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QUALIFICATION OF EQUIPMENT
CORE DOCUMENT

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Note: Mandatory requirements in this guideline and its annexes are defined using the terms "shall" or "must". The use of "should" indicates a recommendation. For these parts of the text other appropriately justified approaches are acceptable. The term "can" indicates a possibility or an example with non-binding character.

Introduction

The standard ISO/IEC 17025 requires that a laboratory shall have access to equipment that is required for the correct performance of laboratory activities. In particular, calibration programmes shall be established, reviewed and adjusted, including intermediate checks to maintain confidence in the calibration status.

In order to guarantee harmonised interpretation and application of ISO/IEC 17025 requirements within the OMCL Network, the guideline "Qualification of Equipment" has been elaborated.

This document should be considered as a guide to OMCLs for planning, performing and documenting the equipment qualification process. It contains the general introduction and general forms for Level I (Selection of instruments and suppliers) and Level II (Installation and release for use) of qualification, which are common to all types of equipment.

Level III (Periodic and motivated instrument calibration/checks) and Level IV (In-use instrument checks) qualification requirements can be found in separate equipment-related annexes. Level III and IV of qualification must be carried out according to ISO/IEC 17025. Requirements and (if applicable) corresponding typical acceptance limits (given in bold) should be applied; however, other appropriately justified approaches are acceptable. Exemplary procedures provided in the annexes are not binding. They can be helpful when carrying out the required qualification. Nevertheless, other procedures can be applied depending, for example, on the type/model of the equipment.

If the qualification of equipment is done by the manufacturer or an external service provider, it is the responsibility of the OMCL to make sure that this is in line with the requirements set out in this guideline and in the equipment-specific annexes.

The following four levels of Equipment Qualification should be considered by the OMCLs:

Level I. Selection of instruments and suppliers

The selection and purchase of new instruments shall follow a documented decision process, based on the needs related to the intended use of the instrument.

An example checklist for setting and documenting such specifications and decisions taken is given in Table I.

Level II. Installation and release for use

When receiving an instrument, the OMCL should check its condition and fulfilment of the order, and monitor the installation process in the selected environment. This includes start-up checks and a full qualification (normally carried out by the supplier) which fulfils (at minimum) the requirements given in Level III.

The release for use shall be authorised by qualified staff, in order to verify that the equipment conforms to the requirements. This decision may be based on the documentation provided by the supplier.

An example checklist for documenting the instrument installation and release for use and decisions taken is given in Table II.

Level III. Periodic and motivated instrument checks

When instruments are installed or moved into a new environment, or after significant repair or maintenance operations, a series of calibrations/checks shall be carried out to maintain confidence in the performance of the equipment, according to a defined procedure. Unless defined in the equipment-specific annexes, the frequency of periodic checks shall be based on pre-defined criteria and documented; where adjustments are made, sound scientific justification shall be provided and documented.

Level IV. In-use instrument checks

During the routine use of the instruments, a series of calibrations/checks shall be carried out to maintain confidence in the performance of the equipment and compliance with the system suitability criteria, according to a defined procedure, e.g. specific analytical method, Ph. Eur. chapter/monograph or manufacturer dossier.

In the case of OMCLs performing routine testing (e.g. batch release of vaccines and blood products), the use of control charts can provide supplementary information on equipment performance, which can also be used in this context.

NOTE:

From experience, the terms DQ (Design Qualification), IQ (Installation Qualification), OQ (Operational Qualification) and PQ (Performance Qualification) (not explicitly mentioned by ISO/IEC 17025) have been used in a non-harmonised way by the OMCLs. Therefore these terms have not been used in this document. This does not exclude their use in OMCL quality systems.

List of instrument-related annexes

The qualification levels dealt with in each annex are indicated in brackets.

- Annex 1: Qualification of HPLC equipment (Levels III and IV)
- Annex 2: Qualification of GC equipment (Levels III and IV)
- Annex 3: Qualification of UV-Visible spectrophotometers (Levels I, III and IV)
- Annex 4: Qualification of IR spectrophotometers (Levels I, III and IV)
- Annex 5: Qualification of automatic titrators (Levels III and IV)
- Annex 6: Qualification of piston pipettes (Levels III and IV)
- Annex 7: Qualification of mass spectrometers (Levels III and IV)
- Annex 8 : Qualification of balances (Levels I to IV)
- Annex 9: Calibration/qualification of pH meters (Levels I to IV)
- Annex 10: Qualification of Atomic Absorption/Atomic Emission Spectrometers (Levels III and IV)

The list of annexes included in this document will be updated as soon as new annexes are issued.

TABLE I

Level I. Selection of instruments and suppliers

Example of checklist (non-exhaustive)

Manufacturer:

Provider/Distributor:

Name of instrument and type:

Attribute (This list may be adapted if necessary)	**Specifications**	**Benefits (Instrument/supplier)**	**Assessment**	
			Pass	**Fail**
Technique				
Communication and data handling				
Interface RS232				
Data transfer to spreadsheets				
Compatible with other hard- and software such as LIMS…				
Safety				
Irradiation				
Explosion protection				
Documentation				
Manual (paper copy)				
Handling				
User language				
Service and maintenance				
Services offered				
Warranty				
Support				
Delivery (duration etc.)				
Installation (Service/Laboratory)				
Training (in-house/external courses)				

TABLE I (cont.)

Requirements for media and environment

Cost/Benefit Analysis

Comments/Decisions

Date/Signature:

Date/Signature for approval:

TABLE II

Level II. Installation and release for use

Example of checklist (non-exhaustive)

Name of instrument and type:

Identification code:

Conformity with order (instrument/material/documentation)

Pass	Fail (description of deficiencies)

Check for damage

Pass	Fail (description of deficiencies)

Check of required media supply (connections/environmental conditions)

Pass	Fail (description of deficiencies)

Installation of instrument(s) including possible control modules

Pass	Fail (description of deficiencies)

Performance of start-up checks and diagnostic functions[1]

Pass	Fail (description of deficiencies)

[1] if available

Comments

Where appropriate, raw data are attached to the instrument documentation.

Date/Signature:

Release and authorisation for use: Date/Signature:

Disclaimer:

The present Core Document of the OMCL Guideline "Qualification of Equipment", as well as its annexes, have been drafted by ad-hoc working groups of technical experts, mainly from Official Medicines Control Laboratories (OMCLs) and only occasionally from other public institutions. These working groups do not include any representative from any commercial organisation.

This Core Document and its Annexes may contain trade names of laboratory instruments, materials and/or reagents. These are exclusively given as examples in order to make these guidelines easier to understand and implement, and were found to be suitable when the guideline was being developed. These references do not in any way imply that the mentioned instruments, materials or reagents, or their suppliers, are especially endorsed, recommended or certified by the EDQM, the OMCL Network or the Council of Europe, in preference to others of a similar nature which are not mentioned. It is therefore acceptable to use instruments, materials and reagents from another source, provided that they fulfil the necessary criteria laid down in these documents and appropriately satisfy the needs of the laboratories concerned in the frame of their specific activities.