

Sector schemes

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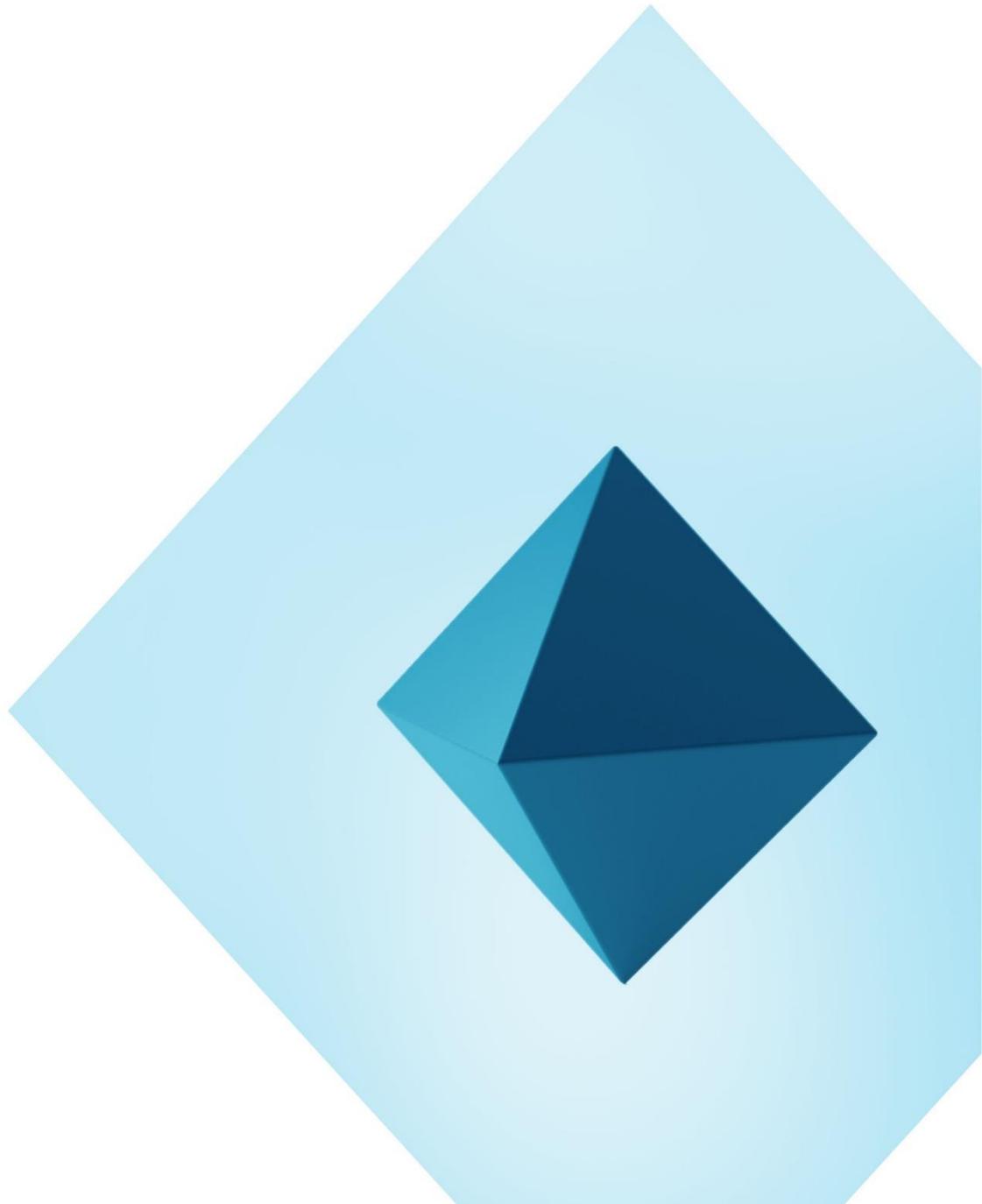


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1 Foreword

This policy document for FINAS was originally drawn up by a working group appointed by the Advisory Committee for Conformity Assessment Matters (VANK), Subcommittee for Accreditation Matters (VANK-P) in 2016. This new version replaces the previous version, A5/2023. FINAS Accreditation Service has updated the policy document to take international guidelines into account.

The purpose of the policy documents is to clarify the application of accreditation requirements in practice. They have been drawn up taking into account the principles agreed within the international cooperation organisations of accreditation bodies (the 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 FINAS decision P1. Information on the policy documents and mandatory guidelines is available on the FINAS website (www.finas.fi).

2 Introduction

Sector schemes have been created and introduced in areas in which a need has been identified to make sector-specific additions or clarifications to general assessment requirements or criteria. These sector schemes may be statutory or part of voluntary sector activities.

The creation of the sector schemes has been based on market (user, customer, authority or stakeholder) needs. The sector schemes have been implemented by FINAS and other accreditation organisations in many areas for several years. When necessary, the operating principles of accreditation organisations have been specified separately for each scheme.

3 Sector schemes

EA (the European co-operation for Accreditation) has established general principles for the assessment of the accreditation eligibility of sector schemes: EA-1/22 A, *EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members*.

The document applies to the assessment of voluntary sector schemes. The application of the document is mandatory when the assessed scheme is an

international sector scheme. Such schemes are introduced in several countries, and several accreditation bodies will carry out accreditation activities within the scope of the schemes. Such sector schemes must be documented, and their requirements must be publicly available.

The application of the above document is not mandatory if

- the sector scheme is statutory
- the sector scheme will only be implemented by the creator of the scheme
- all the requirements of the sector scheme have been published in a national or international standard
- minor changes are made to an existing scheme.

When necessary, FINAS will also apply the document in the above cases to ensure compliance with the requirements of a scheme. Additionally, FINAS uses IAF MD 25 (*Criteria For Evaluation of Conformity Assessment Schemes*) mandatory guide in its activities if needed.

3.1 Sector scheme requirements

Sector schemes must apply the standard that lays down the general requirements for EA MLA level 3 conformity assessment organisations (the standard on accreditation requirements). The sector scheme requirements must not be inconsistent with or exclude the requirements of this standard. Annex 2 of EA-1/22 includes guidelines for drawing up a sector scheme.

The owner organisation of a sector scheme is called the scheme owner. The scheme owner must be able to demonstrate that there is a need for the scheme in the market. Such a need may be demonstrated by added value, the participation of stakeholders or legislative needs.

The scheme owner may be an accredited body or a body that is applying for accreditation, in which case the scheme will be assessed as part of the accreditation process. If the scheme owner is an organisation that is applying for the approval of the sector scheme, a home accreditation body must be selected for the scheme, which is responsible for the assessment of the accreditation eligibility of the scheme. If the scheme is an international scheme, the assessment of the scheme will be approved in the EA member organisations, and the scheme will be published in a specific EA register.

The creator of a sector scheme must be qualified for the task. This qualification includes both technical competence and knowledge of the applicable conformity assessment procedure.

3.2 Sector scheme validation

Scheme owners must validate their scheme and document the validation. Annex 1 of the EA-1/22 document includes a list of issues that may be included in the validation. The validation must indicate at least the following issues:

- The purpose of the sector scheme
- The requirements of the sector scheme
- A description of the methods used to assess conformity
- An analysis of the appropriateness of the requirements and methods of the scheme, which demonstrates that the scheme fulfils its goals
- The conformity assessment activities (the accreditation standard) to be applied and an analysis of its appropriateness.

The assessment of the home accreditation body and/or the approval of the EA member organisations do not demonstrate the technical level or market value of the scheme or the usefulness of its technical requirements. The scheme owner bears full responsibility for the technical level of the scheme and its market approval. However, the home accreditation body that assesses the sector scheme must ensure that the scheme has been appropriately and thoroughly validated.

4 Frequently used sector schemes and sector scheme application opportunities in various areas

Currently, the activities of the bodies accredited by FINAS cover sector schemes that have been approved/acknowledged by the international accreditation community and pertain to testing and certification activities. Examples of testing laboratory schemes applied in laboratories accredited by FINAS include the WADA (World Antidoping Committee) and IEC CB (electrical equipment and component testing) schemes. In practice, these schemes involve cooperation between the relevant international organisations and accreditation bodies. The testing methods in the accreditation scopes have not been specified according to the schemes (by the name of scheme).

In certification activities, sector schemes are used above all in product and personnel certification, but they are also applied in system certification. Examples of sector schemes that are also used frequently in Finnish certification activities include food safety certification (ISO 22000), information security system certification (ISO 27001), medical device quality management (ISO 13485), sustainable forest management certification (PEFC FM) and welding process certification (ISO 3834).

Accreditation organisations and scheme owners collaborate actively in many

sectors. The aim of the collaboration is to harmonise assessment activities and combine the assessment visits of the sector organisations with the accreditation organisations' assessments when possible, as well as to increase the sharing of technical expertise.

5 Introduction of the new sector scheme at FINAS

When new approved sector schemes are introduced, FINAS follows a process in which the information, training and implementation needs, methods and schedules pertaining to the new area are defined. FINAS appoints a person responsible for leading the project. If necessary, a support group will be established, including the other lead assessors of the area, technical assessors/experts and possible stakeholder representatives.

The group will define and present the scheme/project:

- 1) Information needs (internal/external, methods, schedule, etc.)
- 2) Training needs (lead assessors, technical assessors, customers, stakeholders, others)
- 3) The need for a technical background group (e.g., VANK-P or consisting of representatives of the scheme stakeholders)
- 4) Implementation plan, schedules, monitoring, reporting
- 5) Impacts on the FINAS management system and guidelines.

6 Future development – anticipation, monitoring, access to information

The FINAS policy includes the anticipation and monitoring of changes in the operating environment. The assessment of the development of sector schemes is part of these activities. The aim of anticipation is to generate early information of schemes that may affect FINAS's future activities and operating environment. These impacts may be related to future customer needs, demand, development investments, expertise acquisition, outsourcing, specialisation, the collaboration and division of work between various accreditation organisations; training, advice and information needs, etc. FINAS may also need the support and expertise of stakeholders in international contexts to give its view on new sector schemes.

FINAS relies on its existing expert and stakeholder networks and customers in the anticipation, monitoring and acquisition of information of the development of sector schemes. It distributes information regarding new schemes and the development trends of sector schemes when necessary.

Legislation may necessitate the creation of new sector schemes. In its monitoring of the development of national and EU legislation, FINAS relies on its stakeholder network and collaboration with the authorities in particular.

FINAS is a member of EA (the European co-operation for Accreditation), IAF (the International Accreditation Forum) and ILAC (the International Laboratory Accreditation Cooperation). FINAS is an active member of the technical committees of these organisations that address sector-scheme-related issues.

FINAS monitors the national and international standardisation related to sector schemes. In this monitoring, its main focus is on projects conducted under the working programmes of ISO CASCO (ISO Committee on Conformity Assessment). FINAS collaborates with the Finnish Standards Association SFS and the Ministry of Economic Affairs and Employment to improve the distribution of information, monitoring and influencing activities.

FINAS uses technical assessors and experts in the technical assessment of national sector schemes within the scope of EA-1/22. If necessary, FINAS may set up working groups to create assessment criteria for new sectors and enable more thorough assessments. When assembling such working groups, FINAS invites experts from relevant bodies to ensure a balanced representation of various interest groups.

7 Changes from the previous version

Changes 02.02.2024

	Chapter	Change
3	Sector schemes	Updated IAF mandatory guide.
6	Future development – anticipation, monitoring, access to information	Removed section about the Advisory Committee for Conformity Assessment Matters (VANK).