KENAS
Delivering Trust

KENYA
ACCREDITATION
SERVICE

ACC-PR-03-04

Sampling During Assessments Procedure

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1 Background Information

1.1 Purpose

The procedure defines how KENAS undertakes sampling of activities when carrying out the assessments and /or witnessing of the key activities of the conformity assessment body (CAB). It provides a framework for selecting samples of sites, personnel, and areas within the scope of accreditation throughout the accreditation cycle, to support reliable accreditation decisions and maintain confidence in the accredited services.

1.2 Scope

This procedure is applicable to all assessments carried out by KENAS where sampling is required.

1.3 Role(s) and Responsibility

Role	Responsibility
Assessment Personnel	Process owner
SCBO, SCLO, AOML, QRMO	Reviewer
CMLA/CMCI, MRSQ	Recommender
CEO	Approval
Assessment Personnel	Compliance

2 Terms and Definitions

For the purpose of this procedure, the following terms and definitions shall apply in addition to those given in ISO/IEC 17000 and the Kenya Accreditation Act CAP 496A Laws of Kenya.

2.1 Acronyms and Abbreviations

CEO	Chief Executive Officer
SCBO	Senior Accreditation Officer Certification
SCLO	Senior Accreditation Officer Calibration
MRSQ	Manager Research, Strategy and Quality department
QRMO	Quality and Risk Management Officer
MEDOAOML	Accreditation Officer Medical Laboratories
CMLA	Chief Manager Laboratories

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CMCI	Chief Manager Certification and Inspection
CAB	Conformity Assessment Body
ISO	International Organization for Standardization
IEC	International Electrotechnical Commission

2.2 Definition of Terms

2.2.1 Key activities

These are activities undertaken by the CAB that include policy formulation, development of processes and or procedures, contract review, planning conformity assessments, review, approval and decision on the results of conformity assessment.

2.2.2 Conformity assessment services

These are services offered by a CAB under its scope of operation and include; certification, inspection, testing, calibration and medical testing sampling. This is a process in which a pre-determined number of observations are taken from a larger population and involves random and systematic sampling. The sample should be a representation of the general population.

2.2.3 Multi-site Facility

An organization having an identified central function (hereafter refer to as a Central Office – but not necessarily the Head Office of the organization) at which certain activities are planned, controlled or managed and a network of local sites at which activities are fully or partially carried out.

2.2.4 Sampling

Provision of a sample of the objective of conformity assessment according to a procedure.

2.2.5 Witnessing:

Observation of the CAB carrying out conformity assessment services within its scope of accreditation.

2.2.6 Key Activities

Activities such as (but not limited to) policy formulation, process and/or procedure development and, as appropriate, contract review, planning of conformity assessments, review, approval and decision on the results of conformity assessment.

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2.2.7 Technical Signatories

A person deemed as competent by KENAS whose signature confers validity on the organization's certificates, reports and/or results issued under its KENAS accreditation.

3 Process Detail

3.1. The assessment team undertakes the necessary preparations to enable efficient and effective execution of the assessment of a CAB in accordance with Management and reporting of assessments procedure (ACC-PR-07) and Assessor Guide and Terms of Reference (ACC-CD-02).

3.2. Applicants seeking accreditation shall provide KENAS with all the information as required on the application form. The information bearing specific relevance to sampling includes:

a) Description of the main activities of the organization seeking accreditation;

b) Detailed list of fields/parameters/tests for which accreditation is sought;

c) A list of applicant technical signatories (or personnel whose signature confers validity on the organization's certificates) including information on their qualifications and experience;

d) Name and address of all sites where key activities are performed and for which accreditation is sought;

e) Any on-site activities (work performed on the clients' site) for which accreditation is sought; andThe assessment team analyses the information above of the conformity assessment body including the conformity assessment activities being undertaken i.e. certification, inspection, testing, calibration and medical testing.

3.3. The team shall then establish which among the activities of the CAB constitutes key activities and identify any other premises or sites where such key activities are undertaken.

3.4. The team shall make a decisions regarding the representative number of CAB's scope of activities it shall assess in case these are not pre-determined on the assessment program, this include sites under consideration, Scope /Field of assessment and competence requirements as well as evaluation of technical signatories.

3.5. The sampling shall be done in a manner to ensure that a representative sample is assessed to determine the competence of the CAB and where structured that key activities are all covered at the initial assessment while the others that may not be key or whose competence can be derived from the key activities are

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covered within the accreditation cycle. Where sampling is applied, all scopes must be covered for adequacy during the surveillance visits.

3.6. The following table illustrates the sampling expectations:

	Site	**Scope/Field**	**Technical Signatories**
Initial	100% (Where 100% sample is not feasible, only those assessed appear on the schedule	100% (Where 100% sample is not feasible, only those assessed appear on the schedule.	Only those valuated appear on the schedule
Surveillance	≥33% of accredited sites	≥33% of accredited scope	Vertical assessments done reports / certificates signed off
Reassessment	100% of accredited sites	100% of accredited scope	100% of those appearing on the schedule
Extension of scope	100% of sites requested for extension	100% of the scope/field requested for extension	100% of the proposed technical signatories

3.7. For Certification bodies, the additional requirement for sampling are included in the various criteria documents.

3.8. Some of the factors considered when coming up with a sampling plan for CAB assessments include:

3.8.1. Compliance to statutory requirements.

3.8.2. Performance in previous assessments.

3.8.3. Changes in key staff, scope and key processes.

3.8.4. Change of site / Location.

3.8.5. Change of equipment.

3.8.6. Risks associated with the activity.

3.8.7. Complaints and information in the media/public domain.

3.8.8. Variety of products, services, processes and plants.

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3.8.9. Skills needed by the CAB's technical persons i.e. inspectors, auditors, technologists, etc

3.8.10. The extent to which professional judgment is applied.

3.8.11. Qualification and Experience of CAB personnel.

3.8.12. For certification bodies sector specific requirements apply and additional guidance on sampling is provided in the KENAS criteria documents listed in the references.

3.8.13. Possibility of Key activity /location having been covered by an IAF MLA AB.

3.9. For Medical and Veterinary Testing Laboratories with multi-sites, all sites shall be assessed during the accreditation cycle.

4 Associated Documents

Ref	Document Identifier	Document Title
1.	ISO/1EC 17011	Conformity Assessment-Requirements for accreditation bodies accrediting conformity assessment bodies
2.	ISO 19011	Guidelines for management systems auditing
3.	IAF MD 1	IAF MD for Audit and Certification of a Management system operated by Multi-Site organization
4.	QMM-01	KENAS Quality Manual
5.	ACC-CD-02-01	Assessor Guide and Terms of Reference
6.	ACC-PR-07-01	Management and Reporting of Assessments
7.	IAU-PR-01-01	Management of Internal Audits

5 Revision/ Amendment Records

Date	Ver	Revised By	Reason for Revision
10/10/2022	01	RSQ	Newly developed/formatted document
09/12/2022	02	MED	The inclusion of: Medical testing in the conformity assessment activities

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Date	Ver	Revised By	Reason for Revision
			Assessment of all multi-sites during the accreditation cycle for Medical and Veterinary Testing Laboratories
21/07/2023	03	Accreditation Team	Change of document name Remove of reference to Internal Audits and auditors
30/06/2025	04	QRM	Systematic Review of QMS Documentation

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