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QUALIFICATION AND RE-QUALIFICATION OF PERSONNEL INVOLVED IN LABORATORY ACTIVITIES

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N.B. This OMCL Quality Management System document is applicable to members of the European OMCL Network only. Other laboratories might use the document on a voluntary basis. However, please note that the EDQM cannot treat any questions related to the application of the documents submitted by laboratories other than the OMCLs of the Network.

QUALIFICATION AND RE-QUALIFICATION OF PERSONNEL INVOLVED IN LABORATORY ACTIVITIES

Note: Mandatory requirements in this guideline 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

Qualification and re-qualification of all personnel involved in laboratory activities are critical aspects, which contribute to ensuring the validity of results. This document describes how to manage the qualification of new personnel in the different phases as well ensuring maintenance of competences and the steps to be undertaken to re-qualify personnel after e.g. long absence.

This document covers not only the technical qualification of permanent and contractual personnel, which is working in the laboratory, but also qualification of all personnel involved in activities that can have influence on the validity of results.

ISO/IEC 17025:2017 background

The ISO/IEC 17025:2017 standard includes several requirements concerning this issue.

The main reference chapters are 6.2.1, 6.2.2, 6.2.3, 6.2.4 and 6.2.5.

The ISO/IEC 17025:2017 claims "All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall act impartially, be competent and work in accordance with the laboratory's management system."

Furthermore, "The laboratory shall document the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience."

Functions influencing the results of laboratory activities can be included in the following groups (can be adjusted as best fits for the laboratory):

Group 1: Analyst, laboratory technician – responsible for performance of the tests and involved in other laboratory activities such as e.g. monitoring of environmental conditions, qualification of pipettes etc.

Group 2: Supervisor of analysts, Deputy of Supervisor of analysts – responsible for review and/or approval of results, calculation/recalculation, approval of reports/ certificates, monitoring the validity of results etc.

Group 3: Head of the laboratory, other personnel whose activities can influence validity of results – metrologist, function responsible for the management of the quality

system of the laboratory (e.g. quality manager), inspector (if involved in sampling), IT personnel.

Group 4: Supporting personnel – e.g. animal keeper; personnel involved in reception of samples, reference materials and reagents; personnel in wash-rooms; personnel involved in cleaning activities etc.

The competence requirements shall be established and documented for each function in the lab, influencing the results of the lab activities. A list of competences in relation to the functions can be helpful.

According to ISO/IEC 17025:2017, the laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.

Therefore, the OMCL shall ensure that the staff follow internal and/or external trainings and monitor personnel competences (ISO/IEC 17025:2017, clause 6.2.5 f). The OMCL shall record and include information in the Management Review concerning the training (ISO/IEC 17025:2017, clause 8.9.2. o)). The effectiveness of training can be considered in the evaluation of the training plan.

Qualification and re-qualification of personnel

Principally, there are four types of situations where qualification or re-qualification can be needed:

1) New personnel:

After the new staff member has entered the organisation, a personal training plan can be determined based on the employee's skills, knowledge and experience.

This personal training plan can include:

- definition of list of trainings in relation to the function covered by the new personnel (e.g. quality documents such as procedures and instructions, sampling, reception of samples, cleaning rules, methods or part of methods and/or techniques, evaluation of results, calculations, LIMS, metrology…..) time schedule,
- clear definition of the criteria 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 in relation to laboratory activities
    - Laboratory premises,

- global safety in laboratory and laboratory work rules,
- quality management system (procedures and instructions).

- Second part: covering specific requirements for the post in relation to the function and involvement in laboratory activities (e.g. technical).

Depending on the function, successful completion of the training can be achieved e.g. by:

- passing an exam (written/oral),
- performing tests under surveillance of a senior analyst/responsible person (Group 1),
- performing an internal PTS, retesting or recalibration of retained items (with predefined acceptance criteria), inter-laboratory comparisons (Group 1, 2),
- evaluation of results, recalculation and comparison with predefined acceptance criteria or under surveillance of responsible person (Group 2),
- performing practical specific activity under surveillance of responsible person (e.g. management of samples, reagents, reference materials; animal house activities, archiving, integrity of data, sampling, calibration of equipment, monitoring of environmental conditions…).

After the proof of competence the employee shall be informed about the new competence and responsibilities, this can be done in a documented way. The employee's name should be added to the list of competences, if this exists.

2) Personnel who change or enlarge duties:

A personal training plan is established, considering the inputs detailed in paragraph 1), and is based on the past experience and competencies necessary of the employee to carry out a new duty. In this case, only specific parts of the training could be included in the plan and have to be successfully completed.

3) Qualified personnel who needs re-qualification based on the result of the monitoring

If the qualification of the employee was not verified during monitoring, re-qualification should be considered concerning the activity for which the qualification was not maintained. In this case, only specific parts of the training could be included in the plan and have to be successfully completed.

4) Loss of qualification

If the qualification is lost, a new qualification plan and process (e.g. new members of the OMCL) shall be established and the qualification has to be successfully passed. Under special circumstances, the qualification process can be shortened, if justified. A risk-based approach should be defined by the OMCL to establish criteria (e.g. period of time, unsuccessful performance of testing etc.) to evaluate the cases when a staff member has lost the qualification.

Monitoring the qualification of personnel

Monitoring the qualification of personnel means to verify and maintain the qualification for particular competence on regular basis and it should cover monitoring of:

a. Quality management system qualification (applicable to the entire personnel)

- System for nonconforming work

- Successful completion of trainings related to laboratory activities in connection with QMS (management of documents, changes…)

b. Technical qualification

Regarding the technical personnel involved in performance of techniques and evaluation of results of testing, the OMCL shall 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 for monitoring the qualification:

Group 1 (Analysts, laboratory technicians…)

- Participating in external PTS, which has the advantage of getting a measurable 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.

- Periodic evaluation of results obtained for Internal Quality Control or System Suitability samples between analysts.

- A valuable tool for proving (not for maintaining) the qualification of personnel is the system for nonconforming work.

  One good way to keep the qualification of personnel is to monitor the system for nonconforming work in relation to the frequency of performing a test, i.e. in the case that a staff member performs a specific test frequently (this activity has to be documented) and there is no issue from the system for nonconforming work, 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 number of analysis per year that have to be performed by an analyst in order to keep his/her qualification).

- The qualification is kept in case the analyst regularly successfully performs similar testing using techniques as that for which the competence is assessed

(e.g. cell culturing, inoculation of animals, preparation of samples with similar matrix…).

Group 2 (Supervisor of analysts)

- Evaluation of samples/results that have been assessed/calculated before by another qualified person or are available in scientific literature. In this case, the acceptance criteria have to be predefined (photographs of cell cultures with and without CPE, recalculation of statistical data etc.).
- System for nonconforming work in connection with minimal frequency for performing the test/evaluation of results.
- Competent evaluation of results for similar techniques.
- Involvement in validation or qualification of particular methods.
- Active participation in external and internal PTS, which has the advantage of getting a measurable result of the competence.
- Other means (consolidated experience): consideration of education and practice, participation in technical trainings, workshops, conferences...

Group 3 (Other personnel whose activities can influence validity of results)

- System for nonconforming work in connection with specific laboratory activity.
- Consideration of education/practice, participation in specific e.g. legislative or technical trainings, workshops, conferences.

Group 4 (Supporting personnel)

- System for nonconforming work in connection with specific laboratory activity.
- Specific trainings.

Planning, monitoring and documenting qualification activities

All qualification activities shall be planned and monitored which can also be based on the results of risk assessment. The monitoring and detection of the need of new and/or additional competence can be performed regularly e.g. during an appraisal interview.

The documentation of the qualification activities shall be retained (e.g. in the personnel file of the employee).