

# **Policy document for risk-based assessment**

Policy document A13/2024

15.03.2024



## Foreword

This 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) and it has been involved when updating the new version. The new version A13/2024 replaces the previous version A13/2023. Practices were reviewed when updating this policy document.

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 processing of the topic within the international cooperation organisations of accrediting 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 mandatory guides is available on the FINAS website ([www.finas.fi](http://www.finas.fi)).

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## 1 Introduction

A risk-based approach has been integrated into part of requirement standards on which accreditation is based. The main purpose of policy document A13 is to describe how potential risk factors related to activities can be identified and how this information can be used in risk management or in planning and performing assessments. The policy document does not describe a systematic risk analysis based on identified risk factors, risk impact assessment, or a model to support a risk-based assessment.

Chapter 2 of this policy document describes the general principles of risk management, Chapter 3 presents perspectives of risk management by accredited operators, and Chapter 4 discusses risk assessments from the perspective of the accreditation process considering the requirements set in Section 7.4.6 of the ISO/IEC 17011:2017 standard. The assessment of risks threatening the impartiality of the accreditation organisation has been excluded from this policy document.

The appendix to this policy document includes a list of identified risk factors related to Section 7 of the ISO/IEC 17011 standard and their impact, and discusses the assessment process stage at which each risk is taken into account. Risks and opportunities influence the content of the assessment, planning the selection and extent of focus areas, and the assessment methods used. FINAS uses the procedures described in this policy document as an internal tool to identify risks associated with the assessment of its customers.

## 2 Risk management principles

Risk management consists of the assessment of risks and opportunities. The assessment consists of the identification and analysis of risks, the assessment of their impact, and the mitigation of risks to prevent, eliminate or reduce them. Often, risks also involve opportunities that can be used in operational development.

The aim of risk identification is to discover, detect and describe risks. Various methods are available for identifying risks. Risk identification should take into account

- material and immaterial sources of the risk;
- changes in the internal and external operating environment;

- resources; and
- the reliability of data.

Risks should be identified regardless of whether their sources can be influenced.

In risk management, it is important to analyse consequences, probabilities and impacts of risks. Various risk assessment models and methods are available on the internet, among other sources.

Risk management is a process that involves identifying, selecting, planning and implementing optional control measures and evaluating their impact. The operator must define measures to eliminate risks or reduce the risk level and assess any residual risk. “Residual risk” means the risk or its part which remains in force or for which no measures are appropriate. The removal of all risks is not always possible or practical, and control measures may also realise risks to opportunities.

### 3 Risk management by accredited operators

Accreditation standards require operators to conduct their own risk assessments and define procedures for risk management. Risk assessment should include the assessment of current practices, including those related to management, strategy and operations planning, personnel, partners, independence and resources. Continuous risk assessment is a management tool for operational development alongside management reviews and audits, for example.

Risk management procedures are to cover the identified risks and opportunities. Required measures must be defined for identified risks and opportunities. Operators must analyse risks and related measures continuously and update their practices to reduce risks, if required.

### 4 Planning and implementing risk-based assessments

Risk management by accredited bodies can be used as background information in identifying assessment-related risks. Assessments are planned and implemented based on risks so that they take into account risks associated with accredited activities, locations and personnel (ISO/IEC 17011:2017, 7.4.6). It should be noted that an assessment is always conducted by means of sampling.

After the initial assessment and re-accreditation, FINAS prepares a programme spanning the entire accreditation cycle for each body, which will be specified if required. The programme takes into account the primary risks associated with the assessed activities of the body in question. During the accreditation cycle, the focus and target of the assessment will be adjusted based on risks associated with the validity of the activities.

Risk-based planning serves to define the assessment frequency and targeting, as well as to select the assessment methods to be used. During the accreditation cycle, the body's scope will be assessed comprehensively based on programmes. On the basis of the risk assessment, assessments can be targeted at areas identified as critical. Targeting can have an impact on the members of the assessment group, the way the assessment is conducted, the size of the sample or the assessment method (e.g. whether the assessment is conducted remotely in full or in part).

## Appendix 1. Examples of general risk factors to be taken into account in assessments

Table 1. Risk factors associated with activities, location and personnel.

Activities		
	Impact on assessment process	
Risk factor	Planning stage	Assessment stage
Wide and/or multidisciplinary scope of accreditation, specialised fields Deficiencies in quality management and assurance Other functions, e.g. jointly used systems Deficiencies in risk management	For example, the selection of assessment methods, the targeting of assessments  Identification of changes during planning meeting (meetings with customers) and securing assessor resources, e.g. specialists	Comparison of activities against accreditation requirements to ensure conformity and coverage
Location		
	Impact on assessment process	
Risk factor	Planning stage	Assessment stage

<p>Activities at several or different types of locations (field activities, virtual activities or temporary locations) and/or in several countries</p> <p>Unsuitability of facilities</p>	<p>For example, ensured coverage, the selection and use of assessment methods (e.g. remote assessment)</p>	<p>Division of assignments and tasks within the assessment group, sampling and selections</p>
<p><b>Personnel</b></p>		
	<p><b>Impact on assessment process</b></p>	
<p><b>Risk factor</b></p>	<p><b>Planning stage</b></p>	<p><b>Assessment stage</b></p>
<p>Competence of personnel and personnel resources</p>	<p>For example, identifying risks and planning witnessing</p>	<p>Division of assignments and tasks within the assessment group, sampling and selections</p>

## References

SFS-EN ISO/IEC 17011:2017

SFS-ISO 31000:2018

FINAS website [Publications and guidelines supporting accreditation](#)

## Changes from the previous version

15.03.2024

Chapter	Change
Foreword	FINAS Leaflet 10 ceased. The corresponding information is available on the <a href="http://www.finas.fi">www.finas.fi</a> website.
1 Introduction	Updated the content of the policy document to correspond to practise
2 Risk management principles	Previous Chapters 2 and 3 merged and the text reorganised. Opportunities also taken into account
3 Risk management by accredited operators	Content moved to a separate chapter
4 Planning and implementing risk-based assessments	Text reorganised to describe the planning and implementation of risk-based assessments.
	Chapters 5 and 6 removed
Appendices	Examples of risk factors updated and examples of different types of bodies removed