CLINICAL AND LABORATORY STANDARDS INSTITUTE®

2nd Edition

QMS23

General Laboratory Equipment Performance Qualification, Use, and Maintenance

This guideline reflects requirements and provides recommendations for use in planning, recording, and monitoring performance qualification, function checks, calibration verification, and preventive maintenance activities for general laboratory equipment. Examples are included to provide insight and enhance comprehension.

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

QMS23, 2nd ed.
June 2019
Replaces GP31-A

General Laboratory Equipment Performance Qualification, Use, and Maintenance

Debra Kuehl, MS, M(ASCP)
Kathleen A. Grindle, MT(ASCP), CQA(ASQ)CPGP
Melissa M. Hart, MLT(CMLTA)
Donald R. Callihan, PhD, D(ABMM)
Keri J. Donaldson, MD
Mary-Margaret Fisher, BS, MT(ASCP)
Jeffery M. Jarrett, MS
Sharon Verg Johnson, DLM(ASCP)^{CM}, MBA
Stephan P. Marais
Lauren Pearson, DO, MPH
Michael Perry, MS, MS Ed
Giselle R. Rieschick, 1Lt, USAF, BSC
George Rodrigues, PhD
Milenko Tanasijevic, MD, MBA
Cynthia D. Ward, MS, MBA
Katherine Whelchel, MT(ASCP)SH

Abstract

Clinical and Laboratory Standards Institute guideline QMS23—*General Laboratory Equipment Performance Qualification, Use, and Maintenance* provides recommendations for conducting the initial performance qualification as well as the ongoing verification and preventive maintenance of general laboratory equipment that is essential to ensuring the achievement of accurate and reproducible examination results.

Clinical and Laboratory Standards Institute (CLSI). *General Laboratory Equipment Performance Qualification, Use, and Maintenance.* 2nd ed. CLSI guideline QMS23 (ISBN 978-1-68440-045-4 [Print]; ISBN 978-1-68440-046-1 [Electronic]). Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, Pennsylvania 19087 USA, 2019.

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

Suggested Citation

CLSI. *General Laboratory Equipment Performance Qualification, Use, and Maintenance.* 2nd ed. CLSI guideline QMS23. Wayne, PA: Clinical and Laboratory Standards Institute; 2019.

Previous Editions:
June 2007, April 2009

ISBN 978-1-68440-045-4 (Print)
ISBN 978-1-68440-046-1 (Electronic)
ISSN 1558-6502 (Print)
ISSN 2162-2914 (Electronic)
Volume 39, Number 7

Contents

Contents (Continued)

Contents (Continued)

Contents (Continued)

Foreword

Quality system essential (QSE) Equipment Management 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 that each QSE, such as Equipment Management, is a building block to quality and is necessary to support any laboratory's path of workflow from preexamination to examination to postexamination.

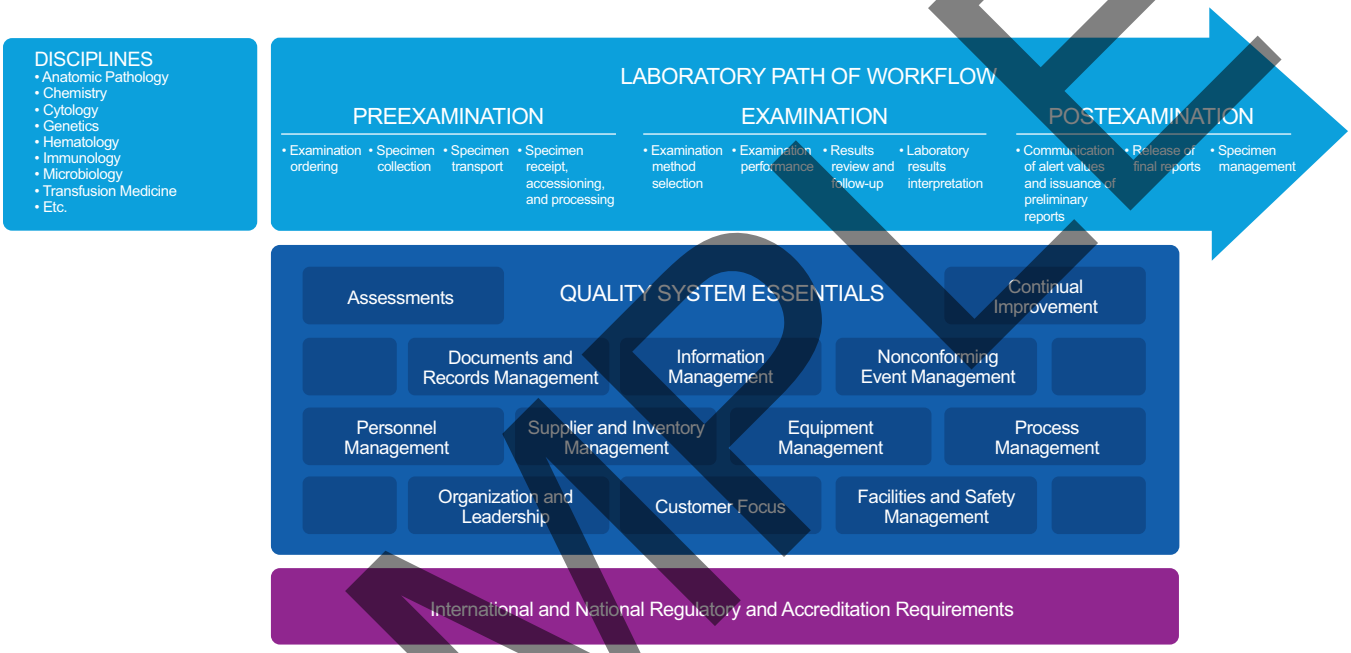

Figure 1. The QMS Model for Laboratory Services (see CLSI document QMS01[1]). The 12 QSEs are building blocks necessary to support any laboratory's path of workflow. This figure represents how the 12 QSEs support a medical laboratory's disciplines and stages of examination.

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 processes. For example, when the laboratory lacks defined processes to properly install, calibrate, and maintain its equipment so that it works effectively, problems in examination processes could cause customer expectations to not be met.

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[2]
- Requirements for both quality management and technical operations of testing and calibration laboratories[3]
- Standards for quality management and technical operations in the medical laboratory environment[4]

QMS23 provides guidance on the performance qualification (PQ), function checks, calibration verification, use, and preventive maintenance of 20 types of commonly used general laboratory equipment and follows the overall equipment management guidance provided in CLSI document QMS13.[5]

Overview of Changes

This guideline replaces the previous edition of the approved guideline, GP31-A, published in 2009. Several changes were made in this edition, including:

- General laboratory equipment is the focus, and specialized laboratory instrumentation is not included.
- Instrument implementation and manufacturer relationships are not discussed.
- PQ is discussed more extensively, and guidance for writing a PQ protocol and examples of the supporting verification forms are provided.
- Safety and environmental sustainability considerations are provided for each equipment type.
- Numerous sample forms and templates that may be modified to reflect the laboratory's needs are included in the appendixes.

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

Calibration
Calibration verification
Equipment
Function checks
Performance qualification
Preventive maintenance
Validation
Verification

Chapter 1

Introduction

This chapter includes:

- Guideline's scope and applicable exclusions
- Background information pertinent to the guideline's content
- Standard precautions information
- "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

General Laboratory Equipment Performance Qualification, Use, and Maintenance

1 Introduction

1.1 Scope

NOTE:

Recommendations in this guideline may supplement but do **not** replace the equipment manufacturer's recommendations.

This guideline specifies recommendations for conducting performance qualification (PQ), routine function checks, calibration verification, and preventive maintenance (PM) of 20 types of general laboratory equipment. Installation qualification (IQ) and operational qualification (OQ) are typically completed by the manufacturer's technical service engineer and are not covered in this guideline. The records showing that IQ and OQ have been completed successfully need to be kept with the equipment documentation as described in CLSI document QMS13.[5]

Recommendations in this guideline may supplement but do **not** replace the equipment manufacturer's recommendations. This guideline describes a quality assurance program for equipment that evaluates performance and stresses PM. This guideline is applicable to medical laboratories of any size, complexity, or specialty and can be used by other types of laboratories, such as public health, research, food, environmental, and veterinary.

This guideline does not include information on equipment and instrumentation exclusive to an individual laboratory section, such as anatomic pathology, chemistry, or hematology. Rather, the focus is on general laboratory equipment, devices common to most laboratories regardless of specialty (eg, centrifuge, fume hood, pipette).

The suggested activities follow the equipment's lifespan. As mentioned, IQ and OQ are not described in this guideline. However, some important equipment-specific considerations for selection, installation, and safety are discussed.

1.2 Background

Most examination results reported by laboratories are generated by methods that use common general laboratory equipment. PQ is the process by which the laboratory confirms that the equipment performs as expected and meets the laboratory's specific needs before use for examinations. **NOTE:** Each piece of laboratory equipment needs to have a **written PQ protocol.** See Appendix A1 for information to include in a PQ protocol. In addition, see Appendix A2 for a laboratory equipment PQ checklist and Appendix A3 for a sample equipment PQ form.

After PQ, function checks, calibration verification, and PM are routinely performed to keep the equipment in optimal operating condition and to

3 General Laboratory Equipment

3.1 Autoclaves

Autoclaves use steam under high pressure to sterilize equipment and supplies. In the laboratory, autoclaves are used for sterilizing (eg, instruments, glassware, solutions, or microbiological growth media) and for inactivating known microbial contamination or biohazardous waste. Standard laboratory autoclaves come in a variety of sizes ranging from small, free-standing tabletop units to large-volume, industrial units. Sterilization conditions are achieved by varying the temperature, time, steam generation, and pressure of the autoclave chamber. For steam sterilization, common autoclaving conditions are 121°C (250°F) at 100 kPa (15 psi) for a minimum of 15 minutes.[24] To reach ideal sterilizing conditions, a vacuum within the autoclave chamber must be maintained to ensure that all of the air is removed so that target temperatures can be achieved. **NOTE:** A typical autoclave cycle does not inactivate prion proteins because they are resistant to heat, irradiation, and chemicals.[25]

3.1.1 Selection and Installation Considerations

When a new autoclave is selected and installed, specifications that should be considered are:

- Ideally, the autoclave should be in a space separate from other laboratory areas where work is performed.
- The room should have level floors, and the various surfaces should be resistant to high heat and humidity.
- The room should be well ventilated with sufficient space to access the back and sides of the autoclave unit for servicing.
- An electrical outlet with a ground pole and sufficient voltage and current should be used.
- The water supply must meet the quality, volume, and pressure needs of the autoclave.
- A drainage system that can withstand high-temperature water is needed.
- Pressure release valves and other safety devices related to superheated steam production should be available and easy to find on the autoclave.
- Some autoclaves require compressed air.

3.3.2 Safety Considerations and Environmental Sustainability Practices

Safety considerations for BSCs are:

- Never modify any portion of the BSC, including utilities.
- Keep laboratory windows closed and minimize opening of doors to ensure negative room pressure to the corridor, if applicable, and proper airflow into the BSC.
- Select PPE based on a risk assessment of the health and physical hazards that could be posed by the material to be used.
- Before use, verify that the sash is open to the proper operating height, which is usually indicated by arrows on the frame.
- Verify that the air gauge indicates the airflow is within the required range.
- Keep the number of materials in the BSC to a minimum. A cluttered work area impedes proper airflow.
- Keep all materials inside the hood at least 4 inches (10.2 cm) from the sash opening.
- Never place one's head inside the hood.
- Perform a surface decontamination to prevent the BSC from releasing contaminants when a spill occurs in the BSC.
- Consider removing UV lamps (found in older models of BSCs), because the lamps might contain mercury. Work should not be performed in the BSC when the UV light is on.
- Ensure flammable, volatile chemicals are **not** used in a BSC. Up to 70% of the air in most BSCs is recycled through the HEPA filter. This feature purifies the air of particles but does not reduce chemicals or gases. Instead, fumes can be **concentrated** in a BSC.

When the BSC is not in use for extended periods, the unit should be turned off when it is determined that doing so will not adversely affect the overall room air balance. If the BSC has been shut down, the blowers should be operated for at least four minutes before work is begun to allow it to purge. This purge will remove any suspended particulates in the BSC.

3.3.3 Performance Qualification

Although PQ for general laboratory equipment is typically performed by laboratory personnel, PQ for BSCs should be performed only by personnel who have received proper training and are certified. PQ on BSCs is typically done by a contracted service provider, although some organizations choose to have their own personnel certified to perform this work. Annual recertification of BSCs is both a manufacturer's requirement and a best practice, as determined by the biosafety community.

950 West Valley Road, Suite 2500, Wayne, PA 19087 USA

P: +1.610.688.0100 **Toll Free (US):** 877.447.1888 **F:** +1.610.688.0700

E: customerservice@clsi.org **www.clsi.org**

PRINT ISBN: 978-1-68440-045-4

ELECTRONIC ISBN: 978-1-68440-046-1