The principles for the assessment of sampling according to the standards SFS-EN ISO/IEC 17025:2017 and SFS-EN ISO 15189:2013

FINAS Finnish Accreditation Service

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Foreword

This FINAS policy document is originally drawn up by a working group appointed by the Advisory Committee for Conformity Assessment Matters, Subcommittee for Accreditation Matters (VANK-P). The new version A1/2020 replaces the previous version A1/2016. In this version standard version SFS-EN ISO/IEC 17025:2017 has been updated.

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

FINAS accreditation criteria, policy documents and guidelines are presented in the valid FINAS Leaflet 10.

Further information: www.finas.fi

Content

1 Introduction

These principles are intended to serve as guidelines when assessing sampling in accordance with the requirements presented in Standards SFS-EN ISO/IEC 17025:2017 and SFS-EN ISO 15189:2013. When relevant, these principles are applicable also in inspection and certification if they contain testing activities. Sampling is always assessed as part of the laboratory activity. Sampling can be under the responsibility of the laboratory or its customer. Sampling methods can be part of the accredited scope of the laboratory. Important is that the persons or units responsible for sampling are defined and clearly identifiable in the laboratory.

Guidance on sampling is also available in FINAS Guidance 2 “Opas akkreditointivaatimusten soveltamiseksi ympäristönäytteenotossa” (Guidance on applying accreditation requirements in environmental sampling, available only in Finnish).

2 Definition of the laboratory’s sphere of operations

The laboratory must define its relationship with sampling in management system. If sampling is included in the sphere of the laboratory’s operations, the quality system must also encompass sampling. Laboratory should include sampling also to the risk assessment.

If the laboratory applies for the accreditation of sampling, the sampling methods are assessed as part of technical assessment, in the same way as other accredited methods.

When sampling is assessed, special attention is paid to the organisation of sampling within the laboratory, to the competence of personnel, to the interface between sampling and laboratory’s activities, and to management processes. Additionally, sampling methods used, and suitability are considered.

Policies and objectives in the laboratory must also be applicable to sampling.

3 Organisation of sampling and its relation to laboratory activities and to the management system

The unit responsible for sampling may form an integral part of the laboratory organisation, it may be a separate unit, or the laboratory may be an organisation that focuses solely on sampling. It is possible to applied accreditation for these sampling activities. It is also possible to subcontract sampling. If laboratory is continually subcontracting sampling activity, subcontracted sampling cannot be part of the scope of accreditation.

The management system must include a definition and description of the unit that is responsible for sampling and the management that is authorised to make decisions about resources allocated to sampling.

When sampling is part of the laboratory's operations, the laboratory's own personnel is generally responsible for its management. The laboratory must have the prerequisites for following the development of sampling both nationally and internationally. The laboratory shall ensure the competence of persons who participate in sampling, including any persons outside the laboratory who may be involved in the activities. Additionally, laboratory has to ensure that sampling methods are capable of meeting the customers' requirements.

The laboratory's process descriptions shall explicitly show each phase in the process of sampling–preliminary treatment–analysis and shall define the questions of authority and responsibility associated with each phase.

Sampling methods are equated with laboratory methods and they shall be described in writing. The terminology and the samples/objects are defined in the description of sampling methods or in other documents.

The laboratory must ensure that the sampling process is documented in a traceable manner even when sampling has been subcontracted. The laboratory is responsible for the filing of sampling documents as described in the management system.

4 Commissions: definition and reporting

A commission is an oral or a written request/order presented to the laboratory for the provision of laboratory services and any sampling that may be associated with these.

The reviews of contracts between the client and the laboratory and the associated documents define the requirements set for sampling and ensure that the requirements are clear and documented. The client and the laboratory also agree on the arrangements pertaining to sampling.

Reviews of contracts are also used to ensure that the unit responsible for sampling has the capabilities and resources for performing sampling. In addition, it is ensured that the sampling method selected meets set requirements.

When the laboratory is responsible for sampling, it is carried out in accordance with guidelines pertaining to the sampling methods in management system taken sampling plan into the account.

When the client or some other unit is responsible for sampling, the laboratory shall provide sufficient guidance or training to ensure the validity of the result of the sampling.

If the client has taken the sample independently, without consulting the laboratory and without receiving guidelines on procedures from the laboratory, the laboratory and the client shall, to the extent necessary, determine the suitability of the sampling for the method used. If the laboratory has reason to suspect faults or shortcomings in the sampling, the laboratory shall inform the client of the effects that deficient sampling may have on the result of testing/calibration.

If the laboratory has reason to assume that, owing to the sampling performed by the client, the correctness of the result is endangered, the laboratory and the client must agree on further actions and possibly on the taking of a new sample. If a faulty or deficient sample is handled by the request of the client or for any other reason defects and their effects on the results shall be reported.

Sampling is reported according to the SFS-EN ISO/IEC 17025:2017 and/or SFS-EN ISO 15189:2013 requirements.

5 Technical assessment of sampling

Technical assessment of sampling is performed always when the laboratory proposes sampling to be included in accreditation. The assessment team has to have the necessary expertise for sampling, and technical assessor or expert shall do witnessing in sampling. When planning the assessment risks will be considered.

In the assessment of sampling, special attention is paid to the interface between sampling and laboratory activities and to questions of responsibility.

Because sampling is equated with laboratory's methods, the whole of SFS-EN ISO/IEC 17025:2017 and/or SFS-EN ISO 15189:2013 must be applied to sampling, including the general procedures for quality control and quality assurance.

The following shall be considered in the sampling plan: the client's special requirements, selection of sampling sites, sampling frequency, representativeness of the sample and methods in use.

Assessment of sampling procedures also includes the validation/verification procedure of sampling methods (identification of risks and critical factors, disturbance factors, etc.) and the traceability of the sampling process.

Moreover, the assessment encompasses resources, the competence of the sampling personnel, the equipment used for sampling, and use of subcontractors, if any.

The technical performance of sampling is assessed by paying special attention to the compatibility of the sampling with the method selected, to the personnel's professional skills and ability to observe and manage exceptional situations, to the functioning of equipment and to the recording of data and reporting.

Changes to the previous version

Changes 21.04.2020

Chapter		**Change**	
	Foreword		Updated SFS-EN ISO/IEC 17025:2017
1	Introduction	1	Updated SFS-EN ISO/IEC 17025:2017
2	Definition of the laboratory's sphere of operations	2	Specified matters acknowledged in assessments like risk analyses
3	Organisation of sampling and its relation to laboratory activities and to the management system	3	Added continually subcontracting
4	Commissions: definition and reporting	4	Specified the text and updated SFS-EN ISO/IEC 17025:2017
5	Technical assessment of sampling	5	Added risk-based assessment, witnessing and verification and updated SFS-EN ISO/IEC 17025:2017
	Changes to the previous version		Added