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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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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Contents

Contents (Continued)

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.

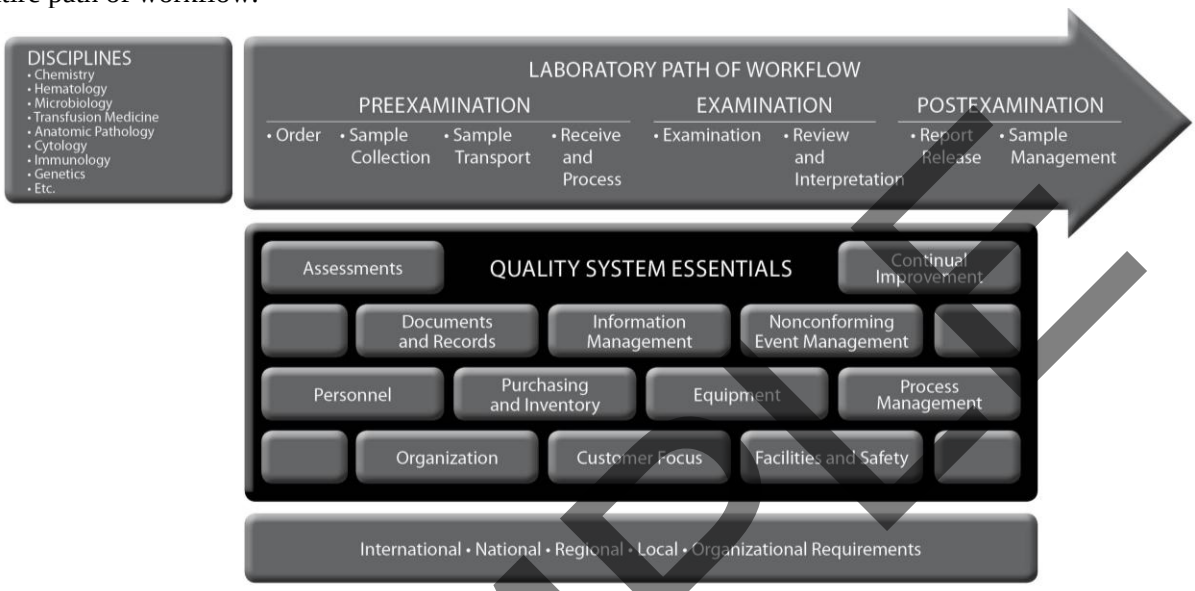


Figure 1. The Quality Management System Model[1]

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

3 Terminology

3.1 A Note on Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization wherever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. CLSI recognizes that medical conventions in the global metrological community have evolved differently in the United States, Europe, and elsewhere; that these differences are reflected in CLSI, ISO, and European Committee for Standardization (CEN) documents; and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. In light of this, CLSI's consensus process for development and revision of standards and guidelines focuses on harmonization of terms to facilitate the global application of standards and guidelines.

Additional important note:

Throughout this guideline, the phrase "the laboratory needs to" explains an action directly related to fulfilling a requirement of the international, national, and accreditation organizations referenced in the Foreword. By taking the actions described in this guideline, the laboratory will fulfill requirements; however, the means by which the requirements are met are left to the discretion of the laboratory unless otherwise specified.

The phrase "the laboratory should" describes a recommendation provided in laboratory literature or that the authors of this guideline believe is good laboratory practice or is a suggestion for how to meet a requirement.

3.2 Definitions

calibration – the process of testing and adjustment of an instrument, kit, or test system to provide a known relationship between the measurement response and the value of the substance measured by the test procedure.[4]

calibration material – a material or device of known or assigned quantitative characteristics (eg, concentration, activity, intensity, reactivity, responsiveness) used to adjust the output of a measurement procedure or to compare the response obtained with the response of a test specimen and/or sample.

calibration verification – confirmation that stated trueness claims for an *in vitro* diagnostic measuring system are achieved (ISO 18113-1)[14]; **NOTE:** Calibration verification requires reference materials with assigned values at concentrations appropriate for the intended use (ISO 18113-1).[14]

competence – demonstrated ability to apply knowledge and skills (ISO 9000).[15]

corrective action – action to eliminate the cause of a detected nonconformity or other undesirable situation (ISO 9000).[15]

error (measurement) – measured quantity value minus a reference quantity value (ISO/IEC Guide 99).[16]

equipment – single apparatus or set of devices or apparatuses needed to perform a specific task (adapted from IEV 151-11-25)[17]; **NOTE:** For the purpose of this guideline, equipment includes general purpose devices.

equipment master file – paper or electronic file in which records of a given instrument or piece of equipment from acquisition to decommission are maintained.

The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The quality management system 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

QMS13-A 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, beginning on page 54.

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	AUTO08 AUTO11 C24 C28 EP05 EP06 EP09 EP15 EP18	GP02	GP02	EP18	EP18	EP18
GP19 GP26	GP19 GP26	GP17 GP19 GP26	GP19 GP21 GP26	GP19 GP26	GP19 GP26 GP31	GP19 GP26 H26	GP19 GP26	GP19 GP26	GP19 GP26	GP26	GP19 GP26 H26

Path of Workflow

A path of workflow is the description of the necessary processes to deliver the particular product or service that the organization or entity provides. A laboratory path of workflow consists of the sequential processes: preexamination, examination, and postexamination and their respective sequential subprocesses. All laboratories follow these processes to deliver the laboratory's services, namely quality laboratory information.

QMS13-A does not address any of the clinical laboratory path of workflow processes indicated in the grid below. For a description of the documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Preexamination				**Examination**			**Postexamination**	
Examination ordering	Sample collection	Sample transport	Sample receipt/processing	Examination	Results review and follow-up	Interpretation	Results reporting and archiving	Sample management
AUTO08 GP26	GP26 H26	GP26	GP26	GP26 H26	GP26	GP26	AUTO08 GP26	GP26 H26

Related CLSI Reference Materials*

AUTO08-A **Managing and Validating Laboratory Information Systems; Approved Guideline (2006).** This document provides guidance for developing a protocol for validation of the laboratory information system (LIS), as well as protocols for assessing the dependability of the LIS when storing, retrieving, and transmitting data.

AUTO11-A **IT Security of *In Vitro* Diagnostic Instruments and Software Systems; Approved Standard (2006).** This document provides a framework for communication of IT security issues between the IVD system vendor and the health care organization.

C24-A3 **Statistical Quality Control for Quantitative Measurement Procedures: Principles and Definitions; Approved Guideline—Third Edition (2006).** This guideline provides definitions of analytical intervals, planning of quality control procedures, and guidance for quality control applications.

C28-A3c **Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition (2010).** This document contains guidelines for determining reference values and reference intervals for quantitative clinical laboratory tests. A CLSI-IFCC joint project.

EP05-A2 **Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition (2004).** This document provides guidance for designing an experiment to evaluate the precision performance of quantitative measurement methods; recommendations on comparing the resulting precision estimates with manufacturers' precision performance claims and determining when such comparisons are valid; as well as manufacturers' guidelines for establishing claims.

EP06-A **Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline (2003).** This document provides guidance for characterizing the linearity of a method during a method evaluation; for checking linearity as part of routine quality assurance; and for determining and stating a manufacturer's claim for linear range.

EP09-A2-IR **Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition (Interim Revision) (2010).** This document addresses procedures for determining the bias between two clinical methods, and the design of a method comparison experiment using split patient samples and data analysis.

EP15-A2 **User Verification of Performance for Precision and Trueness; Approved Guideline—Second Edition (2006).** This document describes the demonstration of method precision and trueness for clinical laboratory quantitative methods utilizing a protocol designed to be completed within five working days or less.

EP18-A2 **Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline—Second Edition (2009).** This guideline describes risk management techniques that will aid in identifying, understanding, and managing sources of failure (potential failure modes) and help to ensure correct results. Although intended primarily for *in vitro* diagnostics, this document will also serve as a reference for clinical laboratory managers and supervisors who wish to learn about risk management techniques and processes.

GP02-A5 **Laboratory Documents: Development and Control; Approved Guideline—Fifth Edition (2006).** This document provides guidance on development, review, approval, management, and use of policy, process, and procedure documents in the medical laboratory community.

GP17-A2 **Clinical Laboratory Safety; Approved Guideline—Second Edition (2004).** 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.

GP19-A2 **Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition (2003).** This document identifies important factors that designers and laboratory managers should consider when developing new software-driven systems and selecting software user interfaces. Also included are simple rules to help prepare validation protocols for assessing the functionality and dependability of software.

* CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.

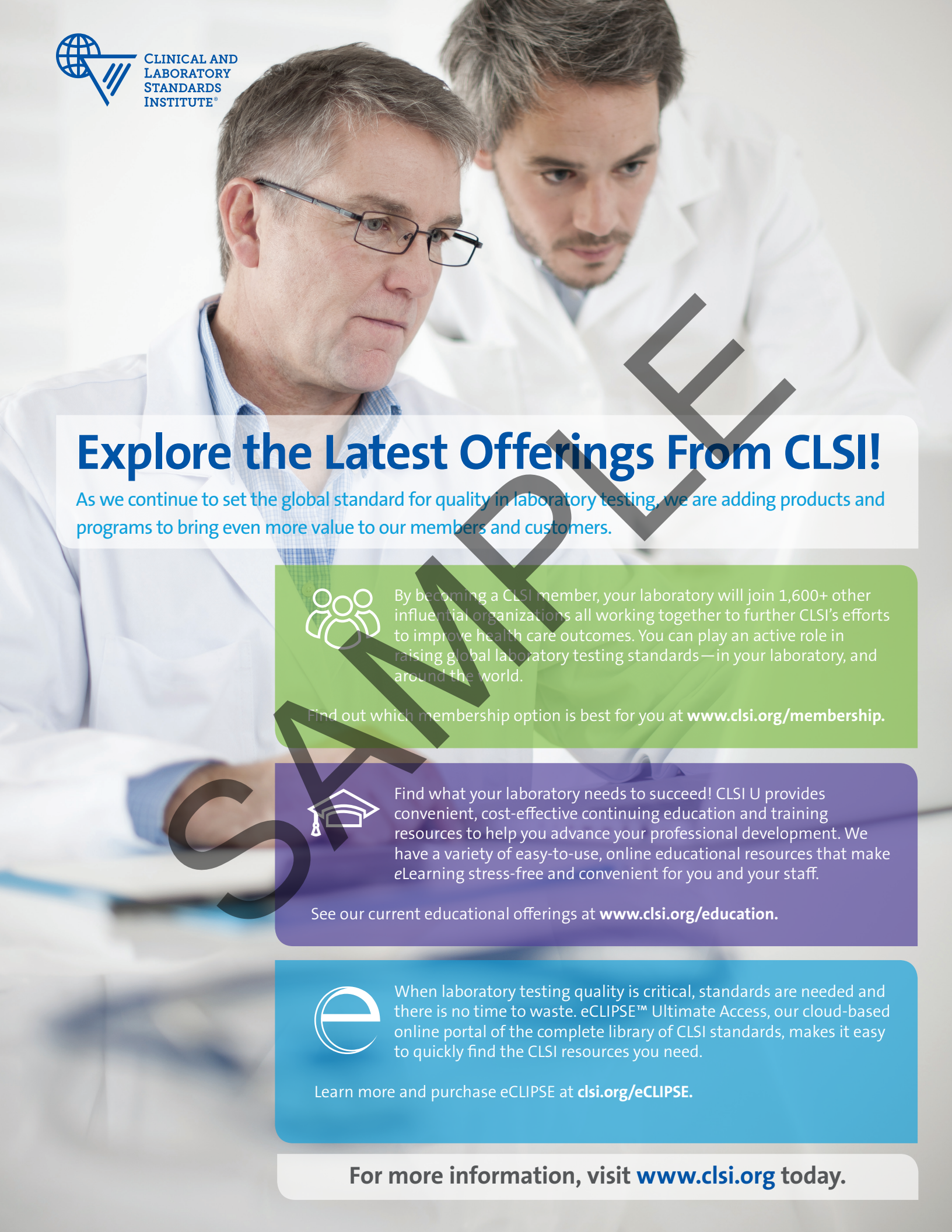
Related CLSI Reference Materials (Continued)

GP21-A3 **Training and Competence Assessment; Approved Guideline—Third Edition (2009).** This document provides background information and recommended processes for the development of training and competence assessment programs that meet quality and regulatory objectives.

GP26-A4 **Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition (2011).** This document provides a model for medical laboratories that will assist with implementation and maintenance of an effective quality management system.

GP31-A **Laboratory Instrument Implementation, Verification, and Maintenance; Approved Guideline (2009).** This guideline provides information about assessing instrument performance and function from the time of instrument purchase to the routine performance of clinical testing.

H26-A2 **Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard—Second Edition (2010).** This document provides guidance for the validation, verification, calibration, quality assurance (QA), and quality control (QC) of automated multichannel hematology analyzers for manufacturers, end-user clinical laboratories, accrediting organizations, and regulatory bodies. In addition, end-user clinical laboratories will find guidance for establishment of clinically reportable intervals and for QA for preexamination and examination aspects of their systems.



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