ACCREDITATION UNIT

POLICY ON TEST & MEASURING EQUIPMENT DOCUMENTATION

Purpose

This policy is based on the requirements for the qualification of equipment for use in testing laboratories. It is based on the ISO/IEC 17025 requirements as well as GLP/GMP.

All procedures for calibration and testing should follow policies established by the legal bodies for each application. Procedures for Equipment Qualifications are described by the manufacturers SOP (Standard Operating Procedures) and are specific to meet the specifications of their equipment. When such SOPs are not available, the laboratory should establish his own SOPs.

Scope:

This policy document is intended to explain the concept of Equipment Qualification, how it can be achieved, and how it can be demonstrated. Accreditation Unit (AU) requirements pertaining to Equipment Qualification are described. This document is intended for all AU accredited and enrolled calibration and testing laboratories.

Authorship

This publication has been written by the Technical Committee, and approved by the Accreditation Director.

Official language

The text may be translated into other languages as required. The English language version remains the definitive version.

Copyright

Further information

This policy is mandatory for laboratories, and shall be implemented within four months from its issuance date.

For further information about this publication, kindly contact AU.

This document is also available at our web site where you can check updates directly.

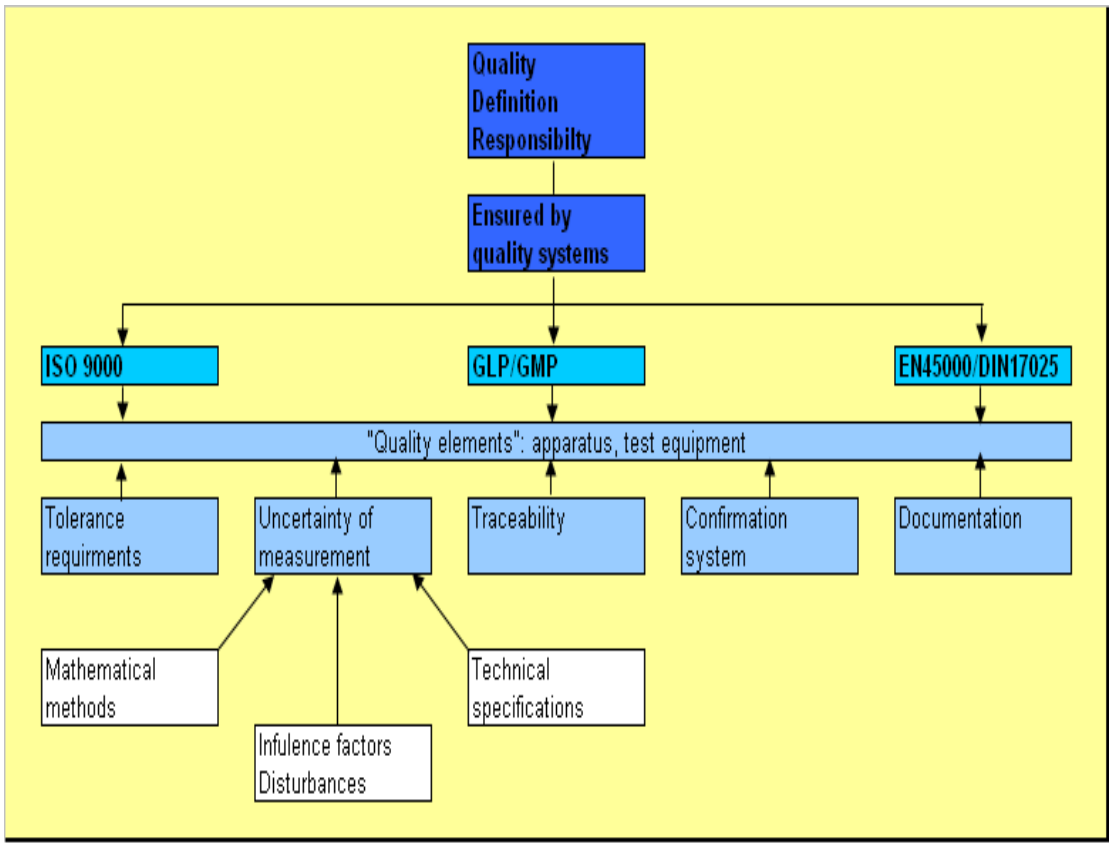
Contents

1 Introduction

The use of inspection, measuring and test equipment in a quality management system requires a detailed description and documentation of the results of measurements and of confirmation. Processes and standard operating procedures must have traceable documentation and must be kept in files.

Such requirements can be compiled in an equipment/instrument logbook which is intended to ensure compliance with the standards and requirements derived from different quality systems, such as GLP/GMP, ISO9000, ISO14000, ISO/IEC17025 to name few.

The equipment/instrument logbook will help the user to document all activities involving the qualification and monitoring of testing equipment/instruments in routine operation. It will also serve as a basis for daily work using the equipment/instruments and scales, and provides the required proof of compliance for inspections and audits.



2 Terminology

Equipment Qualification

Equipment Qualification is subdivided into 5 sections:

1. Design Qualification:	DQ
2. Installation Qualification:	IQ
3. Operational Qualification:	OQ
4. Performance Qualification:	PQ
5. Maintenance Qualification:	MQ

1- Design Qualification (DQ)

In design qualification, the user defines his/her requirements for the test or measuring equipment. Parameters, such as accuracy, method of measurement, and requirements on the supplier that relate to design validation or services, must be defined and documented before purchasing (procurement). The purpose of design qualification is, to ensure that the measuring equipment is suitable for the particular application.

Design qualification is not part of the equipment/instrument logbook, which can only provide information and suggestions that should be considered when selecting a testing equipment/instrument. The requirements for measuring equipment in the International Standard ISO 10012, which are rather specific in most instances, can be taken as a basis. This Standard can be used to compile a short list of measures to be taken within the scope of using measuring instruments to meet the basic requirements.

Because of various influential factors, every measured result has a specific degree of uncertainty. Therefore, the selection of a suitable measuring instrument must be based on answering the question of how great the measurement uncertainty may be to allow reliable evaluation of the measured results (compliance with the required tolerances). A good approach to answer this question is to apply the “Golden Rule” of metrology that says that: the measurement uncertainty of a measuring device may only be 1/10 of the tolerance of the measured values. For economical reasons (frequency of use in relation to investment volume), this ratio can be reduced to 1/3 if these tolerances are met through suitable, supportive measures (frequency of testing).

The basis for the selection of a measuring instrument is provided by the manufacturer’s technical specifications; such as repeatability, linearity or temperature coefficient. Besides these instrument parameters; additional factors that may affect the results of a measurement must be considered. These include the ambient conditions at the place of measurement, qualification of the operator, test object and test procedure.

2- Installation Qualification (IQ)

Installation qualification describes start-up and the detailed sequence of setting up the measuring equipment/instrument. Special attention must be paid to the completeness and correct installation of the equipment supplied.

The most important influences for the equipment/instrument are usually described in the installation/operational manual. Such influences should be taken into consideration at the place of installation, for example: gravitational acceleration, mechanical disturbances, temperature, humidity and barometric pressure, as well as electromagnetic radiation, whether or not caused by electricity flowing through the power cord. Environmental, such as disposal of waste or emitted gases and safety aspects should also be taken into consideration to insure the welfare of the operator and equipment/instrument.

3- Operational Qualification (OQ)

Operational qualification describes the procedure to test each module at the place of installation to insure that the equipment perform according to its specification. Details for the OQ should be provided by the supplier or prepared in-house based on the equipment/instrument specification parameters. Adequately trained personnel must test the equipment/instruments using the corresponding auxiliary test equipment and/or reagents and standards that have the appropriate accuracy. In addition, the test results must be documented in a calibration certificate or test report of the equipment. This testing must be performed at established intervals (known as “intervals of confirmation”).

4- Performance Qualification (PQ)

All manufacturers’ specifications refer to nearly ideal measurement conditions as recommended in the installation and operating instructions. In practice, however, operators frequently operate equipment under conditions that differ from these. Therefore, performance qualification requires verification that measuring equipment functions as intended in its normal operation environment.

Device Qualification/ Final Report

Once all qualification procedures described above have been successfully performed and the adequate performance of the measuring equipment has been verified; device qualification along with a final report is completed.

5- Maintenance Qualification (MQ)

The maintenance of the equipment should be clearly defined and should describe the procedures and frequency of the instrument periodic preventative maintenance and calibration.

3 Responsibilities

This section describes the different phases of the equipment qualifications starting from the manufacturing until its final destination at the testing facility. The tasks are defined and allocated for each party.

Qualification	Phase	Responsibility	Activities	Manufacturer contribution
SQ Specification Qualification	Device Development	Manufacturer (Development)	Device development under Defined Regulations	- Manufacturer certification according to a QM system; i.e. ISO… - The device development is carried out in defined steps and is documented in details.
CQ Construction Qualification	Device Production and Manufacturer Tests	Manufacturer (Production)	Device production and tests under defined quality regulations	- During production and testing of the device; the regulation of the QM system are strictly followed. - Test certificates of the manufacturer.
DQ Design Qualification	Requirement Description and Selection of the device	User	- Description of the requirements of the test equipment - Selection of a suitable test equipment	- Technical advice by the manufacturer - Technical device description (data sheet)
IQ Installation Qualification	Device Installation and Initial operation	User	Documented device installation and initial operation	- Installation instructions - professional installation and initial operation by the manufacturer personnel - Documentation of the device settings
OQ Operational Qualification	Check of the device at the place of installation	User	Initial checking of the device with the issue of a suitable calibration certificate based on the test protocol	- Checking of the device - Issue of suitable calibration certificate based on the test protocol - Instruction of the personnel
PQ Performance Qualification	Checking the Device under user Conditions	User	Checking the device overall function under the user conditions	Professional and documented device checking according to the guidelines set by the manufacturer
Routine Test	Device	User	Periodical	-Calibrated tools and

Qualification	Phase	Responsibility	Activities	Manufacturer contribution
	testing According to defined standards		calibration and adjustments if necessary	certified standards and reagents - Device logbook with SOP
MQ Maintenance Qualification	Maintenance and checking of the device	User	Periodical maintenance with the issue of a calibration certificate based on a test protocol	- Maintenance contracts - Qualified maintenance and checking of the device - Issue of suitable calibration certificate based on the test protocol
RQ Repair Qualification	Malfunctions and Repairs	Supplier and/or user	Documented maintenance, repair and placing the instrument out of order	- Original spare parts - Qualified repair by the manufacturer personnel - Appropriate disposal

Notes:

* SQ and CQ are not part of the logbook
* Calibration of the device should be performed according to acceptable QM Systems.
* Manufacturer contributions can be performed by both manufacturer personnel of qualified service personnel by the representative of the later.
* All calibration tools and standards must be traceable to official accredited bodies to insure the integrity of the tests.

4 Policy

Maintaining the Documents

For each piece of equipment used for testing, all related documents should be properly maintained. Documents should be filed in accordance with the following guidelines to insure the proper access by inspectors and auditors.

For instruments supplied prior to the establishment of a Quality System and Accreditation, the logbook should be filled with the already available documents. New additions will be properly maintained starting with the calibration of the device.

The required documents may differ from one device to the other and mostly on the requirements of the QM system.

Subject	Element	Sub Element
Introduction	EQ Cover page	
	Content	
	Service-Balance/Scale Logbook	
Design Qualification	Commercial Documents	Project overview
		Order confirmation
		Commercial agreements
	Article Specification	
	Product Data Sheet	
	Dimensions/Drawings	
	Certificates/ Declaration of Conformity	DQD-Certificates
		Other-Certificates
		Manufacturer Declaration
		Declaration of Conformity
		Certificate of Conformity
		Material Documentation/Certificate
		Production Certificate
Installation Qualification	Installation and Operation Manual	
	Spare parts Lists	
	Installation Diagrams	
	Production-Logistics plan	
	Offer: Installations-contract (Service-Pricelist)	
Operation Qualification	Manuals for Applications	
	Definition of Confirmation (test-)intervals	
	Offer for Op.Training- and Trainings Contract (Service-Pricelist)	
Performance Qualification		
Repair Qualification	Service price list	
Maintenance Qualification	Offer of Service-Maintenance contract	Backup plans for instruments out of service pending repair

5 References

[1] Balances and Scales in Quality Management System, 1998.

[2] Good Manufacturing Practices, EU 1989.

[3] ISO 9001 – Section: 4.11.