

Assessment of Multi-Sector and Multi-Site Organisations – Principles Applied by FINAS

FINAS Finnish Accreditation Service

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1 Foreward

This policy document for FINAS was drawn up by a working group appointed by the Advisory Committee for Accreditation Matters (VANK-P). The working group had the following members:

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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 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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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 EN ISO/IEC 17011:2004, with which the accreditation bodies have undertaken to comply. Revision of the standard is currently underway within ISO/CASCO WG 42. The revision of the standard may also affect the subject matter being considered by the working group.

2.1 Concepts

Assessment

Refers to all measures by an accreditation body 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, assessment of proficiency testing and monitoring of field activities. The elements of an assessment can be carried out at different times.

EA (European co-operation for Accreditation)

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

IAF (International Accreditation Forum Inc.)

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

ILAC (International Laboratory Accreditation Cooperation)

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

Management system

A system to establish (quality) policy and objectives and to achieve those objectives (ISO 9000 definition).

Multi-sector organisation

Refers to an organisation which has accredited activities in a number of sectors, for example, calibration, certification and inspection. In this case, the organisation may have more than one accreditation symbol.

Multi-site organisation

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

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 (ISO 17025 definition).

2.2 Co-operation with the organisation to be assessed

Assessments are planned in co-operation with an accredited body. 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 can be organised between the accreditation body and the accredited body, 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 bodies can be used in planning and carrying out assessments of accredited bodies. According to risk-based procedures the accreditation body may direct its assessments on the basis of a accredited body's performance and risks.

In risk-based assessment, an accreditation body aims to increase the effectiveness of assessments by forming a general view, or an organisation profile of the performance level of a body's activities and in this way highlight potential risk areas in the activities. The indicators 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 body can target assessment in areas where it is needed most. The aim is to increase the effective-

ness of assessment, to bring more added value to bodies 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) and
- frequency (how often).

The profiles of organisations are regularly examined so any changes in the organisation's activities can be taken into account. Planning of risk-based assessments also includes regular discussion with accredited body about the content of its profile.

3.1 Own monitoring and control procedures of a body

Planning of assessments of bodies should take into account the bodies' 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 a body 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 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 a body's management system meets the requirements for accreditation and whether the body operates in accordance with these requirements. Management system assessments examine, for example, the structure of an organisation, decision-making, management of organisational changes, risk management, the management system's structure and documents, quality policy, management reviews, internal audits, management of documents and records, impartiality of the body and management of impartiality, development and maintenance of personnel competence, management of competencies and

authorisations, handling of customer feedback and complaints, feedback from personnel, subcontracting and review procedures for agreements.

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 body may have operations in several sectors. In this case, the organisation may have more than one accreditation symbol. If the body has a management system which covers several sectors, it is possible to cover more than one sector with a single assessment.

An example is a body 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 body's personnel, location of sites or the assessment group's scope of accreditation may restrict a sector being covered with a single assessment visit.

The prerequisite for covering several sectors by means of a single management system is that the management system is common 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 a body meet the requirements for accreditation and whether the body produces correct, comparable and reliable results. Assessments of technical activities examine, among other things, the competence of technical personnel and maintenance of competence, validation of methods and procedures, verification of their usability, quality assurance procedures, proficien-

cy testing, measurement uncertainty, sampling, maintenance of equipment and calibrations, traceability of measurements, premises and environments and reporting of results (testing and calibration results, certificates, inspection reports, audit reports). 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 a body engaged in product certification, which is accredited in accordance with the standard 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 body and the activities of FINAS. Technical assessment can at the same time be combined with management system assessment. The possibility of combining assessments is agreed in co-operation with a body 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, 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 standard ISO/IEC 17011 sets conditions in accordance with which multi-site organisations should be assessed.

In the initial visit, the assessment visit must be made at all sites considered as key activity locations. In reassessments and period surveillance assess-

ments, the key activity locations should be assessed in accordance with a plan drawn up in advance.

5.2 Key activity location concept

The ISO/IEC 17011 regulating the activities of accreditation bodies sets specific requirements for the assessment of key activity locations. For this reason, the definition and interpretation of the concept of a key activity location have an important impact in the assessment of a multi-site organisation.

The standard ISO/IEC 17011 defines key activities as “policy formulation, process and/or procedure development and, as appropriate, contract review, planning conformity assessments, review, approval and decision on the results of conformity assessments”. The guide IAF/ILAC-A5:11/2013 provides more detailed guidelines on the definition of a key activity location in inspection and certification activities.

Examples of activities that **support** interpreting a site as a key activity location.

- An activity which sets significant requirements for the premises in which the activity is performed.
- An activity which uses equipment necessitating assessment on site.
- An activity consisting of other essential characteristics, the assessment of which would be difficult or impossible other than on site.

Examples of activities which **do not** make a site a key activity location:

- Acceptance and approval of commissions/agreements based on sufficiently precise and unambiguous criteria which have been defined in advance.
- Planning of testing, calibrations, inspections and other procedures based on sufficiently precise and unambiguous criteria which have been defined in advance.
- Assessment of results, approval and decision-making based on sufficiently precise and unambiguous criteria which have been defined in advance.
- An activity of the kind which does not set significant special requirements for the premises in which the activity is carried out and which does not use equipment necessitating assessment on site. In these cases, it is often necessary to assess the activity, but the assessment can be performed elsewhere than at the site in question.

5.3 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 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.

5.4 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.

5.5 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 monitored 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.

5.6 Sites located abroad

As a general principle, each country in Europe has a national accreditation body which operates in the area of the country in question. Many organisations, however, have operations in a number of countries, and the accreditation bodies 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 body of the country in question.

6 Other matters

6.1 Monitoring 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. Monitoring of the activities of individuals in this case plays a significant role in assessments relating to accreditation.

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

6.2 Utilisation of remote assessment methods

In some situations, it may be possible to replace assessment carried out on-site entirely or in part by means of assessments carried out using remote tools. Remote tools may include, for example, speech and video communication, inspection of documents by means of a remote connection, as well as picture, sound and video recordings.

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 a remote tool.

6.3 Time spent on assessments

Planning assessments of multi-sector and multi-site organisation 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.

The IAF guide MD 5:2013 shows a table for QMS and EMS assessments indicating the amount of time that should be spent on initial and surveillance

assessments and on reassessments. The complexity or risks of an activity affect the time used. The IAF document MD1:2007 comments on how many remote sites should be assessed. These guidelines apply to the certification of management systems. Similar norms have not been determined in other sectors.

7 Examples of the application of assessment principles

7.1 Example: Multi-sector organisations

Multi-sector organisations often have accreditations in a number of requirement standard areas: testing, calibration, inspection, certification and notified bodies, 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 body's own internal assessment (for example, management of changes, management reviews, internal audits, monitorings, 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, e.g. for sampling or for analyses.

In the example of a multi-site organisation described above, it is not necessary to implement initial assessment in every individual sampling site; a sample is taken in the assessment of 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
 - o joint management system, which is complied with at all sites
 - o joint practices and procedures, joint operational guidelines
 - o centralised planning of quality assurance and monitoring of functionality
 - o joint competence requirements for the same tasks
 - o centralised management of resources and expertise at the top level
 - o joint orientation and training procedures
 - o internal audits cover all sites and findings in auditing are assessed in respect of the activities of all sites
 - o centralised monitoring of non-conformities and customer feedback
- Quality assurance has to be described and documented for every device (verifications, quality assurance: internal and external quality assurance, possible level comparisons with a reference device located in central laboratory, documented quality objectives).
- Quality assurance of sampling has to be described and it must show how quality and the competence of the personnel taking samples 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.

In addition, the prerequisite for sample-based assessment is that the sites are not responsible for developing or maintaining testing methods, or for assessment of personnel training or competence.

8 References and additional material

Policy documents:

A5/2016 FINAS policy for sector schemes

Guidelines:

EA-2/13M:2012 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation Between EA Members

EA-2/13M S1:2013 Supplement 1 to EA-2/13 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members

EA-6/04:2011 EA Guidelines of Certification of Primary Sector Products on the Accreditation by Means of Sampling of Sites

IAF MD 1:2007 Certification of Multiple Sites Based on Sampling

IAF MD 19:2016 IAF Mandatory Document For The Audit and Certification of a Management System operated by a Multi-Site Organization (where application of site sampling is not appropriate)

IAF MD 5:2013 Duration of QMS and EMS Audits

IAF/ILAC-A5:11/2013 Multi-Lateral Mutual Recognition Arrangements: Application of ISO/IEC 17011:2004