

Policy document for risk-based assessment

FINAS Finnish Accreditation Service

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Foreword

This policy document for FINAS has been prepared in 2016–2019 by the working group appointed by the Advisory Committee for Accreditation Matters, Subcommittee for Accreditation Matters (VANK-P). The working group had the following members:

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The purpose of FINAS policy documents is to clarify the practical application of accreditation requirements. They take into account discussions on the topic in the international cooperation organisations of accreditation bodies (European co-operation for Accreditation (EA), the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF)).

The policy documents currently in force are presented in FINAS Leaflet 10 “FINAS accreditation criteria, policy documents and guidelines”.

Further information: www.finas.fi

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1 Introduction

In the future, accrediting bodies must carry out assessments of conformity assessment bodies with a risk-based approach, as specified in standard ISO/IEC 17011:2017. As the name states, a risk-based assessment takes into account the risks associated with the activity that have been identified in advance. Although accrediting bodies have already employed risk-based thinking in their assessments, the new requirement stipulates that the policies be clarified and supplemented. Current practices for risk identification should be described and, if necessary, supplemented to ensure compliance with the standard's requirements. A risk analysis based on identified risks allows for a systematic, risk-based assessment.

The main purpose of this policy document is to describe how FINAS can identify potential risk factors related to the accredited body and activity, and utilise this information in planning and implementing its assessment. Currently, the accreditation criteria of FINAS do not describe a systematic risk analysis based on identified risk factors, risk impact assessment, or a model to support a risk-based assessment.

The working group acknowledges that risk identification is a broad concept, encompassing risks such as financial risks, business risks and security risks. This policy document focuses on those risk factors that may impact the selection of focus areas for the assessment, the targeting of the assessment, or the specified scope of accreditation. The identification of risk factors is restricted to risks related to those activities, business locations and personnel that fall within the applicant's scope of accreditation.

2 Background to risk identification and analysis

Overall risk management includes a risk assessment, which in turn comprises risk identification, analysis and impact assessment.

The aim of risk identification is to discover, detect and describe risks. Various methods are available for identifying risks and uncertainties associated with them. Risk identification should always take into account material and immaterial sources of the risk, causes and events, threats and opportunities, vulnerabilities and strengths, changes in internal and external operating environment, risk indicators, characteristics and value of assets and resources, consequences and their impact, restrictions on the reliability of data, time-

related factors, and subjective viewpoints. Risks should be identified regardless of whether their sources can be influenced.

In order for risk management to be possible, the risks and their related uncertainties, sources, consequences, probabilities, management methods and impact should be analysed. The analysis should use available qualitative and quantitative methods relevant for the risk in question. Through analysis, the risk's significance and impact to decision-making and the tools for its management can be determined.

In this policy document, risk assessment focuses on facilities, resources and the operating environment, and is used for planning and selecting focus areas and carrying out the assessment. Risk management measures employed by the accredited bodies are broader in scope than those taken into account in planning and carrying out the assessment.

3 Risk categories based on significance

Depending on the significance and category of a risk, risk assessment may result in either no further action or one of the available mitigation methods, such as a more detailed analysis or the use of an existing or new risk management method. If necessary, the objectives of the assessment may be reviewed and adjusted. Risk mitigation is a process that involves identifying, selecting, planning and implementing options and evaluating their impact and residual risk.

In risk impact assessment, the results of the risk analysis are compared against risk criteria in order to determine whether the risk or its magnitude is acceptable or tolerable, what are the risk's impacts, and what possible mitigation measures are needed for the identified risk.

Comparing risk impact and risk level against defined risk criteria helps decide on appropriate risk mitigation measures. The purpose of impact assessment is to decide which risks are relevant and significant, and what is the order of priority for the implementation of risk management measures.

The removal of all risks is not always possible or practical. The decision on risk impact means deciding on whether or not the risk should be mitigated based on the defined criteria.

In risk analysis, each risk is assigned a level of severity and probability.

Example: the assessment may use a three-step scale (table 1).

Probability	Severity		
	Minor	Serious	Critical
Improbable	1 Negligible risk	2 Marginal risk	3 Moderate risk
Possible	2 Marginal risk	3 Moderate risk	4 Major risk
Probable	3 Moderate risk	4 Major risk	5 Unacceptable risk

Example: the threshold for mitigation measures may be the risk's numerical value. If a risk's value is significant or unacceptable, the risk must be mitigated (table 2).

Risk value	Risk mitigation measures
Negligible risk	Risk is too low to warrant further action
Marginal risk	No further action is necessarily required The situation must be monitored to ensure that the risk is managed
Moderate risk	Risk mitigation measures must be taken. The measures and their schedule must be planned.
Major risk	Risk mitigation is absolutely necessary Measures must be taken as soon as possible High-risk activity must be stopped without delay
Unacceptable risk	Removing the risk is absolutely necessary Measures must be taken immediately High-risk activity must be stopped, activities may not resume until risk is removed

4 Risk assessment

Risk assessment in the assessment process

In assessments related to accreditation, the risks associated with the accredited body's activities are particularly important in the planning of individual assessments and the accreditation cycle as a whole, the targeting of assessments, and the content of assessment in the scope required by accreditation standards.

After its initial assessment, FINAS prepares each accredited body a plan to cover the accreditation cycle. If necessary, the plan is adjusted before periodic surveillance assessments. The plan takes into account the primary risks associated with the accredited activities of the body in question. During the accreditation cycle, the focus and target of the assessment is adjusted based on identified risks. Identified risks may impact, for example, the reclassification

of the body in question to a different segment, the frequency of re-assessments, and the assessment methods and techniques used. Risk identification uses a table that lists risks typical of the activities of accredited bodies (table 3).

When the accrediting body selects assessors of technical functions for the applicant, the approval process takes into account their aptitude and qualifications for the scope of accreditation in question, as well as factors that may affect the assessor's impartiality, such as professional networks and their effects on the activities and competitive standing of the body under assessment. When using international assessors, issues may arise in the assessment of documents prepared in Finnish. In such situations, it is crucial that cooperation between the Lead Assessor and technical assessor is successful. The technical assessor's assessment focuses on risks related to technical operations and resources of the body in question, as identified in the assessment plan. The Lead Assessor is responsible for evaluating the body's risk assessment, overall risks and risk management, both in terms of the body's activities and from the perspective of customers of the accredited body.

Accredited bodies' internal risk assessment

Risk assessment is an integral part of operations in any accredited body. Risk assessment must be carried out at all levels of the organisation. Risk assessment includes the assessment of current practices, including those related to management, strategy and operations planning, personnel, partners and resources. The latest 17000-series of standards on accreditation requirements provide comprehensively for accredited bodies' internal risk assessment.

Risks can also be divided into four groups: strategic, financial, operational and hazard risks. These may be further categorised based on the source and type of risk. Strategic business risks can be further divided into general risks associated with the activity, business risks, and risks related to development activities. Operational risks are related to day-to-day operations, and may include, for example, hazard risks related to service production, information systems and data security, compliance with legal obligations, and personnel, logistics and the environment.

An organisation's activities also involves financial risks. In accreditation assessments, these are addressed only in terms of possible threats to business continuity. Personnel-related risks and risks in data processing and communications technology, including cyber security, are particularly important for business continuity and security. These issues are discussed in detail in the EU General Data Protection Regulation (2016/679) (GDPR). Accredited bodies

must form a risk management system, in which the risks related to the activity are assessed and any required measures taken into account. The accredited body must continuously re-evaluate risks and update its practices in order to mitigate risk. Risk probability and impact and activities related to risk mitigation and prevention must be evaluated. The body must also evaluate and determine the amount of acceptable residual risk. Documentation on risk assessment typically consists of data related to strategic, financial and operational functions, all of which are usually considered business secrets of the body in question.

For this reason, accreditation assessments must take into account that not all risk assessment material of an accredited body may be requested to be disclosed as advance material. Some documentation is often available for review only during the assessment visit.

5 Impact on planning the assessment and assessment methods

Risk-based thinking has been adopted as part of all new standards on conformity assessment, including ISO 9001:2015, ISO/IEC 17025:2017 and ISO/IEC 17011:2017. At this point, no international guidelines have been published on the principles of risk-based assessment.

The working group has decided that in this policy document, the discussion on risk assessment in the accreditation process shall take into account the requirements of ISO/IEC 17011 chapter 7. ISO/IEC 17011 chapter 7 lists the risk areas associated with a body's accredited activities, including facilities, resources and the operating environment. Assessment of the accrediting body's impartiality is excluded from this policy document.

In accreditation standards, bodies are required to undertake internal risk management and procedures, regardless of their sector, either comprehensively or focused on specific areas of operation. Examples of risks found in different sectors are listed in table 3. In preparing this policy document, the working group has also referred to standard ISO 31000.

The working group has compiled a list of identified risks related to standard ISO/IEC 17011 chapter 7 and their impacts in the table appended to this policy document, and discusses the assessment process stage in which each risk should be taken into account. Risks influence the content of the assessment, planning of selection and extent of focus areas, and the assessment methods used. During 2019, FINAS will publish practices for the documentation and

customer communication of risks that influence assessments during the accreditation cycle.

6 Conclusions and further actions

Accreditation requirements on various bodies are continuously expanding. With the advent of digitalisation, for example, assessments must take into account requirements on information security and data protection, all of which remained undefined just a few years ago. Despite this, the resources available for accreditation are not increasing, rather the contrary. The inevitable outcome is that planning and implementation of assessments must be directed in a systematic and risk-based manner. However, risk-based assessment requires that the risks are identified and evaluated.

The evaluation principles described here are primarily a starting point for further developing risk-based assessment methods, not an applicable method as such. The main focus in the work has been to record and discuss observed sources of risk in accordance with assessment requirements. Even a general overview of assessment principles can help accredited bodies understand the basis for planning and targeting assessments. The question of what kind of risk management procedure might be practical and appropriate as a tool in planning assessments must be answered by further policy development. In order to develop practical procedures, existing identified risks and potential new risks in assessments should be documented for risk analysis. In addition, the criteria for risk probability and severity that serve as the basis for assessing risk impact should be described. The first step towards practical adoption of risk-based assessment could be, for instance, documenting identified potential problems in each site as background information for planning the assessment. In addition, the documentation could address how these site-specific identified sources of risk are currently taken into account in implementing the assessment. The internal risk analyses of assessed bodies may also be used as initial data in identifying risks related to the accreditation.

After identifying and documenting the risks, the process of developing a suitable and practical risk-based assessment method may take time, even as there are methods suitable for risk management readily available for application. At the outset, the process may involve describing established practices related to planning assessments. However, risk-based assessment cannot be achieved without a transparent process of risk identification, impact assessment and choice of measures.

An effective risk-based assessment method allows resources to be allocated more efficiently in the future. The method also helps improve the effectiveness of accreditation and develop the operations of the accredited body. Assessment of an accredited body is always based on sampling. Risk-based assessment can help improve the accuracy of sampling.

This policy document shall be updated on the basis of new methods and the experiences gained from their application in practice.

Examples of identified risk sources and risks

Table 3 below lists typical risk sources and risks identified by the working group. In addition to these, other case-specific risks to be taken into account may be identified.

The risks listed in the table are based on the requirements of standard ISO/IEC 17011:2017

7.4.6 In selecting the activities to be assessed the accreditation body shall consider the risk associated with the activities, locations and personnel covered by the scope of accreditation.

		Impact on assessment process	
	Risk factor	Planning stage	Assessment stage
Activities (activities)	Broad and/or multidisciplinary scope of accreditation, specialised fields <ul style="list-style-type: none"> - various types of functions, critical areas (e.g. health, safety, environment) - significant scale differences between areas - significant differences in clientele (such as businesses, private individuals, authorities) - flexible scope of accreditation - a part of activities already accredited, blending with non-accredited activities - regulated (public administrative function) and voluntary activities - shortcomings in observing scheme requirements 	<ul style="list-style-type: none"> - accuracy and sufficiency of the assessment unit's competence, availability of assessors - choice of assessment methods - acknowledgement of historical data and experiences (prior assessments and observations) - documentation request: changes, extensions, clientele - familiarisation with the received documentation, communication material, references to accreditation planning meetings between assessors, focus areas and emphases, identifying 	Comparison of activities against accreditation requirements to ensure conformity: <ul style="list-style-type: none"> - amount, quality and placement of resources - new or changed areas of activity - implementation and schedule of assignments - supplier evaluation and monitoring, cooperation and communication - industry monitoring - non-conformities, feedback, complaints, risk management, effectiveness of quality assurance Correlation between the scope of accreditation and the assessed activity Sample-based performance evaluation

	<p>Deficiencies in quality management and assurance</p> <ul style="list-style-type: none"> - problems with management review, internal audits, processing of feedback and corrective measures - shortcomings in utilising the results of previous assessments <p>Non-accredited functions</p> <ul style="list-style-type: none"> - horizontal systems (e.g. management system, IT), processes, resources, etc. <p>Deficiencies in risk management</p> <ul style="list-style-type: none"> - the body's internal risk management does not meet accreditation requirements for the activity - insufficient (competence, amount) or incorrectly targeted resource allocation (personnel, equipment, facilities, etc.) - dependence on third parties (e.g. subcontractors, partners, suppliers) <p>Other risk factors</p> <ul style="list-style-type: none"> - according to type of activity 	<p>special requirements, time management</p> <ul style="list-style-type: none"> - lists of questions, report templates 	
<p>Location</p>	<p>Activities at several or different types of locations (field activities, virtual activities or temporary locations) and/or in several countries</p> <ul style="list-style-type: none"> - unsuitability of the location - inconsistency of activities and practice (quality assurance, procedures, IT, inconsistencies in legislation and other requirements) - logistics 	<ul style="list-style-type: none"> - ensuring sufficient sampling: selection of locations and workstations for assessment - factors affecting the assessment unit's work: travel times and distances - focus on critical functions and a representative sample of all functions - use of remote assessment methods 	<ul style="list-style-type: none"> - division of labour and tasks within the assessment unit - sampling and selections - communication between the assessment unit - assessment of field activities - use of necessary protective equipment <p>Sample-based performance evaluation</p>

	<p>Unsuitability of facilities</p> <ul style="list-style-type: none"> - environmental and work conditions - special demands for critical functions 	<ul style="list-style-type: none"> - choice of assessment methods and their use - scheduling of assessments and time management - applicability of the assessment unit's expertise in various operating environments, knowledge of national requirements - observing requirements for workplace safety and hygiene 	
Personnel (personnel)	<p>Qualifications and number of personnel</p> <ul style="list-style-type: none"> - correct allocation of skills based on areas of expertise and division of labour - securing of critical expertise - practices for developing and maintaining qualifications - third party resources - personnel turnover - human resources management (orientation, development of expertise, transfer of passive knowledge, well-being at work) 	<ul style="list-style-type: none"> - size, expertise and up-to-dateness of the assessment unit - risk identification: availability of critical expertise and ensuring continuity - impartiality of assessors - focus areas, extensions, changes - choice of assessment methods 	<ul style="list-style-type: none"> - qualification requirements for various tasks and areas - orientation, qualification (levels of expertise), training measures/regular maintenance of skills (following trends, new technologies/tasks) - division of labour, workload, sufficiency - assessment of competence management - methods for identifying training needs - performance monitoring (indicators) <p>Sample-based performance evaluation</p>
Other factors	<p>Confidentiality</p> <ul style="list-style-type: none"> - integrity, availability and confidentiality of data <p>Impartiality and independence of activities</p> <ul style="list-style-type: none"> - methods of risk identification and management <p>Negative impact of market or competitive situation on the quality of activities</p>	<ul style="list-style-type: none"> - supplementing the assessment unit with possible special expertise, such as ICT - physical security - principles and guidelines related to information security in material requests - secure delivery of materials - identifying competitive factors in the activity 	<ul style="list-style-type: none"> - effectiveness of impartiality and independence management methods - availability, integrity and confidentiality of data - responsibilities and authorisations - procedures for storing and destroying data - data administration <p>Sample-based performance evaluation</p>

Fictitious examples of risks associated with various types of accredited bodies
The risk matrices/evaluations should be used in planning and updated after each assessment visit.

Table 4 a)

Risk assessment of a fictitious laboratory

Activity		
Risk factor	Applicable to the example body (x)	Details of the risk factor and how to take it into account in assessments
Flexible scope of accreditation		Not applicable
Dependency on subcontractors		Occasional use of subcontractors
Large volume of commissions, varies depending on the area of testing	x	The differences in volume between areas of testing must be taken into account in planning the accreditation cycle. Areas of testing with large volumes should be assessed at each assessment visit. Tests with less volume should be assessed at least 1 to 2 times per accreditation cycle, depending on the test's difficulty.
Critical purpose of use of test reports (such as related to health, safety or the environment)	x	The activity is subject to official requirements to be taken into account in the assessment. Ensuring that the methods used and reporting comply with official requirements.
Sampling		Internal samplers
Other risk, what?		
Location		
Risk factor	Applicable to the example body (x)	Details of the risk factor and how to take it into account in assessments
Several locations, differences between locations (for example, one location with only minor activities or a limited scope of accreditation)		To be taken into account in planning the accreditation cycle Accredited body has activities at only a single location
Field testing or other activities in field conditions within the scope of accreditation	x	Field monitoring must be planned yearly. Field monitoring should evaluate different personnel and types of tests. Field monitoring during the accreditation cycle must be planned comprehensively.

International commissions, significant volume of test reports submitted to international customers	x	Possible country-specific differences in requirements to be taken into account, sizing and targeting of assessment measures.
Other risk, what?		
Personnel		
Risk factor	Applicable to the example body (x)	Details of the risk factor and how to take it into account in assessments
Small organisation, low number of personnel	x	Personnel hold several parallel areas of responsibility, quality manager also serves as a technical manager of one area. Possible conflicts caused by differing responsibilities and the sufficiency of personnel resources to be taken into account.
Inadequate experience of technical personnel	x	Qualifications and their relevance to be ensured
Use of third party resources or temporary personnel		Third party resources used only on a temporary basis, mainly summer help and interns
Personnel turnover	x	A significant part of personnel have long experience, but one key employee has recently been replaced. The efficiency and sufficiency or orientation practices should be ensured.
Other risk, what?		
Other risk factors		
Risk factor	Applicable to the example body (x)	Details of the risk factor and how to take it into account in assessments
Significant non-conformities observed at times in previous assessments	x	Effectiveness of corrective measures must be ensured.
Complaints addressed to FINAS		FINAS has received information about one complaint two years prior. The efficiency of processing complaints must be taken into account in the assessment.
Activities in a specialised field, pesticide testing	x	Binding international guides to be taken into account Only one technical assessor available to FINAS.
Other risk, what?		

Table 4 b)
**Risk assessment of a fictitious
inspection body**

Activities		
Risk factor	Applicable to the example body (x)	Details of the risk factor and how to take it into account in assessments
Broad and diverse scope of accreditation, several types of inspected fields	x	Several technical assessors, qualifications of the assessment unit to be verified Number of inspectors and inspections to be taken into account in targeting the assessment. Areas with high volumes to be assessed annually and areas with low volumes every 2 to 3 years, provided there are no changes or significant non-conformities detected in the activity
Observing the requirements for a notified body in activities		The assessment must acknowledge the requirements of directives and European law Does not function as a notified body
Large differences in volume between areas or objects of inspection	x	Occasional inspections and inspections carried out at a fixed time annually to be taken into account in planning the assessment and monitoring The body should be notified of assessment needs in advance in order to schedule the assessment program to include rarely performed inspections.
Significant social impact of the inspection activities (related to safety or the environment, for example)		Technical assessors from the Finnish Radiation and Nuclear Safety Authority STUK must be used in assessing nuclear power plants
Other risk, what?		
Location		
Risk factor	Applicable to the example body (x)	Details of the risk factor and how to take it into account in assessments
Several locations/sites across the country	x	Not all locations include facilities used by the inspection body, sufficient assessment coverage to be ensured over the accreditation cycle Ensuring whether the location engages in accredited activities, otherwise the assessment must be targeted at locations where inspections are performed.

Several different objects and types of inspection.	x	Field monitoring must be planned annually and involve assessments of various types of inspection, inspectors and inspection volumes. If necessary, a separate planned is prepared.
Differences in activities between locations (e.g location with only minor activities or a limited scope of accreditation)		Differences between locations must be taken into account in planning assessment visits during the accreditation cycle Activities at only a single location
International commissions and/or activities		Country-specific differences in requirements to be taken into account No international activities
Other risk, what?		
Personnel		
Risk factor	Applicable to the example body (x)	Details of the risk factor and how to take it into account in assessments
Several inspectors operating at various locations around the country	x	To be taken into account in planning and defining the scope of assessment Evaluating how the inspection body ensures consistency between inspectors and targeting assessments accordingly. Several, independently managed areas, assessment to be balanced across the areas to ensure consistency of activities, taking into account monitoring practices.
Limited experience of the technical manager, specialised fields with only a handful of competent inspectors	x	Attention to orientation and the maintenance of qualifications, ensuring that a substitute system is in place Ensuring consistent operating and monitoring practices between inspection bodies.
Use of third party resources or subcontractors	x	Subcontractors used to a limited extent in balancing workloads and carrying out some tests related to inspections. Qualifications of third party resources and subcontractors to be verified
Some key employees are near retirement age	x	Ensuring preparedness for employee turnover
Other risk, what?		
Other risk factors		
Risk factor	Applicable to the example body (x)	Details of the risk factor and how to take it into account in assessments
Supervision by authorities has previously detected shortcomings	x	Ensuring that the corrective measures have been implemented and reported to authorities

Identifying and applying requirements for public administrative functions	x	The assessment must ensure that said requirements are recognised and observed in activities
Other risk, what?		

Table 4 c)

Risk assessment of a fictitious certification body

Activity		
Risk factor	Severity (critical/major/negligible)	Details of the risk factor and how to take it into account in assessments
Includes both voluntary and regulated sector functions with different requirements	M	Legal requirements, possible public administrative function and guidelines issued by the competent authority to be taken into account.
Varying volume of commissions between different areas of activity	M	Consistency of activities must be ensured in areas with high volumes. Very few commissions in some areas, challenges in obtaining and maintaining qualifications for new auditors. Assessment plan should take into account the coverage and availability of monitoring activities.
Risk of lack of impartiality in activities outside the scope of accreditation	M/N	The assessment must review how the certification body obtains information on possible affiliations of personnel and how it uses this information to identify and mitigate risks to impartiality. It must be ensured that accredited activities are not affected.
Critical scope of accreditation	C	Low number of industries with various certification programmes, including critical certification. Influences the frequency of assessments: critical activities must be assessed often, while ensuring that all programmes are assessed over the assessment period.
Availability of assessors (at FINAS)	M	Specialised field, FINAS has access to only one assessor/expert. If necessary, international assessors must be used.
Other risk, what?		
Location		
Risk factor	Severity (critical/major/negligible)	Details of the risk factor and how to take it into account in assessments
No geographic scope of activities has been specified	N	In the case of international customers, knowledge of local requirements must be ensured. If

		necessary, assessments should cooperate with the accrediting body of the country in question.
Parent company/group has activities in several countries	N	At present, accredited activities are carried out only in Finland.
Other risk, what?		
Personnel		
Risk factor	Severity (critical/major/negligible)	Details of the risk factor and how to take it into account in assessments
Low number of auditors	M	Ensuring competence management and the continuity of necessary competencies.
Use of third party resources	M	Third party resources used only occasionally, competence, availability and impartiality must be ensured.
Non-accredited activities of personnel	M	Personnel also perform third party assessments not included within the scope of accreditation - relationship with accredited activity must be taken into account. Risk assessment on the relationship between accredited and non-accredited activities and potential conflicts in responsibilities.
Other risk, what?		
Other risk factors		
Risk factor	Severity (critical/major/negligible)	Details of the risk factor and how to take it into account in assessments
Clientele includes operators subject to licence	N	The assessment must ensure that the accredited body is familiar with the legal requirements of its customers' sector.
Other risk, what?		

References

- SFS-EN ISO/IEC 17011:2017
- SFS-ISO 31000:2018
- SFS-EN ISO 9001:2015
- SFS-EN ISO/IEC 17025:2017