

FINAS Rules for Accreditation

Leaflet 1

6.6.2022

FINAS Finnish Accreditation Service

Helsinki 2022

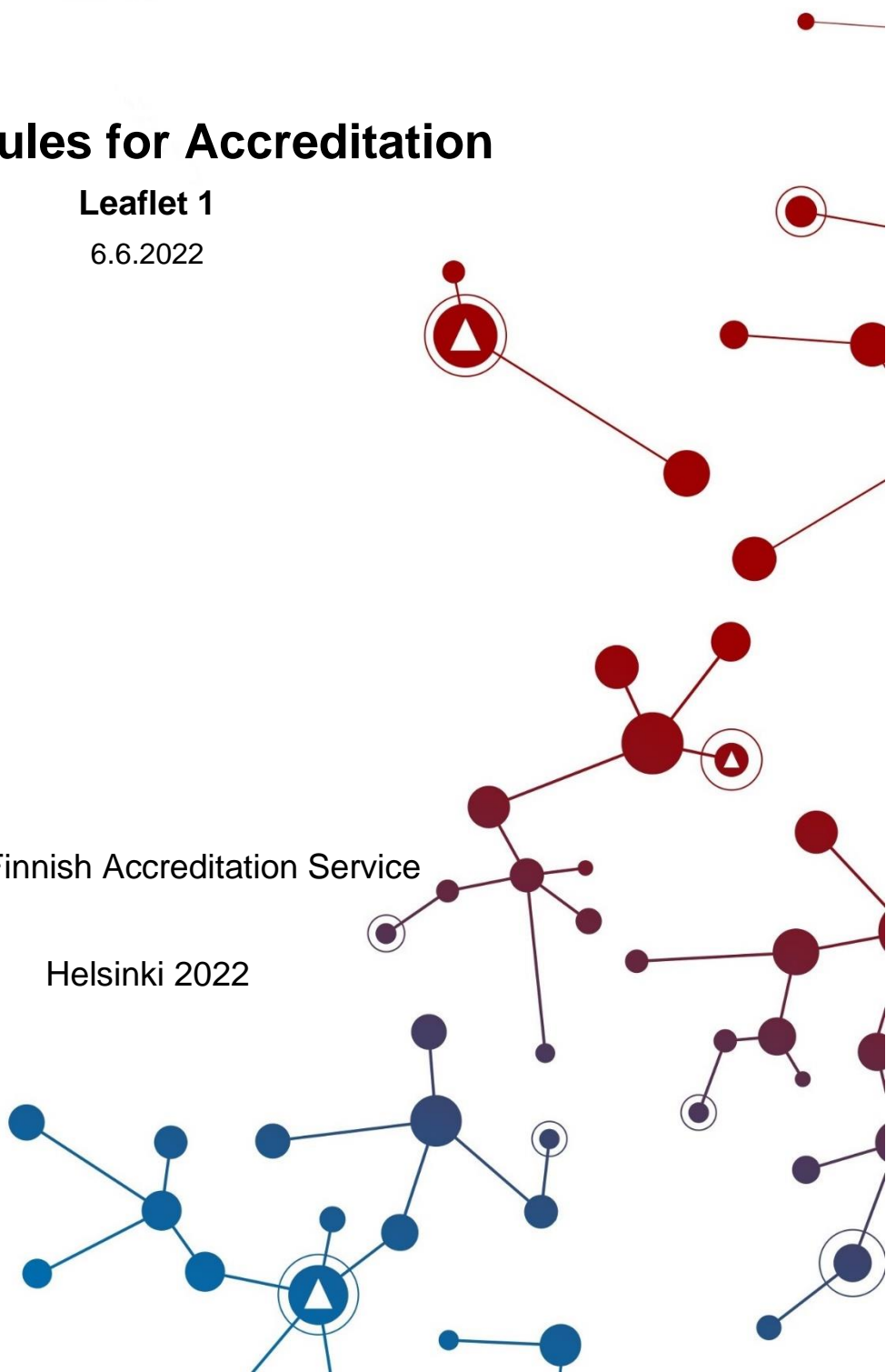


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1 Introduction

This document specifies the procedures for accreditation and assessment processes applied by FINAS Finnish Accreditation Service and describes cooperation between FINAS and its clients. Accreditation requirements are set out in Decision P1, available on the FINAS website. The website also presents the obligatory documents according to each accreditation area and has additional information on accreditation procedures and on how to apply for accreditation. By applying for accreditation and engaging in accredited operations, the client undertakes to comply with these rules for accreditation.

In addition to accreditation, FINAS may carry out assessments of competence against special requirements, such as criteria agreed upon with the authorities. In such cases, the principles and rules followed are the same as those specified for accreditation.

The operations of FINAS are based on Finnish statutes concerning accreditation activities and the EU Regulation on accreditation and market surveillance (EC 765/2008). In addition, FINAS conducts its accreditation and assessments in line with internationally harmonised procedures and requirements.

FINAS's operating principles include fair and equal treatment of clients as well as impartial and independent activities. Confidential treatment of client data is ensured at every stage of the process. The principles for the confidential processing of data are described in Leaflet 2. In accordance with the principle of transparency, accreditation decisions are public, and information on the clients' scopes of accreditation is maintained on the FINAS website.

Through close cooperation with national stakeholders, FINAS ensures that accreditation meets the needs and expectations of both clients and stakeholders. FINAS is also actively engaged in European and international co-operation bodies for accreditation in order to influence the procedures and development of accreditation activities.

Accreditation is carried out according to globally uniform policies and requirements. International evaluations demonstrate that FINAS's accreditation activities stand up to international comparison. This enables the world-wide acceptability of certificates and results issued by bodies accredited in Finland.

Kansallinen akkreditointiorganisaatio FINAS-akkreditointipalvelu vastaa akkreditointitoiminnasta Suomessa ja myöntää akkreditoinnin sitä hakeneelle ja päteväksi todetulle toimijalle.

2 Initial assessment

2.1 Applying for accreditation or assessment

The accreditation or assessment process is initiated by submitting a written application to FINAS. The application specifies the applicant and the operations to be assessed, i.e. the scope of accreditation. The application form and information on the appendices needed for the application are available on the FINAS website. The application must be submitted signed and preferably in an electronic form. Appendices to the application should be submitted electronically. The client receives user credentials for the FINAS Extranet for the purpose of transferring electronic materials between FINAS and the client. By submitting the application, the applicant undertakes to provide FINAS with the information requested for assessing competence, approves the assessment procedures defined by FINAS and agrees to comply with the rules for accreditation.

2.2 Handling of the application

FINAS reviews the application and its appendices and establishes the applicant's needs. Together with the applicant, FINAS determines any statutory and other requirements that may pertain to the application and that must be taken into account when processing the application. FINAS contacts the client when the application arrives and as its handling proceeds. FINAS may request additional information or documentation while processing the application. FINAS will reject the accreditation or assessment application if, during the assessment process, the applicant is found to have provided inaccurate or fraudulent information.

2.3 Assembling the assessment unit

For the assessment, FINAS assembles an assessment unit with sufficient expertise to cover the scope of accreditation proposed by the applicant. The unit is led by the Lead Assessor, who also assesses the management system. Besides the FINAS Lead Assessor, the unit generally includes one or more technical assessors or technical experts trained for assessment tasks and tasked with assessing technical competency.

In assembling the assessment unit, the following factors are considered:

- that the members of the assessment unit are competent
- that the members of the assessment unit are impartial for the assessment
- that the client accepts the assessment unit members

Members of the assessment unit are subject to the non-disclosure obligation under the State Civil Service Act. All members of the assessment unit have signed a non-disclosure agreement to ensure the non-disclosure obligation.

2.4 Establishing accreditation readiness (preliminary assessment visit)

In most cases, the assessment process for new applicants includes a meeting to assess readiness for accreditation at the client's premises. A decision on proposing a preliminary visit is made once FINAS has received all the documents needed for the assessment and has reviewed the application documents. The purpose of the preliminary visit is to determine the applicant's readiness in relation to the assessment requirements and to agree on the progress of the assessment process, the implementation of the assessment visit, potential monitoring of activities, and other proof of competence. If the conditions for continuation of the assessment process are not met, the outcome of the preliminary assessment visit may also be that the assessment process is discontinued.

A brief summary is drawn up of the preliminary visit, describing the observations made and matters agreed during the visit. The purpose of the visit is not to guide the client in meeting the accreditation requirements.

The preliminary visit may be supplemented or replaced by preliminary assessment based on documents. Preliminary visit can also be carried out via remote access.

2.5 Planning of assessment

The purpose of the preliminary assessment is to obtain proof of competence and the expertise of personnel in terms of the accreditation requirements. The extent of the scope of accreditation and the client's sites included within the scope of accreditation are taken into account when planning the assessment. FINAS agrees with the client and the assessment unit on the schedule and content of the assessment. The assessment consists of assessment visits to sites named in the application and other assessment tasks, such as any monitoring of field operations and competence tests. The assessment programme is drawn up on the basis of this information.

2.6 Assessment for the purpose of accreditation or initial assessment

The assessment unit's task is to assess how the client meets the accreditation requirements within the scope of accreditation specified in the application. By interviewing the management, people in charge and other personnel, by monitoring operations and by reviewing guidelines and data files, the assessment

unit ensures the competence of operations and the reliability of results or certificates.

If the assessment unit observes that the accreditation requirements are not met, these observations are recorded as non-conformities. Non-conformities are divided into two categories: non-conformities and major non-conformities. Deficiencies that do not directly endanger the validity of the results or the functional entity are recorded as non-conformities. Severe individual non-conformities or several minor non-conformities that may endanger the reliability of technical operations or the accuracy of results are classified as major non-conformities. Examples of major non-conformities include severe failures in internal or external quality assurance processes detected in the assessment, or shortcomings in the orientation or qualifications of the body's personnel.

At the closing of the assessment, the assessment unit issues the client a summary and conclusions of the assessment, the non-conformities discovered, and the grounds for recording them as such. At the same time, timetables for the correction of detected non-conformities are agreed. In order to ensure the progress and efficiency of assessment, the timetable for the corrective actions should be sufficiently short. In initial assessments, the timetable for correcting non-conformities may not exceed three months except in exceptional cases.

After the assessment, each assessor draws up a report describing how the operations assessed meet the requirements of accreditation. The reports present the observations and conclusions made during the assessment and indicate the conditions under which each assessor is ready to recommend the granting of accreditation. The reports are given to the client.

Within the timetable agreed, the client provides FINAS with descriptions of the root causes of non-conformities and the corrective actions taken. On the basis of the material received, the unit assesses the adequacy of the actions and analyses of root causes and, whenever necessary, asks the client to supplement these. In general, corrective actions may be supplemented only once, after which the assessment unit assesses the adequacy of the corrective actions. If necessary, a follow-up assessment visit is made to ensure the adequacy of the corrective actions. Accreditation cannot be granted until all non-conformities have been corrected and the root cause analyses, and corrective actions have been assessed and found adequate.

2.7 Accreditation decision

When the assessment unit has ascertained that the accreditation requirements are met, the Lead Assessor compiles a summary overview of the assessment, which presents the grounds for the accreditation decision in accordance with the Administrative Procedure Act. The accreditation decision is

made by the Director of FINAS after a proposal by the Lead Assessor. The precondition for a positive decision is that the client has been found to meet all the accreditation requirements. An accreditation decision is generally valid for four years, but in special cases the validity period may be shorter. By applying for accreditation, the client commits themselves to comply with the terms of accreditation.

2.8 Assessments of demonstration of competence and statement of assessment

When a client applies for a competence assessment, such as for the purpose of obtaining approval from the authorities, the assessment process and its stages follow those of the accreditation process. The client receives a summary of the assessment and access to the assessment reports listing the observations and conclusions on whether the assessment requirements were met.

After the root cause analyses and corrective actions recorded in the assessment visit have been found sufficient, FINAS will prepare and issue a statement of assessment instead of an accreditation decision on the fulfilment of assessment requirements. The statement is signed by the Director of FINAS after a proposal of the Lead Assessor. The public authority in question makes its decision on the basis of the statement.

3 Maintenance of accreditation

3.1 General

After the accreditation has been granted, i.e. the accreditation decision has been given, FINAS prepares a plan for the maintenance of accreditation by means of assessments during the accreditation period. The plan covers the four-year accreditation period starting from the accreditation, including periodic surveillance and re-accreditation for the following accreditation period. The plan for the accreditation period covers the entire scope of accreditation and, where possible, all of the client's sites, taking into account the risks of operations and the accreditation requirements. If necessary for large clients, the scope of accreditation and client sites may be covered by sampling. In general, periodic surveillance is carried out once per year. The first periodic surveillance is carried out within 6 to 9 months of the accreditation decision. Periodic surveillance may be planned to target different sub-fields at different times in order to ensure sufficiently frequent and thorough surveillance of critical subfields. Surveillance during the accreditation period must cover all fields within the scope of accreditation and all subfields of the relevant requirement

standard.

If, during the accreditation period, the accredited body acts fraudulently in light of the obtained evidence or violates the rules of accreditation, FINAS has the right to revoke the body's accreditation. FINAS also has the right to carry out unplanned assessments without prior notice if the accredited body has acted or is suspected or acting fraudulently or in violation of the rules.

3.2 Periodic surveillance

The principles presented above for the initial assessment stages also apply to the periodic surveillance process. Periodic surveillance is agreed with the client well in advance. Prior to periodic surveillance assessments, FINAS sends the accredited body a documentation request for the material to be used in the assessment. Periodic surveillance may focus on specific subfields of the scope of accreditation on the basis of risk analysis.

The time limit for correcting possible non-conformities detected in periodic surveillance is 1 to 2 months. In the event of major non-conformities, the accredited body must take immediate action and the time limit for the corrections is shortened to 1 to 2 weeks. A delay in correcting major non-conformities may result in temporary suspension of the scope of accreditation or of specific subfields. The detailed timetable for corrections is always agreed with the client.

3.3 Re-accreditation

Should the client wish to continue as an accredited body, operations within the scope of accreditation are re-assessed during the last year of validity of the accreditation decision. Consent to re-accreditation is usually agreed at the final periodic surveillance assessment visit of the current accreditation period. Re-accreditation ensures compliance with all requirements of the relevant requirement standard and assesses whether competence is demonstrated extensively in all subfields of technical operations. Re-accreditation makes use of information obtained in previous assessments of the client's operations.

3.4 Extending and amending the scope of the accreditation decision

The client may propose changes to its valid scope of accreditation. These changes are assessed on the basis of the application. If the application pertains to extending or amending the scope of accreditation, the grounds for competence must be presented in the application material. After receiving sufficient material, FINAS decides on the applicable assessment procedures, including, for instance, an assessment visit or assessment based on documents. A restriction to the scope of accreditation is considered a form of amendment for which the client is not required to present grounds.

Minor extensions or amendments to the scope of accreditation can be assessed during periodic surveillance if the application for extension or amendment and the related material have been submitted to FINAS in good time before the date of surveillance. Applications for major extensions to the scope of accreditation, such as new subfields and new techniques, may require a separate application and review by FINAS. Once the review has been completed, the assessment date is set and the composition of the assessment unit is decided. The client is informed of the measures required by the application for extension.

Extensions and amendments to the scope of accreditation are confirmed by issuing an amendment to the accreditation decision.

3.5 Suspension and withdrawal of accreditation

A client may give up accreditation during the period of validity of the accreditation decision by notifying FINAS thereof in writing. FINAS issues a decision on the withdrawal of accreditation.

If periodic surveillance or other assessment reveals that the accreditation requirements are not met, FINAS informs the client in writing that it will initiate the process to temporarily suspend the accreditation. The client is requested to present corrective actions by a certain deadline. If the corrections are not made within the time specified, or the corrective actions are insufficient, the scope of accreditation is reduced or the accreditation is temporarily suspended. The client is not allowed to issue results, reports or certificates as an accredited body during the temporarily suspension or within the revoked area of the scope of accreditation. During the suspension, the client has the opportunity to demonstrate compliance with the accreditation requirements, after which accreditation may be restored. Accreditation is withdrawn if it is deemed after the suspension that the accreditation requirements are still not met.

Accreditation can be withdrawn if the accreditation requirements or the rules for accreditation presented in the accreditation decision are neglected or if, despite requests, the observed non-conformities are not corrected.

4 Re-assessments of demonstration of competence required by public authorities

The client is responsible for applying re-assessments of the demonstration of competence from FINAS. The assessment is applied from FINAS according to the requirements of the respective public authority. The application form is available on the FINAS website. By applying for the assessment, the client agrees to comply with the terms of assessment in force.

5 Rights and obligations in accreditation

5.1 General

By applying for accreditation or assessment, the client agrees to comply with the rules of accreditation.

The client agrees to comply with the competence requirements for accredited operations, as confirmed by FINAS. The current accreditation requirements are listed on the FINAS website. FINAS informs accredited clients of any revisions made to accreditation requirements and of transition periods applied to assessment. If the accreditation requirements are revised, clients must show that they meet the revised requirements within a certain transition period. Otherwise, the validity of the accreditation will expire after the end of the transition period.

Accreditation requires that the client constantly meets the valid accreditation requirements and other conditions for accreditation. FINAS must always be able to ensure the fulfilment of the requirements and conditions.

The accredited client agrees to notify FINAS promptly of all changes that take place in the client's legal, commercial or organisational status and in the management of its organisation. Information shall also be given of all changes that are important in view of accreditation, especially as concerns the personnel, equipment, premises, the scope of accreditation, or procedures.

5.2 Reference to accreditation

When granted accreditation, the client receives an accreditation symbol. The use of the symbol in reports and certificates issued as a result of accredited operations indicates the reliability of the results. When accredited laboratory, inspection body, verifier, proficiency test provider or biobank reports results that are obtained with the methods in its accredited scope, they must refer to accreditation. Exception to this can be made when customer asks, and it is

literally agreed that they do not want the reference to accreditation. Bodies certifying persons, products and management systems must always issue the certificates with accreditation and include a reference to accreditation if the certification is within the scope for which the certification body is accredited. Clients may also utilise accreditation in other communications. The rules on reference to accreditation are published in requirement document V1, which is available on the FINAS website.

5.3 Client feedback

FINAS hopes to receive feedback on its activities. Clients have the opportunity to give feedback on the implementation of the assessment process, the assessment unit's work, the reporting, and on other aspects pertaining to FINAS's activities. Feedback may be given on the client feedback form sent to the assessed body after the assessment. Feedback may also be given in free form either verbally or in writing directly to FINAS personnel. All feedback is processed at FINAS and taken into account in developing operations.

5.4 Requests for rectification of decisions and assessment reports and appeals against decisions

FINAS undertakes to process complaints and requests for corrections concerning its activities, such as errors or deficiencies in a scope of accreditation, impartially and independently and without delay.

If the recipient of the decision or assessment report finds that there is a factual or clerical error in the decision or assessment report concerning FINAS's accreditation or their appendices, FINAS must be notified (akkreditointi@finas.fi). FINAS will process a request for rectification of a decision or assessment report and, if necessary, issue a corrected decision or assessment report.

The right to appeal against FINAS's accreditation decision can be appealed to the Administrative Court. Instructions on how to make a complaint are attached to the accreditation decision and available from FINAS.

5.5 Payment of fees

FINAS charges a fee for the evaluation services it provides, based on cost equivalence. The payment criteria and valid prices are based on the payment decree of the Ministry of Employment and the Economy and the price list is publicly available on the FINAS website.

At the outset of the assessment process, the client is informed of the estimated costs. Invoicing takes place according to actual costs incurred. Additional costs incurred in the assessment may include, for example, additional

time required to plan the assessment of observed non-conformities and/or additional further assessments. If actual costs exceed the cost estimate by at least 10%, the client is provided an estimate of the additional costs.

To maintain accreditation, the accredited client must pay the fees arising from accreditation. The payment terms also apply to bodies applying for an assessment.

5.6 Restrictions on the use of accreditation standards

FINAS' clients cannot offer the same assessment service as the accreditation body, i.e. FINAS. In other words, accredited clients cannot offer accreditation service on the basis of standards that are used as the internationally approved accreditation criteria confirmed by FINAS (FINAS Decision P1). If an accredited client assesses its subcontractors according to standards that are used as accreditation requirements, the results of the assessment must show clearly that the assessment was conducted for the purpose of subcontracting. The process of withdrawing accreditation is initiated if accreditation standards are misused.

6 Commitments made by FINAS

6.1 General

FINAS' operations are founded on openness, equality and confidentiality. In line with the Finnish regulations on accreditation activities, FINAS is committed to serving as an impartial and independent third-party assessor of competence.

FINAS is committed to maintaining and developing accreditation activities according to the relevant international requirements. FINAS cooperates with national stakeholders in the development and adoption of new accreditation programmes. FINAS develops the effectiveness and consistency of the Finnish accreditation system on the basis of information and experience acquired from European and international cooperation. Clients' needs are surveyed by means of regular questionnaires and by reviewing feedback that FINAS receives from clients and other parties. FINAS holds training events on accreditation requirements and trains the experts it uses for assessment tasks.

6.2 Accredited operations abroad

As a signatory to international agreements, FINAS is committed to the promotion of cooperation among accreditation bodies and the international harmonisation and recognition of accreditation activities. FINAS works in accordance

with these obligations and the international cross-border principles of accreditation. In line with these principles, FINAS only accredits bodies registered in Finland. When assessing sites abroad and in certain other special situations, FINAS adheres to international principles and works in cooperation with the local accreditation body of the respective country. Clients are required to consent to these forms of international cooperation.

6.3 Expanding the scope of accreditation and assessment to new areas

FINAS' accreditation and assessment services are continuously utilised in new areas of operation. In the main, these apply internationally agreed procedures and principles. In the case of activities related to national legislation, the assessment principles, requirements and procedures are agreed in consultation with stakeholders.

6.4 Information about changes

FINAS announces changes in accreditation requirements and procedures directly to the target groups by email and publicly on its website. The transition periods applied to changes in accreditation requirements are agreed upon internationally. FINAS complies with these agreements and informs its clients thereof. If necessary, FINAS will organise training events for clients on the changes to requirements.

6.5 Publicity

FINAS is committed to keeping publicly available information about the assessment process, the accreditation requirements, and other rules and regulations applied to its operations. The scopes of accreditation of accredited clients are listed on the FINAS website. However, the information and assessment reports handled during the assessments are confidential. Despite this, it should be noted that as a public organisation, FINAS complies with requirements for public authorities in its operations. FINAS complies with the principles of good governance, as specified in the Administrative Procedure Act (434/2003). The same Act also provides for the principles of openness of government activities.

7 Entry into force

This Leaflet will enter into force on 6th of June 2022 and is valid until further notice.

This Leaflet supersedes Leaflet 1 issued on 10th of October 2019 by FINAS Finnish Accreditation Service.

Director Risto Suominen

Lead Assessor Annika Wickström

Changes from the previous version

6.6.2022

	Chapter		Change
1	Introduction	1	Reference to Leaflet 10 removed
2	Initial assessment	2	Updated application submission policies. Preliminary Visit Term changed. Updated procedures for evaluation planning and initial evaluation.
5	Rights and obligations in accreditation	5	Change in reference to accreditation taken into account. The appeals process for appeals against decisions and requests for rectification of decisions and assessment reports described
7	Entry into force		Updated
	Changes from the previous version		Updated