

## Utilisation of Accreditation in New Sectors – Views on Eligibility for Accreditation

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## 1 Preface

Cooperation with stakeholders plays an important role for maintaining and developing accreditation. In Finland, the Advisory Committee for Conformity Assessment (VANK) appointed by the Government and especially the Advisory Committee for Accreditation Matters (VANK-P), are important cooperation partners for FINAS Finnish Accreditation Service. One of the tasks undertaken by the VANK-P Committee appointed for the period 2007–2010 was to examine the principles concerning eligibility for accreditation. For this purpose, a working group was set up; this report is the result of the working group's deliberations. The topic, which was initially given the working title "What can be accredited", has also been discussed in various international forums. The working group has therefore had access to many views on the matter.

## 2 Background

As society changes, the requirements and expectations set for accreditation also change. The goal is to develop accreditation so that it is able to meet future needs and to provide the services needed by society and clients.

## 3 Accreditation and accreditation bodies

Based on international criteria, accreditation is a procedure for producing reliable proof of a body's competence and of the credibility of the certificates it has issued. The European Parliament and the Council have issued a Regulation (765/2008/EC) on the organisation and functions of accreditation in the Member States. The Regulation defines the accreditation body's responsibilities and tasks and the Member State's responsibility for the provision of accreditation. Within the territory of the European Union, each Member State has one national accreditation body. FINAS has been named as the Finnish national accreditation body.

Internationally, accreditation is governed by uniform procedures and requirements. International evaluations have shown that FINAS's operations are equal to the practices followed by accreditation bodies in other countries. FINAS is party to all Mutual Recognition and Multilateral Recognition Arrangements (MLA/MRA) drawn up by European and international organisations. The international agreements signed reduce the need to obtain accreditation in various countries and increase the global acceptability of results given by accredited bodies.

Accreditation bodies do not compete against each other within the European Union. Nor do accreditation bodies offer the same services as their clients. Similarly, an accredited body cannot offer the same services as accreditation bodies.

The bodies to be accredited are various types of organisations engaged in conformity assessment, such as laboratories, inspection bodies and certification bodies. Accreditation is utilised in both voluntary and statutory verification of competence. The sectors that make use of accreditation, such as industries or public administration, may set accreditation as a precondition for the approval of a body.

In some sectors, accreditation is particularly important for society; these include risks associated with safety, people's health and the environment, and consumer protection. By means of accreditation, customers needing a particular service can be shown that the service provider meets a sufficient and appropriate standard of quality and competence and will continue to do so.

To benefit from accreditation, it is essential both that people and organisations are increasingly familiar with accreditation and that information on the scope of accreditation is easily available.

## 4 Future challenges faced by accreditation

### 4.1 *Changes in the operating environment*

Changes in organisations and operating models pose challenges for the maintenance of service quality. In consequence, the targeting of the scope of accreditation according to customers' needs is analysed more frequently and more critically.

Owing to internationalisation, some of the companies engaged in inspection, testing and certification are multinational. Companies working in the same sector either merge to form larger entities or network with each other. Similarly, companies give up many functions that they used to do and outsource them to enterprises based in Finland or abroad. For instance, decision-making and conformity assessment associated with inspections may take place in a country different to the country where the actual field work is done. Responsibility for the maintenance and development of management systems may be delegated to offices overseas where the operating culture differs from that in Finland.

Accreditation of multinational operators is challenging, and it has been observed that cooperation between accreditation bodies yields better results. On the basis of the international agreements signed, FINAS is committed to promoting

cooperation among accreditation bodies and the harmonisation of accreditation internationally. In line with these obligations and the Cross Frontier principles, FINAS acts in cooperation with local accreditation bodies in each country when assessing the foreign operations of accredited bodies or bodies applying for accreditation.

Tests requiring expensive investments in equipment are increasingly often concentrated in bodies that have access to special expertise. In consequence, enterprises often use ever wider networks of subcontractors and experts.

Subcontractors are assessed against the same accreditation standards as the principal operator. An operator using subcontractors is responsible for the quality of the subcontractors' input, and the quality must be on a par with the operator's own work. Overall responsibility for activities is vested in one body that must have enough expertise to understand the meaning of the results and opinions given by subcontractors.

#### *4.2 Environmental considerations*

Society keeps analysing and developing issues in order to ensure a better tomorrow. The topics studied range from measures to secure people's health and safety to issues concerning adequate supply of energy, food and natural resources. Concern for the environment and actions to combat climate change increase the need for measurements and assessment. The goal set in the Government Foresight Report on Climate and Energy Policy is to achieve a radical cut in greenhouse gas emissions; this calls for reliable measurement and verification of emissions. The government's new policies and measures to reduce emissions, such as linking the real estate tax to the building's energy consumption, require reliable verification.

Aside from the views of experts, various measurements are used to support forecasts based on models and trends. The quality of such measurements and analyses should be high. The high standard of sampling is also important to the quality of results. In addition to statutory requirements, private enterprises strive to meet their customers' and stakeholders' increasing demands and to manage environmental risks better than before.

#### *4.3 Demands for productivity and reorganisation of the State's sectoral research*

The changes that have taken place in various business sectors during the past couple of decades are still continuing. Organisations providing laboratory and assessment services have grown through company acquisitions, and services that used to be produced by the public sector have been transferred to private operators. The economic recession has also made it more urgent to raise

efficiency. In business, the supply of services must match their demand, stricter requirements are placed on profitability, organisational models are revised, the use of resources is retargeted and optimised. The government has various projects in progress: reorganisation of sectoral research; the productivity project; and decentralisation of government agencies. All these changes in operations that have already been accredited pose a major challenge. Maintaining competence during a phase of transition calls for good and expert planning and proper documentation.

#### *4.4 Changing legislative demands*

The Regulation of the European Parliament and the Council (765/2008/EC) lays down rules for the organisation and tasks of accreditation services in the Member States. The legislation can be expected to lead to the introduction of new accreditation areas, such as the accreditation of notified bodies. Moreover, alongside new and revised Directives, additional new sectors will be covered by accreditation. It is important that FINAS and the ministries in the relevant administrative branches go through the legislation in order to achieve a uniform assessment system for services, many of which are important for consumers.

#### *4.5 Technical solutions*

Targets that undergo conformity assessment contain increasing amounts of electronics and IT applications that affect the target's ability to meet the requirements set for it. The assessment of a body also requires the ability to assess and demonstrate the reliability of hardware and software. The real risks of hardware and software must be recognised and it must be ensured that attention is paid to the right things.

The developments that have taken place in on-line measurements and in the associated hardware and software also set new requirements for the quality of operations and for the related accreditation.

## 5 Views on the eligibility for accreditation

To be able to be accredited, operations must be reliable, correct and independent.

Two differing viewpoints have been presented in the European debate on accreditation. The traditional view on accreditation is that the accreditation process is guided by the existing standards, which are used as accreditation requirements. In this model, testing, inspection and certification bodies are

treated separately even if they are part of the same organisation. A more liberal model departs from the assumption that the standards laying down the accreditation requirements can be used side by side when assessing a body.

According to the working group's view, accreditation of combinations will be needed increasingly often in the future. This view is supported, on the one hand, by mergers of existing accredited bodies and, on the other, by the emergence of new organisations owing to sectoral arrangements and developments in public administration. The current accreditation of notified bodies is an example of activities where the traditional division between testing, inspection, and certification bodies is becoming blurred.

### *5.1 Operations where the use of accreditation would be possible*

In the working group's opinion, there are certain sectors where accreditation has not yet been utilised in Finland. Examples of such sectors include:

- Consultative assessment services, such as condition assessments and surveys and condition monitoring
- Land surveying
- Building inspection
- Periodic inspection of cars
- Investigations determining the reasons for disputes, including inspection of goods
- Measurements of electricity, water and energy consumption
- Measurement of energy efficiency
- Health care, including aspects other than certain determinations carried out in a laboratory
- Investigations determining the reasons for damage, such as investigations for moisture damage, indoor air or accidents
- Sampling, provided that reliable requirement criteria are available

There are many reasons why accreditation is little used in some sectors. For instance, the following:

- Most of these services are very old. Procedures have become established and organisations have been developed before the accreditation system was adopted.
- Some of these services are clearly associated with the authorities. Traditionally, such services have not been accredited, not even when some of the authorities' tasks have been transferred to private operators. Attitudes to accreditation have varied depending on the administrative branch, and no direct reference to accreditation is made in regulations or other legal provisions. Traditionally, operations associated with health care and other medical functions have also used other means besides accreditation to demonstrate quality.

- In addition to testing methods and other similar procedures, the above services include a definite element of expert assessment. There is often reluctance to consider these elements as inspection or certification measures. For this reason, the option of accreditation has not been noted and accreditation has not been applied to the processes followed by laboratories to give opinions.
- Some services are associated with fields where the process approach and quality management by means of operating systems have proved difficult owing to the project nature of operations. In particular, this observation pertains to the building sector, where accredited operations are mainly associated with materials testing, product testing and the certification of building products.

Most of the above cases meet the criteria set for accredited operations. Accreditation could enhance the reliability of these services. This would be a positive development, especially for consumers.

Accreditation could also be utilised for assessing the competence of commercial assessment services. These services have found their market quite recently and have grown rapidly. In these sectors, there may not have been enough time to consider the utilisation of accreditation from the perspectives of the quality of operations or the customer. Various condition surveys of buildings and the associated measurements are examples of these sectors. This is the situation even when decisions on long-term and expensive renovation investments are based on these surveys.

### *5.2 Operations where the application of accreditation is not considered probable*

The splintering of activities is becoming increasingly common among accreditation clients. For example, some tasks are delegated to external service providers. The working group does not endorse the accreditation of an organisation that produces only a small part of the entire process. An example of this is the pretreatment of samples, which alone does not provide an assessment of conformity for the customer. Accreditation should be limited to the assessment of entire processes meeting customers' needs; these, of course, may include subcontractors.

Accreditation does not compete with other types of conformity assessment. In other words, accreditation cannot cover, for instance, a scope that could be certified by means of voluntary certification of operating systems.

### *5.3 Characteristics of a reliable method*

Mutual international recognition of accreditation requires the use of generally approved, standardised methods. Moreover, obtaining the approval of the

authorities generally requires the use of methods that are well known or defined by the authorities. However, testing laboratories also use in-house methods.

A measurement, method, procedure or process can be accredited when certain jointly agreed criteria are met. The method or process must serve its purpose and must be documented. In addition, it must be possible to show the correctness and comparability of the result. In most cases, this is done by participating in interlaboratory comparisons or by using certified reference materials.

There may sometimes be a wish to include rare or new methods lacking reference data within the scope of accreditation. Then it is particularly challenging to demonstrate the correctness and comparability of results. In such a case, the procedures of internal quality assurance play a pivotal role when operations are assessed. Any proficiency testing that may have been carried out with accredited or non-accredited bodies abroad or in Finland must be taken into account during the assessment. There are three central elements for demonstrating competence: assessment of the uncertainty of measurement; verification of the operation of testing equipment; and documentation of the method.

Accreditation in a sector where there are few national operators is a challenge. The standard of operations is harmonised in cooperation with other accreditation bodies and stakeholder organisations. The goal is to verify the quality and competence level of operations against other accredited operators. Interlaboratory comparisons are an important indication of the quality of operations.

## 6 Conclusion

In this report, the working group has listed principles pertaining to eligibility for accreditation. Some of the principles are already in use but raising them here is helpful when eligibility for accreditation is evaluated. The discussion on eligibility for accreditation will also continue in the international cooperation forums of accreditation bodies. The cross-cutting principle is that accreditation is a way to assess the competence of bodies engaged in conformity assessment, and accreditation bodies do not compete with providers of commercial services. To be accredited, a body must provide its customers with comprehensive conformity assessment service, not a small, possibly subcontracted segment of it. It must be possible to assess the reliability of the operations that are accredited. This excludes certain one-off or rare tasks from accreditation.

This report presents some sectors where accreditation has not generally been utilised to date. These sectors are either old and established functions

undertaken by the authorities or new needs introduced by changes in the operating environment. Often they pertain to the protection of consumers and the environment and to energy efficiency. The need for these services will persist in the future, and in the working group's opinion, accreditation should be utilised to an increasing extent.

## FINAS Policy Documents

This FINAS Policy Document was drawn up by an ad hoc working group (2008–2010) appointed by the Advisory Committee for Accreditation Matters (VANK-P). The working group comprised the following persons:

Lanu, Matti, Chairman	VTT Expert Services Oy
Kuitunen, Marja-Leena	Eurolab
Hartikainen, Eeva Liisa	Finnish Environment Institute
Roine, Jouko	Inspecta Oy
Kantanen, Marja Leena (until 31 March 2009)	National Institute for Health and Welfare
Waddington, Christina (expert)	FINAS
Mäkinen, Marjukka, Secretary	FINAS

The purpose of the policy documents is to clarify the application of accreditation requirements in practice. The policy documents have been drawn up in accordance with principles agreed within the international cooperation organisations of accreditation bodies (European co-operation for Accreditation, International Laboratory Accreditation Cooperation and International Accreditation Forum).

Further information about policy document is available from FINAS Finnish Accreditation Service:

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