



KENYA ACCREDITATION SERVICE

Document Title: **PROCEDURE FOR SAMPLING DURING ASSESSMENTS AND INTERNAL QUALITY AUDITS**

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Approval and Authorization

Completion of the following signature blocks signifies the review and approval of this Document.

Name	Job Title / Role	Signature	Date
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Periodic Review Approval and Authorization

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1 OVERVIEW CONTENT

1.1 Process Overview

This Operating Procedure (OP) defines sampling requirements during assessments and internal audits. The desired outcome of this OP is objective sampling of key processes by assessors and internal auditors.

1.2 Purpose

This procedure defines how KENAS shall undertake sampling when carrying out the assessments and /or witnessing of the key activities of the conformity assessment body (CAB) and when carrying out internal audits. It is desired that a representative sample is selected to ensure proper evaluation of a CAB's competence or sound management of internal processes.

1.3 Scope

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

1.4 Role(s) and Responsibility

Role	Responsibility
ADs TECHNICAL SERVICES	The ADs responsible for the various fields of accreditation are principally responsible in ensuring that this procedure is implemented within their schemes.
INTERNAL QUALITY AUDITORS/ASSESSORS	Ensure appropriateness of sampling during internal audits / assessments
MR	Ensure that this procedure remains suitable for its intended use.

2. DEFINITIONS/ ABBREVIATION

The table below defines terms that are included in or associated with this process.

Term	Definition
Key activities	These are activities undertaken by the CAB and include policy formulation, development of processes and or procedures, contract review, planning conformity assessments, review, approval and decision on the results of conformity assessment.
Conformity assessment services	These are services offered by a CAB under its scope of operation and include certification, inspection, testing and calibration services.



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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.
KENAS	Kenya Accreditation Service
CAB	Conformity Assessment Body
MR	Management Representative
ADs	Assistant Directors

3 PROCESS INSTRUCTIONS

- 3.1 The assessment team shall undertake the necessary preparations to enable efficient and effective execution of the assessment of the CAB in accordance with KENAS-TS-OP-010 and KENAS-GUD-003.
- 3.2 The team shall analyze the scope of the conformity assessment body including the conformity assessment services already provided i.e. certification, inspection, testing and calibration.
- 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 then make a decision regarding the representative number of CAB's scope of activities it shall assess. This shall 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 covered within the accreditation cycle. Where sampling is applied, all scopes must be covered for adequacy during the surveillance visits. 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 evaluated appear on the schedule
Surveillance	≥33% of accredited sites	≥33% of accredited scope	Vertical assessments done reports / certificates signed off.



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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

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

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

- 3.7.1 Compliance to statutory requirements.
- 3.7.2 Performance in previous assessments.
- 3.7.3 Changes in key staff, scope and key processes.
- 3.7.4 Change of site / Location of site
- 3.7.5 Change of equipment.
- 3.7.6 Risks associated with the activity.
- 3.7.7 Complaints and information in the media/public domain.
- 3.7.8 Variety of products, services, processes and plants
- 3.7.9 Skills needed by the CAB's technical persons i.e. inspectors, auditors, technologists, etc
- 3.7.10 The extent to which professional judgment is applied.
- 3.7.11 Qualification and Experience of CAB personnel.
- 3.7.12 For certification bodies sector specific requirements apply and additional guidance on sampling is provided in the KENAS guidance documents listed in the references.

3.8 For internal audits, all sections of the organization will be audited as provided for in the audit schedule. Where a sampling plan is applied, the following factors will be taken into consideration:

- 3.8.1 Nature and number of non-conformities arising from various departments.
- 3.8.2 Risks and risk mitigation plans.
- 3.8.3 Operational requirements to demonstrate compliance to ISO/IEC 17011.
- 3.8.4 Results of previous audits.

4 REFERENCE AND RELATED DOCUMENTS

Ref	Document Identifier	Document Title
1.	KENAS-QM-MAN-01	KENAS Quality Manual



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Ref	Document Identifier	Document Title
2.	KENAS-GUD-003	Assessor Guide
3.	ISO/IEC 17011	Conformity Assessment-General requirements for accreditation bodies accrediting conformity assessment bodies
4.	ISO 19011	Guidelines for management systems auditing
5.	KENAS-TS-OP-010	Procedure for assessment, surveillance, re-assessments and reporting
6.	KENAS-TS-OP-005	Management of internal audits
7.	KENAS-TS-F-018	KENAS Risk Register
8.	ILAC/IAF A5	Application of ISO/IEC 17011;2014
9.	KENAS-GUD-008	Criteria for QMS
10.	KENAS-GUD-009	Criteria for EMS
11.	KENAS-GUD-010	Criteria for FSMS
12.	KENAS-GUD-011	Criteria for OHSAS

5 PROCEDURE TRAINING

Awareness of this procedure is required of KENAS Staff performing one or more of the roles specified in this procedure. A period not more than one month shall be allocated between the issue date and effective date to facilitate such awareness.

6 REVISION HISTORY

Date	Ver	Revised By	Reason For Revision
03/02/2012	01	ADTC	Initial on the new numbering system, supersedes KENAS/OP/18
03/02/2014	02	ADIV	<ul style="list-style-type: none">Included requirements of ILAC/IAF A5 on inspection body accreditation.Provide for guidance documents for certification in the references.
03/08/2015	03	ADIV	<ul style="list-style-type: none">Provision of a table under 3.5 for guidance on Sampling