

QMS16

Laboratory Personnel Management

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.

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

Laboratory Personnel Management

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Abstract

Clinical and Laboratory Standards Institute document QMS16—*Laboratory Personnel Management* provides guidance for processes involved in managing personnel resources such as personnel qualifications, preparation and maintenance of effective job descriptions, introduction of new personnel to the laboratory organization, continuing education, professional development, and contents of personnel records. This guideline focuses on how to meet regulatory and accreditation requirements for personnel. Useful tools and templates related to these topics are also provided.

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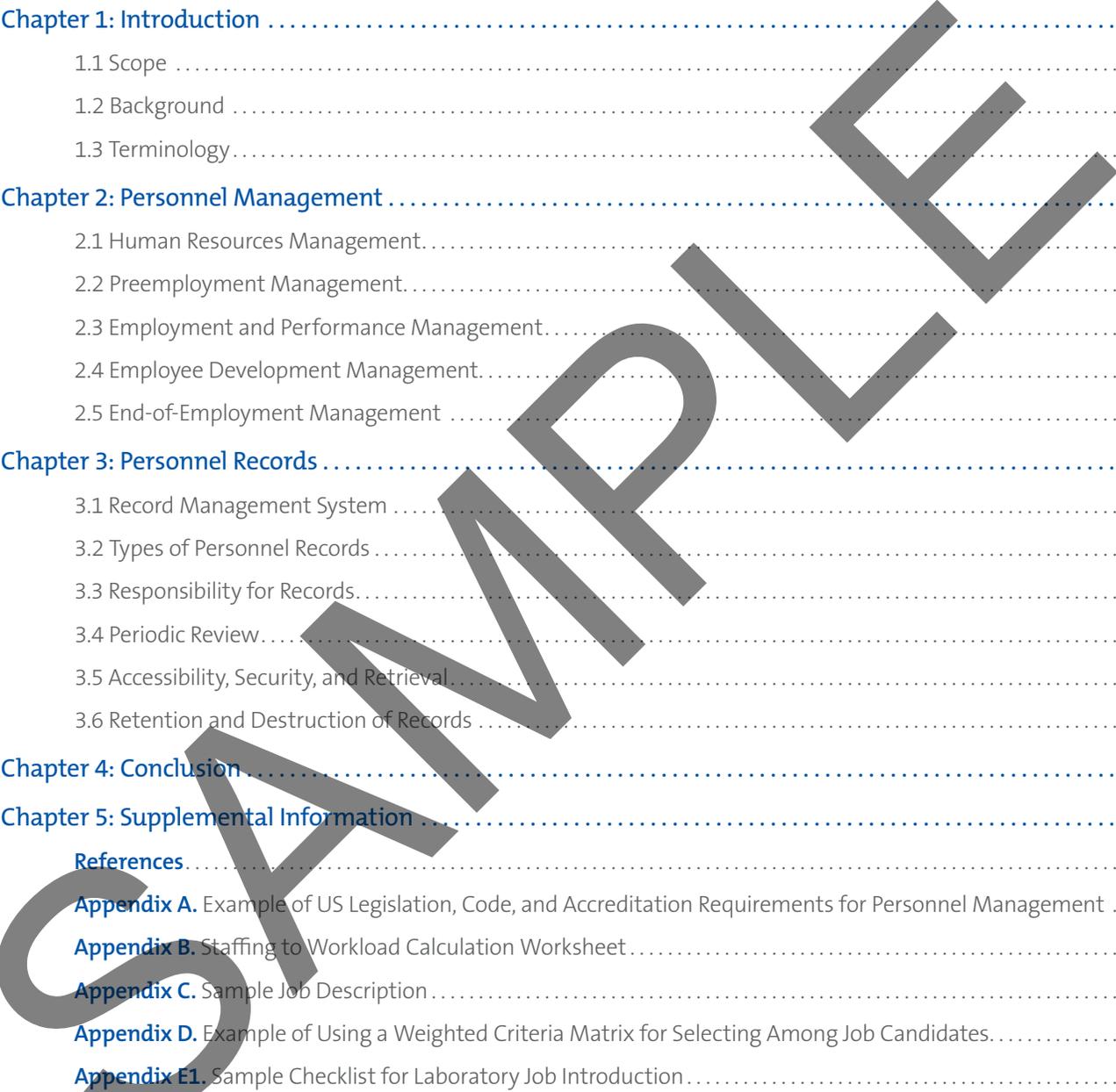
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Foreword

Quality system essential (QSE) Personnel 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 Personnel, 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 QMS01¹). The 12 QSEs function as building blocks that are necessary to support any laboratory’s path of workflow and laboratory disciplines. This example represents how the 12 QSEs support a clinical laboratory’s disciplines.

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 personnel management, including training or performance evaluation, problems will arise in the laboratory path of workflow.

International guidance related to the QEs and the laboratory's path of workflow is described in selected International Organization for Standardization (ISO) standards. ISO 9001² defines a process-based model for quality that any business should use to manage its operations—the information relates directly to the QEs. ISO 17025³ specifies requirements for both quality management and technical operations of testing and calibration laboratories. ISO 15189⁴ defines standards for quality management and technical operations in the medical laboratory environment.

KEY WORDS

Competence assessment

Employment management

End of employment

Hiring

Human resources management

Interview

Job description

Leadership

Performance criteria

Personal development

Personnel

Personnel management

Records

Retention

Staff

Succession planning

Supervision

Training

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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



Laboratory Personnel Management

1 Introduction

1.1 Scope

This guideline is intended to assist laboratories in meeting the personnel management requirements for their QMS, as represented by quality system essential (QSE) Personnel. Laboratory personnel can benefit from reading this guideline because it explains management's expectations and personnel responsibilities.

QSE Personnel involves recruiting, hiring, and retaining an adequate number of qualified, well-trained, and competent laboratory personnel to perform and manage the activities of the laboratory. The processes and procedures needed to achieve these goals are described in QSE Personnel.

This guideline is intended for use by laboratory directors, managers, supervisors, quality managers, and others responsible for implementing, maintaining, and evaluating the laboratory's QMS as it relates to the requirements contained in QSE Personnel. The processes described and examples provided can be used in any size, type, or scope of laboratory, anywhere in the world, to meet published regulatory and accreditation requirements.

This guideline **does not** address, in detail, the following topics and content, and the information covered in other CLSI documents:

- Communication between the laboratory and other health care providers or regulatory agencies as related to patient-centered care activities
- Communication theory and practices
- Behavioral management theory and practices
- Personnel interaction management theory and practices
- Training and competence assessment (refer to CLSI document QMS03⁵)
- Leadership and management development (refer to CLSI document QMS14⁶)

In addition, this guideline is not meant to be prescriptive, but rather suggestive, in approach. It is not a comprehensive instructional manual for application of the concepts discussed.

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

QMS16 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 100.

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
			QMS03								
QMS14											

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.

QMS03 **Training and Competence Assessment. 3rd ed., 2009.** This document provides background information and recommended processes for the development of training and competence assessment programs that meet quality and regulatory objectives.

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.

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