

## SAMPLING FOR ASSESSMENT PURPOSES

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## 1. PURPOSE AND SCOPE

The sampling of different sites 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.

The purpose of this document therefore is to give effect to the requirements of ISO/IEC 17011 by defining SADCAS procedure and specific requirements for sampling of sites, personnel and the scope of accreditation within the accreditation cycle.

The scope of this document covers the assessment process including the assessment of all sites of the CAB where key activities are performed, and where applicable, witnessing of a representative sample of the CAB's scope of accreditation as well as a representative number of technical staff.

The objective of this procedure is to ensure that SADCAS implements an assessment sampling plan for each applicant and accredited facility based on representative samples which are appropriate to the CAB's scope of accreditation.

This document applies to all accreditation schemes within SADCAS. However the sampling of the witnessing of scopes for Certification Bodies is defined in SADCAS AP 12: Part 3.

## 2. DEFINITIONS

- 2.1. **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. **Sampling:** Provision of a sample of the objective of conformity assessment according to a procedure.
- 2.3. **Witnessing:** Observation of the CAB carrying out conformity assessment services within its scope of accreditation.
- 2.4. **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.
- 2.5. **Technical Signatories:** A person deemed as competent by SADCAS whose signature confers validity on the organization's certificates, reports and/or results issued under its SADCAS accreditation.

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

- 2.6. **Personnel:** Employees of an organization including technical signatories.

### **3. INFORMATION FOR PLANNING**

- 3.1. Applicants seeking accreditation shall provide SADCAS 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; and
  - f) In the case of medical laboratories:
    - A list of all specimen collection sites and their addresses;
    - The number of phlebotomists at each specimen collection site;
  - g) In the case of certification bodies – a list of auditors per scope

### **4. SAMPLING**

During the assessment SADCAS will sample locations and personnel to determine the competence of the CAB to perform the activities covered by the scope(s) of accreditation. In selecting the activities to be assessed, SADCAS shall consider the risks associated with the activities, locations and personnel covered by the scope(s) of accreditation.

#### **4.1. Methodology**

##### **4.1.1. Sampling covers:**

- a) The sampling of sites from which key activities are performed and the selection of these sites taking into consideration the random element of sampling;
- b) The sampling of the scope of accreditation; and
- c) The sampling of personnel whose signature confers validity on the organization's certificates (in most cases referred to as "technical signatories")

##### **4.1.2. Sampling sites**

Sampling of sites, including specimen collection sites, where key activities are being performed shall as a minimum be in accordance with Table 1.

#### 4.1.2.1. Selection sites

The sample will be partly selective based on the factors set out below and partly non-selective, resulting in a representative range of different sites being selected without excluding the random element of sampling.

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

The remainder will be selected so that the differences among the sites selected over the period of validity of the certificate covers all sites from where key activities are performed.

#### 4.1.2.2. The 75% of site selection may as a minimum take into consideration:

- a) The Central Office and the geographical spread of its activities.
- b) The number, range, size, complexity and location of sites.
- c) The degree of central office's involvement in the management of the sites (structure of the management system).
- d) The results of internal audits from central office and sites.
- e) The results of management reviews.
- f) Complexity of the management system.
- g) Variations in working practices including, where applicable, equipment and methods used.
- h) Variations in activities undertaken, e.g. fields of inspection/testing/calibration/ verification, etc., types of inspection/testing/calibration.
- i) Where applicable, the level of performance over the assessment cycle.
- j) Extent of changes within the organization.
- k) The level of confidence which can be placed in performance measures and control systems of the CAB.

#### 4.1.3. Sampling of scope of accreditation

Sampling of a facility's scope of accreditation shall as a minimum be in accordance with **Table 1**.

##### 4.1.3.1. Selection of scopes to be assessed

The selection will be partly selective based on the factors set out below and partly non-selective, resulting in a representative range of different scopes being selected without excluding the random element of sampling.

A least 25% of the sample will be selected at random.

The remainder will be selected so that the differences among the scopes selected over the period of validity of the certificate covers all main scopes.

##### 4.1.3.2. The 75% of scope selection may as a minimum take into consideration:

- a) The availability of assessment team members with the necessary technical knowledge to cover the desired scope of accreditation during the relevant period.
- b) A representative sample of all scopes of activities must be assessed at the initial assessment prior to granting accreditation.
- c) The different equipment or methods and an estimation of the amount of time that will be required for each assessment.
- d) A representative sample of all scopes of activities must be covered at least once within the accreditation cycle.
- e) The competency of Technical Signatories of the CAB shall be verified prior to the granting of accreditation and at least once within assessment cycle.

#### 4.1.4. Sampling of personnel

Sampling of personnel shall as a minimum be in accordance with Table 1.

##### 4.1.4.1. Selection of personnel

The selection of personnel will be partly selective based on the factors set out below and partly non-selective resulting in a representative range of different signatories and other personnel being selected for assessment without excluding the random element of sampling. Assessment can be done through witnessing or vertical assessment of work done by an individual or both.

At least 10% of the sample will be selected at random.

The remainder will be selected so that the differences among the personnel selected over the period of validity of the certificate covers all technical signatories.

##### 4.1.4.2. When deciding on the 90% of personnel to be assessed, the following aspects may as a minimum be considered by SADCAS:

- a) The fields and types of activities on the accreditation schedule.
- b) 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 activities.
- c) The internal auditing arrangements of the CAB.
- d) The locations from which the staff operate;
- e) Any statutory requirements.
- f) Where required by the standard, the extent to which the staff are required to exercise professional judgment.
- g) Effectiveness of the laboratory's own witnessing activities.

##### 4.1.4.3. When deciding on the types of activities to be assessed account will be taken of the following:

- a) Variety of products, services, processes and plants covered by the activities;

- b) Skills needed by inspector/ calibration technician/phlebotomist, etc.;
- c) Any statutory requirements; and
- d) Where required by the standard, the extent to which the staff are required to exercise professional judgment;

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

4.1.4.4. When deciding on which personnel will be assessed, account will be taken of:

- a) New recruits or new authorizations;
- b) Qualifications and experience;
- c) Location;
- d) Any statutory requirements; and
- e) Where required by the standard, the extent to which the staff are required to exercise professional judgment;

4.2. **Sample Size**

Table 1 below depicts the determination of the sample sizes for 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/Field	Personnel (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% (as far as practicable)
		B. Within A above: Tests/ Verifications/ Inspection service/ measured quantity or instrument 100%	B. Within A above: Tests/ Verifications/ Inspection service/ measured quantity or instrument 25% subject to the proviso that a 100% review of the records of each applicant

Type of assessment	Sampling percentage & Area				Scope/Field	Personnel (Technical Signatories)
	Sites (Satellite or Branch offices) where key activities are performed					
Periodic on-site Assessment (POA)	100% of main/ Central offices, including the following number of sites:  <b>Minimum surveillance = <math>0.8\sqrt{n}</math></b> 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%	<b>Pers = <math>0.6\sqrt{n}</math></b> where n represents the number of signatories
	<b>n</b>	<b>POA</b>	<b>n</b>	<b>POA</b>	B. Within A above: Tests/ Verifications/ Inspection service/ measured quantity or instrument Minimum of 25% depending upon associated risk	
	1	1	15	4		
	2	2	25	4		
	4	2	30	5		
	6	2	50	6		
10	3	100	8			
Re-assessment	100% sites However experiences gained during the previous assessment shall be taken into account when determining the final percentage to be assessed				A. Scope/Field/Discipline/ Scheme (e.g. Chemistry, Microbiology, Mass Metrology) 100%	<b>Pers = <math>0.8\sqrt{n}</math></b> where n represents the number of signatories
					B. Within A above: Tests/ Verifications/ Inspection service/ measured quantity or instrument Minimum of 75% subject to the past performance of the facility	
Extension including Evaluation of Personnel	New sites 100%				A. Scope/Field/Discipline/ Scheme (e.g. Chemistry, Microbiology, Mass Metrology) 100%	New Signatories 100%
					B. Within A above Tests/ Verifications/ Inspection service/ measured quantity or instrument 100%	

Type of assessment	Sampling percentage & Area		
	Sites (Satellite or Branch offices) where key activities are performed	Scope/Field	Personnel (Technical Signatories)

#### 4.3. Risk

SADCAS may increase the sample size depending on the risks identified.

##### 4.3.1. The type of risks may include:

- a) Operating in a region or country that SADCAS has identified as representing a significant risk area in terms of maintaining accreditation requirements or in terms of political or safety reasons;
- b) Is subject to a formal complaint under investigation by SADCAS;
- c) Has a history of poorly managed compliance to accreditation requirements;
- d) Has revised its key activities performed at sites;
- e) Weak implementation of corrective actions throughout an organization including their sites
- f) Signatory or inspector turnover at accredited facility.

## 5. 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 - Audit and certification of a management system operating by a multi-site organization
- IAF MD 5 - Determination of audit time of QMS and EMS Audits
- SADCAS TR 11 - Criteria for the accreditation of Calibration satellite laboratories and branch offices
- SADCAS AP 12: Part 1 - Accreditation process for testing/calibration/medical laboratories
- SADCAS AP 12: Part 2 - Accreditation of inspection bodies regulatory and voluntary domain
- SADCAS AP 12: Part 3 - Accreditation Process for certification bodies

**APPENDIX - AMENDMENT RECORD**

Revision status	Change			Approved by	Effective Date
	Page No.	Clause	Description of change		
Issue 1	-	-	-	SADCAS CEO	2013-12-12
Issue 1	3	1	Paragraph 5, Line 1: "programmes" deleted and substituted with "schemes"		
	4	4	Added after the title: During the assessment SADCAS will sample locations and personnel to determine the competence of the CAB to perform the activities covered by the scope(s) of accreditation. In selecting the activities to be assessed, SADCAS shall consider the risks associated with the activities, locations and personnel covered by the scope(s) of accreditation.		
	5	4.1.2.2 c)	"quality" deleted and substituted with "management"		
	8	Table 1	"Surveillance" deleted and substituted with "Periodic on-site"		