

Assessment of Multi-Sector and Multi-Site Organisations

Policy document A10/2024

07.02.2024



Table of contents

1	Foreword	3
2	Introduction	4
2.1	Concepts	4
2.2	Co-operation with the organisation to be assessed	5
3	Risk assessment as part of the planning of assessments	5
3.1	Own monitoring and control procedures of an operator	6
4	Assessment of multi-sector organisations	6
4.1	Coverage of multiple sectors with a single management system assessment	6
4.2	Combining assessments of technical activities	7
4.3	Reporting of assessments in situations where assessments are combined	8
5	Assessment of multi-site organisations	8
5.1	General principles in the assessment of multi-site organisations	8
5.2	Temporary site	8
5.3	Field operations	9
5.4	Sampling	9
5.5	Sites located abroad	9
6	Other matters	9
6.1	Witnessing of individuals' activities	9
6.2	Utilisation of remote assessment methods	10
6.3	Time spent on assessments	10
7	Examples of the application of assessment principles	10
7.1	Example: Multi-discipline organisations	10
7.2	Example: Multi-site organisations	11
8	Changes from the previous version	13

1 Foreword

The original policy document for FINAS was drawn up by a working group appointed by the Advisory Committee for Conformity Assessment Matters, Subcommittee for Accreditation Matters (VANK-P). The new version A10/2024 replaces the previous version A10/2022.

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 (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 binding guidelines are available on the FINAS website (www.finas.fi).

2 Introduction

This policy document discusses issues according to which the assessment of multi-sector and multi-site organisations should be targeted and implemented at intervals. FINAS utilises policies and aspects presented in the policy document in planning assessments.

Accreditation and assessments are guided by the international standard SFS-EN ISO/IEC 17011:2017 and international mandatory guidelines.

2.1 Concepts

2.1.1 Assessment

Refers to all measures by an accreditation organisation through which the fulfilment of accreditation requirements is verified and ensured. In addition to or as an alternative to assessment visits, assessment measures include, for example, inquiries, reports, assessment of documents, remote assessment, assessment of proficiency testing and monitoring of field activities. The elements of an assessment can be carried out at different times.

2.1.2 EA (European co-operation for Accreditation)

A co-operation organisation for national accreditation organisations in Europe.

2.1.3 IAF (International Accreditation Forum Inc.)

An international co-operation organisation for accreditation organisations covering management system, product, service and personnel certification.

2.1.4 ILAC (International Laboratory Accreditation Cooperation)

An international co-operation organisation for accreditation organisations covering laboratories and inspection bodies.

2.1.5 Management system

A system to establish a policies and objectives, and to achieve these objectives. The terms quality management system or integrated management system are often used to refer to a management system. These terms may, depending on the context, have slight differences in nuance, but they can generally be taken to mean the same thing.

2.1.6 Multi-discipline organisation

Refers to an organisation which has accredited activities in a number of

sectors, for example, calibration, testing, certification, inspection and proficiency testing. In this case, the organisation has more than one accreditation.

2.1.7 Multi-site organisation

An organisation which performs accredited activities at a number of different sites.

2.1.8 Sampling

Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing or calibration of a representative sample of the whole.

2.2 Co-operation with the organisation to be assessed

Assessments are planned in co-operation with an accredited operator. Practices vary, depending on, among other things, the size of the organisation and the number of the sites and sectors. At the end of an assessment visit, the aim is to arrange the date for the next assessment. In order to facilitate the planning of assessments of, in particular, large organisations operating in several sectors and/or at more than one site, a co-operation meeting will be organised between the accreditation organisation and the accredited operator, for example, once a year.

3 Risk assessment as part of the planning of assessments

A risk-based procedure within the limits of the requirements regulating the activities of accreditation organisations will be used in planning and carrying out assessments of accredited operators. According to risk-based procedures the accreditation organisation may direct its assessments on the basis of an accredited operator's performance and risks.

In risk-based assessment, an accreditation organisation aims to increase the effectiveness of assessments by forming a general view, or an organisation profile of the performance level of an operator's activities and in this way highlight potential risk areas in the activities. The indicators and criteria used to form an overall picture take into account the characteristics of each type of organisation and their differing requirements.

By utilising organisation profiles, the accreditation organisation can target assessment in areas where it is needed most. The aim is to increase the effectiveness of assessment, to bring more added value to operators and to strengthen their self-monitoring.

Planning of risk-based assessments aims to obtain answers to assessment

- targeting (who)
- content (what)
- scope/depth
- resources
- time (when)
- frequency (how often).

The profiles of organisations are regularly examined so any changes in the organisation's activities can be taken into account.

3.1 Own monitoring and control procedures of an operator

Planning of assessments of operators should take into account the operators' own control procedures and monitoring procedures, as well as their adequacy and analysis of results. Control and monitoring procedures include, for example, competence management procedures, internal audits, monitoring procedures for corrective actions, monitoring of individuals' activities and management reviews. If an operator is able to show that it monitors and controls its activities functionally and efficiently, this information will be utilised as proof of competence, which will affect the content of and the time spent on the assessment.

4 Assessment of multi-sector organisations

4.1 Coverage of multiple sectors with a single management system assessment

Management system assessments assess whether an operator's management system meets the requirements for accreditation and whether the operator operates in accordance with these requirements.

The line between a management system assessment and an assessment of technical activities is narrow. For example, assessment of personnel competence and assessment of the development of competence is included both in the assessment of the management system and in the assessment of technical activities. As a general principle, management system assessments assess procedures throughout the organisation, while assessments of technical activities focus on the implementation of procedures in the area of technical activities in question.

The same operator may have operations in several sectors. If the operator

has a management system which covers several sectors, it is possible to cover more than one sector with a single assessment.

An example is an operator which has both testing and calibration activities. If both testing and calibration activities fall within the scope of the same management system, the management system of both activities can be covered during the same assessment visit.

When combining assessments, the time required to conduct them must be taken into account. Other factors too, for example, availability of the operator's personnel, location of sites or the assessment group's scope of qualification may restrict a sector being covered with a single assessment visit.

The prerequisite for covering several sectors by means of a single management system assessment is that the management system is integrated and that there are no significant differences between the sectors with respect to the practices followed. Examples of activities in which the procedures followed should be similar include management of the expertise and competencies of the personnel, management reviews, internal audits, monitoring of corrective and preventive actions, management of documents and records, and quality assurance procedures.

4.2 Combining assessments of technical activities

Assessments of technical activities assess whether the technical activities of an operator meet the requirements for accreditation and whether the body produces correct, comparable and reliable results. The content of an assessment of technical activities varies according to sector. For example, technical assessments of testing and certification activities are often very different in terms of content.

In some cases, the technical element of the activities is entirely or partially integrated in various sectors. An example is an operator engaged in product certification, which is accredited in accordance with the standard SFS-EN ISO/IEC 17065, and in testing, in accordance with the standard SFS-EN ISO/IEC 17025. In cases such as these, testing results produced in accredited testing activities are typically utilised in accredited certification activities. The results of the technical assessment of testing activities can be utilised in the assessment of certification activities.

Combining different sectors in the same assessment benefits both the operator and the activities of FINAS. A technical assessment can at the same time be combined with a management system assessment. The possibility of combining assessments is agreed in co-operation with an operator and FINAS on a case-by-case basis.

4.3 Reporting of assessments in situations where assessments are combined

As a general principle, in initial assessments and reassessments, separate assessment reports are drawn up on each sector assessed or assessment report has different section for different sectors, even if the assessment itself was carried out in a single assessment visit. In periodic surveillances it is possible to draw up only one assessment report, which covers several sectors. If the different sectors have been accredited in accordance with different requirement standards, it may be clearer to draw up separate reports also in conjunction with periodic surveillance assessments.

5 Assessment of multi-site organisations

5.1 General principles in the assessment of multi-site organisations

The requirements of the SFS-EN ISO/IEC 17011 standard sets conditions according to which multi-site organisations must be assessed comprehensively. The SFS-EN ISO/IEC 17011 standard, which regulates the activities of accreditation organisations, requires the accreditation organisation to have procedures in place to comprehensively verify the competence of a site applying for accreditation or a previously accredited site, covering the procedures or functions for which accreditation is applied or which are already within the scope of accreditation. The assessment plan drawn up for the accreditation cycle must address the difference of sites based on risks (FINAS policy document A13). Depending on the sector, internationally agreed procedures may also have an impact on the assessment plan.

If there are several sites, the sites to be assessed during the initial visit will be selected randomly based on risks. In addition, the number of procedures or functions to be accredited and the difference of sites will be addressed so that the coverage of the initial visit is high. During the following period surveillance assessments and reassessments, the sites and/or non-assessed sites will be assessed in accordance with a pre-defined assessment plan.

5.2 Temporary site

A temporary site is in use for only a short period. Examples of temporary sites include, for example, moves to temporary premises or a temporary laboratory space established in the vicinity of the testing location. It is usually necessary to assess an activity performed at a temporary site, but it is not always appropriate to make an assessment visit to a temporary site.

If the same temporary site is used repeatedly or regularly, the same principles

will be observed as in assessments of multi-site organisations assessments in general.

5.3 Field operations

Testing, calibration or inspections may be carried out, for example, at customers' premises or otherwise in multiple and changing locations. In that case, the accreditation decision's scope of accreditation will contain a reference to field testing, field calibration or field inspection. In conjunction with assessments, field operations are monitored under the sampling principle at selected sites in accordance with an assessment plan.

5.4 Sampling

Sampling may also be within the scope of accreditation. If sampling is carried out, for example, in customers' premises or otherwise in multiple and in changing locations, the principles for assessment of field operations will be applied in sampling assessments, in other words, the activity will be witnessed using the sampling principle in the chosen locations in accordance with an assessment plan. Sampling in medical laboratories can be very extensive and carried out at more than one site. The sampling principle is also used in assessments of sampling in medical laboratories.

5.5 Sites located abroad

As a general principle, each country in Europe has a national accreditation organisation which operates in the area of the country in question. Many accredited organisations, however, have operations in a number of countries, and the accreditation organisations have drawn up principles for the accreditation and assessment of operations located in different countries (EA's cross border principles).

Branches of a Finnish organisation located abroad may come within the scope of FINAS's accreditation if the sites comply with a common management system. Assessment of the branches in question is carried out in collaboration with the accreditation organisation of the country in question.

6 Other matters

6.1 Witnessing of individuals' activities

Some activities are highly dependent on the actions of the persons who perform them. Examples of operations of this kind include inspection activities and certification of management systems. Witnessing of the activities of individuals in this case plays a significant role in assessments relating to

accreditation.

The witnessing of activities of persons in conjunction with assessments should be planned in such a way that different persons are witnessed in different assessments. If an operator only has a few persons, it is often possible to witness the activities of all of them for a certain time period, for example, during the accreditation cycle. If there is a large number of individuals, witnessing will be focused intentionally on different persons, taking into consideration that it is not possible to witness the activities of everyone.

6.2 Utilisation of remote assessment methods

In some situations, it is possible to replace assessment carried out on-site entirely or in part by means of assessments carried out using remote tools. Remote assessments are conducted using a video connection, for example, to examine documents and registers and witness activities. In addition, image, audio and video recordings can be used.

Decisions to replace an assessment visit with a remote assessment must be made on a case-by-case basis. In principle this depends on how well the objectives set for the assessment visit can be met by using remote connections. (see also A14 Policy document for remote assessments)

6.3 Time spent on assessments

Planning assessments of multi-sector and multi-site organisations should take into consideration the aim of and needs for the assessment, and on this basis the time needed to perform the assessment is determined. The time available has to be divided in an appropriate way between the various sectors and the sites.

7 Examples of the application of assessment principles

7.1 Example: Multi-discipline organisations

Multi-sector organisations often have accreditations in a number of requirement standard areas (testing, calibration, inspection, certification, notified bodies and proficiency testing providers), covering both fixed sites and field activities carried out at the customer's premises. A management system has been built to cover the requirements of all individual standards; the special characteristics of the technical activities are covered by means of sector-specific guidelines.

Assessment of a multi-sector organisation's management system is carried out every year, covering all the standards used as a requirement for

accreditation. Assessment is targeted at assessing the application of the management system. The assessment's planning and implementation takes into account the comprehensiveness of the operator's own internal assessment (for example, management of changes, management reviews, internal audits, monitoring, assessments of risks and impartiality). Assessment of technical activities is carried out by means of separate assessment and surveillance visits in accordance with a plan. The results of assessments of technical activities are utilised in management system assessment and vice versa.

7.2 Example: Multi-site organisations

An example of a multi-site organisation is a medical laboratory in which analysis has been centralised in one larger central laboratory within a large hospital as well as in ten smaller laboratories in the region's hospitals. All of them have the same management system and similar equipment. There are several dozen sampling sites, and samples are taken both in the hospital laboratories and in the region's health centre laboratories, which range from sites with one person to sites with several dozen people. The distances may also be long. In addition, the region's health centre laboratories carry out analyses using small appliances (same equipment in all the laboratories), and the health centres carry out analyses supported by the laboratory using the same small appliances. The aim is to seek accreditation simultaneously for all of the sites, including sampling and analyses.

In the example of a multi-site organisation described above, it is not necessary to implement an initial assessment in every individual sampling and analysis site; the sites are selected through sampling on the basis of which a general picture of the competence is created. The prerequisites for sample-based assessment are:

- A joint organisational structure and management
- Uniform procedures at different sites
 - joint management system, which is complied with at all sites
 - joint practices and procedures, joint operational guidelines
 - centralised planning of quality assurance and monitoring of functionality
 - joint competence requirements for the same tasks
 - centralised management of resources and expertise at the top level
 - joint orientation and training procedures

- internal audits cover all sites and findings in auditing are assessed in respect of the activities of all sites
- centralised monitoring of non-conformities and customer feedback
- Quality assurance has to be described and documented for every device (verifications, internal and external quality assurance, possible level comparisons with a reference device located in a central laboratory, documented quality objectives).
- Quality assurance of analysis and sampling has to be described and it must show how quality and the competence of the personnel is monitored.
- Documented training for equipment users, staff taking samples and persons in charge.
- Responsibilities must be defined clearly: who is responsible for the operations of a site, which functions are the responsibility of the site.
- The responsibilities of persons in charge must be described comprehensively.
- Practices in potential problem situations must be described clearly.
- Internal audits, peer assessments and reviews of operation must be documented.

8 Changes from the previous version

07.02.2024

Chapter	Change
6 Other matters	Remote assessments updated.