OMCL Network of the Council of Europe
QUALITY MANAGEMENT DOCUMENT

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QUALIFICATION OF EQUIPMENT
CORE DOCUMENT

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Introduction

The standard ISO/IEC 17025 requires an appropriate choice and qualification of equipment to be used for testing purposes. Particularly, checks and calibrations before and during use and, if needed, intermediate tests (see ISO/IEC 17025 chapter 5.5.10) are necessary.
In order to guarantee a harmonized interpretation and application within the OMCL Network, the guideline « Qualification of Equipment » has been elaborated.

From experience, the terms DQ, IQ, OQ and PQ (not explicitly mentioned by ISO/IEC 17025) have been used in a non-harmonized way amongst the different OMCLs. Therefore their mention has been avoided in this document. This does not exclude their use in OMCL's quality systems where already approved and in application, or a reference to literature using this nomenclature.

In order to simplify the management of the guideline, the present document contains only the general introduction and the first two levels of qualification, which are common to all type of equipment. The third and fourth levels of qualification can be found in separate instrument-related annexes. When considered appropriate, additional requirements and/or examples related to Level I and/or Level II have also been included in the annexes, which are to be used in combination with the general recommendations given in the core document.

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

This document should be considered as a guide to OMCLs for planning, performing and documenting the equipment qualification process. It should not be taken as an exhaustive list of compulsory tests. It is left to the professional judgement and background experience of each OMCL to decide on the most relevant tests and the most appropriate tolerance limits for each of the parameters, in order to give evidence that the instrument is working properly and is appropriate for its intended use.

If the qualification of equipment is done by the manufacturer itself or an external service, it is under the responsibility of the OMCL to make sure that the checks performed are in line with the minimum requirements set in this guideline.

To facilitate the implementation of a documented qualification process for the various analytical instruments, specific recommendations on minimum requirements are given in the corresponding annexes.

For the more technique-related aspects of equipment qualification checks, practical examples of possible approaches are also presented in the 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 conscious decision process, based on the needs related to the intended use of the instrument.
An example 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 that it is received in good conditions, as ordered, and should monitor and document the installation process of the instrument in the selected environment. This includes the start up checks done by the supplier, followed by a full periodic check as described in Level III.
The release for use shall be documented and authorised by the person responsible for the instrument.
An example 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 a series of checks have to be carried out to verify the key performance parameters of the instrument avoiding additional contributory effects from the analytical method. Depending on the frequency of use and the experienced stability of the instrument this shall be repeated periodically.
The same verifications (or a relevant part of them) shall be carried out following events like significant repair or maintenance operations.

Examples of parameters to be checked on instruments and their typical acceptance limits can be found in the Table III of the corresponding instrument-related annex.
The specifications from the manufacturer of the instrument should be taken into account when setting the tolerance limits.

Some examples on how these checks may be performed on each type of instrument are also provided in the corresponding Annexes.

Level IV. In-use instrument checks

During the day-to-day use of the instruments, checks are necessary to demonstrate continued evidence of satisfactory performance by the instrument itself and compliance with the system suitability criteria as defined in the applied analytical procedure for each product or group of products tested at this occasion.

Examples of parameters to be checked on instruments and their typical acceptance limits can be found in the Table IV of the corresponding instrument-related annex.

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

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)

TABLE I

Level I. Selection of instruments and suppliers

Example of check-list (non-exhaustive)

Manufacturer:

Provider/Distributor:

Name of instrument and type:

Attribute (This list may be adapted if necessary)	**Specifications**	**Benefits (Instrument/supplier)**	**Assessment**	
			Pass	**Fails**
Technique				
Communication and data handling				
Interface RS232				
Data transfer to spread sheets				
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 check-list (non-exhaustive)

Name of instrument and type:

Identification code:

Conformity with order (instrument / material / documentation)

Pass	Fails (description of deficiencies)

Check of damages

Pass	Fails (description of deficiencies)

Check of required media supply (connections / environmental conditions)

Pass	Fails (description of deficiencies)

Installation of instrument(s) including possible control modules

Pass	Fails (description of deficiencies)

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

Pass	Fails (description of deficiencies)

[1] if available

Comments

When 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 all its Annexes, have been drafted by ad-hoc working groups of technical experts, mainly coming 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 example 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 imply in any way 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 concerned laboratories in the frame of their specific activities.