

Equipment and Calibration

APHL Quality Management System (QMS) Competency Guidelines

This course will help staff understand what ISO/IEC 17025 requires for equipment, including which equipment to calibrate and verify, and what records to keep.

Objectives:

1. Participant will learn what ISO/IEC 17025:2017 says about equipment and calibration
2. Participant will learn what documentation is required in regards to equipment and calibration

What is calibration? A response to a known value which establishes a relationship between the known value and an indicator and established tolerance

Public health laboratory competency guidelines:

Quality Management System (QMS) domain

QMS 3.00. Facilities and safety: ensures that the laboratory's physical environment, maintenance, and safety programs* meet applicable requirements

QMS 6.00. Laboratory equipment: ensures that laboratory equipment selection, installation, use, maintenance, and troubleshooting meet performance standards

QMS 6.01. Acquisition and decommissioning

QMS 6.02. Equipment qualification plan

QMS 6.03. Maintenance process

QMS 6.04. Instrument and equipment calibration

General (GEN) domain

GEN 1.00. General technical and laboratory practice knowledge: demonstrates general knowledge and skills related to the scientific and technical components of laboratory testing

GEN 1.05. Troubleshooting

Some questions to ask:

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- Is there a system with a procedure on commissioning equipment, verifying its performance and calibration prior to use?
- What is the plan/procedure for continuing calibration and verification of the equipment's performance?
- Are there records that show the continuing calibration and verification is ongoing on regularly scheduled intervals?
- Are there labels that a user may see immediately to determine the status of the regular checks and calibrations?



GEN 3.00. Equipment use: adheres to policies and principles regarding the use, maintenance, and calibration of laboratory equipment

GEN 3.01. Equipment operation

GEN 3.02. Equipment maintenance

GEN 3.03. Instrument and equipment calibration

GEN 3.04. Preventive maintenance and calibration records

Safety (SHC) subdomain: Hazard control

SHC 5.00. Preventive maintenance: conducts regular maintenance to ensure effective functioning of laboratory equipment* and to extend the life of equipment

SHC 5.01. Planned maintenance

SHC 5.02. Corrective maintenance

Microbiology (MCB) domain

MCB 6.02. Proficiency testing (PT) and alternative assessment: Performs PT and alternative assessment

Chemistry (CHM) domain

CHM 4.00. Examination: performs chemistry examination procedures

CHM 4.04. Equipment troubleshooting

Terms and Acronyms

Calibration-the comparison of two measurement devices or systems (one of known uncertainty (your standard) and one of unknown uncertainty (your test equipment))

NIST-National Institute of Standards and Technology

Quality Critical Equipment-Those items of equipment necessary to perform a test and which have a significant effect on the uncertainty of measurement of test results

SOP-Standard Operating Procedure

Traceability-the property of a measurement result whereby the result can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty

Traceability to the SI (International System of Units)-metrological traceability to a measurement unit of the International System of Units. Test equipment calibration is not traceable to the US National Institute Standard of Technology (NIST), but to the SI through NIST



