Principles for the Assessment of Subcontracting

Policy document A11/2023

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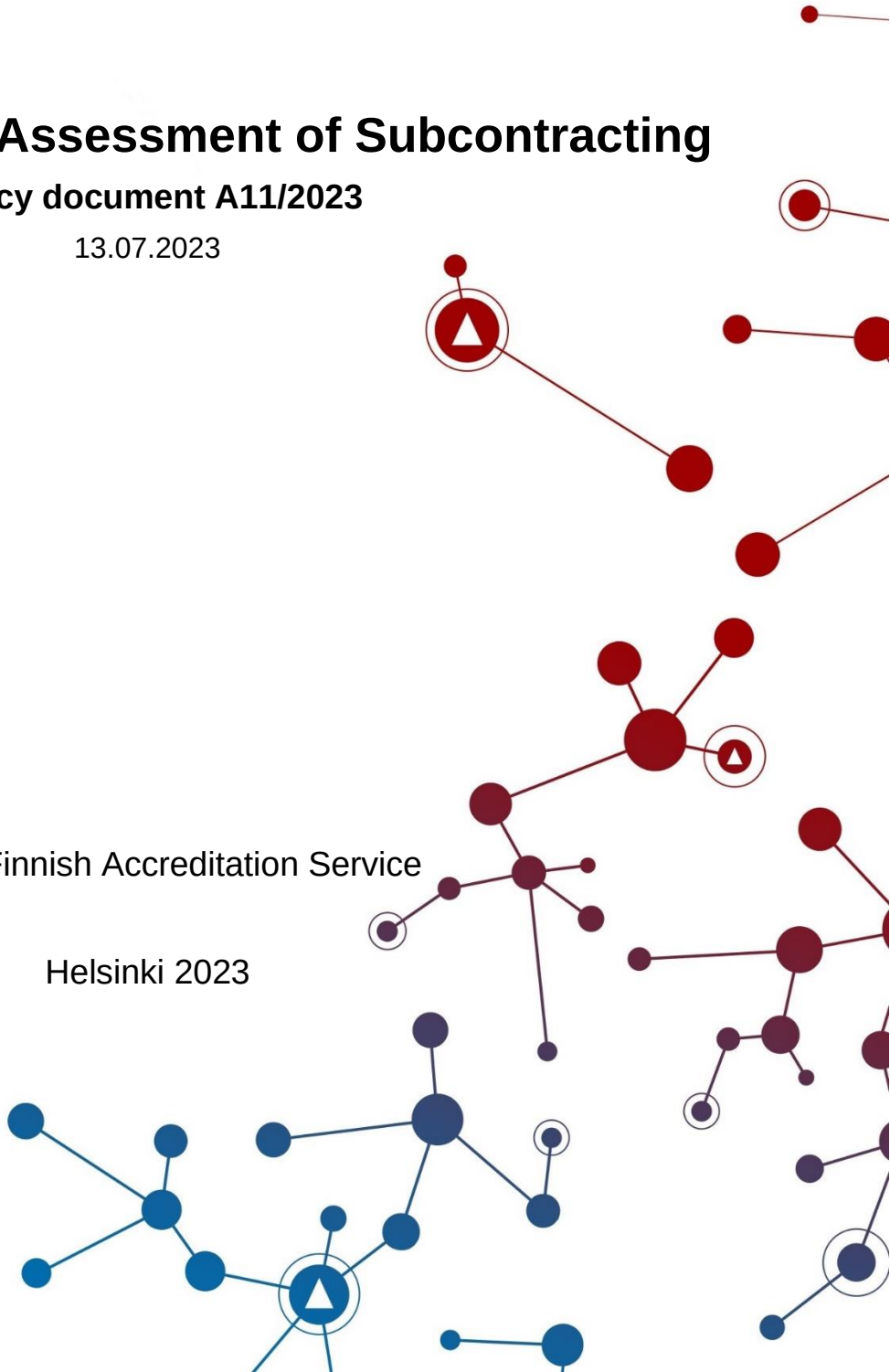

FINAS Finnish Accreditation Service

Helsinki 2023

Table of contents

1 Foreword

The original policy document for FINAS was drawn up by a working group appointed by the Advisory Committee for Conformity Assessment Matters, Subcommittee for Accreditation Matters (VANK-P). The new version A11/2023 replaces the previous version A11/2016. This policy takes into account the completion of the delivery of FINAS Leaflet 10. In addition, requirements have been reviewed. In addition, a table of requirements set for subcontracting in various requirement standards has been removed from the end of this policy.

The purpose of the policy documents is to clarify the accreditation requirements in practice. They have been drawn up taking into account the principles agreed within the international cooperation organisations of accreditation bodies (European co-operation for Accreditation (EA), the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum (IAF)).

The requirements for accreditation activities are set out in Decision P1. Information on the policy documents and mandatory guides are available on the FINAS website (www.finas.fi).

2 Summary

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

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 requirement standards.

Appendices 1–5 of the policy document include 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 practices in accordance with which the subcontracting has been carried out.

3 Background to the use of subcontracting

The role of subcontracting in testing, calibration, inspection, certification, proficiency testing and biobanking has increased significantly during recent years. The field of activities and forms of services have become more diverse, and subcontracting can respond to the varying needs of customers. 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.

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 operator must assess the significance of subcontracting in the supply chain as 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 an 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.

4 Definitions of terms

4.1 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 have may have different meanings.

4.1.1 Conformity assessment body (CAB)

Refers to a body that performs conformity assessment services, but not accreditation (Source: ISO/IEC 17000:2020). A conformity assessment body can be, for example, an inspection body, a testing laboratory, or a certification body.

4.1.2 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). Certain requirement standards determine that subcontracting is part of outsourced service activities, e.g. SFS-EN ISO/IEC 17025.

Accreditation requirement standards determine that under subcontracting an accredited operator has some of the activities falling within the scope of accreditation performed by a subcontractor.

4.1.3 Outsourcing

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

The terms subcontracting and outsourcing are used as synonyms in several accreditation requirement standards.

4.1.4 Referral laboratory

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

4.1.5 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/IEC 17020:2012).

Medical 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.

4.1.6 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 operator may have more than one accreditation symbol (Source: FINAS policy document A10).

4.1.7 Multi-site organisation

Refers to an organisation which performs an accredited activity at a number of different sites (Source: FINAS policy document A10).

4.1.8 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. Continuous subcontracting is not entered within the FINAS scope, as it is not included in the operator's accredited activities.

4.1.9 Serial subcontracting, subcontracting in a 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, is responsible for the work performed by a subcontractor.

4.1.10 EA

European co-operation for Accreditation, EA, is European association for accreditation. It is formally appointed by the European Commission in Regulation (EC) No 765/2008 to develop and maintain a multilateral agreement of mutual recognition, the EA MLA, based on a harmonized accreditation infrastructure and procedures.

4.1.11 ILAC

International Laboratory Accreditation Cooperation, ILAC, is international association for accreditation. The international arrangements in accreditation are managed by ILAC in the fields of calibration, testing, medical testing, inspection, proficiency testing providers and reference material producers.

4.1.12 IAF

International Accreditation Forum Inc., IAF, is international association for accreditation. The international arrangements in accreditation are managed by IAF in the fields of management systems, products, processes, services, personnel, validation and verification and other similar programmes of conformity assessment.

5 Requirements of accreditation standards

The standards that have been confirmed as accreditation requirements in decision FINAS P1 have been taken into consideration in this policy document. In principle, all standards permit the use of subcontracting but, in other respects, there are various requirements and focuses.

6 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.

6.1 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).

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.

6.2 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.

7 International policies

The use of subcontracting is a topical issue internationally and especially in Europe.

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.

8 Principles for the Assessment of Subcontracting

The policy document describes 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 special requirements and practices to which attention should be paid in an assessment.

8.1 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 verify the competence of the individuals who are in charge of the use of subcontracting.

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

8.2 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 and functions used.

8.3 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.

Exceptions include situations where the customer or an authority defines the subcontractor to be used.

8.4 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 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:2019. The principles describe the conditions under which an organisation operating in more than one country can offer services under the same accreditation decision.

8.5 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 subcontractors requirements relating to the nature of an activity. The rights of use of results and the reporting method must be agreed.

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

8.6 Impartiality and independence

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

party.

8.7 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.

8.8 Approval by the customer

As a rule, the customer should be informed of the use of subcontracting, e.g., in conjunction with agreements. In many cases, the customer's approval is also required.

For example:

ISO/IEC 17025:2017: a laboratory must notify its customers of any laboratory functions carried out by an external supplier and obtain the customer's approval for them.

ISO 15189:2013: service agreements must indicate any work that is carried out by a referral laboratory or external expert.

ISO/IEC 17020:2012: an inspection body must notify the customer if it intends to use a subcontractor in any part of an inspection.

8.9 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. Addressing logistics applies to environmental and medical laboratories, for example.

8.10 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.

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

8.11 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 subcontractors.

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.

9 References

EA 2/13M:2019 EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members

FINAS policy document A10 Assessment of Multi-Sector and Multi-Site Organisations – Principles Applied by FINAS

FINAS P1 Requirements applied to the accreditation activities

FINAS V1 Rules on reference to accreditation

ISO/IEC 17000:2020 Conformity assessment Vocabulary and general

principles

The New Dictionary of Modern Finnish, Institute for the Languages of Finland and Kielikone Oy

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 17025:2017 General requirements for the competence of testing and calibration laboratories

SFS-EN ISO/IEC 17029:2019 Conformity assessment – General principles and requirements for validation and verification bodies

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

SFS-EN ISO 20387:2020 Biotechnology – Biobanking. General requirements for biobanking.

10 Changes from the previous version

Changes 13.07.2023

	Chapter	Change
1	Foreword	FINAS Leaflet 10 ceased. The corresponding information is available on the www.finas.fi website. A brief description of changes.

2	Summary	-
3	Background to the use of sub-contracting	-
4	Definitions of terms	Certain terms revised.
5	Requirements of accreditation standards	-
6	Legal requirements	-
7	International policies	-
8	Principles for the assessment of subcontracting	Addressed impartiality in subcontracting, and presented examples used in stand-ards of the requirements for notifying cus-tomers of subcontracting.
9	References	Updated.
10	Changes from the previous version	New header and content.
	Appendices 1–5	
	Tables 1 and 2	Tables removed.

Appendices 1–5 of the policy document

The appendices to the policy document 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 practices 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 an 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 -Lääk 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. S -Lääk test 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 at a short notice.

2. Service response of a test is changed

YKS-LAB Oy's subcontracting laboratory NEDER-LAB reorganises its production and the 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 -Lääk 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 Subcontracting in food and environmental laboratory

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 the 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 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 general 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 operators 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 operator 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.

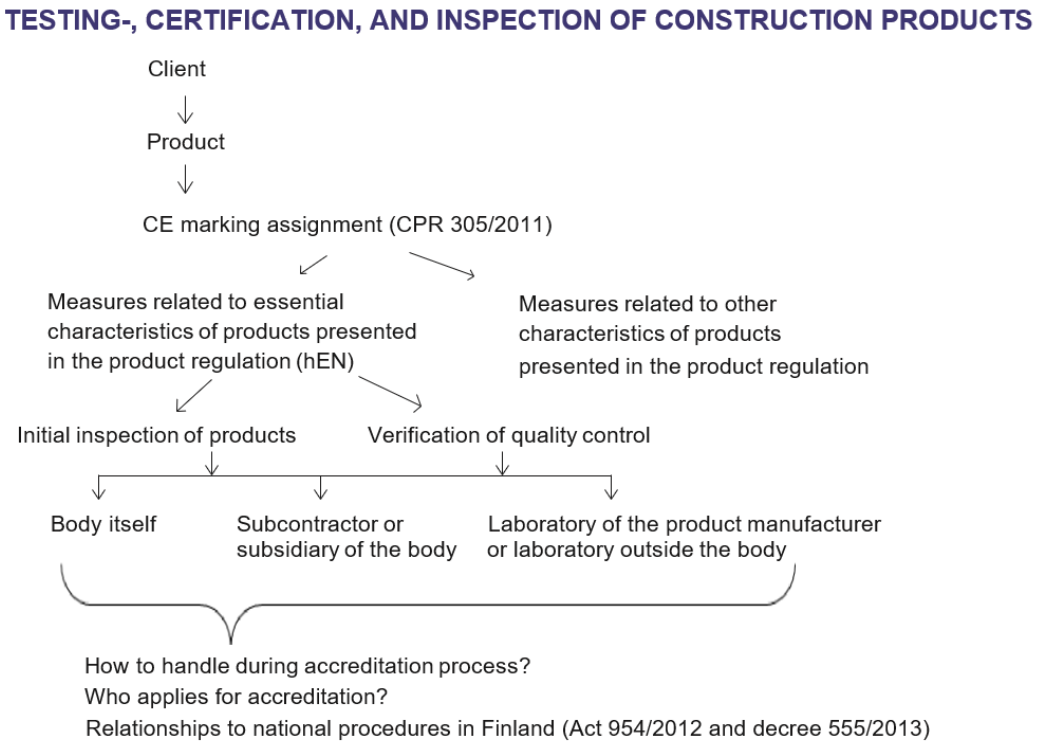

Figure 1: Measures of a notified body relating to the CE marking mandate

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 in accordance with Figure 1: measures carried out by a notified body itself; measures sourced in the form of subcontracting or from a subsidiary of the operator, and measures carried out in the laboratory of the product manufacturer or in a laboratory outside the operator. With these procedures it should consider how different options are handled during accreditation process and who is applying accreditation. In addition, it should be considered what is the relationship to national procedures.

Measures carried out by a notified body itself are the most common method. The second procedure consists of measures sourced 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 their 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 operator 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?

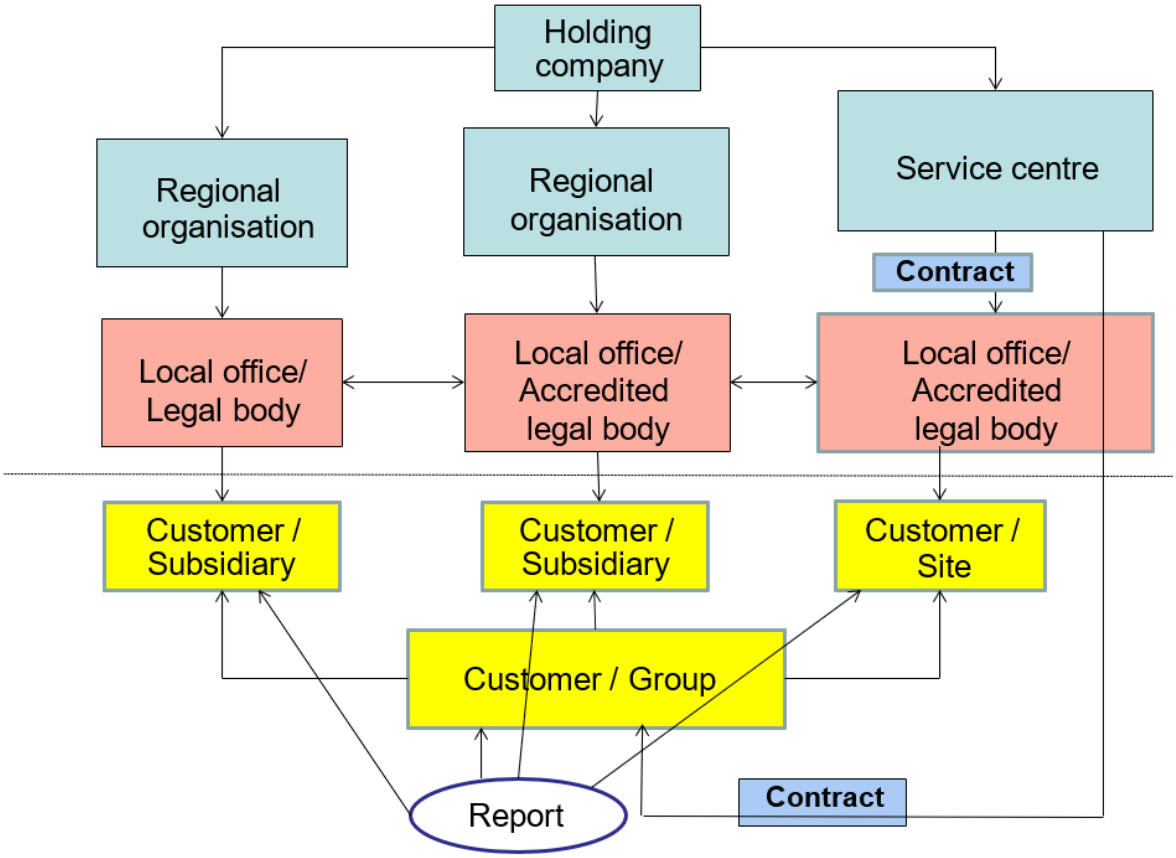

Figure 2: Internal subcontracting relationships in a multi-site organisation.

In the case shown in the figure 2 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 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

The NLF (New Legislative Framework) Regulation (765/2008) is directly applicable in all Member States. The NLF Decision (768/2008) is a framework decision, a guideline for EU legislators.

A notified body must be established under national law and have registered legal person. 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 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 with 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.