
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.

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.

The Clinical and Laboratory Standards Institute consensus process, which is the mechanism for moving a document through two or more levels of review by the health care community, is an ongoing process. Users should expect revised editions of any given document. Because rapid changes in technology may affect the procedures, methods, and protocols in a standard or guideline, users should replace outdated editions with the current editions of CLSI documents. Current editions are listed in the CLSI catalog and posted on our website at www.clsi.org.

If you or your organization is not a member and would like to become one, or to request a copy of the catalog, contact us at:

P: +1.610.688.0100 **F:** +1.610.688.0700 **E:** customerservice@clsi.org **W:** www.clsi.org

Copyright ©2019 Clinical and Laboratory Standards Institute. Except as stated below, any reproduction of content from a CLSI copyrighted standard, guideline, derivative product, or other material requires express written consent from CLSI. All rights reserved. Interested parties may send permission requests to permissions@clsi.org.

CLSI hereby grants permission to each individual member or purchaser to make a single reproduction of this publication for use in its laboratory procedures manual at a single site. To request permission to use this publication in any other manner, e-mail permissions@clsi.org.

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

SAMPLE

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

Abstract	i
Committee Membership	iii
Foreword	ix
Chapter 1: Introduction	1
1.1 Scope	2
1.2 Background	2
1.3 Standard Precautions	3
1.4 Terminology	3
Chapter 2: Processes in the Equipment Lifespan	9
Chapter 3: General Laboratory Equipment	13
3.1 Autoclaves	14
3.2 Balances and Scales	19
3.3 Biological Safety Cabinets	22
3.4 Centrifuges	28
3.5 Fume Hoods	33
3.6 Heat Blocks and Hot Plates	37
3.7 Incubators	39
3.8 Labware Washers	44
3.9 Microscopes	48
3.10 Osmometers	52
3.11 Ovens	56
3.12 pH Meters	59
3.13 Pipettes and Liquid Handling Instruments	62
3.14 Refractometers	66
3.15 Refrigerators and Freezers	70
3.16 Rotators, Shakers, and Vortex Mixers	75
3.17 Slide Stainers	78
3.18 Thermometers	82
3.19 Timers	84
3.20 Water Baths	86
Chapter 4: Moving Equipment Within the Laboratory	91
Chapter 5: Equipment Adverse Incident Reporting	93
Chapter 6: Equipment Decommissioning	95

Contents (Continued)

Chapter 7: Conclusion	99
Chapter 8: Supplemental Information	101
References	102
Additional Resource	106
Appendix A1. Information to Include in a Performance Qualification Protocol.....	107
Appendix A2. Laboratory Equipment Performance Qualification Checklist	108
Appendix A3. Laboratory Equipment Performance Qualification Form	110
Appendix B1. Autoclave Verification by Biological Indicator Testing	112
Appendix B2. Spore Results Log for Autoclave Sterilization Verification.....	114
Appendix B3. Autoclave Function Check and Preventive Maintenance Summary Sheet.....	115
Appendix B4. Autoclave Operation Log	116
Appendix B5. Autoclave Maintenance Log	117
Appendix C1. Balance Calibration Procedure	118
Appendix C2. Balance Calibration Log.....	119
Appendix C3. Balance Repeatability Testing.....	120
Appendix C4. Balance Verification Log for Repeatability Testing.....	121
Appendix C5. Balance and Scale Operation Log	122
Appendix C6. Balance and Scale Maintenance Log	123
Appendix D1. Biological Safety Cabinet Drip or Drain Pan Cleaning	124
Appendix D2. Biological Safety Cabinet Operation Log.....	125
Appendix D3. Biological Safety Cabinet Maintenance Log.....	126
Appendix E1. Centrifuge Operation Log.....	127
Appendix E2. Centrifuge Calibration Verification Log	128
Appendix E3. Centrifuge Maintenance Log	130
Appendix F1. Fume Hood Operation Log.....	131
Appendix F2. Fume Hood Maintenance Log.....	132
Appendix G1. Heat Block and Hot Plate Daily Temperature Log	133
Appendix G2. Heat Block and Hot Plate Maintenance Log	134
Appendix H1. Incubator Temperature Mapping Procedure	135
Appendix H2. Incubator Temperature Mapping Log	136
Appendix H3. Incubator Maintenance Log	138
Appendix I1. Detergent Residue Test for Labware Washer.....	140
Appendix I2. Detergent Residue Test Results Log	142

Contents (Continued)

Appendix I3. Labware Washer Maintenance Log	143
Appendix J1. Ocular Micrometer Calibration	145
Appendix J2. Microscope Ocular Micrometer Calibration Log	147
Appendix J3. Microscope Maintenance Log	148
Appendix K. Freezing Point Osmometer Maintenance Log	150
Appendix L1. Dry Heat Oven Sterilization Verification Log	153
Appendix L2. Dry Heat Oven Temperature Verification Log	154
Appendix L3. Dry Heat Oven Maintenance Log	155
Appendix M1. pH Meter Calibration Procedure	156
Appendix M2. pH Meter Calibration Verification	158
Appendix M3. pH Meter Performance Qualification Summary	159
Appendix M4. pH Meter Calibration Log	161
Appendix M5. pH Meter Maintenance Log	162
Appendix N1. Proper Pipetting Technique	164
Appendix N2. Pipette Calibration by the Gravimetric Method	165
Appendix N3. Pipette Maintenance Log	167
Appendix O1. Refractometer Calibration and Quality Control Procedure	168
Appendix O2. Refractometer Verification Log	170
Appendix O3. Refractometer Maintenance Log	172
Appendix P1. Refrigerator and Freezer Temperature Mapping Procedure	174
Appendix P2. Refrigerator and Freezer Daily Temperature Verification Log	175
Appendix P3. Refrigerator and Freezer Maintenance Log	176
Appendix Q. Rotator, Shaker, and Vortex Mixer Maintenance Log	177
Appendix R. Slide Stainer Maintenance Log	178
Appendix S. Thermometer Verification Log	181
Appendix T1. Timer Verification by the Direct Comparison Method	182
Appendix T2. Timer Verification Log	183
Appendix U1. Water Bath Temperature Verification Log	184
Appendix U2. Water Bath Maintenance Log	185
Appendix U3. Water Bath Cleaning Log	187
Appendix V. Equipment Reverification Checklist	188
Appendix W. Equipment Decommissioning Plan	190
Appendix X. Hazard Analysis Checklist	191

Contents (Continued)

Appendix Y. Equipment Decontamination Label Template	192
The Quality Management System Approach	194
Related CLSI Reference Materials	196

SAMPLE

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.

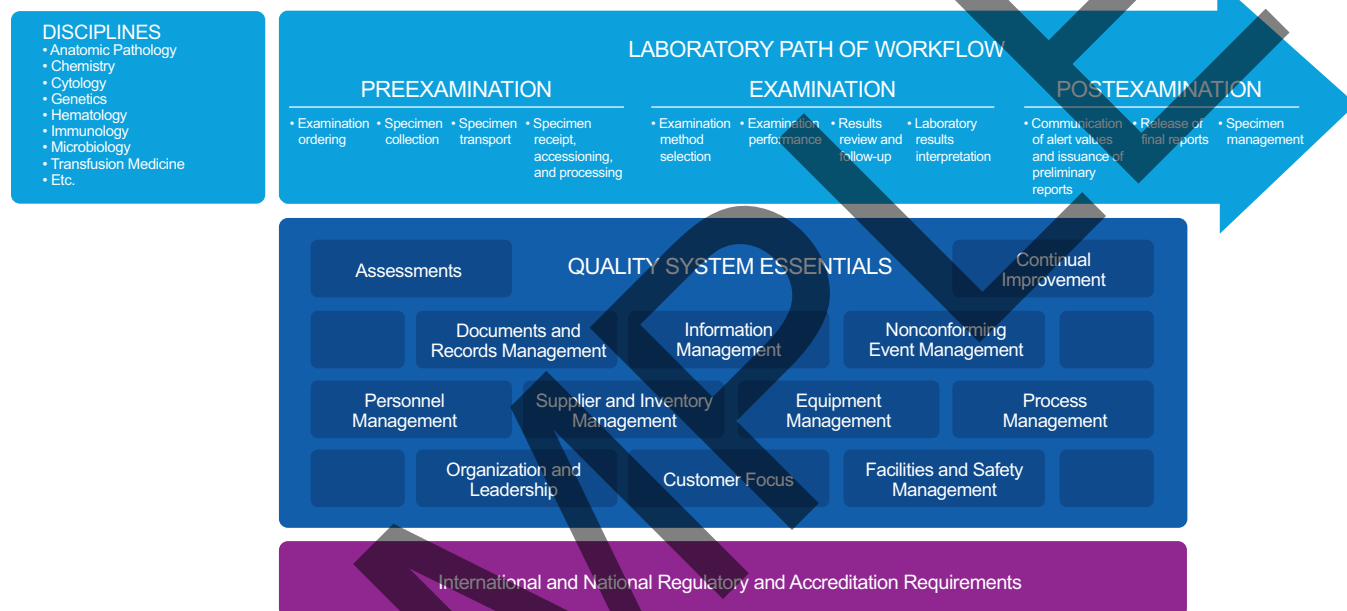


Figure 1. The QMS Model for Laboratory Services (see CLSI document QMS01¹). The 12 QSEs are building blocks necessary to support any laboratory's path of workflow. This figure represents how the 12 QSEs support a medical laboratory's disciplines and stages of examination.

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 QSEs²
- Requirements for both quality management and technical operations of testing and calibration laboratories³
- Standards for quality management and technical operations in the medical laboratory environment⁴

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

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

NOTE:

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

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.

Discover How CLSI Can Improve Your Organization



The leading source for the latest medical laboratory standards.



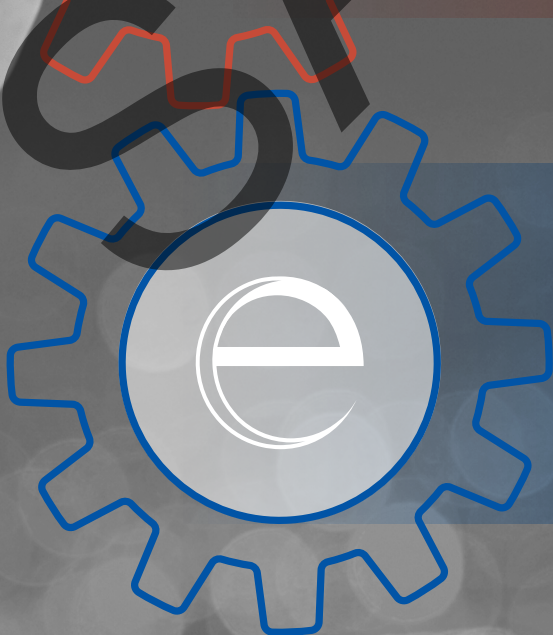
CLSI membership lets you directly impact best practice standards used to improve patient care worldwide—standards you use every day. Membership provides you with standards access, volunteering opportunities, influence in the standards development process, networking opportunities, discounts, and more.

Discover the membership option for you at clsi.org/join.



Our educational and training programs provide convenient, cost-effective continuing education and training resources to help you advance your professional development. We have a variety of easy-to-use, online educational resources and in-person trainings that make learning stress-free and convenient for you and your staff.

See our current offerings at clsi.org/global-training.



Ensure high-quality laboratory testing with CLSI standards. eCLIPSE Ultimate Access™, our complete online library of standards, makes it easy for you and your staff to quickly find the CLSI resources you need. Read, search, link, annotate, bookmark, and share notes with your staff, all within one easy-to-use platform.

Learn more at clsi.org/eCLIPSE.

SAMPLE



CLINICAL AND
LABORATORY
STANDARDS
INSTITUTE®

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