

# OMCL Network of the Council of Europe QUALITY MANAGEMENT DOCUMENT

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## QUALIFICATION AND REQUALIFICATION OF ANALYSTS

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## QUALIFICATION AND REQUALIFICATION OF ANALYSTS

### Introduction

The present document should be used as a possible approach for dealing with the qualification, requalification and maintenance of the qualification of personnel within an OMCL.

This document covers only the technical qualification of permanent and contractual personnel which is working in the laboratory.

### ISO/IEC 17025 background

The ISO/IEC 17025 standard includes several requirements concerning this issue.

The main reference chapters are: 5.2.1, 5.2.2 and 5.2.5.

The ISO/IEC 17025 claims that “The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates”<sup>1)</sup>.

Therefore, the OMCL is obliged to provide internal and/or external training.

According to the ISO/IEC 17025, the OMCL should also measure the effectiveness of training actions.

To manage the competences linked to the individual employee, a list of competences should exist in the OMCL Quality Management System.

Principally, there are 4 types of situations where qualification is needed:

#### 1) New personnel:

Before recruiting new employees, a description of the needed qualification and education for this post, based on the job description, should be established.

After the new staff member has entered the organisation, a personal training plan is determined based on the employee’s skills, knowledge and past experience.

This personal training plan includes:

- definition of the targets of the training (methods or part of methods and/or techniques),
- time schedule,
- clear definition of the conditions for successfully completing the training for each specific part,
- responsible person for each specific part of the training,

- responsible person for the approval of each particular part of the training,
- responsible person for the approval of the whole personal training program.

The training could be divided in two parts:

- First part: covering general training issues (e.g. global safety in laboratory, ...),
- Second part: covering specific requirements for the post.

Successful completion of the training can be achieved either by:

- passing an exam,
- performing tests under surveillance of a senior analyst, or
- performing an internal PTS (with predefined acceptance criteria)

(It is improper to perform an external PTS (e.g. EDQM PTS) for this purpose)

After the proof of competence the employee should be officially informed about the new competence and responsibilities in a documented way. The employee's name should be added to the list of competences.

## **2) Members of the OMCL who change or enlarge duties:**

A personal training plan is established as per paragraph 1) and is based on the past experience and competencies of the employee. In this case, only specific parts of the training could be included in the plan and have to be successfully completed.

## **3) Maintaining and proving the qualification of personnel:**

The OMCL should have a procedure, which defines the need for requalification and the minimal intervals depending on the complexity of the individual technique to keep the particular staff member qualified.

There are some possible approaches:

- Participating in external PTS, which has the advantage of getting a measureable result of the competence.

Due to the fact that the number of PTS is limited, it is not likely that this approach covers the needs of one entire OMCL.

- Perform internal PTS with samples that have been analysed before by another qualified analyst.

In this case, acceptance criteria have to be predefined.

- A valuable tool for proving (not for maintaining) the qualification of personnel is of course the failure management system.

One good way to keep the qualification of staff is to merge the failure management system with the frequency of performing a test.

If a staff member performs a test frequently (this activity has to be documented) and there is no issue from the failure management system, the qualification can be considered as sustained.

In this case, a minimal frequency for performing the test has to be defined (e.g. a minimum of X analysis per year that have to be performed by an analyst in order to keep his/her qualification).

#### **4) Loss of qualification**

If the qualification is lost, a new qualification plan and process like the approach for qualifying members of the OMCL who change or enlarge duties has to be established and the qualification has to be successfully passed through. Under special circumstances the qualification process can be shortened, if justified.

#### **Planning, reviewing and documenting qualification activities**

All qualification activities have to be planned and reviewed periodically.

The review and detection of the need of new and/or additional qualification can be performed during an appraisal interview, if it is done periodically.

The documentation of the qualification activities has to be stored (preferably in the personnel file of the employee).