FINAS
Finnish Accreditation Service

Principles for the assessment of the quality assurance and proficiency testing practices in laboratories

Policy document A2/2024

12.02.2024

Foreword

The original policy document for FINAS was drawn up by a working group appointed by the Advisory Committee for Accreditation Matters, Subcommittee for Accreditation Matters (VANK-P). The new version A2/2024 replaces the previous version A2/2022. The references have been updated.

The purpose of FINAS policy documents is to clarify the practical application of accreditation requirements. They have been drawn up taking into account the principles agreed within the international cooperation organisations of accreditation bodies (European co-operation for Accreditation (EA), the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF)).

The requirements for accreditation activities are set out in Decision P1. Information on the policy documents and binding guidelines can be found on the FINAS website (www.finas.fi).

Table of contents

1 General principles

The accreditation assessment is carried out to verify the reliability and correctness of a laboratory's results. The laboratory must have procedures for the quality assurance of testing and calibration results to demonstrate the comparability of results. These quality assurance procedures can include participation in proficiency testing (PT) and/or interlaboratory comparisons (ILCs), use of certified reference material, internal comparisons using various testing or calibration methods and laboratory comparisons.

Assessment of the results of PTs and/or ILCs is an essential element of accreditation. Laboratories applying for accreditation are expected to give an account of their participation and success in PTs and/or ILCs in their own scope of accreditation. The comprehensiveness and frequency of PTs and/or ILCs are assessed on the basis of the suitable supply and the practice prevailing in the sector. If PTs and/or ILCs are not available in a certain sector, the laboratory has to prove its competence correspondingly by using other quality assurance procedures. Calibration laboratories have to demonstrate their competence by external PTs and/or ILCs.

The PTs and/or ILCs programmes, in which the laboratory participates, can be provided by national or international providers meeting international criteria (SFS-EN ISO/IEC 17043), or by other providers who are known and respected in their field.

The same principles are also applicable in the assessment of other CABs than laboratories when testing and/or calibration results have essential impact on the result of the activities.

2 Requirements set for the laboratory

1. The laboratory must have a quality assurance programme that includes both a policy for PTs and/or ILCs and a plan for implementing the quality assurance programme. The quality assurance programme should cover the methods under accreditation for a longer period than one year. A recommended term for plan is at least an accreditation period (4 years). The laboratory should evaluate the suitability of its plan's extent annually. This evaluation must cover changes in the operations and the risks related to these changes. The quality assurance programme should also include alternative procedures that the laboratory can use to ensure the correctness of its results if PTs and/or ILCs are not available.

2. The plan and policy for comparisons must cover the laboratory's scope of accreditation including flexible scope if relevant. The plan should contain the principles applied to the selection of the PTs and/or ILCs provider, the selected PTs and/or ILCs, the frequency of participation, the laboratory's own criteria for success as well as implementation of corrective actions, and utilisation of results and corresponding information of alternative procedures if PTs and/or ILCs are not available.

3. Before accreditation, the laboratory must indicate the correctness and comparability of its results by means of PTs and/or ILCs or in some other reliable manner (such as parallel determination with another accredited laboratory) if PTs and/or ILCs is not available. However, a precondition for the accreditation of a calibration laboratory is always that the laboratory primarily participates in proficiency testing arranged by a national or an international standard laboratory.

4. Prior to the assessment, the laboratory shall draw up and submit (annual)summaries of its participation in PTs and/or ILCs to assess the laboratory's participation and success in these PTs and/or ILCs. The summary should include information of the providers and the testing programme in which the laboratory participated, and the laboratory's success and conclusions. The summary should also clarify how and to what extent the PTs and/or ILCs covers the different areas of the scope. The laboratory must document its actions in case it fails to fulfil the criteria set for success.

5. The laboratory's analysis of the results of PTs and/or ILCs , monitoring of result trends and the analysis of causes for deviant results, their impact on operations and the corrective measures are assessed during the assessment visit in addition to the quality assurance programme If the laboratory has not participated in PTs and/or ILCs, alternative means of demonstrating the correctness of the results will be assessed.

6. Repeated success of the laboratory in PTs and/or ILCs is taken into account in the targeting of assessments.

7. If the success do not meet the criteria and the laboratory fails to prove the validity of results with corrective measures or other report, the method in question will be reduced from the scope. The method can be added back into the scope when the validity of the results has been shown.

3 Additional aspects

When preparing a quality assurance programme, the laboratory should take into account the requirements set by different entities for participation in PTs and/or ILCs and the frequency of participation. (legislation, authorities, customers, partners, etc.).

Interlaboratory comparison (ILC): design, performance and evaluation of measurements or tests on the same or similar items by two or more laboratories in accordance with predetermined conditions. ILCs are used to assess the comparability of participants' results.

Proficiency testing (PT): evaluation of participant performance against pre-established criteria by means of interlaboratory comparisons.

A PT is considered available, if it is offered by a competent PT provider and the required documents are provided in the national language of the participating body or a language understood by the CAB and it does not require a development by the PT provider.

A PT and/or ILC can be regarded as technically appropriate, if the scope of activity being provided is similar to the current practice of the accredited CAB. In the case of specific test or measurement techniques, for which no regular PT and/or ILCs is available, it may be adequate to choose a PT and/or ILCs other than PT, which is similar to the scope or which covers an important partial aspect of the activity

4 References

SFS-EN ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories.

SFS-EN ISO 15189:2022 Medical laboratories – Requirements for quality and competence.

SFS-EN ISO/IEC 17043:2023 Conformity assessment. General requirements for proficiency testing.

ISO 20387:2018 Biotechnology - Biobanking - General requirements for biobanking

ISO/IEC 17020:2012 Conformity assessment - Requirements for the operation of various types of bodies performing inspection

ILAC G27:07/2019 Guidance on measurements performed as part of an inspection process

EA-4/02 M:2022 Evaluation of the Uncertainty of Measurement In Calibration

ILAC P9:01/2024 ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing

EA-4/18 G 2021 Guidance on the level and frequency of proficiency testing participation

EA-4/21 INF:2019 Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation

Changes from the previous version

12.02.2024

	Chapter	**Change**
1	General principles	Added PTs and/or ILCs alongside proficiency testing and application of principles to all testing and calibration activities
2	Requirements set for the laboratories	Added PTs and/or ILCs alongside proficiency testing and updated textual outfit. Completed issues to go through during the assessment
3	Additional aspects	Added explanation of differences between PTs and ILCs, as well as availability and technical suitability
4	References	Updated the references