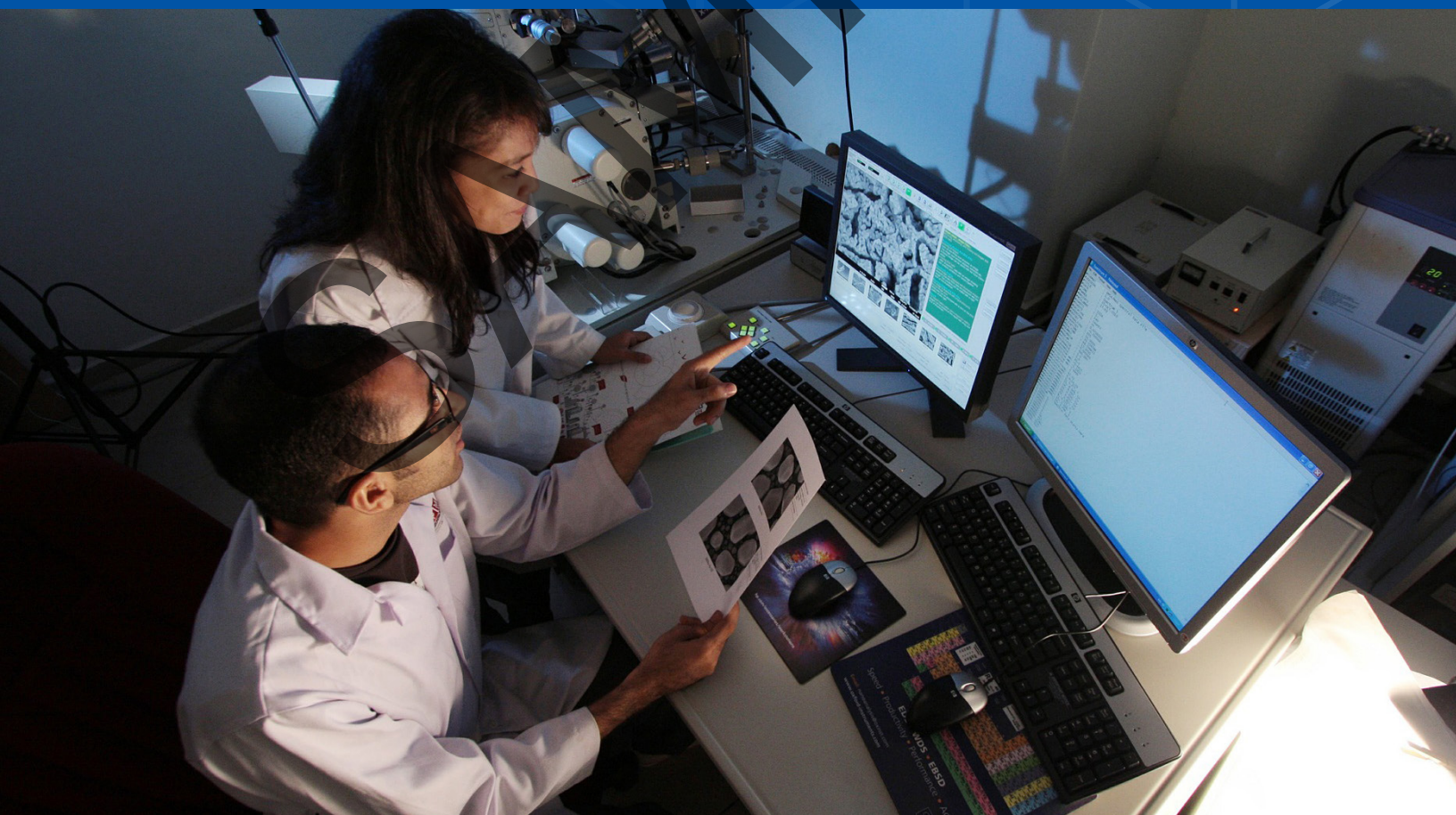
Management of Paper-based and Electronic Laboratory Information

1 Introduction

1.1 Scope

This guideline is intended to help laboratories meet quality management system requirements for quality system essential (QSE) Information Management. In addition to discussing the requirements for how data and information are generated and entered into paper-based or electronic recordkeeping systems, this guideline also offers suggestions and examples for meeting the intent of the requirements.

This guideline is applicable to medical laboratories of any size, complexity, or specialty, including point-of-care testing. Because the concepts of information management are generic, this guideline can be used by other types of laboratories, such as public health, research, food, environmental, and veterinary.

This guideline does not provide specific procedures for information management.

1.2 Background

Patient care is complex and depends on accurate and timely information, including patient examination information provided by the laboratory. The laboratory's end product is the report of examination results and reports. The results report is a valuable resource used to support clinical decision making for improving patient outcomes.

This guideline expands on the requirements for information management discussed in CLSI document QMS01.[1] QSE Information Management incorporates the laboratory's commitment to quality into the flow of information into and out of the laboratory. This QSE includes assessing information expectations, planning and designing to meet those expectations, and disseminating information in a timely and accurate manner. In addition, this guideline considers how information flows from external sources into the laboratory, within the laboratory, and from the laboratory to the end user (see Figure 2).

⚠ **NOTE:**

QSE Information Management includes assessing information expectations, planning and designing to meet those expectations, and disseminating information in a timely and accurate manner.

2.1.3 Movement of Data and Information Throughout the Laboratory's Path of Workflow

The path of workflow is generic for medical laboratories and is represented in Figure 5.
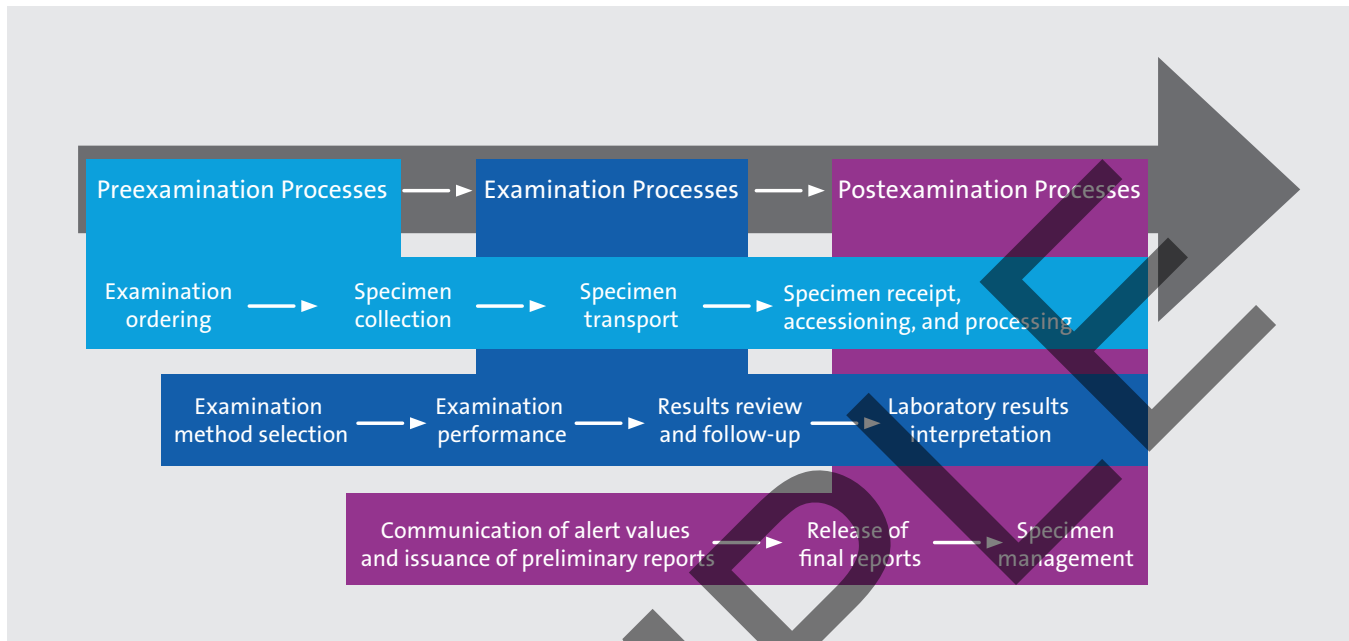

Figure 5. The Laboratory's Path of Workflow

Laboratories should record their expectations for how information should flow throughout each of the preexamination, examination, and postexamination processes shown. Details on how these expectations need to and can be fulfilled are provided in Subchapter 2.2.

2.1.4 Information Expectations for Anticipated Future Laboratory Operations

Laboratories should plan for the implementation of a paper-based or electronic information management solution by considering future expectations. The laboratory should analyze its processes and operations to ensure implemented solutions will remain applicable in the future.

Potential internal and external factors that may affect the laboratory as time progresses include:

- Changes in examination frequency
- Changes to examination menus
- Changes in reimbursement
- Changes in regulatory and/or accreditation requirements
- Geographic and/or demographic considerations based on the laboratory's location
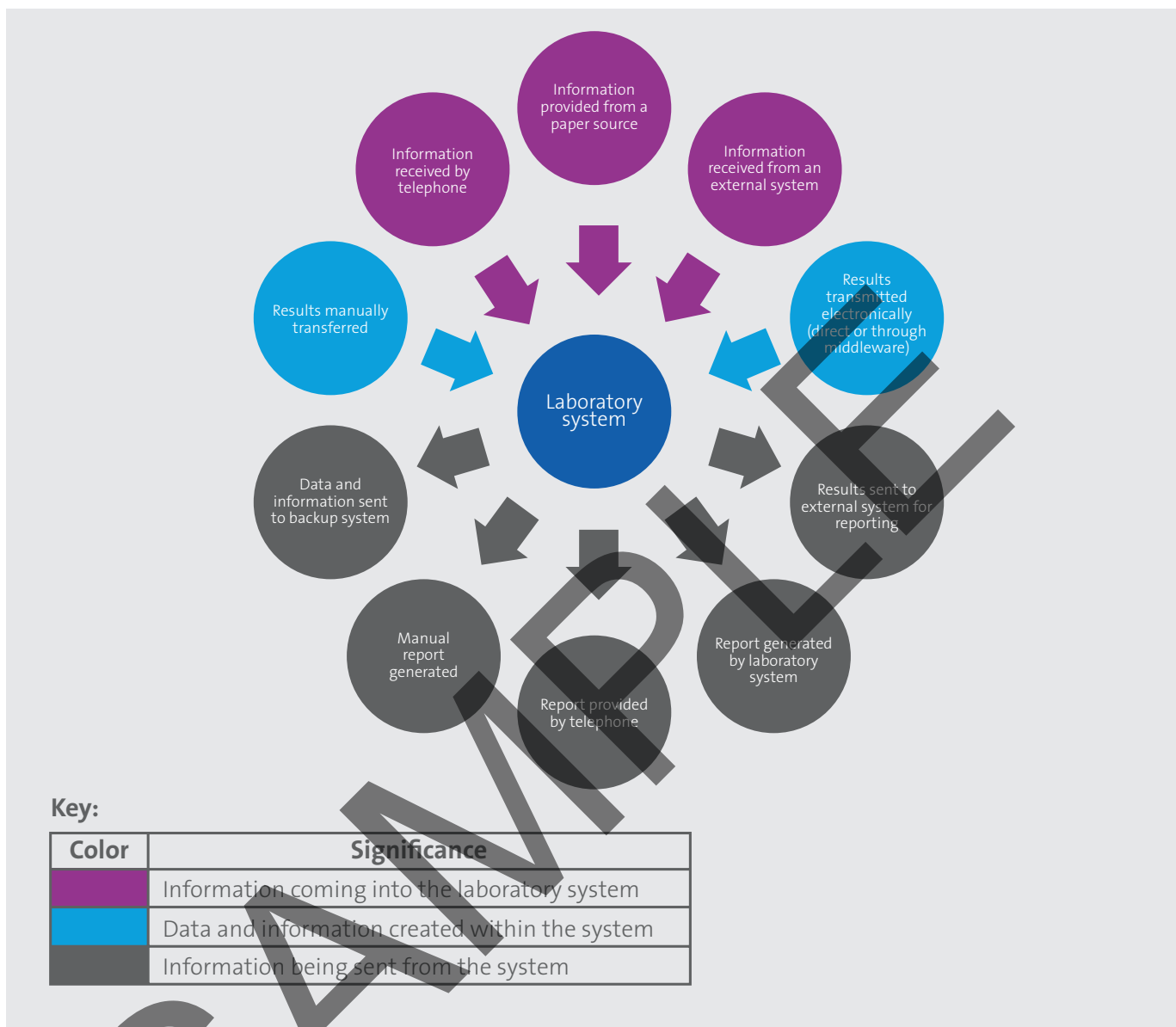
Key:

Color	Significance
![purple]	Information coming into the laboratory system
![blue]	Data and information created within the system
![gray]	Information being sent from the system

Figure 9. Examples of Data and Information Transfers and Transmissions

When electronic methods are used to transfer or transmit data and information, the following variables should be considered:

- Internal or external data and information transmission
- Type of interface
- Bidirectional or unidirectional interface
- Transmission security (eg, encrypted data, access control)
- Type of technology used to view data and information (eg, HTML, smartphones)