

## **Principles for the Assessment of Subcontracting**

## Foreword

This policy document for FINAS was drawn up in 2014–2016 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](http://www.finas.fi)

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## Summary

The Principles for the Assessment of Subcontracting are aimed at the clients, assessors and stakeholders of FINAS Finnish Accreditation Service. The principles can be utilised when assessing subcontracting used by a client applying for accreditation or by a accredited conformity assessment body (CAB). Hereinafter in this policy document, a conformity assessment body (CAB) will referred to as the operator. The use of subcontracting has increased and it will become subject to comprehensive assessment in the assessment of various operators.

The requirements relating to subcontracting are described in the accreditation requirement standards. All requirement standards permit the use of subcontracting, and the general principles for the use of subcontracting are the same in all requirement standards. Subcontracting must be transparent throughout the entire subcontracting chain, which increases confidence in the subcontracted activity. Use of subcontracting should be agreed on in sufficient detail with the customer. An operator using subcontracting is always responsible for the results of a subcontractor, also in the case of serial subcontracting. Moreover, the competence of the subcontractor and the correctness of the results should continuously be ensured. The requirement standards contain, in addition to general principles, sector-specific requirements, which are taken into account when assessing subcontracting in these sectors.

Legislation may have sector-specific additional requirements, which are taken into account in assessments, particularly in the activities of a regulated sector. The international EA, IAF, and ILAC guidelines may also contain interpretations on the use of subcontracting, but they do not have additional requirements with regard to accreditation requirement standards.

Appendices 1–5 of the Assessment Principle contains examples of the use of subcontracting in various sectors. The examples aim to highlight aspects to which particular attention should be paid in assessing subcontracting, as well as good practice in accordance with which the subcontracting has been carried out.

## Background to the use of subcontracting

The role of subcontracting in testing, inspection and certification has increased significantly during recent years. The field of activities and forms of services have become more diverse and through subcontracting the varying needs of customers can be met. The use of subcontracting brings new opportunities for operators already working in a sector and also for operators entering the field. Operators can focus on their core areas, in which they are better and more efficient than others, and procure other activities in the form of subcontracting. The principle of subcontracting and other co-operation models are good solutions in a diversifying field of activities.

On the other hand, when considering subcontracting, benefits are offset by other factors, which should be addressed. The operator has the responsibility and obligation to ensure the competency of the subcontracted activity. An operator must have procedures for ensuring the reliability of a subcontracted activity and suitability for customers' needs. Quality assurance pertaining to subcontracting may give rise to additional expenses. The role of subcontracting in the delivery chain must be assessed as a part of the final service.

Centralisation can increase risks if the delivery capacity of fewer and potentially more specialised service providers causes delays or other problems. The transition from a own service to the use of subcontracting takes its own time, as does knowing how to identify risks realistically. Traditional subcontracting has been joined by other forms of co-operation, which bring new challenges to the use of subcontracting and to its assessment. This also involves the added perspective of internationalisation. When using a foreign subcontractor, the operator must ensure that the subcontracted activity meets the needs of customers and any national requirements.

## Definitions of terms

Accreditation requirement standards, legislation and other sources use parallel terms to refer to subcontracting. Depending on the case, the terms refer to the same thing or they may have different meanings.

### **Conformity assessment body (CAB)**

Refers to a body that performs conformity assessment services (Source: ISO/IEC 17000:2004). A conformity assessment body can be, for example, an inspection body, a testing laboratory or a certification body.

### **Subcontracting**

Refers to the supply of product parts to a principal manufacturer, or to the provision of a service, design, etc. to a company responsible for the overall contract (Source: The New Dictionary of Modern Finnish).

Accreditation requirement standards determine that under subcontracting a subcontractor is engaged by the accredited body to perform some of the activities falling within the scope of accreditation. The standards exclude from the definition of subcontracting the use of external personnel, procurement of supplies and support functions.

## **Outsourcing**

Refers to the contracting out a job or task previously performed in-house by a company, an organisation (Source: The New Dictionary of Modern Finnish).

The terms subcontracting and outsourcing are used as synonyms in a number of accreditation requirement standards.

## **Referral laboratory**

An external laboratory to which a sample is submitted for examination (Source: SFS-EN ISO 15189:2013).

## **External personal resources**

Refer to all the resources that are used as external personal resources in a contractual but non-employment relationship with an operator. External personal resources work in compliance with the system of the operator. In general, external personal resources refer to persons, but they may also refer to another operator. The use of external personal resources is not the same as subcontracting; instead they are treated as the operator's own personnel.

For example, where an inspection body engages individuals or employees of other organisations to provide additional resources or expertise, these individuals are not considered to be subcontractors provided they are formally contracted to operate under the inspection body's management system (Source: SFS-EN ISO/IEC17020:2012).

Clinical laboratories may use external experts who provide opinions and interpretations on demanding testing in various specialities (Source: SFS-EN ISO 15189:2013). An expert may also be referred to as a consultant.

## **Multi-sector organisation / Multi-discipline 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 (Source: FINAS Assessment Principle A10/2016).

## **Multi-site organisation**

Refers to an organisation which performs an accredited activity at a number of different sites (Source: FINAS Assessment Principle A10/2016).

## **Temporary subcontracting**

Subcontracting can be used either on a continuing basis or for unforeseen reasons. Reasons for using temporary subcontracting may be, for example, excessive workload, need for further expertise or temporary incapacity. (Source: SFS-EN ISO/IEC 17025:2005)

## **Serial subcontracting, subcontracting in chain**

Serial subcontracting uses subcontractors of subcontractors, which means that an activity is subcontracted to an operator further down the chain. An operator using a subcontractor is, regardless of serial subcontracting, responsible for the work performed by a subcontractor.

### **EA**

European co-operation for Accreditation

### **ILAC**

International Laboratory Accreditation Cooperation

### **IAF**

International Accreditation Forum Inc.

## **Requirements of accreditation standards**

The standards, which have been confirmed as accreditation requirements in decision FINAS P1/2015, has been taken into consideration in this Assessment Principles. All standards permit the use of subcontracting but, in other respects, there are various requirements and focuses. Tables 1 and 2 bring together the requirements described in the accreditation standards, which may change with updates to new standard versions.

## **Legal requirements**

National and European legislation contains requirements for operators, which should be taken into account by them. These requirements apply not only to the activities of the operator but correspondingly also to the subcontracted activity. Accreditation can also focus on sectors in which special requirements laid down in legislation

are taken into account as assessment criteria. Assessments in the voluntary sector likewise review the requirements set out in legislation, where applicable, and it is ensured that the operator has taken them into account.

Described below are the requirements laid down in the Constitution of Finland for bodies providing public administration functions. Sector-specific sectoral legislation may contain special requirements for operators and also for the use of subcontracting.

## Requirements laid down in the Constitution of Finland for bodies providing public administrative functions

Competence as provided for by law is required in order to perform a public administrative task. In general, authorities and individual civil servants are responsible for public administrative tasks. The Constitution of Finland (731/1999) restricts the delegation of public administrative tasks to other than public authorities, such as private-sector bodies. Under section 124 of the Constitution, a public administrative task may be delegated to others than public authorities only by an Act or by virtue of an Act, if this is necessary for the appropriate performance of the task and if basic rights and liberties, legal remedies and other requirements of good governance are not endangered. The requirement of appropriateness is a legal precondition, the fulfilment of which should be assessed on a case-by-case basis separately in respect of each public administrative task proposed to be delegated outside an authority organisation. However, a task involving significant exercise of public powers can only be delegated to public authorities.

When assigning administrative tasks to others than public authorities, the law must guarantee the legal protection and compliance with the requirements of good governance in the activity. This requires, as a rule, that the general laws on administration are followed in handling matters and that individuals dealing with matters perform their duties while subject to liability for acts in office. General laws on administration, without specific reference in sectoral legislation, are applied in the activity (the Act on the Openness of Government Activities (621/1999), the Act on Electronic Services and Communication in the Public Sector (13/2003), the Administrative Procedure Act (434/2003) and the Language Act (423/2003) when said individuals are carrying out public administrative tasks.

Securing the requirements of good governance requires that when delegating a public administrative task to others than public authorities, the competence and suitability of those carrying out administrative tasks, monitoring and guidance of administrative tasks as well as the rigour of regulation and other appropriateness are ensured. Due to this, the legislation requires that authorities monitor those bodies to which it has transferred public administrative tasks. For this reason, the



notified bodies report on their activities and are obliged to notify the appointed body of subcontractors they use.

Organisations performing public administrative tasks may be inspection bodies, verifiers, laboratories, certification bodies and notified bodies.

## Special features of subcontracting of a notified body

General laws of administration are applied to a subsidiary of a notified body or to activities subcontracted by a notified body, and criminal liability for acts in office are applied to persons in their employment while they are carrying out tasks of the notified body. A notified body always has overall responsibility regarding customers and it may not transfer overall assessment to a subcontractor. A notified body may subcontract parts of activities.

See more detailed description of notified bodies in Appendix 5.

## International policies

The use of subcontracting is a highly topical issue internationally and especially in Europe. The issue has been addressed in EA committee work, but uniform policies have not yet been formed internationally. Documented operating principles describing these policies may be available in the future.

The use of subcontracting has been interpreted in sector-specific EA, IAF ILAC documents, but they do not contain additional requirements relating to subcontracting, in contrast to accreditation requirement standards.

## Principles for the Assessment of Subcontracting

The assessment principles describe the general principles which should be taken into account in the assessment of subcontracting. In addition to these general principles, there may be sector-specific requirements and practices to which attention should be paid in an assessment.

## Competencies

The competence of a subcontractor should be demonstrated and bodies using subcontracting should be able to show that the competence of the subcontractor has been confirmed. A subcontracting body must determine the competencies for persons who are responsible for the use of subcontracting and who confirm a subcontractor's competence.

In regulated sectors the body may be obliged to keep available to the relevant authorities information relating to a subcontractor.

## Continuous assessment of subcontractor competence and methods of assessment

In an assessment, an indication must be obtained that the operator has procedures in place for the continuous monitoring of subcontractor competence.

Methods for demonstrating competence can include, for example, subcontractor accreditation, audits and results of proficiency testing. In addition, it should be ensured that the activity to be subcontracted meets other requirements set for it, for example, in relation to the suitability of the methods used.

## Responsibilities

An operator using subcontracting is always responsible for the part of the work carried out by a subcontractor. The responsibility also extends to cases in which serial subcontracting is used,

Exception is the case where the customer or a regulatory authority specifies which subcontractor is to be used (Source: SFS-EN ISO/IEC 17025:2005).

## Interfaces

Assessment must identify whether subcontracting is involved or whether the work is from another site within the same organisation (multi-site organisations). In addition to traditional subcontracting, a service may be provided by some other site within a multi-site organisation. In the special cases, a separate subsidiary of the operator may be a subcontractor.

The EA's Cross Border principles are described in the document EA 2/13M:2012. The principles describe the conditions under which an organisation operating in more than one country can offer services under the same accreditation decision.

## Agreements with subcontractors

With respect to subcontracting, the body concerned shall always have a valid agreement with a subcontractor. The requirement for drawing up an agreement has been described in various ways in different requirement standards. Through agreements, an operator can set for subcontractor's requirements relating to the nature of an activity. The ownership of results, rights of use and reporting method must be agreed.

When using subcontracting, attention must be paid to the requirements set by the national legislation.

## Impartiality

The same level of impartiality is required from the operator and the subcontractor it uses. Subcontractor impartiality must be ensured in particular if the operator is required to act as a third party.

## Meeting customer needs

The customer may have needs which require the use of the subcontracting or which prevent the use of the subcontracting. Legislation may set requirements for subcontractors. The customer or an authority may require that a specific subcontractor is used. These requirements must be identified in the assessment.

## Approval by the customer

As rule, the customer should be informed of the use of subcontracting. In many cases, the customer's approval is also required.

## Logistics

The assessment must ensure that subcontracting quality assurance takes into account logistical aspects relating to, for example, sample transportation and storage conditions as well as the location of the activity.

These factors may affect both the reliability of the activity and delivery times.

## Reporting of results, reference to accreditation

The subcontractor must comply with the practices observed in the sector when reporting results and take into account the needs of the operator, the customer and the relevant authorities.

Utilisation of accreditation in connection with an operator's results requires that they are accompanied by reference to accreditation. If the certificates or reports do not contain a reference to accreditation, the operator cannot refer to competence shown by means of accreditation. The principles for reference to accreditation in connection with subcontracting are described in requirement FINAS V1:2016.

When reporting laboratory results, it must be indicated that the analysis has been

subcontracted. The customer should be informed of the use of subcontracting and about the subcontractor used. The results of serial subcontracting involve an additional requirement in the requirement FINAS V1:2016. The laboratory's own reports and certificates may not include subcontracted results that have been obtained from a third laboratory (serial subcontracting). Such results acquired from a third laboratory are reported in a separate report, which may include a reference to the accreditation of the laboratory that performed the tests (the subcontractor's accreditation symbol and the name of the accreditation body that granted it).

### Non-conformities in a subcontracted activity, complaints and notices of defect

Non-confirming work identified must be reacted to in the same way as in non-conformities in an operator's own activities. It must be ensured in assessment that an operator using subcontracting has procedures to react to non-conformities and that correction extends to subcontractor.

An operator must handle complaints and notices of defect from customers or other bodies in the same way as those relating to their own activities.

### Sampling

An operator may subcontract sampling. The same requirements apply to sampling as to other subcontracted activities. The competence of the operator responsible for sampling must be ensured.

## References

- EA 2/13M:2012 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members
- FINAS Assessment Principle A10/2016 Assessment of Multi-Sector and Multi-Site Organisations – Principles Applied by FINAS
- FINAS P1/2015 Requirements applied to the accreditation activities
- FINAS Leaflet 10/2015 Accreditation criteria, policy documents and guidelines
- FINAS V1/2016 Rules on reference to accreditation
- ISO/IEC 17000:2004 Conformity assessment Vocabulary and general principles
- The New Dictionary of Modern Finnish, Institute for the Languages of Finland and Kielikone Oy
- SFS-EN ISO/IEC 14065:2013 Greenhouse gases – Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition
- SFS-EN ISO 15189:2013 Medical laboratories – Requirements for quality and competence
- SFS-EN ISO/IEC 17020:2012 Conformity assessment Requirements for the operation of various types of bodies performing inspection
- SFS-EN ISO/IEC 17021-1:2015 Conformity assessment. Requirements for bodies providing audit and certification of management systems. Part 1: Requirements
- SFS-EN ISO/IEC 17024:2012 Conformity assessment – General requirements for bodies operating certification of persons
- SFS-EN ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories
- SFS-EN ISO/IEC 17043:2010 Conformity assessment – General requirements for proficiency testing
- SFS-EN ISO/IEC 17065:2012 Conformity assessment – Requirements for bodies certifying products, processes and services

## Appendices 1–5 of the Assessment Principle

The appendices to the Assessment Principle show typical examples of the use of subcontracting in various sectors. The examples aim to highlight aspects to which particular attention should be paid in assessing subcontracting, as well as good practice in accordance with which the subcontracting has been carried out. The names of the organisations and those of any studies used in the examples are fictitious and are not related to existing organisations.

Appendix 1	Medical laboratory, serial subcontracting
Appendix 2	Food and environmental laboratory, serial subcontracting
Appendix 3	Testing, inspection and verification of construction products
Appendix 4	International multi-site organisation – internal subcontracting?
Appendix 5	Requirements set by a NLF decision and sectoral legislation for subcontractors of notified bodies

## Appendix 1 Medical laboratory, serial subcontracting

LÄÄKET-LAB subcontracts from YKS-LAB Oy a 9999 S Pharm test, the assay of which due to analytical, technical, as well as production-related and economic reasons is not worth maintaining in the laboratory's own range of laboratory tests. LÄÄKET-LAB's customers in its own hospital district order approximately 170 tests per year. On average, three to four patient samples are delivered to YKS-LAB OY every week. P Pharm is an uncommon pharmaceutical test, which is not included in the range of tests performed by laboratories in Finland. For this reason, YKS-LAB Oy subcontracted it from NEDER-LAB, a laboratory based in central Europe. In patient treatment, the pharmaceutical substance is used to treat infections and its therapeutic concentration range is narrow. Excessively high doses have toxic effects. It is essential that the test is available in the treatment of patients with specific types of infections.

Serial subcontracting may have consequences in the three example cases presented below.

### 1. The assay method and the result level of the test change

YKS-LAB Oy's subcontracting laboratory NEDER-LAB changes its assay method at short notice and the result level changes. This changes the therapeutic range and the commissioning body must be informed of the changing result level promptly. LÄÄKET-LAB is responsible for providing information a short notice.

### 2. Service response of test is changed

YKS-LAB Oy's subcontracting laboratory NEDER-LAB reorganises its production and testing frequency is decreased. The sample consignments arrive from outside LÄÄKET-LAB's central laboratory and are forwarded to YKS-LAB Oy. The planning of sample logistics scheduling with courier services must in this case be reconsidered, as customer service is suffering.

### 3. The test is discontinued

YKS-LAB Oy's subcontracting laboratory NEDER-LAB discontinues the analysis service with respect to the 9999 S Pharm test, as the need to order it has decreased among the actual customer base. YKS-LAB Oy informs LÄÄKET-LAB that the test is being discontinued. LÄÄKET-LAB is obliged to notify the ordering body that a) the test is either temporarily unavailable, or b) no longer available at all. LÄÄKET-LAB has to consider arranging the assay method in its own laboratory at high cost, as the availability of the test must be guaranteed.

## Appendix 2 Food and environmental laboratory, serial subcontracting

The Finnish laboratory LiiniLab orders an analysis from Quant Finland Oy, which is part of the global Quant Group. The issue at hand is a sample required by the authorities. Requirements for analysis of the sample are laid down in the relevant legislation (method and efficiency). The sample is sent to Quant Finland Oy's unit from which it is forwarded to the Quant Group's laboratory in Europe. LiiniLab receives Quant Finland Oy's test certificate, which shows the results of the analysis performed by the laboratory in Europe.

### Good practice in subcontracting

- Before concluding/placing a subcontracting agreement/order, the customer-laboratory LiiniLab already receives information on the Quant Group's in-house subcontracting and on where each analysis will be carried out; a written agreement or other order document is drawn up.
- The criteria for subcontracting are entered in the agreement or the order at analysis level (incl. the analysis method to be used, delivery of test results, etc.) so that the information on the requirements of the relevant authority set for the method are retained up to the end of the subcontracting chain (= the laboratory carrying out the analysis), and so that LiiniLab can ensure that the laboratory performing the analysis uses an appropriate method.
- Serial subcontracting and the actual laboratory that performed the analysis are clearly indicated in the Quant Finland Oy test certificate received by LiiniLab.
- Quant-Finland Oy's test certificate is accompanied by the original test certificate (in which reference is made to accreditation) of the laboratory in Europe that performed the analysis. The accreditation standard and whether the accreditation body that granted the accreditation falls within the scope of international agreements on recognition of accreditation (EA MLA or ILAC MRA) is indicated in the test certificate.
- If LiiniLab does not have expertise in the analysis to be subcontracted or, for example, in a matrix to be analysed, it will agree with Quant-Finland Oy on who will draw up a valid and reliable statement of competence on the result in the language of the customer.



## Appendix 3 Testing, inspection and verification of construction products

The requirements for construction products are presented in product standards in which reference is made to standards for testing and classification. Some of the requirements for standards have been adopted, with standard references, also in the approval of construction products. This case describes on a generally level issues regarding accreditation requirements for testing, inspection and verification measures when they are carried out externally.

The European Union has a Directive, issued in 2011, relating to construction products. Products for which a European harmonised product standard has been published must bear the CE marking.

Eligibility of products for which a harmonised product standard has not been published are assessed on the basis of national procedures. National procedures in use in Finland consist of type approval, verification certificates and certificates of verification of quality control.

### **Accreditation requirements**

In testing, inspection and certification relating to CE marking, the authorities of each country notify the European Union of which bodies are authorised to determine and assess the characteristics and permanence of a product. The prerequisite for authorisation is that the authorising authority has verified that the body is competent for the activity in question. In Finland, the prerequisite for acting as a notified body for construction products is the accreditation of the activity.

**TESTING-, CERTIFICATION AND INSPECTION OF CONSTRUCTION PRODUCTS**

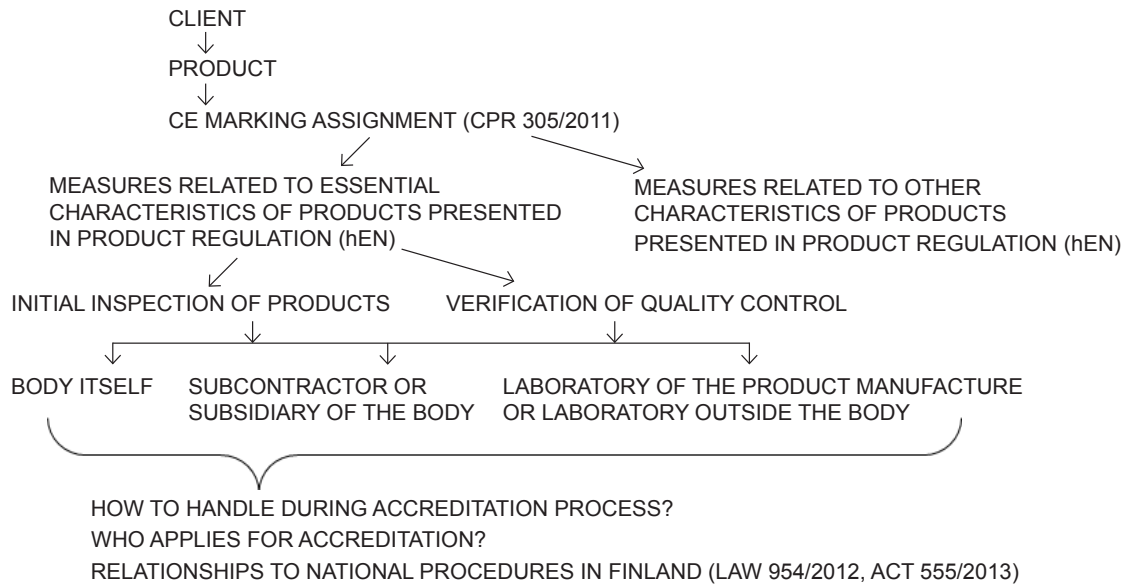


Figure 1 measures of a notified body relating to the CE marking mandate.

The Construction Product Regulation sets requirements for various alternative procedures in accordance with Figure 1. Accreditation requirements apply only to determination of the essential characteristics of a product listed in the so-called “Annex ZA”. The initial inspection of a product involves inspection of production quality control and initial testing of the product (type-testing). Following the initial inspection, production is subjected to continuous quality control verification, including quality control tests.

**Procedures and issues emerging on a case basis**

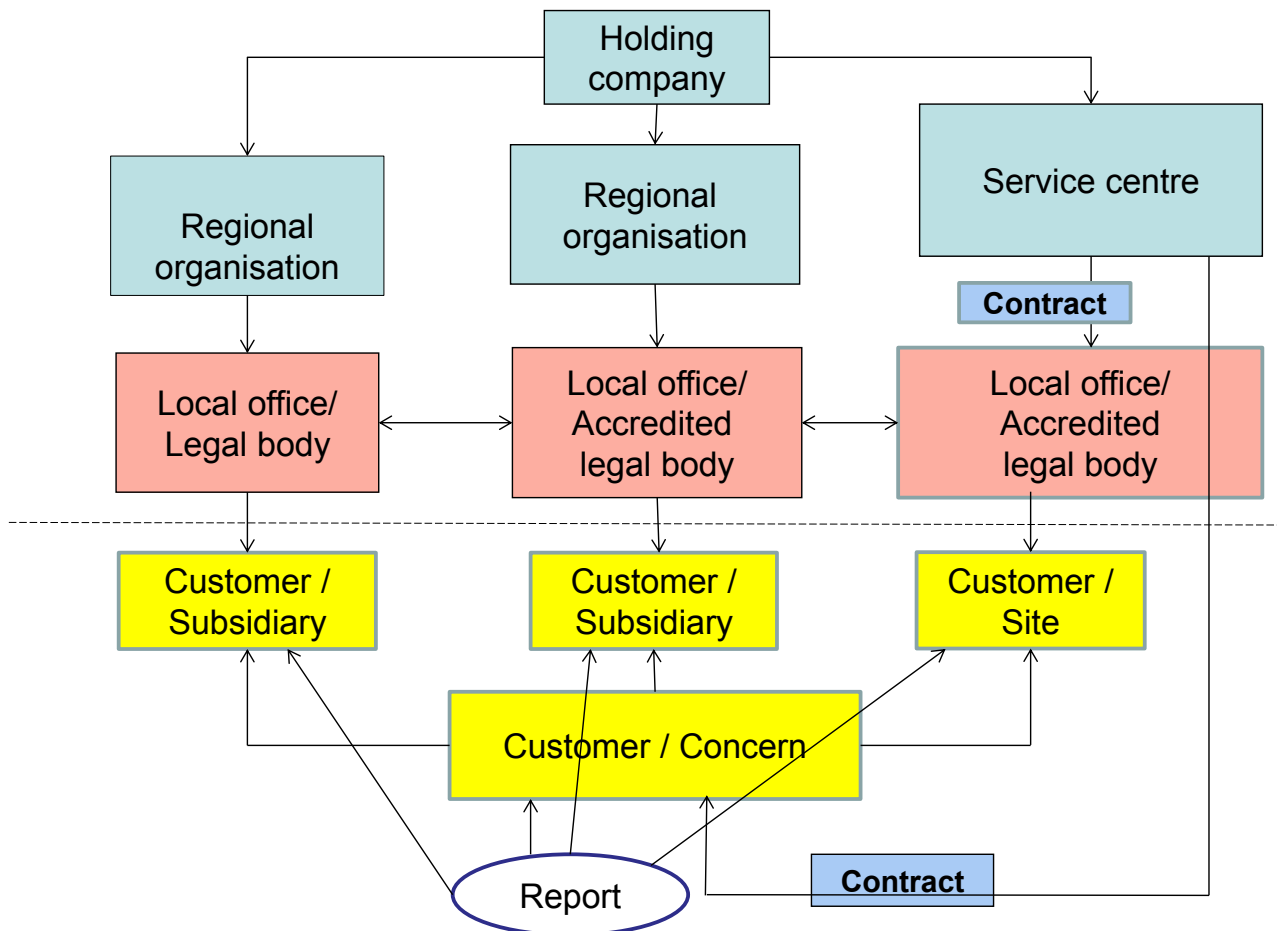
The Construction Product Regulation recognises three procedures: measures carried out by a notified body itself; measures sourced in the form of subcontracting or from a subsidiary of the body, and measures carried out in the laboratory of the product manufacturer or in a laboratory outside the body.

Measures carried out by a notified body itself are the most common method. The second procedure consists of measures in the form of subcontracting or from a subsidiary of the body. In both cases, the subcontractor or the subsidiary have their own operational systems with which they comply. They often have they own accreditation for testing, inspection or verification methods. A notified body should have a valid agreement on subcontracting.

The third procedure recognised by the Construction Product Regulation is to

conduct some of the measures of the CE marking mandate in the laboratory of the client of the CE marking mandate or in another laboratory outside the body using the equipment of the laboratory in question. The notified body must, however, be separately notified to use external resources in the method in question.

Appendix 4 International multi-site organisation – internal subcontracting?



In the case shown in the figure above, a customer operating in more than one site and in different companies purchases a service from a conformity assessment body that is part of an entity administered by a holding company.

The holding company’s entity includes a number of regional organisations and local offices. In addition, the holding company has one or more service centres which are able to provide, for example, specific sector-specific services independently of regional organisation division. This is the case shown here, in which a service centre has concluded an agreement with the customer. In practice, the local offices take care of providing the service pursuant to the agreement within the framework of an agreement between the service centre and the customer.

Lastly, the service centre provides the customer with a certificate which covers all the companies belonging to the customer group.

Assessment of the situation pursuant to this arrangement should take numerous factors into consideration:

- Potential division of the service pursuant to the agreement or delivery as separate parts
- An agreement on subcontracting in respect of a service provided by an internal unit of a group based, however, in an another country
- Customer approval of a subcontractor when using in-house subcontracting
- Responsibility and procedure for ensuring the competence of a subcontractor

If there is no agreement between the local office providing the service and the customer or their subsidiary, the local office will not be able to influence the content of the agreement or take into account any local special requirements either.

## Appendix 5 Requirements set out in the NLF Decision and in the sectoral legislation for subcontractors of notified bodies

NLF (New Legislative Framework) Regulation (765/2008) is directly applicable in all Member States. NLF Decision (768/2008) is a framework decision, a guideline for EU legislators. The articles in the NLF Decision will become applicable legislation when the directives and EU regulations are adapted to a new legislative framework.

A notified body must be established in Finland under national law and have registered legal personality. Furthermore, it must for the entire period of its operations fulfil the requirements and obligations of national legislation and of the NLF Regulation as well of other applicable legislation of the Community. Article R17 of the NLF Decision determines the requirements relating to notified bodies. These requirements as determined in Article R17 of the NLF Decision have been incorporated almost unchanged in most product directives and EU regulations.

A notified body may subcontract part of the work for which it is responsible to another competent body, whose competence will be monitored regularly. A notified body may subcontract a task for which it is qualified itself. Under no circumstances may a notified body subcontract its entire operations as, in that case, notification would be rendered meaningless. Article R20 of the NLF Decision regulates the responsibility of a notified body and its subsidiary as well as that of a subcontractor. Under the Article, where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article [R17].

A body acting as a subcontractor for a notified body must be technically competent and demonstrate its independence and impartiality on the same basis and under the same conditions as a notified body. The body in question does not, however, need to be a notified body. A notified body must ensure that a subcontractor remains competent, for example, by regularly conducting assessments and continuously procuring detailed information on the tasks performed by subcontractors. A notified body must also be able to demonstrate that its subcontractors meet the requirements of the Community's harmonisation legislation. A notified body shall in all cases be in a direct contractual relationship with subcontractors governed by private law in order to ensure that the general obligations of the notified body are fulfilled. Subcontracting must be based on an agreement by means of which the transparency and reliability of a notified body can be ensured.

Information in relation to subcontracted activities and the competence of subcontractors shall be at the disposal of the notifying authority so that it can implement the necessary measures and so that the information requested by the Commission and Member States can be submitted to them without delay. As in the case of a notified body, compliance with the EN ISO/IEC 17000 series of standards by a subcontractor likewise implies that the body and/or subcontractor fulfils the

requirements. If a notified body has not demonstrated its competence through accreditation, the relevant authority shall carry out inspections at the premises of the subcontractor to the same extent as has been laid down in respect of accreditation. An addition condition for subcontracting is that conformity assessment procedures may be divided into technical activities and assessment activities, and that when performing technical activities the procedures used are sufficiently precise. A subcontractor of a notified body must, however, carry out technical activities that constitute significant parts making up a cohesive whole.

Subcontractors of notified bodies do not in themselves need to notify. A notified body must, however, notify the Member State in question of their intention to subcontract a specific job. In that case, the Member State can decide in its capacity as the notifying authority that it will not take overall responsibility for this type of arrangement, but will cancel the arrangement or restrict the sector it covers. Notified bodies must keep a register on subcontracted activities, which they shall systematically keep up to date.

Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established. A notified body is solely responsible for the work a subcontractor carries out for it. A notification concerning a notified body can be cancelled for any reason relating to subcontractor. A notified body using a subcontractor remains responsible for all activities covered by the notification. Subcontracting does not mean the transfer of rights or obligations. Certificates are issued in the name of the notified body.

The Act on Notified Bodies Concerning Certain Product Groups (278/2016) governs separate procedural provisions in respect of product groups falling within the scope of the Act on the approval of a conformity assessment body and designation as a notified body and on their notification to the European Commission and other Member States. The Act provides on necessary definitions, on application concerning approval as a notified body, on competent authorities and on national approval and notification procedures. In addition, the Act contains provisions on the general requirements for a notified body and on the requirements in respect of the activities of the body and its personnel; on the general obligations of a notified body; on the obligation to provide information and on the obligation to participate in standardisation activities and the work of the coordination working group; as well as on subcontracting tasks or on having them carried out by a subsidiary.

**Table 1**

The requirements described in the accreditation standards for the use of subcontracting (SFS-EN ISO/IEC 17025:2005, SFS-EN ISO 15189:2013, SFS-EN ISO/IEC 17043:2010 and SFS-EN ISO/IEC 17020:2012)

	<b>SFS-EN ISO/IEC 17025:2005</b>	<b>SFS-EN ISO 15189:2013</b>	<b>SFS-EN ISO/IEC 17043:2010</b>	<b>SFS-EN ISO/IEC 17020:2012</b>
Responsibility of the subcontractor's work	4.5.3. The laboratory is responsible to the customer for the subcontractor's work, except in the case where the customer or a regulatory authority specifies which subcontractor is to be used.	4.5.1. The laboratory, with the advice of users of laboratory services where appropriate, is responsible for selecting the referral laboratory and referral consultants, monitoring the quality of performance.	5.5.4. The proficiency testing provider shall be responsible to the participants and other customers for the subcontractor's work, except in the case where a regulatory authority specifies which subcontractor is to be used.	6.3.3. Whenever subcontractors carry out work that forms part of an inspection, the responsibility for any determination of conformity of the inspected item with the requirements shall remain with the inspection body.
Restrictions for the use of the subcontracting	-	-	5.5.2. The proficiency testing provider shall not subcontract the planning of the proficiency test scheme (see 4.4.1.2), the evaluation of performance (see 4.7.2.1) or the authorization of the final report (see 4.8.1).	6.3.1. The inspection body shall itself normally perform the inspections that it contracts to undertake.
Selection of subcontractor, planning of the activities		4.1.1.4. The laboratory director shall select referral laboratories and monitor the quality of their service.  4.5.1. The laboratory shall have a documented procedure for selecting and evaluating referral laboratories and consultants who provide opinions as well as interpretation for complex testing in any discipline.	4.4.1.3. The proficiency testing provider shall document a plan before commencement of the proficiency testing scheme that addresses the objectives, purpose and basic design of the proficiency testing scheme, including the following information and, where appropriate, reasons for its selection or exclusion c) the activities to be subcontracted and the names and addresses of subcontractors involved in the operation of the proficiency testing scheme	



	<b>SFS-EN ISO/IEC 17025:2005</b>	<b>SFS-EN ISO 15189:2013</b>	<b>SFS-EN ISO/IEC 17043:2010</b>	<b>SFS-EN ISO/IEC 17020:2012</b>
Competence of the subcontractor	4.5.1. The work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this International Standard for the work in question.	4.5.1. The laboratory is responsible for ensuring that the referral laboratories or referral consultants are competent to perform the requested examinations.	5.5.1. When a proficiency testing provider subcontracts work, the proficiency testing provider shall demonstrate that the subcontractors' experience and technical competence are sufficient for their assigned tasks and that they comply with the relevant clauses of this International Standard and other appropriate standards.	6.3.1. Where an inspection body subcontracts any part of the inspection, it shall ensure and be able to demonstrate that the subcontractor is competent to perform the activities in question and, where applicable, complies with the relevant requirements stipulated in this International Standard or in other relevant conformity assessment standards.
Agreement with the subcontractor	-	4.5.1. Arrangements with referral laboratories and consultants are reviewed and evaluated periodically to ensure that the relevant parts of this International Standard are met. Records of such periodic reviews are maintained.	-	-
Maintenance of the information of subcontractors	4.5.4. The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this International Standard for the work in question.	4.5.1. A register of all referral laboratories, and consultants from whom opinions are sought, is maintained.  Requests and results of all samples referred are kept for a pre-defined period.	5.5.5. The proficiency testing provider shall maintain a register of all subcontractors used in the operation of proficiency testing schemes, including the scope of subcontracting and a record of the competence assessment against relevant parts of this International Standard and other appropriate standards for the work in question.	6.3.4. The inspection body shall record and retain details of its investigation of the competence of its subcontractors and of their conformity with the applicable requirements of this International Standard or in other relevant conformity assessment standards. The inspection body shall maintain a register of all subcontractors.

	SFS-EN ISO/IEC 17025:2005	SFS-EN ISO 15189:2013	SFS-EN ISO/IEC 17043:2010	SFS-EN ISO/IEC 17020:2012
Control of environmental conditions			<p>4.3.2. The proficiency testing provider shall ensure that the environmental conditions do not compromise the proficiency testing scheme or the required quality of operations. Particular care shall be taken when operations are undertaken at sites away from the proficiency testing provider's permanent facilities or are undertaken by subcontractors. The technical requirements for accommodation and environmental conditions that can affect the proficiency testing shall be documented.</p>	
Informing the client of the use of subcontracting, approval of the subcontracting	<p>4.4.3. The review shall also cover any work that is subcontracted by the laboratory.</p> <p>4.5.2. The laboratory shall advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer, preferably in writing.</p>	<p>4.4.1. In a service agreement a reference shall be made to any work referred by the laboratory to a referral laboratory or consultant.</p> <p>5.4.2. The laboratory shall have information available for patients and users of the laboratory services about the types of clinical services offered by the laboratory including examinations referred to other laboratories.</p>	<p>5.5.3. The proficiency testing provider shall inform participants, in advance and in writing, of services that are, or may be, subcontracted.</p> <p>5.4.3. The review of requests, tenders and contracts shall cover all aspects of the request, including any work that is subcontracted by the proficiency testing provider.</p>	<p>6.3.2. The inspection body shall inform the client of its intention to subcontract any part of the inspection.</p>

	<b>SFS-EN ISO/IEC 17025:2005</b>	<b>SFS-EN ISO 15189:2013</b>	<b>SFS-EN ISO/IEC 17043:2010</b>	<b>SFS-EN ISO/IEC 17020:2012</b>
Reporting of subcontracted results	<p>5.10.6. When the test report contains results of tests performed by subcontractors, these results shall be clearly identified. The subcontractor shall report the results in writing or electronically.</p> <p>When a calibration has been subcontracted, the laboratory performing the work shall issue the calibration certificate to the contracting laboratory.</p>	<p>4.5.2. Unless otherwise specified in the agreement, the referring laboratory (and not the referral laboratory) shall be responsible for ensuring that examination results of the referral laboratory are provided to the person making the request.</p> <p>When the referring laboratory prepares the report, it shall include all essential elements of the results reported by the referral laboratory or consultant, without alterations that could affect clinical interpretation. The report shall indicate which examinations were performed by a referral laboratory or consultant.</p> <p>The author of any additional remarks shall be clearly identified.</p> <p>Laboratories shall adopt the most appropriate means of reporting referral laboratory results, taking into account turnaround times, measurement accuracy, transcription processes and interpretative skill requirements. In cases where the correct interpretation and application of examination results needs collaboration between clinicians and specialists from both referring and referral laboratories,</p>	<p>4.8.2. Reports shall include the following, unless it is not applicable or the proficiency testing provider has valid reasons for not doing so: d) an indication of which activities are subcontracted by the proficiency testing provider</p>	<p>7.4.4. Where the inspection report or inspection certificate contains results supplied by subcontractors, these results shall be clearly identified.</p>

	SFS-EN ISO/IEC 17025:2005	SFS-EN ISO 15189:2013	SFS-EN ISO/IEC 17043:2010	SFS-EN ISO/IEC 17020:2012
		<p>this process shall not be hindered by commercial or financial considerations.</p> <p>5.9. When examination results fall within established “alert” or “critical” intervals: a physician (or other authorized health professional) is notified immediately [this includes results received on samples sent to referral laboratories for examination (see 4.5)];</p>		
Confidentiality of the activities				<p>6.1.13 All personnel of the inspection body, including sub-contractors, personnel of external bodies, and individuals acting on the inspection body’s behalf, shall keep confidential all information obtained or created during the performance of the inspection activities, except as required by law.</p>

**Table 2**

The requirements described in the accreditation standards for the use of subcontracting (SFS-EN ISO/IEC 17021-1:2015, SFS-EN ISO/IEC 17065:2012, SFS-EN ISO/IEC 17024:2012 and SFS-EN ISO/IEC 14065:2013)

	<b>SFS-EN ISO/IEC 17021-1:2015</b>	<b>SFS-EN ISO/IEC 17065:2012</b>	<b>SFS-EN ISO/IEC 17024:2012</b>	<b>SFS-EN ISO/IEC 14065:2013</b>
Responsibility of the subcontractor's work	7.5.3. The certification body shall: a) take responsibility for all activities outsourced to another body.	6.2.2.4. The certification body shall take responsibility for all activities outsourced to another body.	6.3.2. The certification body shall take full responsibility for all outsourced work.	6.6. Verification body shall retain full responsibility for the validation or verification
Restrictions for the use of the subcontracting	7.5.2. Decisions for granting, refusing, maintaining of certification, expanding or reducing the scope of certification, renewing, suspending or restoring, or withdrawing of certification shall not be outsourced.	4.2.8 ...The personnel of the separate legal entity shall not be involved in the management of the certification body, the review, or the certification decision.  7.6.3 The person(s) [excluding members of committees (see 5.1.4)] assigned by the certification body to make a certification decision shall be employed by, or shall be under contract with, one of the following: the certification body (see 6.1); an entity under the organizational control of the certification body (see 7.6.4).	9.4.2. Decisions for granting, maintaining, recertifying, extending, reducing, suspending or withdrawing certification shall not be outsourced.	6.6. In the absence of GHG programme prohibitions on outsourcing, the validation or verification body may outsource  5.4.2. The verification body shall not outsource the review and issuance of the validation or verification statement

	<b>SFS-EN ISO/IEC 17021-1:2015</b>	<b>SFS-EN ISO/IEC 17065:2012</b>	<b>SFS-EN ISO/IEC 17024:2012</b>	<b>SFS-EN ISO/IEC 14065:2013</b>
Selection of subcontractor	<p>5.2.8. The certification body shall not outsource audits to a management system consultancy organization, as this poses an unacceptable threat to the impartiality of the certification body (see 7.5). This does not apply to individuals contracted as auditors covered in 7.3.</p> <p>7.5.1. The certification body shall have a process in which it describes the conditions under which outsourcing (which is subcontracting to another organization to provide part of the certification activities on behalf of the certification body) may take place.</p> <p>7.5.3. The certification body shall ensure that the body that provides outsourced services, and the individuals that it uses, are not involved, either directly or through any other employer, with an organization to be audited, in such a way that impartiality could be compromised.</p>	<p>6.2.2.4. The certification body shall ensure that the body that provides outsourced services, and the personnel that it uses, are not involved, either directly or through any other employer, in such a way that the credibility of the results could be compromised.</p>		

	<b>SFS-EN ISO/IEC 17021-1:2015</b>	<b>SFS-EN ISO/IEC 17065:2012</b>	<b>SFS-EN ISO/IEC 17024:2012</b>	<b>SFS-EN ISO/IEC 14065:2013</b>
Competence of the subcontractor	<p>7.5.3. The certification body shall ensure that the body that provides outsourced services, and the individuals that it uses, conform to requirements of the certification body and also to the applicable provisions of this part of ISO/IEC 17021, including competence, impartiality and confidentiality.</p>	<p>6.2.2.1. The certification body shall outsource evaluation activities only to bodies that meet the applicable requirements of the relevant International Standards and, as specified by the certification scheme, of other documents. For testing, it shall meet the applicable requirements of ISO/IEC 17025; for inspection, it shall meet the applicable requirements of ISO/IEC 17020; and for management system auditing, it shall meet the applicable requirements of ISO/IEC 17021. The impartiality requirements of the evaluation personnel stipulated in the relevant standard shall always be applicable.</p> <p>6.2.2.2. Where evaluation activities are outsourced to non-independent bodies (e.g. client laboratories), the certification body shall ensure that the evaluation activities are managed in a manner which provides confidence in the results, and that records are available to justify the confidence.</p> <p>6.2.2.4. The certification body shall have documented policies, procedures and records for the qualification, assessing and monitoring of all bodies that provide outsourced services used for certification activities.</p>	<p>6.3.2. The certification body shall ensure that the body conducting outsourced work is competent and complies with the applicable provisions of this International Standard.</p> <p>Assess and monitor the performance of the bodies conducting outsourced work in accordance with its documented procedures.</p> <p>Have records to demonstrate that the bodies conducting outsourced work meet all requirements relevant to the outsourced work.</p>	<p>6.6. Verification body shall require the outsourced body to provide independent evidence that demonstrates conformity with this International Standard and with ISO 14064-3</p>

	SFS-EN ISO/IEC 17021-1:2015	SFS-EN ISO/IEC 17065:2012	SFS-EN ISO/IEC 17024:2012	SFS-EN ISO/IEC 14065:2013
		6.2.2.4. The certification body shall implement corrective actions for any breaches of the contract in 6.2.2.3 or other requirements in 6.2.2 of which it becomes aware.		
Agreement with the subcontractor	7.5.1. The certification body shall have a legally enforceable agreement covering the arrangements, including confidentiality and conflicts of interests, with each body that provides outsourced services.	6.2.2.3. The certification body shall have a legally binding contract with the body that provides the outsourced service, including provisions for confidentiality and conflict of interest as specified in 6.1.3, item c).	6.3.1. The certification body shall have a legally enforceable agreement covering the arrangements, including confidentiality and conflict of interests, with each body that provides outsourced work related to the certification process.	6.6. The verification body shall have a properly documented agreement
Monitoring and maintenance of the information of subcontractors	7.5.4. The certification body shall have a process for the approval and monitoring of all bodies that provide outsourced services used for certification activities, and shall ensure that records of the competence of all personnel involved in certification activities are maintained.	6.2.2.4. The certification body shall maintain a list of approved providers of outsourced services.	6.3.2. The certification body shall maintain a list of the bodies conducting outsourced work.	
Informing the client of the use of subcontracting, approval of the subcontracting		6.2.2.4. The certification body shall inform the client in advance of outsourcing activities, in order to provide the client with an opportunity to object.	-	6.6. The verification body shall obtain consent from the client and responsible party to use the outsourced body
Reporting of subcontracted results		-	-	-



	<b>SFS-EN ISO/IEC 17021-1:2015</b>	<b>SFS-EN ISO/IEC 17065:2012</b>	<b>SFS-EN ISO/IEC 17024:2012</b>	<b>SFS-EN ISO/IEC 14065:2013</b>
Confidentiality of the activities				7.3. The validation or verification body shall have a policy and mechanisms to safeguard the confidentiality of information obtained or created during the validation or verification. The policy shall meet all legal requirements necessary to be enforceable and shall include the personnel and activities of the validation or verification body and outsourced bodies