

Requirements applied to the accreditation activities

Decision FINAS P1/2024

08.11.2024



Content

1	General	3
1.1	The adoption of assessment criteria	3
1.2	Obligation to meet the requirements	3
1.3	Mandatory guidelines	3
2	Requirements applied to the accreditation activities	3
2.1	Testing and calibration laboratories	3
2.1.1	Clinical laboratories	4
2.2	Certification bodies	4
2.3	Inspection Bodies	5
2.4	EMAS verifiers	5
2.5	Verification organisations	6
2.6	Providers of proficiency testing	6
2.7	Biobanks	6
3	Requirement applied to assessment of competence	6
4	Reference to Accreditation	7
5	Accredited scopes	7
6	Entry into force	8
7	Changes from the previous version	9

1 General

1.1 The adoption of assessment criteria

According to the Act of the Accreditation of Conformity Assessment Services 920/2005 (amendment Act 764/2014) Section 6, Paragraph 1 Finnish Accreditation Service decides on the adoption of assessment criteria after having heard the views of stake holders playing a central role on the accreditation system and conformity assessment services.

1.2 Obligation to meet the requirements

The accreditation system is based on voluntary participation. At their discretion, bodies engaged in testing, inspection, certification, calibration and bi-banking, bodies providing proficiency testing, verifiers may apply for accreditation. The requirements confirmed in this decision are applied when the competence of these bodies is assessed. In accordance with Section 6 of the Act 920/2005 (amendment Act 764/2014), before a body is accredited, it must demonstrate that it meets the requirements confirmed in this decision for the activities in question.

For an accredited body it is mandatory to continuously meet the relevant accreditation requirements. At its discretion, a body may terminate its accreditation.

1.3 Mandatory guidelines

In addition to requirements applied to the accreditation activities set out in paragraph 2, body applying for accreditation or already accredited body must take into account the requirements of international mandatory guidelines in accreditation activities. The mandatory guidelines in accreditation activities are listed on FINAS website.

2 Requirements applied to the accreditation activities

2.1 Testing and calibration laboratories

It is confirmed that the following requirements are applied to the accreditation of testing and calibration laboratories

- standard SFS EN ISO/IEC 17025:2017 Testaus- ja kalibrointilaboratorioiden pätevyys. Yleiset vaatimukset / General requirements for the competence of testing and calibration laboratories.

The standard is available in Finnish and in English.

2.1.1 Clinical laboratories

It is confirmed that the following requirements are applied to the accreditation of clinical laboratories from 1.1.2024

- standard SFS-EN ISO 15189:2022 Lääketieteelliset laboratoriot. Laatu ja pätevyyttä koskevat vaatimukset / Medical laboratories -- Requirements for quality and competence.

The standard is available only in English at the moment.

The standard replaces SFS-EN ISO 15189:2013 (EN ISO 15189:2012). The transition period is until 06.12.2025.

In special cases, like imaging, it is confirmed that the following requirements are applied to the accreditation alternatively

- standard SFS EN ISO/IEC 17025:2017 Testaus- ja kalibrointilaboratorioiden pätevyys. Yleiset vaatimukset / General requirements for the competence of testing and calibration laboratories.

The standard is available in Finnish and in English.

2.2 Certification bodies

It is confirmed that the following requirements are applied to the accreditation of certification bodies engaged in product certification

- standard SFS-EN ISO/IEC 17065:2012 Vaatimustenmukaisuuden arviointi. Vaatimukset tuotteita, prosesseja ja palveluita sertifioiville elimille / Conformity assessment -- Requirements for bodies certifying products, processes and services.

The standard is available in Finnish and in English.

It is confirmed that the following requirements are applied to the accreditation of bodies engaged in the certification of management systems

- standard SFS-EN ISO/IEC 17021-1:2015 Vaatimustenmukaisuuden arviointi. Vaatimukset johtamisjärjestelmiä auditoiville ja sertifioiville elimille. Osa 1: Vaatimukset / Conformity assessment – Requirements for bodies providing audit and certification of management systems. Part 1: Requirements.

The standard is available in Finnish and in English.

It is confirmed that the following requirements are applied to the accreditation of bodies engaged in the certification of personnel

- standard SFS-EN ISO/IEC 17024:2012 Vaatimustenmukaisuuden arviointi. Yleiset vaatimukset henkilöitä sertifioiville elimille / Conformity assessment - General requirements for bodies operating certification of persons.

The standard is available in English.

2.3 Inspection Bodies

It is confirmed that the following requirements are applied to the accreditation of inspection bodies

- standard SFS-EN ISO/IEC 17020:2012 Vaatimustenmukaisuuden arviointi. Vaatimukset erityyppisten tarkastuslaitosten toiminnalle / Conformity assessment – Requirements for the operation of various types of bodies performing inspection.

The standard is available in Finnish and English.

2.4 EMAS verifiers

The following regulation is applied to accreditation and to assessing the competence of EMAS verifiers

- EC No 1221/2009 Regulation of the European Parliament and of the Council allowing voluntary participation by organisations in a Community eco-management and audit scheme (EMAS) and
- standard SFS-EN ISO/IEC 17021-1:2015 Vaatimustenmukaisuuden arviointi. Vaatimukset johtamisjärjestelmiä auditoiville ja sertifioiville elimille. Osa 1: Vaatimukset / Conformity assessment – Requirements for bodies providing audit and certification of management systems. Part 1: Requirements.

The standard is available in Finnish and in English.

2.5 Verification organisations

It is confirmed that the following requirements are applied to the accreditation of verification organisations.

- standard SFS-EN ISO/IEC 17029:2019 Conformity Assessment. General principles and requirements for validation and verification bodies

Standard SFS-EN ISO/IEC 17029:2019 is a generic standard and shall be specified with programme specific requirements. The standard is available in English.

2.6 Providers of proficiency testing

It is confirmed that the following requirements are applied to the accreditation of bodies providing proficiency testing

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

The standard is available in English.

2.7 Biobanks

It is confirmed that the following requirements are applied to the accreditation of biobanks

- standard SFS-EN ISO 20387:2020 Biotechnology. Biobanking. General requirements for biobanking (ISO 20387:2018)

The standard is available in English.

3 Requirement applied to assessment of competence

It is confirmed that the following requirements are applied to assessing the competence

- standard SFS-EN ISO/IEC 17011:2017 Conformity assessment. Requirements for accreditation bodies accrediting conformity assessment bodies.

4 Reference to Accreditation

It is confirmed that the requirements in the following document are applied to using the national accreditation logo and to referring to accreditation performed by the Finnish Accreditation Service

- Requirement FINAS V1 Rules for Reference to Accreditation.

The Rules are based on international documents by

- EA (European co-operation for Accreditation)
- ILAC (International Laboratory Accreditation Cooperation)
- IAF (International Accreditation Forum Inc.).

5 Accredited scopes

The procedures and methods covered by accreditation are defined in accredited scopes as either fixed or flexible scopes. The requirement for the use of accredited scopes is established in the valid document published by Finnish Accreditation Service:

- Requirement FINAS V2 Rules for Accredited Scopes.

The rules for accredited scopes are based on the requirements applied in competence assessment, as well as international documents published by

- EA (European co-operation for Accreditation)
- ILAC (International Laboratory Accreditation Cooperation)
- IAF (International Accreditation Forum Inc.).

6 Entry into force

This decision shall come into force 08.11.2024 and it shall be valid until further notice.

This decision replaces the decision FINAS P1/2023 issued by FINAS Finnish Accreditation Service on 09.02.2024.

Director

Katriina Luoma

Senior Specialist

Jenni Harjuoja

7 Changes from the previous version

Changes 08.11.2024

	Chapter	Change
5	Accredited scopes	The new FINAS requirement FINAS V2 Rules for Accredited Scopes has been noted.