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GENERAL REQUIREMENTS FOR INFREQUENTLY PERFORMED TECHNIQUES

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General Requirements For Infrequently Performed Techniques

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.

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SCOPE

This document is a guideline intended to support OMCLs in maintaining ISO/IEC 17025 compliance for infrequently (e.g. less than once a year) performed techniques or methods. Throughout this document the term “technique” is used. Techniques may be infrequently used when items for testing are not available for significant periods (e.g. over a year), which may influence the consistent capability of the laboratory to generate valid results.

GENERAL REQUIREMENTS

As stated in the introduction of ISO/IEC 17025:2017 “This document contains requirements for laboratories to enable them to demonstrate that they operate competently, and are able to generate valid results.”

In ISO/IEC 17025:2017, relevant requirements are described in several chapters, including:

- 6.2 Personnel
- 6.4 Equipment
- 7.7 Ensuring the validity of results
- 8.4 Control of records

Detailed descriptions of the clauses and quotations are given in Table 1 in Appendix 1.

The laboratory should identify the impacted technique and define how compliance with the requirements of ISO/IEC 17025 shall be guaranteed, considering the following elements:

1) Competence of management and technical staff: personnel involved in laboratory activities shall have the competence to perform the technique, and to generate and evaluate results in a way that guarantees their validity;
2) Qualification/calibration of the equipment: conformity with the specified requirements (given in the manufacturer's documentation, OMCL Guideline [1] and Annexes, internal laboratory procedures, etc.) shall be verified before use;

3) Generation of valid results: to prove the ability of the laboratory to successfully perform the technique and assure the quality of the results.

In relation to the above-mentioned elements, the following exemplary approaches can be considered:

- Conservative approach:
  - maintain periodic qualification/calibration of the equipment by external or internal service, according to the laboratory qualification plan/procedure;
  - maintain qualification of the technical and management staff, according to the laboratory procedure(s) and the OMCL Guideline [2];
  - generate data by testing of samples (e.g. shared with other laboratories or from Proficiency Testing Schemes (PTS)) or successful performance of the system suitability verification.
- Intermediate approach, e.g.:
  - perform the periodic qualification/calibration of the equipment; and
  - re-qualify the staff and generate results whenever the technique is needed.
- Silent approach (not recommended in general):
  - qualify the equipment and personnel before applying the technique.

A risk-based strategy may be a useful tool to deal with infrequently performed techniques, to address risks and document actions in a proactive manner.
The choice of approach should consider aspects such as risk of not meeting the deadlines agreed with the customer, costs, resources and complexity of the technique.

The frequency of performance of techniques should be monitored to regularly evaluate appropriate measures to maintain the operational confidence in the laboratory activities.
Evaluation of such techniques during internal audits may be considered.

Regardless of the approach, the following elements shall be documented to prove compliance with the requirements of ISO/IEC 17025:2017:

- Staff competence [2]
  - Identify staff with the relevant training and competence for the technique;
  - Consider the minimum reasonable period of time for trained staff to retain competence for the technique;
  - Define criteria for maintaining competence, for example,
    - perform similar techniques regularly,
    - perform the technique periodically,
    - participate in PTS, interlaboratory comparisons, intralaboratory comparison.
- Equipment [1]

  Ensure that the laboratory has access to suitable equipment for the correct performance of the technique:
  - Ensure that suitable reagents, kits, references and controls are available, are not expired and are fit for the purpose;

- Ensure that the laboratory remains aware of changes a manufacturer may make to reagents, kits, software, etc. Ensure that equipment is identified, calibrated and qualified before a test is performed;
- Apply an adapted calibration/qualification programme, as a function of the frequency of use.

o Management of documents and generation of technical records

Quality documents must be up-to-date and technical records established and retained in order to demonstrate fulfilment of the requirements of ISO 17025:2017 for the infrequently performed techniques [3].

REFERENCES

[1] OMCL Guideline *PA/PH/OMCL (08) 73 (current version)* "Qualification of Equipment" Core Document and Annexes

[2] OMCL Guideline *PA/PH/OMCL (20) 95 (current version)* "Qualification and Re-Qualification of Personnel Involved in Laboratory Activities"

[3] OMCL Guideline *PA/PH/OMCL (14) 19 (current version)* "Management of Documents and Records"

APPENDIX 1

Table 1 – Chapters and quotations (full or partial) of the clauses of ISO/IEC 17025:2017 relevant to infrequently performed techniques.

Chapter	Clause
6.2 Personnel	6.2.2 “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.” 6.2.3 “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.” 6.2.5 “The laboratory shall have procedure(s) and retain records for: c) training of personnel; d) supervision of personnel; f) monitoring competence of personnel.”
6.4 Equipment	6.4.4 “The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service.” 6.4.7 “The laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.” 6.4.10 “When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure.”
7.7 Ensuring the validity of results	7.7.1 “The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to: a) use of reference materials or quality control materials; b) use of alternative instrumentation that has been calibrated to provide traceable results; c) functional check(s) of measuring and testing equipment; d) use of check or working standards with control charts, where applicable; e) intermediate checks on measuring equipment; f) replicate tests or calibrations using the same or different methods; g) retesting or recalibration of retained items; h) correlation of results for different characteristics of an item; i) review of reported results; j) intra-laboratory comparisons; k) testing of blind sample(s).” 7.7.2 “The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following: a) participation in proficiency testing; b) participation in interlaboratory comparisons other than proficiency testing.”
8.4 Control of records	8.4.1. “The laboratory shall establish and retain legible records to demonstrate fulfilment of the requirements of this document.”