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Contents

0. Introduction

Sampling and sample taking is an important part of the conformity assessment process. Sampling may significantly influence the results of this process. This is why it is necessary to establish criteria for the accreditation of sampling by accreditation bodies. It is recommended that accreditation bodies take into account the factors herein documented. However some criteria herein defined are not relevant for all types of sampling.

1 Purpose

The sampling of different sites, technical signatories, technical personnel and the scope of accreditation covered by the Conformity Assessment Body (CAB) is paramount to ensuring proper evaluation and assurance of the competence of the CAB across its scope of accreditation. Therefore the purpose of this document is to ensure that EAS assessments appropriately address the requirements of ISO/IEC 17011 in a uniform way. It defines the EAS procedure and specific requirements for sampling of sites, personnel and the scope of accreditation within the EAS accreditation cycles for laboratories, inspection and certification bodies.

2 Scope

The scope of this document covers all of the assessment process, including sites where key activities are performed and representative samples of both the CAB scope of accreditation and its technical staff.

This document applies to all accreditation scopes within ENAO; however the sampling of the witnessing of scopes for Certification Bodies is defined in EAS P07/02: clause 8.3

3 References

ISO/IEC 17011- Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies

ISO/IEC 17000 - Conformity assessment – Vocabulary and general principles

IAF MD 1:2018 IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization

IAF MD 5:2019 Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems

EAS P07.0 - EAS Accreditation Process

EAS P07/01 - Specific Accreditation Process for Inspection Bodies

EAS P07/02 - Specific accreditation Process for Certification Bodies

4 Definitions

4.1. **Multi-site organization** is defined as an organization having an identified central function (hereafter referred to as a central office – but not necessarily the headquarters of the organization) at which certain activities are planned, controlled or managed and a network of local offices or branches (sites) at which such activities are fully or partially carried out.

4.2. **Sampling**: Provision of a representative sample of the objective of conformity assessment, according to a defined and agreed procedure.

4.3. **Witnessing:** An expert observation of the conformity assessment body (CAB) carrying out conformity assessment services within its scope of accreditation.

4.4. **Key Activities:** Activities including (but not limited to), policy formulation, procedure and/or process development and, when appropriate, contract review, planning of conformity assessment activities, review, approval and decision making related to the results of conformity assessment.

4.5. **Technical Signatory (TS):**A person, or persons, whose competency, is declared by the organization, and confirmed by ***ENAO***, and whose signature confers validity on the organization's certificates, reports and/or results issued in terms of its ***EAS*** accreditation.

Note: *Although not all accredited facilities use the term "Technical Signatories", the emphasis is on those individuals whose signature confers validity on the organization's certificates, reports and/or results issued under its* ***EAS*** *accreditation.*

4.6. **Personnel:** Employees of an organization, either permanently employed or contracted, including technical signatories

5 Abbreviations

ENAO:	Ethiopian National accreditation Office
TS:	Technical Signatory
CAB:	Conformity Assessment Bodies
IB:	Inspection Bodies
IAF:	International Accreditation Forum
IAF MD:	IAF Mandatory Documents
EMS:	Environmental Management system

QMS: Quality Management System

ILAC: International Laboratories Accreditation Cooperation

AFRAC: African Accreditation Cooperation

HRD: Human Resource Development

6 Information for Planning

6.1. Applications for accreditation shall provide all the information required on the relevant EAS application form. The information relevant to, and required for, the planning of sampling activities includes:

i) A description of the main activities of the organization seeking accreditation;

ii) A detailed list of the fields / parameters / tests for which accreditation is sought;

iii) A list of proposed technical signatories (however named) including information on their qualifications and experience;

iv) The total number of personnel (excluding technical signatories) performing technical work within the scope applied for, e.g. analysts, inspectors, metrologist, technologists, auditors etc.

v) The name and address of all CAB sites where key activities are performed, and for which accreditation is now sought;

vi) Any on-site activities (Work performed on the clients' site) for which accreditation is sought;

vii) In the case of *Certification Bodies* – a list of auditors for each of the different EAS scopes in the application.

viii) In the case of *Medical Laboratories*:

- A list of all specimen collection sites and their addresses; and
- The number of phlebotomists at each specimen collection site

Note: Total number of personnel means those which are permanent, contracted, part-time personals engaged in CAB activities.

6 Sampling

6.1. **Methodology**

Assessment related s*ampling considers and appropriately covers:*

i) sampling of sites from which key activities are performed and the selection of these sites after due consideration of the uncertainty related to sampling;
ii) The sampling of scope of accreditation;
iii) CAB personnel whose signature confers validity on the organization's certificates (normally referred to as "technical signatories"); and
iv) The CAB technical personnel, other than technical signatories, who perform the tests / calibrations / inspections / audits, etc.

6.1.1 **Sampling of Sites**

The sampling of sites, including sample collection sites, where key activities are performed shall, as a minimum, comply with the requirements specified in Table 1.

6.1.2 **Selection of Sites**

A representative sample for site visitation purpose shall be partly selective and partly non-selective. The outcome should result in a representative range of different sites being selected, while still respecting the need for a random element within the finalized sample.

At least 25% of the sample shall be selected at random.

The remainder of the selected sample shall ensure that the list of sites selected for the period of the validity of the accreditation certificate includes all sites where key activities are performed.

6.1.2.1 **Nonrandom component of site selection**

The nonrandom component (75%) of the list of sites selected for assessment should, as a minimum, take the following into consideration:

i) The central office and the geographical spread of its activities;
ii) The number, range, size, complexity and location of sites;
iii) The degree of central office involvement in the management of sites (the structure of the quality system);
iv) The results of internal audits from the central office and sites;
v) The results of management reviews;
vi) The complexity of the management system;
vii) Variations in working practices including, where applicable, equipment and methods used;
viii) Variations in the activities undertaken (e.g. fields of inspection / testing /calibration / verification…etc., and types of inspection/ testing / calibration /verification);
ix) Where applicable, the level of performance over the assessment cycle;

x) extent of changes within the organization;

xi) The level of confidence which can be placed in the performance measures and control systems of the CAB.

6.1.3 **Sampling of the Scope of Accreditation**

The sampling of a Facility's scope of accreditation shall, as a minimum, comply with the requirements specified in Table 1.

6.1.3.1 **Selection of scopes to be assessed**

A representative sample for the assessment of the scope of accreditation shall be partly selective and partly non-selective. The outcome should result in a representative range of different scopes being selected, while still respecting the need for a random element within the finalized sample.

At least 25% of the sample shall be selected at random.

The remainder of the selected sample shall ensure that the list of scopes selected for the period of validity of the accreditation certificate covers all of the main scopes of accreditation.

6.1.3.2 **Nonrandom component of scope selection.**

The nonrandom component (75%) of the list of scopes selected for assessment should, as a minimum, take the following into consideration:

i) The availability of assessment team members with the necessary technical knowledge to cover the desired scope(s) of accreditation, during the relevant period;

ii) A representative sample of all scope of activities must always be assessed at the initial assessment prior to the granting of accreditation;

iii) The different equipment or methods involved; and an estimation of the amount of time that would be required for each assessment;

iv) A representative sample of all the accredited scope of activities must be covered at least once within the accreditation cycle;

v) The competency of Technical Signatories of the CAB shall be verified prior to the granting of accreditation and at least once within an assessment cycle.

6.1.4 **Sampling of Personnel**

The sampling of personnel shall, as a minimum, comply with the requirements specified in Table 1.

6.1.4.1 **Selection of Personnel**

A representative sample for the assessment of personnel shall be partly selective and partly non-selective. The outcome should result in a list of representative technical signatories and other personnel selected for assessment. The assessment of personnel can be performed through

either witnessing or a vertical assessment of work done by an individual or an appropriate combination of both techniques.

6.1.4.2 When finalizing the list of personnel that are to be assessed the following aspects, as a minimum, shall be considered by ENAO:

i) The fields and types of activities contained in the accreditation schedule;
ii) The CABs procedures for selecting, training, authorizing and monitoring of the staff conducting these activities, including the qualifications and experience required for different fields and types of accredited activities;
iii) The internal auditing arrangements of the CAB;
iv) The locations from which the staff are required to operate;
v) Any statutory requirements;
vi) Where required by the relevant standard, the extent to which the staff are required to exercise professional judgment.
vii) Effectiveness of the CAB's own witnessing activities

6.1.4.3 When deciding on the types of activities that are to be assessed, appropriate consideration will include at least the following aspects:

i) The variety of products, services, processes and plants covered by the accreditation;
ii) The skills needed by the inspector / auditor / calibration and / or test technician / medical technologist etc;
iii) Any statutory requirements;
iv) Where required by the relevant standard, the extent to which the selected CAB staff are required to exercise professional judgment.

All signatories shall be assessed during an assessment cycle. If any on-site activity is not available simulation / talk-through and vertical assessment may be considered.

6.1.4.4. When deciding on *which* of the CAB personnel will be assessed, appropriate account will be taken of:

i) New recruits or new technical authorizations;
ii) Qualifications and experience;
iii) Location;
iv) Any statutory requirements;
v) Where required by the relevant standard, the extent to which the selected personnel are required to exercise professional judgment.

6.2 **Sample size**

Table 1 provides details regarding the EAS requirements for the determination of the sample sizes for witnessing of sites, personnel and scopes of accreditation.

Table 1: Sample size determination

Type of assessment	**Sampling percentage & area**			
	Sites (Satellite or Branch offices) where key activities are performed	***Scope / Fields***	***Technical Signatories***	***Technical Personnel (excluding Technical Signatories***
Initial Assessment	100% (As per ISO/IEC 17011 requirement)	A. Scope/ Field /Discipline /Scheme (e.g. Chemistry, Microbiology, Mass Metrology).**100%**	A. Scope/ Field /Discipline / Scheme (e.g. Chemistry, Microbiology, Mass Metrology). **100%**	A. Scope/ Field /Discipline / Scheme (e.g. Chemistry, Microbiology, Mass Metrology). **100%**
		B. Within A above: Tests/inspection service/ measured quantity or instrument **100%**	B. Within A above: Tests/inspection service/ measured quantity or instrument: **25%** (subject to the 100% review of the Records of each applicant).	B.. Within A above: Tests/inspection service/ measured quantity or instrument: **20%** ❖ Proof of competence for Technical

			❖ Proof of competence for Technical Signatory by assessing the personal records (assessing objective evidence for personnel competence on the methods requested to signatory) shall be done at least for 50% of the personnel involved in accredited scope activities.	personnel by assessing the personal records (assessing objective evidence for personnel competence on the methods requested to signatory) shall be done at least for 50% of the personnel involved in accredited scope activities.

Remark

- ❖ If the number of personnel in the CABs are three or less, all the personnel shall witnessed
- ❖ At least each method for which accreditation sought shall be witnessed by using different personnel and witnessing other personnel during the follow up assessment, where possible.
- ❖ Techniques on the application of a method with multiple reports need at least one witnessing.
- ❖ Vertical assessment shall be done for all methods.

- ❖ For all assessment main /central offices and all Sites (Satellite or Branch offices where key activities are performed) shall be assessed.
- ❖ Interviewing to technical signatory shall include ENAO's PT policy, Traceability policy, Uncertainty Calculation, Method Validation/Verification, relevant working Standard

Follow up assessment	**100%** of main / central/ head offices, including the following number of sites: **Minimum follow up = 0.8√n** (rounded off to the next whole number, where n represents the number of sites).	A. Scope/ Field /Discipline / Scheme (e.g. Chemistry, Microbiology, Mass Metrology). **100%**	**75% of 100% multiplied by (0.6√n)** (where n represents the number of signatories). The remaining 50% record of technical signatories shall be assessed during follow up cycle.	**25% of100% multiplied by (0.6√n)** (where n represents the number of technical personnel excluding signatories). The remaining 50% record of technical personnel shall be assessed during follow up cycle.
		B. Within A above: Tests/inspection service/ measured quantity or instrument: Minimum of **25%** depending up on associated risk.		
Re-assessment	***100%****of sites.* *Experience gained during the previous assessment shall be taken into account*	A. Scope/ Field /Discipline / Scheme (e.g. Chemistry, Microbiology, Mass		

	when determining the final percentage to be assessed	Metrology). **100%** B. Within A above: Tests/inspection service/ measured quantity or instrument: Minimum of **75%** and dependent on the past performance of the Facility.	**75% of 100 multiplied by (0.8√n)** where n represents the number of technical Signatories.	**25% of 100 multiplied (0.8√n)** where n represents the number of technical Personnel (excluding signatories).
Extension Including Evaluation of personnel	New Sites - **100 %**	A. Scope/ Field /Discipline / Scheme (e.g. Chemistry, Microbiology, Mass Metrology). **100%** B. Within A above: Tests/inspection Service/ measured quantity or instrument. **100%**	New Signatories - **100%**	*All personnel records will be covered*

6.2.1 **Guidance on Calculating √n**

i) Sampling for Follow up Assessments: 0.8√n, (where n = the number of sites), rounded up to the next whole number:

Example: There are 30 sites from which key activities are performed:

0.8 X (√30) = 0.8 x5.48 = 4.38

4.38 rounded off to the next whole number = 5 sites to be sampled

No. of sites (n)	Sample of sites to be assessed 0.8√n
1	1
2	2
4	2
6	2
10	3
15	4
25	4
30	5
50	6
100	8

ii) Sampling for witnessing of CAB personnel at Follow up Assessment: 0.6√n, (where n =the number of personnel), rounded off to the next whole number:

Example 1*:* There are 30*Technical Signatories* on which to base the sample:

0.6 X (√30) X 75% = (0.6 X 5.48) X 75% = $\frac{3.29 \text{ X } 75}{100}$ = 2.47

2.47 rounded up to the next whole number = 3

Example 2: There are 30 Technical Staff (Excluding technical signatories) from which to sample:

0.6X (√30) X 25%= (0.6 X 5.48) X 25%= 3.29 X 25/100 = 0.82

0.82 rounded off to the next whole number = 1

No. of Technical Signatories (n)	Sample of Technical Signatories to be assessed at Follow up Assessment 75% of 0.6√n	No. of Technical Personnel (excl. Technical Signatories) (n)	Sample Personnel to be assessed at Follow up Assessment (non signatories) 25% of (0.6√n)
1	1	1	1
2	1	2	1
4	1	4	1
6	2	6	1
10	2	10	1
15	2	15	1
25	3	25	1
30	3	30	1
50	4	50	2
100	5	100	2

iii, Sampling for witnessing of personnel at Re-Assessment: 0.8√n , (where n = the number of personnel),

rounded off to the next whole number:

Example *1:* There are 30 technical signatories from which to sample:

$$0.8 \times (\sqrt{30}) \times 75\% = (0.8 \times 5.48) \times 75\% = \frac{4.38 \times 75}{100} = 3.29$$

3.29 rounded off to the next whole number = 4

Example *2:* There are 30 technical staffs (excluding technical signatories) from which to sample:

$$0.8 \times (\sqrt{30}) \times 25\% = (0.8 \times 5.48) \times 25\% = \frac{3.29 \times 25}{100} = 1.10$$

1.10 rounded up to the next whole number = 2

No. of Technical Signatories (n)	Sample of Technical Signatories to be assessed at Re-Assessment	No. of Technical Personnel (excluding Technical Signatories) (n)	Sample Personnel to be assessed at Re-Assessment (non signatories)

	75% of 0.8√n		25% of (0.8√n)
1	1	1	1
2	1	2	1
4	2	4	1
6	2	6	1
10	2	10	1
15	3	15	1
25	3	25	2
30	4	30	2
50	5	50	2
100	6	100	2

6.3 **Risk**

EAS may increase the sample size depending on the type and extent of the risks identified.

6.3.1 The type of risks may include that a CAB:

i) Operates in a region or country that EAS has identified as representing a significant risk area in terms of maintaining accreditation requirements, or in terms of political or safety reasons;

ii) Is subject to a formal complaint under investigation by ENAO;

iii) Has a history of poorly managed compliance to accreditation requirements;

iv) Has revised its key activities performed at sites;

v) Has a history of weak implementation of corrective actions throughout the CAB organization including sites;

vi) Has significant Technical Signatory turnover.

Revision No.	Date Approved	Revision History
1	2018-10-16	This document was revised because of the new ISO/IEC 17011:2017
1.1	2021-05-13	Update references IAF MD 1:2018 IAF Mandatory Document for the Audit and Certification of a Management System Operated by a Multi-Site Organization IAF MD 5:2019 Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems Added **Note:** Total number of personnel means those which are permanent, contracted, part-time personals engaged in CAB activities under clause 6.1 Table 1 under column Technical signatory and technical personnel initial onsite assessment added Proof of competence for Technical Signatory by assessing the personal records (assessing objective evidence for personnel competence on the methods requested to signatory) shall be done at least for 50% of the personnel involved in accredited scope activities Under remark included Interviewing to technical signatory shall include ENAO's PT policy, Traceability policy, Uncertainty Calculation, Method Validation/Verification, relevant working Standard The remaining 50% record of technical signatories shall be assessed during follow up cycle added on follow up assessment on Technical signatory and technical personnel Extension – under technical personnel included *All personnel records will be covered*
1.2	2022-05-09	The document is revised due to the name Ethiopian National Accreditation Office (ENAO) change to Ethiopian Accreditation Service (EAS) and new logo developed.

1.3	2023-02-07	• Correction done on page 1 that, this document was prepared by Meseret Tessema replaced by Zewdu Ayele (new quality manager). • Former director general was resigned and replaced by Mrs. Meseret Tessema.