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# QMS13-A

## Quality Management System: Equipment; Approved Guideline



This guideline provides recommendations for establishing equipment management processes from selection through decommission of equipment used in the provision of laboratory services.

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

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## Quality Management System: Equipment; Approved Guideline

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### Abstract

Clinical and Laboratory Standards Institute document QMS13-A—*Quality Management System: Equipment; Approved Guideline* provides recommendations for establishing criteria and methods for all aspects of managing laboratory equipment including selection, identification, validation, reverification, use, and decommission of equipment required for the provision of laboratory services. This guideline focuses on general and service-specific equipment, instruments, and analytical systems. This guideline is intended for individuals and laboratories that perform medical testing.

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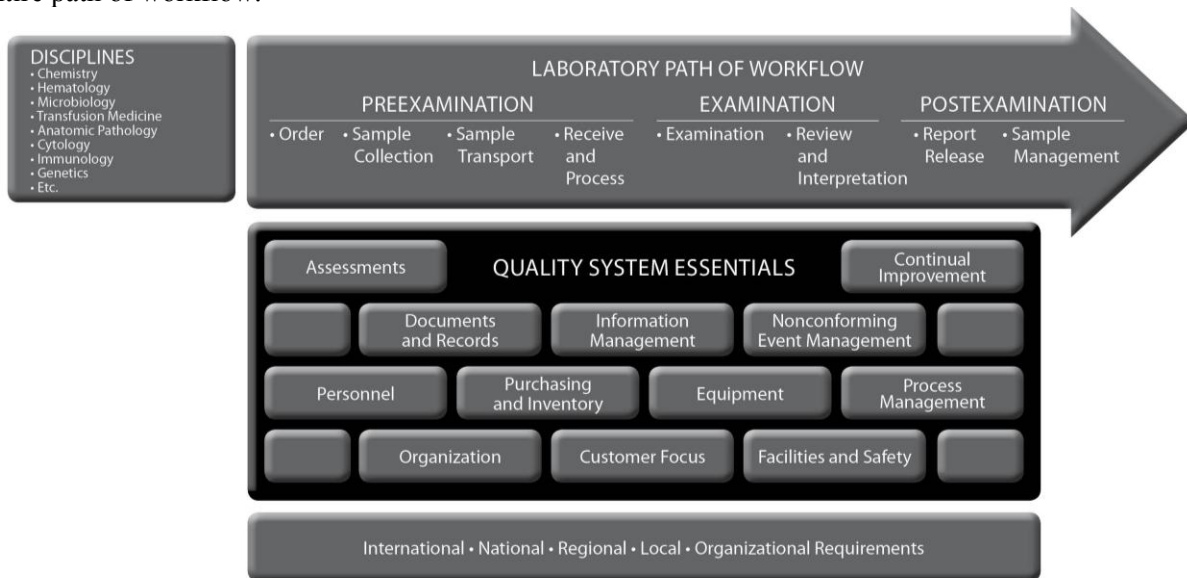
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## Foreword

Equipment is one of the 12 quality system essentials (QSEs) described in CLSI document GP26,<sup>1</sup> which describes a structured approach for organizing, creating, and maintaining the management infrastructure for quality. The quality management system model, as depicted in Figure 1, demonstrates how each QSE, such as Equipment, serves as one of the building blocks for quality needed to support the laboratory's entire path of workflow.



**Figure 1. The Quality Management System Model<sup>1</sup>**

International guidance for quality management and the laboratory's path of workflow is described in selected International Organization for Standardization (ISO) standards. ISO 9001<sup>2</sup> defines a process-based model for quality management that any business should use to manage its operations—the information relates directly to the QSEs. ISO 17025<sup>3</sup> specifies requirements for both quality management and technical operations of testing and calibration laboratories. ISO 15189<sup>4</sup> defines standards for quality management and technical operations in the medical laboratory environment.

QMS13 provides guidance for selecting appropriate equipment; performing installation qualification; and using, calibrating, and maintaining equipment according to established schedules and processes based on the international, national, and accreditation requirements for laboratory equipment.<sup>2-10</sup>

The requirements are sorted into the sequence of activities that represents the lifespan of any piece of laboratory equipment. Laboratories are well advised to follow the guidance offered in this document as the best means to ensure compliance with requirements as well as provide accurate examination results for patient care.

### **Note on Appendixes**

A number of sample templates and forms are provided as appendixes to this guideline. These examples are not meant as all-inclusive and may be modified as appropriate or applicable to specific organizations and equipment.

**Key Words**

Acquisition, calibration, decommissioning, equipment, identification, instrument, maintenance, quality control, records, repair, selection, servicing, validation

## Quality Management System: Equipment; Approved Guideline

### 1 Scope

This guideline is intended for individuals and laboratories that perform medical testing and focuses on general and service-specific equipment, instruments, and analytical systems. Recommendations for establishing criteria and methods for all aspects of equipment operation—including selection, identification, validation, reverification, use, and decommission of equipment—are provided.

Although the requirements for the quality system essential (QSE) Equipment include those for computer system hardware, middleware, and software, guidance for meeting those requirements is provided in other documents<sup>8-10</sup> and CLSI documents AUTO08,<sup>11</sup> AUTO11,<sup>12</sup> and GP19.<sup>13</sup>

A detailed description of acquisition options is beyond the scope of this document.

### 2 Introduction

Published requirements for medical laboratory equipment can be summarized into a set of activities that take place across the lifetime of an instrument or piece of equipment from selection through use and decommission. In this guideline, the set of published requirements for laboratory equipment is used as an outline to describe the activities laboratories need to perform to meet these requirements. If laboratories follow the guidance provided herein, they should meet requirements in the course of doing laboratory work and therefore succeed in the equipment portion of laboratory audits and assessments.

The laboratory equipment discussed in this guideline can be classified into two major categories: general laboratory equipment and laboratory instrumentation. For the purpose of this guideline, general laboratory equipment is that which can be used in various laboratory settings or methods, and instrumentation is that which produces measurements in an examination/analytical system or method. Table 1 provides examples of these types of equipment.

**Table 1. Examples of General Laboratory Equipment and Laboratory Instrumentation**

General Laboratory Equipment		Laboratory Instrumentation	
Autoclave	Osmometer	Automated tissue stainer	Pipettor
Automated cover glass/cassettes instrumentation	Oven	Blood cell analyzer	• Mechanical
Balance/scale	pH meter	Blood chemistry analyzer	• Automated
Biological cabinet	Photometers/light-based device	Blood gas analyzer	Thermal cycler
Centrifuge	Polarimeter	Blood typing equipment	Thin layer chromatograph
• General purpose	Refractometer	Centrifuge	• Automated cell washing
• Microhematocrit (dedicated, fixed RPM)	Rotator	• Automated cell washing	Urine analyzer
• Refrigerated	Shaker	Co-oximeter	
• Stand-alone	Temperature-controlled equipment	Densitometer	
Fume hood	• Refrigerator	Electrode-based instrument	
Glassware washer	• Freezer	Electrophoresis system	
Laboratory thermometer	• Incubator	Flow cytometer	
Light box	• Water bath	Ion-selective electrode	
Manual pipettor	• Blood bank transport container	Mass spectrometer	
Microscope	Timer	Microbial identification instrumentation	
Microtome	Tissue processor	Nephelometer	
	Water purifier		