

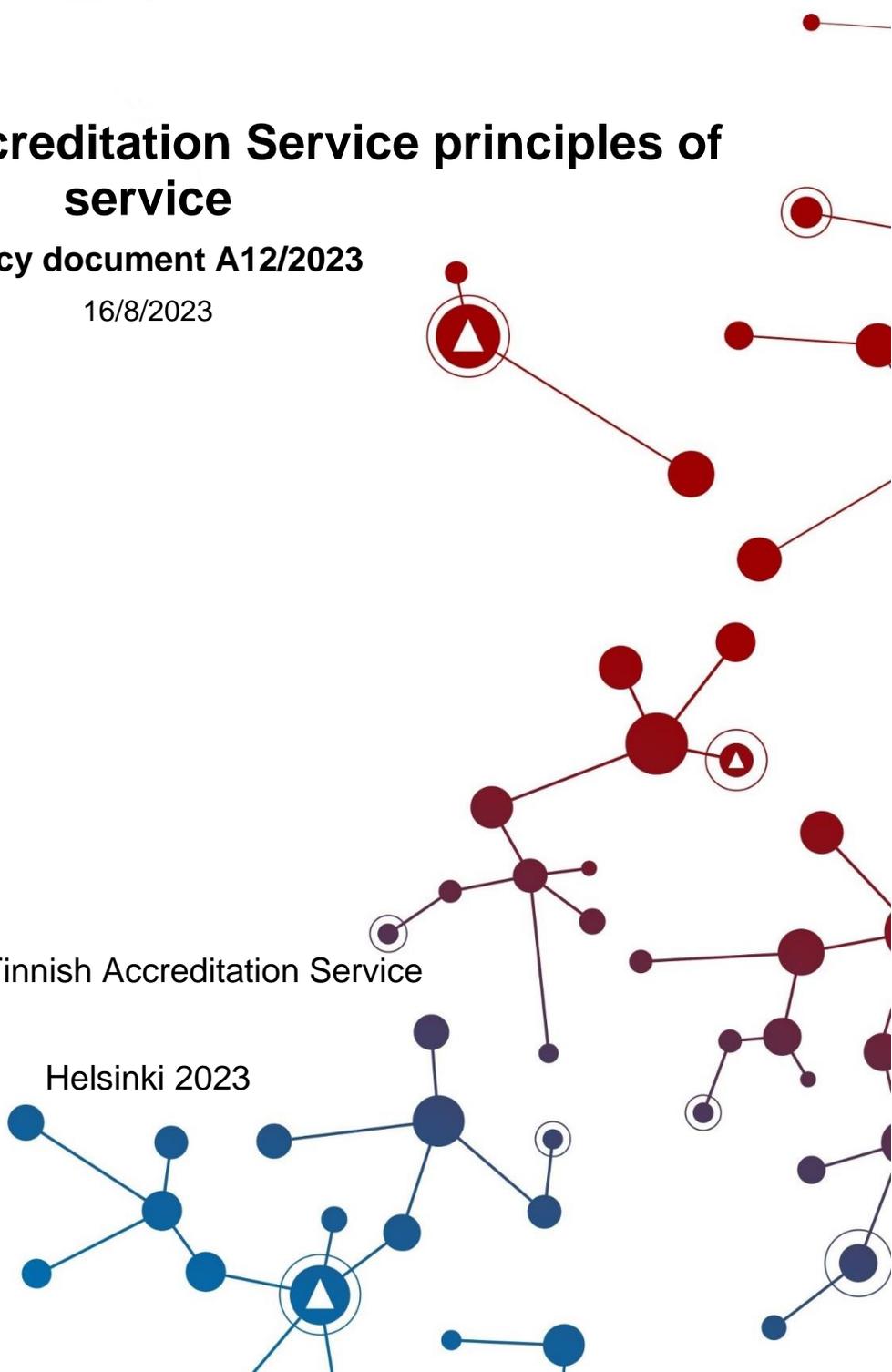
# FINAS Finnish Accreditation Service principles of service

Policy document A12/2023

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FINAS Finnish Accreditation Service

Helsinki 2023



## Foreword

The original principles of service for FINAS were drawn up by a working group appointed by the Advisory Committee for Conformity Assessment Matters, Subcommittee for Accreditation Matters (VANK-P). The new version A12/2023 replaces the previous version A12/2019.

The service principle of FINAS represents the shared view of FINAS and its stakeholders on the principles of customer service at FINAS, which serve to ensure that customer service by FINAS meets the needs of its customers.

The requirements for accreditation activities are set out in Decision P1. Information on the policy documents and binding guidelines can be found on the FINAS website ([www.finas.fi](http://www.finas.fi)).

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## 1 Introduction

As a national accreditation body, FINAS has a legal obligation (Act on the verification of competence of conformity assessment services, No 920/2005 and its Amendment 764/2014, Regulation (EC) No 765/2008 of the European Parliament and of the European Council setting out the requirements for accreditation and market surveillance relating to the marketing of products) to provide services related to accreditation and competence assessment. FINAS customers include laboratories, inspection bodies, certification bodies, verifier organisations, biobanks, and proficiency testing providers. FINAS customers operate in very different industries and may have varying needs. Despite this, a number of common expectations on services by FINAS are shared by all customers. This description of service principles at FINAS lists principles of good customer service that apply to all customers.

The aim of this description of FINAS service principles is to clarify the structure and schedule of the assessment process from the customers' perspective, as well as bring attention to viewpoints related to modern collaboration between organisations and their personnel.

In addition to assessment services, FINAS offers training and expert services. This description of the service principles of FINAS focuses on assessment services and their related customer communication and expert collaboration.

## 2 The service promise of FINAS

The service promise of FINAS to its customers is to provide a structure and schedule for the assessment process. The need for the service promise is mutual. It improves transparency of the rules of assessment at various stages of the process, takes into account international requirements and makes the policies of FINAS public or available to customers upon request. In turn, customers are expected to commit to accreditation and its requirements.

The service promise involves the following areas:

- A clear description of the accreditation process and its stages, requirements, timetables and costs. The description is public or available upon request.
- Comprehensive planning of assessments during the accreditation cycle
- High-quality and impartial assessment work, equal treatment of customers

- Confidentiality
- Reporting principles and quality
- FINAS delivery times – time limits and minimum service times
- Scope of accreditation: FINAS shall maintain its scopes of accreditation up-to-date and consistent to allow for international comparability
- Digital services: FINAS shall develop its procedures for electronic services and introduce new functionalities and tools for its customers
- Collecting customer feedback and describing trends to customers based on the results
- Up-to-date public communication on issues related to accreditation

To cover its costs, FINAS charges a fee for the assessment services it provides. The grounds for the fees and the currently valid rates are given in the price list published annually.

### 3 The accreditation process

Accreditation is based on qualification requirements described in international ISO standards. FINAS shall inform its customers of the currently valid requirements and of any changes to these.

In order to ensure a smooth accreditation process, good collaboration and long-term planning is required between the accredited bodies or prospective accredited bodies and the accreditation body. FINAS shall prepare for its customers an assessment plan that covers the entire accreditation cycle and takes into account operational risks. By ensuring the competence and expertise of the assessment team, FINAS ensures that assessment is targeted to areas critical for activities. The customer is responsible for facilitating the smooth progress of the assessment process, including ensuring that all necessary persons are present at assessments and all information required for the assessment is available.

The scope of accreditation of accredited bodies indicates the activity that has been deemed competent. It is the duty of FINAS to ensure that the scopes of accreditation are up-to-date and internationally comparable. For the purpose of reassessment, the customer is obligated to notify FINAS of changes to its activities that fall under the scope of accreditation.

To ensure the equal treatment of customers and compliance with international

practices, FINAS trains experts in an industry to act as technical assessors in accordance with international requirements. FINAS shall also organise regular conventions for assessors on the harmonisation of assessment procedures. By actively taking part in international collaboration on accreditation in the form of general conventions, committees, working groups and peer evaluation, FINAS maintains its own competence and participates in the development of accreditation.

It is the duty of FINAS to provide the assessment process with tools and resources that make use of collaboration, planning and competence. The customer is expected to commit to using the provided tools. All assessors shall use document templates that follow a common format and have been prepared by FINAS for each specific purpose.

The **accreditation process** (initial assessment, re-assessment, periodic surveillance) is described in the tables below. The tables describe the various process stages and responsibilities. The tables also list target times for various process stages and aspects that may be employed to streamline and speed up the process.

**Table 1: Processing the application and/or material request with target schedules**

| FINAS   | Customer  | Assessment streamlining   |
|---|---|---|
| -   | A new customer submits the application with attachments to FINAS.                             | The new customer provides a clear proposal of the scope of accreditation.                               |
| Confirmation of receipt of the application. Access rights to FINAS extranet for the new customer (1 week).<br><br>Processing of the application review (4 weeks after application is received). | -   | -   |
| -   | -   | In large-scale extensions of the scope the customer must notify FINAS 4–6 months before the assessment. |
| -   | Delivering the material request and material to the extranet (3 weeks before the assessment). | Sufficient material in advance from the customer.   |

| <b>FINAS</b>   | <b>Customer</b> | <b>Assessment streamlining</b> |
|--|-----------------|--------------------------------|
| Processing of a submitted material request and the material. | -               | -                              |

**Table 2: Forming the assessment team with target schedules**

| <b>FINAS</b>   | <b>Customer</b>  | <b>Assessment streamlining</b>  |
|--|--|---|
| <p>Requesting customer's approval of the assessors:</p> <p>Forming the assessment team for a new customer. Proposal of the composition of the team (1-3 months of receiving the application).</p> <p>Forming the assessment team for an accredited customer. Proposal of new assessors (3-6 months before the assessment visit) if there are changes made to the team.</p> | <p>Feedback on the proposed assessors (2 weeks of the proposal).</p> <p>Approving the assessors.</p> | <p>The customer will inform FINAS 6 months prior to the assessment visit if significant changes to the scope are requested, as this may require the acquisition of new assessors for the assessment team.</p> |
| Confirming the assessment team (2-4 months before the assessment visit).   | -  | -   |

**Table 3: Planning of assessment with target schedules**

| <b>FINAS</b>  | <b>Customer</b>                                      | <b>Assessment streamlining</b>  |
|---|--|---|
| Proposed assessment date:<br><br>Proposal for the date of the accreditation assessment for a new customer when the assessment team is ready.<br><br>Proposal for the date of the assessment visit or confirmation of the date agreed at the previous visit for the customer (4-6 months before the time of assessment visit). | Approving the date.                                  | -   |
| Planning the assessment content and program and delivering it to the customer (1-2 weeks). For existing customers, the program is based on the plan of the accreditation cycle.   | Notifying FINAS of any requests and needs (3 weeks). | At large-scale or multidisciplinary sites (broad scope of application and/or several locations), planning is carried out together with FINAS and the customer 3-6 months before the assessment visit. |
| Cost estimate of the assessment for the customer.   | -  | -   |

**Table 4: New customer: investigation of readiness for accreditation**

| <b>FINAS</b>   | <b>Customer</b>  | <b>Assessment streamlining</b> |
|--|--|--------------------------------|
| Investigation of the new customer's readiness for accreditation and preparation of a summary. The agreed follow-up actions are presented at the end of the evaluation. | The customer implements the follow-up actions before the actual assessment visit and provides FINAS with possible additional material for future assessment. | -                              |
| Agreement on the timing of the initial assessment.   | The customer confirms the date.  | -                              |

**Table 5: Assessment with target schedules**

| <b>FINAS</b>   | <b>Customer</b>   | <b>Assessment streamlining</b>   |
|--|---|--|
| Assessment team reviews the assessment material.   | -   | -  |
| Assessment visit.  | The customer ensures the success of the assessment visit (e.g., all relevant personnel present, access to premises, possibility to monitor activities). | Remote or hybrid assessment if necessary.                                  |
| Presentation of the summary of the assessment and non-conformities at the final meeting.   | -   | Opportunity to clarify the assessment's observations at the final meeting. |
| Sending customer feedback survey to the customer   | Answering to the customer survey.   | FINAS processes the customer feedback speedily.                            |
| Assessment reports to the customer (3–4 weeks).  | Possible comments to the reports.   | FINAS ensures timeliness and clarity of the reports.                       |
| -  | Actions to correct non-conformities and root cause analyses (1–2 months, max. 3 months).  | The customer investigates the root causes of non-conformities.             |
| Assessment and processing of corrective actions (2–3 weeks) and, if necessary, requesting further clarification from the customer. | If requested, the customer provides further clarification to the non-conformities (1–2 weeks).  | -  |
| Processing of additional investigations (2–3 weeks).   | -   | -  |

**Table 6: Accreditation decision with target schedules**

| <b>FINAS</b>   | <b>Customer</b>  | <b>Assessment streamlining</b>  |
|--|--|---|
| Preparation of the decision documents (3–6 weeks after approval of corrections or completion of assessment).           | -  | -   |
| Request to review the scope of accreditation and confirmation of the scope (3–6 weeks from approving the corrections). | -  | Defining the scope of accreditation together with FINAS, the assessment team, and the customer. |
| -  | Review and confirmation of the scope of accreditation for FINAS. | -   |
| Accreditation decision (3–6 weeks from approving the corrections).   | -  | -   |
| Publishing the scope of accreditation on the FINAS website (1 week from the decision).                                 | -  | -   |
| Customer feedback survey enclosed with the decision.   | Answering to the customer feedback survey.                       | FINAS processes the customer feedback speedily.   |

**Table 7: Events during the accreditation cycle with target schedules**

| FINAS   | Customer   | Assessment streamlining |
|---|--|-------------------------|
| Planning the accreditation cycle.   | -  | -                       |
| Planning meetings with large-scale or multidisciplinary sites (broad scope of application and/or several locations). Delivering the memos.  | -  | -                       |
| -   | Reporting changes between assessments in accordance with FINAS guidelines. | -                       |
| Assessment of changes (e.g., documentation review, interview, assessment visit), result of the assessment, change of accreditation decision if necessary (3-6 weeks from the assessment/approval of corrections). | -  | -                       |

### 3.1 Quality assurance of the accreditation process

FINAS employs procedures for the quality assurance of the accreditation process and the implementation of customer service principles:

- The assessment criteria are based on international ISO standards and international guides applicable to accreditation.
- FINAS employs a quality management system that takes into account the requirements of standard ISO/IEC 17011 for accreditation bodies. The quality management system is developed according to needs.
- FINAS demonstrates compliance with the requirements imposed on its activities by means of international peer evaluations every 4 years.
- FINAS also carries out internal audits to monitor the conformity of its activities.
- FINAS collects customer feedback both from each assessment and by means of periodic customer satisfaction surveys. The results of these are compared to predefined performance metrics and used for the

development of activities.

- Qualification requirements have been specified for FINAS personnel (own personnel and third party assessors), the fulfilment of which is ensured by means of qualification training and orientation and periodic monitoring.
- FINAS personnel (own personnel and third party assessors) are committed to impartiality and confidentiality in their work.
- The consistency of practices is ensured by means of continuous harmonisation of practices, both internally and internationally.
- The FINAS operations monitoring system is used to collect up-to-date data on the implementation of the accreditation process and the fulfilment of quality objectives. The system employs various metrics to evaluate the performance of activities.

## 4 Confidentiality of accreditation

The principles of confidential conduct of FINAS are described in FINAS leaflet 2, which is available on the FINAS website. The principles of confidential conduct define the principles of openness of activities by FINAS and the confidential processing of documents used in accreditation, responsibilities in document management, procedures for document transfer, and the confidential destruction of documents. The principles of conduct take into account guidelines on data protection in government activities, guidelines published by Tukes, and the requirements of Regulation (EC) No 765/2008 and standard SFS-EN ISO/IEC 17011 on the confidentiality of activities.

## 5 Digital services

The use of digital services between the accreditation body and customers is continuously developing and expanding. Exchange of documents electronically via extranet and remote assessment with remote connections are available. FINAS develops and provides digital assessment services for its customers, with the aim to allow as much of the accreditation process as possible to be handled electronically. It is the duty of customers to use the provided tools. FINAS' future goals include a digital database for the preparation, management and handling of scopes of accreditation. The current extranet used for document exchange will be developed according to needs, and FINAS will evaluate other potential tools.

## 6 Data collection and communication

The accuracy of data produced by the accrediting body and the timeliness of communications are central to the assessment process. For this reason, in addition to providing accurate assessment, FINAS aims to focus on providing a comprehensive service. FINAS employs various practices for collecting and communicating data.

FINAS collects data on topical issues related to accreditation by participating in international accreditation cooperation (EA European co-operation for Accreditation, ILAC International Laboratory Accreditation Cooperation, IAF International Accreditation Forum Inc.). EA encompasses a number of networks and working groups that discuss matters related to accreditation in various sectors and in the notification procedure of EU directives. FINAS is an active member in these networks and is able to technical support for its own activities. FINAS also makes use of the experiences of other accrediting bodies in its own assessment duties.

National stakeholder cooperation is a means to collect and distribute information on matters related to accreditation. FINAS works in close cooperation with public authorities on the use of accreditation in regulated sectors. The principles of stakeholder cooperation are described in the FINAS policy document A6 Principles for cooperation with national authorities.

Where necessary, FINAS has set up technical support groups for various fields.

They are tasked with supporting FINAS in developing its assessments by various means, including providing information such as insight on the field's current situation and prospects. These support groups mainly handle technical details related to a specific field. The aim of the support groups is to foster mutual understanding in assessment activities, and to identify and attempt to solve problems specific to the field under assessment. The support groups also communicate information on topical matters related to accreditation. The support groups consist of members of expert organisations in the field (such as in the technical support group for clinical analysis) or representatives of public authorities and accreditation customers (as in the technical support group for food and water control laboratories). Meetings of the support group and secretary services are arranged by FINAS. The principles of FINAS for the establishment and activities of support groups are described in FINAS policy document A9 Technical support for assessment – Principles applied by FINAS. Detailed information on the support groups' work is available on the FINAS website.

Information on recent developments in accreditation is communicated to

FINAS customers on the FINAS website and social media channels, on customer days and at meetings, and via leaflets and training events. The FINAS website contains information about FINAS as an accrediting body, general information on accreditation in Finland and internationally, a description of the accreditation process, instructions on how to apply for accreditation, and a list of accredited bodies and their scopes of accreditation. The website also contains news about the activities of FINAS and information about training services offered by FINAS. FINAS holds open events for its customers every two years. Customer meetings are held regularly with larger customers and with smaller customers according to need. Leaflets are published on the FINAS website and sent to customers by email if necessary.

## References

SFS-EN ISO/IEC 17011:2017, Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies

FINAS Finnish Accreditation Service policy documents:

A6 Principles for cooperation between FINAS and national authorities

A9 Technical support for assessment – Principles applied by FINAS.

Leaflet 2 FINAS Finnish Accreditation Service principles of confidential conduct

## Changes from the previous version

Changes 16/8/2023

|   | <b>Chapter</b>                    | <b>Changes</b>   |
|---|-----------------------------------|--|
|   | Foreword                          | Updated texts. Leaflet 10 on updates have been ceased. |
| 1 | Introduction                      | Biobank operations taken into account                  |
| 2 | The service promise of FINAS      | -  |
| 3 | The accreditation process         | Revised, updated and clarified tables                  |
| 4 | Confidentiality of accreditation  | -  |
| 5 | Digital services                  | Some updates to the text.                              |
| 6 | Data collection and communication | -  |
|   | References                        | -  |
|   | Changes from the previous version | New Sheet  |