

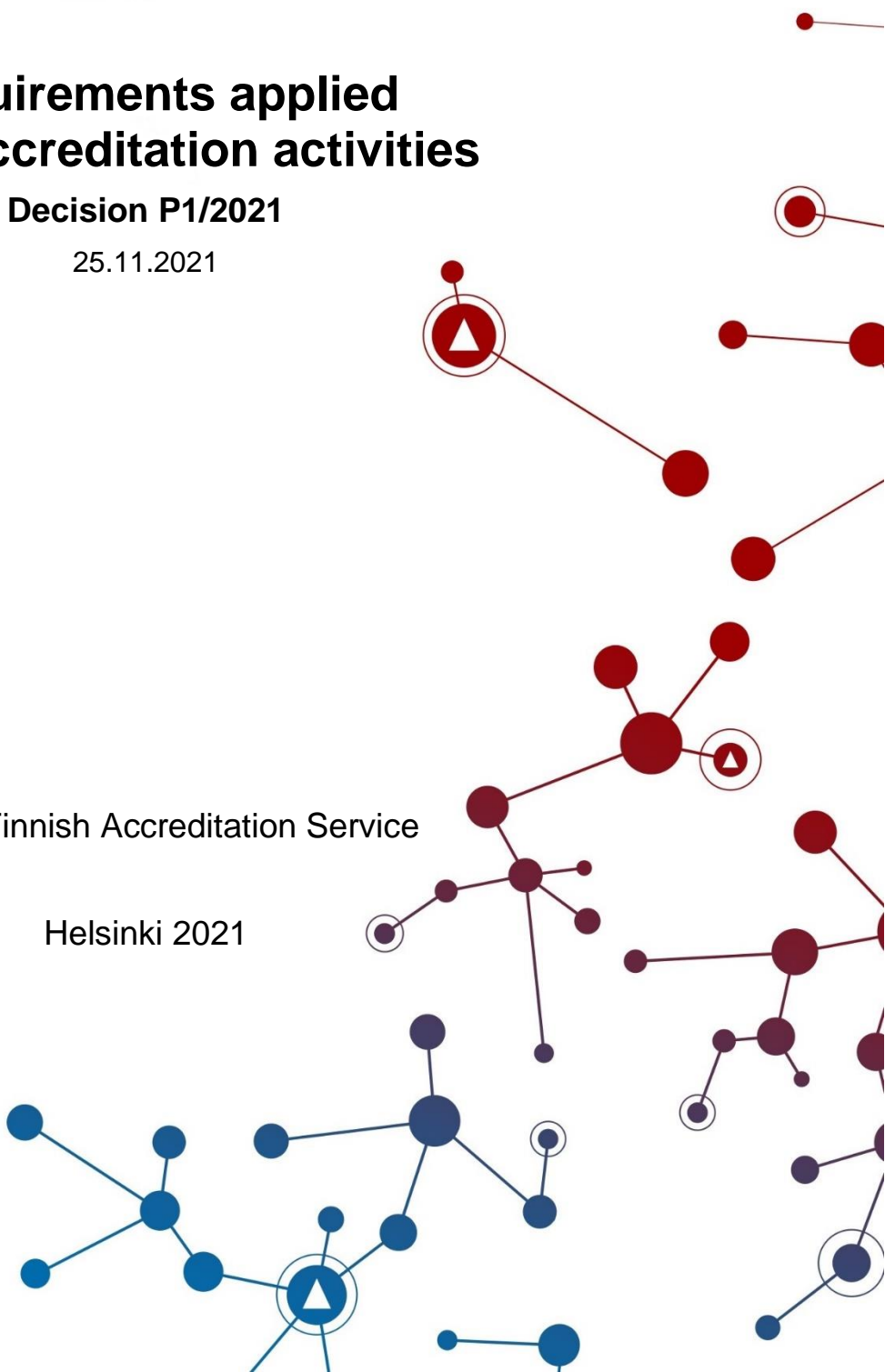
Requirements applied to the accreditation activities

Decision P1/2021

25.11.2021

FINAS Finnish Accreditation Service

Helsinki 2021



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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 and calibration, bodies providing proficiency testing, EMAS verifiers and greenhouse gas 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.

During the accreditation procedure, assessors approved by the Finnish Accreditation Service evaluate the competence of the body. The assessors shall meet the sections of the accreditation requirements that apply to them.

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 General requirements for the competence of testing and calibration laboratories.

The standard is available in Finnish and in English.

It is confirmed that the following requirements are applied to the accreditation of clinical laboratories alternatively with the standard SFS-EN ISO/IEC 17025

- standard SFS-EN ISO 15189:2013 Lääketieteelliset laboratoriot. Laatu ja pätevyyttä koskevat vaatimukset / Medical laboratories -- Requirements for quality and competence.

The standard is equal to EN ISO 15189:2012 Medical laboratories -- Requirements for quality and competence.

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 sertifioiduille 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 sertifioiduille 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 sertifioiduille 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 14065:2013 Greenhouse gases – Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition

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

The standard is available in Finnish and 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 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 Entry into force

This decision shall come into force 25.11.2021 and it shall be valid until further notice.

This decision replaces the decision P1/2018 issued by FINAS Finnish Accreditation Service on 11.6.2018.

Director

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Lead Assessor

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