

Annex 1

Knowledge, competences required for assessors, experts participating in the accreditation of testing, calibrating, medical laboratories and sampling organisations.

- Knowledge of Standard MSZ EN ISO/IEC 17025, knowledge on the fulfilment of its requirements and methodology of testing knowledge, and ability to apply it in practice.
- Knowledge of applicable EA, ILAC mandatory documents, ability to test knowledge of their requirements.
- 5 years' experience in testing in identical technical area, furthermore, testing performed in identical technical area within 2 years preceding appointment as assessor or expert.
- Knowledge of technical terms related to the given testing area and its auditing, and their appropriate application;
- Knowledge of applicable test methods, in details:
 - Knowledge of requirements for the given tests, calibration and surveillance,
 - Knowledge of applicable sampling and sample preparation methods,
 - Knowledge of typical problem areas of tests connected to the accredited area,
 - Knowledge of special external requirements related to the accredited area,
 - Knowledge of applicable assessment methods and their auditing.
- Knowledge in sufficient depth of auditing activities and calibration procedures;
- Suitability to test knowledge in practice of the evaluation of measurement uncertainty estimation;
- Checking the determination of limit of detection (LOD), and limit of quantification (LOQ)
- Interpretation of the analysis of proficiency test results containing:
 - Interpretation of the given values and conformity criteria in all proficiency tests concerned, including inter-laboratory comparisons and measurement checks in order to have the evaluation of the quantity and quality results of laboratories,
 - Use of different types of proficiency tests for accreditation purposes, making laboratory work suitable,
 - Evaluation of proficiency test planning

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Further requirements for medical laboratories

- Knowledge of Standard MSZ EN ISO/IEC 15189, knowledge of the fulfilment of its requirements and methodology of testing that knowledge, and ability to apply it in practice.
- Knowledge of EA, ILAC mandatory documents applicable to auditing medical laboratories, and ability to test knowledge on the requirements.
- Knowledge of technical terms suitable for auditing medical laboratories and their appropriate application;
- Knowledge of the test methods applied in the technical area in the medical laboratory for which the assessor or expert was appointed:
 - Knowledge of calibration and surveillance requirements in relation with medical laboratory tests that are technical requirements,

Further requirements in case of sampling organisations

- Knowledge of NAR-19-IV (Accreditation of organisations performing environmental sampling)

Further requirements in case of calibrating laboratories

- Knowledge of measuring devices, equipment and calibration methods applicable to the given area.
- Knowledge of the International Vocabulary of Metrology (VIM)

Applicable EA, ILAC documents:

- EA-4/16 G EA guidelines on the expression of uncertainty in quantitative testing
- EA-4/18 INF guidance on the level and frequency of proficiency testing participation
- ILAC-P9 Policy for participation in proficiency testing
- ILAC-P10 Policy on traceability of measurement results
- ILAC G17 Introducing the concept of uncertainty of measurement in testing in association with the application of the Standard ISO/IEC 17025
- ILAC G18 Guideline for the formulation of scopes of accreditation for laboratories