CLINICAL AND LABORATORY STANDARDS INSTITUTE®

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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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Clinical and Laboratory Standards Institute
950 West Valley Road, Suite 2500
Wayne, PA 19087 USA
P: 610.688.0100
F: 610.688.0700
www.clsi.org
standard@clsi.org

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Quality Management System: Equipment; Approved Guideline

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Susan Blonshine, RRT, RPFT, FAARC
Dorothy J. Ball, PhD
Christine Flaherty, MHA, CLS, CPHQ
Jason Majorowicz, BS
David Manalan, F(ASQ), CSQE, CBA, CQA
Caroline Satyadi, MS, MBA, DLM(ASCP), SM; SLS, CLS
Diane I. Szamosi, MA, MT(ASCP)SH

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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Committee Membership

Consensus Committee on Quality Systems and Laboratory Practices

Carl D. Mottram, BA, RRT, RPFT, FAARC
Chairholder
Mayo Clinic
Rochester, Minnesota, USA

Devery Howerton, PhD
Vice-Chairholder
Centers for Disease Control and Prevention
Atlanta, Georgia, USA

Deirdre Astin, MS, MT(ASCP)
New York State Department of Health
Albany, New York, USA

Lucia M. Berte, MA, MT(ASCP)SBB, DLM; CQA(ASQ) CQM/OE
Laboratories Made Better!
Broomfield, Colorado, USA

Theresa Billups, MBA, MT(ASCP)DLM
Thermo Fisher Scientific
Lake Charles, Louisiana, USA

Michael B. Cohen, MD
University of Iowa
Iowa City, Iowa, USA

Nancy Dubrowny, MS, MT(ASCP)SC
BD Preanalytical Systems
Franklin Lakes, New Jersey, USA

Michelle Jenkins, MS, MT(AMT) ASQ, CQE, CMQ/OE
Abbott Diagnostics
Irving, Texas, USA

Jennifer Schiffgens, MBA, MT(ASCP), CLS
California Pacific Medical Center
San Francisco, California, USA

Tonya Wilbon, BS, M(ASCP)
FDA Ctr. for Devices/Rad. Health
Rockville, Maryland, USA

Subcommittee on Quality Management Systems

Lucia M. Berte, MA, MT(ASCP)SBB, DLM; CQA(ASQ)CMQ/OE
Chairholder
Laboratories Made Better!
Broomfield, Colorado, USA

Tania Motschman, MS, MT(ASCP)SBB; CQA(ASQ)
Vice-Chairholder
Mayo Clinic
Department of Laboratory Medicine & Pathology
Rochester, Minnesota, USA

Joan M. Carlson, MLT(ACMLT), BSc(MLS)
Alberta Health Services – Edmonton General Hospital
Edmonton, Alberta, Canada

Anne T. Daley, MS, CMQ/OE, CSSBB,DLM
Chi Solutions, Inc.
Mesa, Arizona, USA

Christine Flaherty, MHA, CLS, CPHQ
Sutter Health Sacramento Sierra Region Laboratories
Sacramento, California, USA

Willem Huisman, PhD
Medical Center Haaglanden
Den Haag, Netherlands

John Kim, PhD
Public Health Agency of Canada
Ottawa, Ontario, Canada

Debra Kuehl, MS, M(ASCP)
Centers for Disease Control and Prevention
Atlanta, Georgia, USA

Dave Petrich, MBA
AcroMetrix Corporation
Benicia, California, USA

Elizabeth Sheppard, MBA, HT(ASCP)
Ventana Medical Systems, Inc.
Tucson, Arizona, USA

Miki Van Houten, MT(ASCP)
Oregon State Public Health Laboratory
Hillsboro, Oregon, USA

Harriet R. Walsh, MA, MT(ASCP)
Centers for Medicare & Medicaid Services
Baltimore, Maryland, USA

Working Group on Equipment

Susan Blonshine, RRT, RPFT, FAARC
Chairholder
TechEd, Consultants, Inc.
Mason, Michigan, USA

Dorothy J. Ball, PhD
Abbott
Irving, Texas, USA

Christine Flaherty, MHA, CLS, CPHQ
Sutter Health Sacramento Sierra Region Laboratories
Sacramento, California, USA

Jason Majorowicz, BS
Mayo Clinic
Rochester, Minnesota, USA

David Manalan, F(ASQ), CSQE, CBA, CQA
INQC Consulting, Inc.
Acton, Massachusetts, USA

Caroline Satyadi, MS, MBA, DLM(ASCP), SM; SLS, CLS
E-Sat Consulting, Inc.
Yuba City, California, USA

Diane I. Szamosi, MA, MT(ASCP)SH
Becton Dickinson
Franklin Lakes, New Jersey, USA

Staff

Clinical and Laboratory Standards Institute
Wayne, Pennsylvania, USA

Luann Ochs, MS
Vice President, Standards Development

Jennifer K. Adams, MT(ASCP), MSHA
Staff Liaison

Melissa A. Lewis, ELS
Editorial Manager

Megan P. Larrisey, MA
Assistant Editor

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Foreword

Equipment is one of the 12 quality system essentials (QSEs) described in CLSI document GP26,[1] 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.

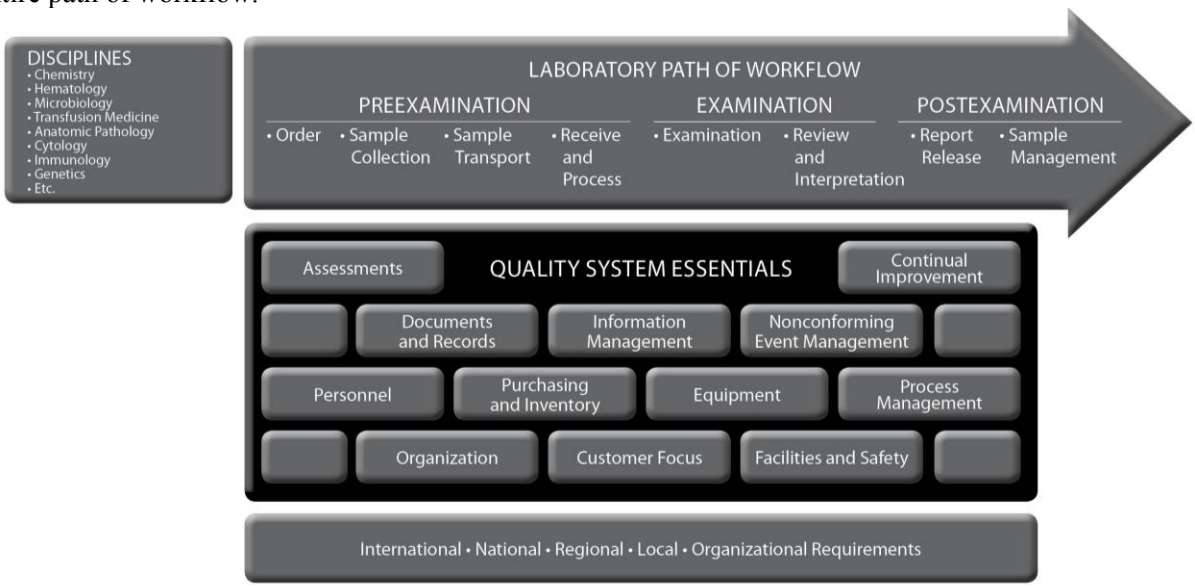

Figure 1. The Quality Management System Model[1]

International guidance for quality management and the laboratory's path of workflow is described in selected International Organization for Standardization (ISO) standards. ISO 9001[2] 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[3] specifies requirements for both quality management and technical operations of testing and calibration laboratories. ISO 15189[4] 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.[2-10]

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[8-10] and CLSI documents AUTO08,[11] AUTO11,[12] and GP19.[13]

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