MP 21 - 01

Sampling for Assessment Purposes

Prepared by:	OkechukwuEjiofor, Quality Manager
Reviewed by:	LawrenaOkoro, Director of Accreditation
Approved by:	Celestine Okanya, DG/CEO
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1. Purpose

The purpose of this document is to give effect to the requirements of ISO/IEC 17011:2017 clauses 7.4.4 to 7.4.7 by defining NiNAS' procedure and specific requirements for sampling of sites, personnel and the scope of accreditation, within the accreditation cycle.

2. Scope

The scope of this document covers the assessment of all sites of the CAB where activities covered in the scope of accreditation 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. This document applies to all accreditation programmes within NiNAS, however the sampling of the witnessing of scopes for Certification Bodies also takes into consideration requirements of IAF MD12, IAF MD15 and IAF MD17.

3. Definitions

Definitions related to this procedure are given in A01-01 Definitions and Abbreviations used in NiNAS Documentation.

4. Reference Documents

- ISO/IEC 17011:2017 *Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies*
- QM 1.0 *NiNAS Quality Manual*
- MP 06 Accreditation
- IAF MD12 *Accreditation assessment of conformity assessment bodies with activities in multiple countries*
- IAF MD15 *IAF mandatory document for the collection of data to provide indicators of Management System Certification Bodies' performance*
- IAF MD17 *Witnessing activities for the accreditation of Management Systems Certification Bodies*

5. General

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 to perform all activities in its scope of accreditation irrespective of where these activities are performed.

5.1 Information for Planning

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

i) Description of the main activities of the organisation seeking accreditation;

ii) Detailed list of scopes / parameters / activities for which accreditation is sought; iii) A list of applicant technical signatories (however named) including information on their qualifications and experience;

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

v) Name and address of all sites for which accreditation is sought; vi) Any on-site activities (Work performed on the clients' site) for which accreditation is sought; and

vii) 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;

viii) In the case of *Certification Bodies* – a list of auditors per scope.

5.2 Sampling

5.2.*1. Methodology*

In selecting activities to be assessed, the risk associated with the activities, sites and personnel covered by the scope of accreditation shall be considered.

5.2.2 Sampling covers:

i) The sampling of sites from which activities in its scope of accreditation are performed and the selection of these sites taking into consideration the random element of sampling;

ii) The sampling of the scope of accreditation;

iii) The sampling of personnel whose signature confers validity on the organisation's certificates (In most cases referred to as "technical signatories")

iv) The sampling of technical personnel other than technical signatories, who perform the tests / calibrations / inspections, etc. (See 3.1 iv)

5.2.3 Sampling of Sites

Sampling of sites at which activities in its scope of accreditation are being performed, shall as a minimum, be in accordance with ***Table 1***.

5.2.3.1 Selection of 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 activities in the scope of accreditation are performed.

5.2.3.2 The 75% of site selection may as a minimum take 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's involvement in the management of the sites (the structure of the quality system);
iv) the results of internal audits from central office and sites;
v) the results of management reviews;
vi) complexity of the management system;
vii) variations in working practices including, where applicable, equipment and methods used;
viii) variations in activities undertaken e.g. scopes of inspection / testing / calibration / verification…etc., types of inspection/ testing / calibration / verification;
ix) Where applicable, the level of performance over the assessment cycle;
x) extent of changes within the organisation;
xi) the level of confidence which can be placed in performance measures and control systems of the CAB.

5.2.4 Sampling of Scope of Accreditation

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

5.2.4.1 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.

At 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.

5.2.4.2 The 75% of scope selection may as a minimum take into consideration:

i) The availability of assessment team members with the necessary technical knowledge to cover the desired scope of accreditation, during the relevant period;
ii) A representative sample of all scope of activities must be assessed at the initial assessment prior to granting accreditation;
iii) The different equipment or methods; and an estimation of the amount of time that will be required for each assessment;
iv) A representative sample of all 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 assessment cycle.

5.3 Sampling of Personnel

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

5.3.1 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.

5.3.2 When deciding on the personnel to be assessed, the following aspects may as a minimum be considered by NiNAS:

i) the fields and types of activities on the scope of accreditation;
ii) the CABs procedures for selecting, training, authorising and monitoring of the staff conducting these activities, including the qualifications and experience required for different scopes and types of activities;
iii) the internal auditing arrangements of the CAB;
iv) the locations from which the staff operate;
v) any statutory requirements;
vi) where required by the standard, the extent to which the staff are required to exercise professional judgement.;
vii) Effectiveness of the CAB's own witnessing activities

5.3.3 When deciding on the ***types*** of activities to be assessed account will be taken of the following:

i) variety of products, services, processes and plants covered by the activities;
ii) skills needed by inspector / VO / calibration technician / phlebotomist etc;
iii) any statutory requirements;
iv) where required by the standard, the extent to which these staff are required to exercise professional judgement.

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.

5.3.4 When deciding on ***which*** personnel will be assessed account will be taken of:

i) new recruits or new authorisations;
ii) qualifications and experience;
iii) location;
iv) any statutory requirements;
v) where required by the standard, the extents to which personnel are required to exercise professional judgement.

5.2.3 Sample Size

Table 1 below depicts the determination of the sample sizes for the 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 activities in the scope of accreditation 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/ verifications/ inspection service/ measured quantity or instrument **100%**	B. Within A above: Tests/ verifications/ inspection service/ measured quantity or instrument: • **25%** subject to the	B.. Within A above: Tests/ verifications/ inspection service/ measured quantity or instrument: • **10%**

			proviso that a 100% review of the records of each applicant	
Surveillance assessment	100% of main / central/ head offices, including the following number of sites: **Minimum surveillance = 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%** B. Within A above: Tests/ verifications/ inspection service/ measured quantity or instrument: Minimum of **25%** depending upon associated risk	**75% of (0.6√n)** where n represents the number of signatories	**25% of (0.6√n)** where n represents the number of personnel (excluding signatories)

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%**	**75% of (0.8√n)** where n represents the number of signatories	**25% of (0.8√n)** where n represents the number of personnel (excluding signatories)
		B. Within A above: Tests/ verifications/ inspection service/ measured quantity or instrument: Minimum of **75%** subject to the past performance of the CAB		
Extension Incl. Evaluation of Personnel	New Sites - 100 %	A. Scope/ Field /Discipline / Scheme (E.g. Chemistry, Microbiology, Mass Metrology) **100%**	New Signatories - 100%	N/A
		B. Within A above: Tests/ verifications/ inspection service/ measured quantity or instrument **100%**		

5.4 Guidance on Calculating √n

i) Sampling for surveillance assessments: 0.8√n , (where n = the number of sites), rounded off to the next whole number:

Example: There are 30 sites from which activities in the scope of accreditation are performed:

0.8 x (√30) = 0.8 x 5.48 = 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 personnel at *Surveillance Assessment*: 0.6√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:

$$0.6 \times (\sqrt{30}) \times 75\% = (0.6 \times 5.48) \times 75\% = \frac{3.29 \times 75}{100} = 2.47$$

2.47 rounded off to the next whole number = 3

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

$$0.6 \times (\sqrt{30}) \times 25\% = (0.6 \times 5.48) \times 25\% = \frac{3.29 \times 25}{100} = 0.82$$

0.82 rounded off to the next whole number = 1

No. of Technical Signatories (n)	Sample of Technical Signatories to be assessed at Surveillance assessment 75% of (0.6√n)
1	1
2	1
4	1
6	2
10	2
15	2
25	3
30	3
50	4
100	5

No. of Technical Personnel (excl. Technical Signatories) (n)	Sample Personnel to be assessed at Surveillance Assessment (non-signatories) 25% of (0.6√n)
1	1
2	1
4	1
6	1
10	1
15	1
25	1
30	1
50	2
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 staff (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 off to the next whole number = 2

No. of Technical Signatories (n)	Sample of Technical Signatories to be assessed at Surveillance assessment 75% of (0.8√n)
1	1
2	1
4	2
6	2
10	2
15	3
25	3
30	4
50	5
100	6

No. of Technical Personnel (excl. Technical Signatories) (n)	Sample Personnel to be assessed at Surveillance Assessment (non-signatories) 25% of (0.8√n)
1	1
2	1
4	1
6	1
10	1
15	1
25	2
30	2
50	2
100	2

5.5 Risk

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

5.5.1 The types of risks may include:

i) operating in a region or country that NiNAS 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 NiNAS;
iii) has a history of poorly managed compliance to accreditation requirements;
iv) has revised its activities performed at sites;
v) Weak implementation of corrective actions throughout an organization including their sites; and/or
vi) Signatory or Inspector turnover at accredited CAB.

6. Forms

Table: 21-1 Forms in use with MP 21	
Form Number	Title

7. Document History

Modification No/Date	Proposed by	Page No.	Summary of Modification
23/07/2024	Quality Manager		Initial release