

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

FINAS Finnish Accreditation Service

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Foreword

This FINAS policy document is originally drawn up by a working group appointed by the Advisory Committee for Conformity Assessment Matters, Subcommittee for Accreditation Matters (VANK-P). The new version A2/2020 replaces the previous version A2/2016. Reference to MLAs operation in proficiency testing programmes has been deleted. The reference list has been updated.

The purpose of the policy documents is to clarify the application of accreditation requirements in practice. The policy documents have been drawn up in accordance with principles agreed within the international cooperation organizations of accreditation bodies (European co-operation for Accreditation (EA), the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF)).

FINAS accreditation criteria, policy documents and guidelines are presented in the valid FINAS Leaflet 10.

Further information: www.finas.fi

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1 General principles

When a laboratory is accredited, the reliability and correctness of its results are ensured. The laboratory shall have procedures for the quality assurance of testing and calibration results. These quality assurance procedures can include, but not be limited to: participation in proficiency testing, use of certified reference material, internal comparisons using various testing or calibration methods and inter laboratory comparisons.

Assessment of the results of proficiency testing is an essential element of accreditation. Laboratories applying for accreditation are expected to give an account of their participation and success in proficiency testing in their own scope of accreditation. The comprehensiveness and frequency of proficiency testing are assessed on the basis of the supply of suitable proficiency tests and the practice prevailing in the sector. If proficiency testing programmes are not available in some sector the laboratory has to prove its competence by using other quality assurance procedures.

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

The same principles are used also in the assessment of inspection bodies when testing results have essential impact on the result of the inspection. Legislation may also set requirements for inspection bodies to participate proficiency testing programs.

2 Requirements set for the laboratory

1. The laboratory shall have a quality assurance programme that includes both a policy and a plan for proficiency testing. The quality assurance programme shall cover the operations of the entire laboratory (especially methods encompassed by accreditation) over a longer term. A recommended term for plan is at least an accreditation period (4 years). The laboratory shall yearly evaluate the suitability and extent of its proficiency testing plan. This evaluation shall cover among others changes in the laboratory operations and the risks related to these changes. The quality assurance programme shall also include alternative procedures that the laboratory can use to ensure the correctness of its results if proficiency testing is not available.
2. The plan and policy for proficiency testing shall cover the laboratory's scope of accreditation including flexible scope if relevant. The plan shall contain the principles applied to the selection of the provider, the selected programmes, 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 proficiency testing is not available.
3. Before accreditation, the laboratory shall indicate the correctness and comparability of its results by means of proficiency testing or in some other reliable manner if proficiency testing is not available. However, a precondition for the accreditation of a calibration laboratory is always that the laboratory participates in proficiency testing arranged primarily by a national or an international standards laboratory.
4. Proficiency testing activity is evaluated using laboratory's annual summary that the laboratory has delivered before the assessment. The summary shall include information of the proficiency testing programmes and providers, success of laboratory and conclusions. The summary shall also contain information how and to what extent the proficiency testing programmes cover the accredited scope. The laboratory shall document its actions in case it fails in proficiency testing.
5. Laboratory's analysis of the proficiency testing results, long time follow up and effectiveness of the corrective actions are assessed during the assessment visit.
6. Continuous successful proficiency testing results are taken into account when planning assessment of different methods or techniques during the accreditation period.

7. Results of the proficiency testing are taken into account in the accreditation decision making process. The method in question will be reduced from the scope if the proficiency results do not meet the requirements and the validity of the results has not been proved by laboratory, the method can be added back into the scope when the validity has been shown.

3 Additional aspects

When a laboratory is planning its quality assurance programme including participation and frequency of proficiency testing it should take into account requirements set by legislation, authorities, clients, stakeholders, etc.

In addition to prove its competence, the laboratory can use proficiency test results for development of test methods, training of personnel, calculations of measurement uncertainties and in the risk management.

Further information of proficiency testing and proficiency testing providers is available from the FINAS web pages.

5 References

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

SFS-EN ISO/IEC 15189:2013 Medical laboratories. Requirements for quality and competence.

SFS-EN ISO/IEC 17043:2010 Conformity assessment – General requirements for proficiency testing.

EA-4/02 M:2013 Evaluation of the Uncertainty of Measurement In Calibration

ILAC P9:06/2014 ILAC Policy for Participation in Proficiency Testing Activities

EA-4/18 INF:2010 Guidance on the level and frequency of proficiency testing participation

EA-4/21 INF:2018 Guidelines for the assessment of the appropriateness of small interlaboratory comparisons within the process of laboratory accreditation

Changes to the previous version

Changes 21.04.2020

Chapter	Change
Foreword	Updated
1 General principles	1 -
2 Requirements set for the laboratory	2 -
3 Additional aspects	3 -
4 Proficiency testing pertaining to accreditation	4 Deleted
4 References	4 Updated
Changes to the previous version	Added