MAURITAS A24

Procedure for sampling of different sites, personnel and scope of accreditation

Mauritius Accreditation Service
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Foreword

The MAURITIUS ACCREDITATION SERVICE (MAURITAS) is a governmental body established in 1998 to provide a national, unified service for the accreditation of Conformity Assessment Bodies (CABs) such as calibration/testing laboratories, certification bodies and inspection bodies. Organizations that comply with the MAURITAS requirements are granted accreditation by MAURITAS.

About MAURITAS publications

MAURITAS publications are categorized as follows:

- **R series** Publications containing general policy and requirements related to MAURITAS accreditation.
- **G series** Publications providing guidance on MAURITAS requirements.
- **A series** Publications related to assessment procedures.
- **P series** MAURITAS quality system procedures
- **F series** MAURITAS Forms
- **Directories** Classified listing of accredited organizations.
Procedure for sampling of different sites, personnel and scope of accreditation

1 Purpose

1.1 This procedure defines the sampling methods to be used in order to ensure a proper evaluation of the competence of the CAB for which it has been accredited, where the CAB works from various premises.

2 Scope and Responsibilities

2.1 This procedure shall be used by MAURITAS staff for sampling of different sites, personnel and scope of accreditation covered by the CAB to ensure proper assessment during assessment and re-assessment. The document covers 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. MAURITAS implements an assessment sampling plan for each accredited CAB appropriate to the CAB’s scope of accreditation. It is the responsibility of MAURITAS staff to adhere to this document when planning for assessments.

3 References

The following documents contain provisions which, through reference in this text, constitute provisions of the MAURITAS accreditation system. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. For undated MAURITAS references, the latest edition of the document referred to, applies. MAURITAS maintains a register, of the current valid MAURITAS accreditation documents.

3.1 ISO/IEC 17011 : Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies
3.2 ISO/IEC 17000 : Conformity assessment – Vocabulary and general principles
3.3 IAF MD1 : Certification of multiple sites based on sampling
3.4 IAF MD5 : Duration of QMS and EMS Audits
3.5 IAF MD17 : Witnessing Activities for the Accreditation of Management Systems Certification Bodies
3.6 MAURITAS A8 : Procedure for assessment – Laboratories
3.7 MAURITAS A18 : Procedure for Assessment of Accredited Certification Bodies
3.8 MAURITAS A19 : Extension of Scope of Accreditation in Field of Activities regarding System Certification

4 Definition

4.1 Multi-site Facility
A multi-site facility is 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.

4.2 Sampling
Sampling is the provision of a sample of the objective of conformity assessment according to a procedure.

4.3 Key Activities
Key activities are activities such as (but not limited) 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.

4.4 Technical Signatory
A technical signatory is a person deemed as competent by MAURITAS whose signature confers validity on the organization’s certificates, reports and/or results issued under its MAURITAS accreditation.

5 Information for sampling and planning of assessment

5.1 Accredited CABs shall provide MAURITAS with all the necessary information prior to the assessment or re-assessment visit. Accordingly, MAURITAS staff shall plan the assessment and shall select appropriate sample, taking into consideration the following:

   a) The sampling of sites from where key activities are performed;
   b) The sampling of the scope of accreditation; and
   c) The sampling of personnel who perform key activities, where applicable.

6 Sampling of sites

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

6.2 A representative range of different sites will be selected without excluding the random element of sampling. The sample will be selected over the period of validity of the certificate to cover all sites from where key activities are performed and will take into consideration the following:
7 Sampling of scope of accreditation

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

7.2 A representative range of different accreditation scope will be selected without excluding the random element of sampling. The sample will be selected over the period of validity of the certificate to cover all scopes and will take into consideration the following:

   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.

8 Sampling of personnel

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

8.2 A representative range of different technical staff performing key activities will be selected without excluding the random element of sampling. The sample will be selected over the period of validity of the certificate to cover technical staff to be assessed and will take into consideration the following:

   a) The fields and types of activities covered on the accreditation schedule.
   b) The CABs procedures for selecting, training, authorizing and monitoring of the staff who carry out these key activities, including the qualifications and experience required for different fields and types of activities.
c) Skills needed by auditor/inspector/calibration technician/phlebotomist, etc.;

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

e) The internal auditing arrangements of the CAB.

f) The locations from which the staff operate;

g) Any statutory requirements.

h) Where required by the standard, the extent to which the staff are required to exercise professional judgment.

i) Effectiveness of the CAB’s previous witnessing activities.

8.3 A representative sample of technical staff performing key activities will be assessed during an assessment cycle.

8.4 Example of Technical Staff:

For Laboratories:
- Technical Signatories
- Analysts/Technicians authorised to perform accredited parameters (tests/calibrations)

For Certification Bodies:
- Lead auditors and auditors

8.5 If an on-site activity is not available a simulation/talk-through and vertical assessment (for laboratories only) may be considered. When deciding on which personnel to be assessed, consideration will be given to the following:

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;
### TABLE 1

Determination of the sample sizes for sites, personnel and scopes of accreditation over the period of validity of the certificate

<table>
<thead>
<tr>
<th>Type of assessment</th>
<th>Sampling percentage &amp; Area</th>
<th>Scope/Field</th>
<th>Personnel (Technical Staff)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sites (Satellite or Branch offices) where key activities are performed</strong></td>
<td></td>
<td>A. Scope of accreditation/Field/Discipline/Scheme (e.g. Chemistry, Microbiology, Mass Metrology, QMS) 100%</td>
<td>Pers = $0.6\sqrt{n}$ where n represents the number of technical staff</td>
</tr>
<tr>
<td>Assessment</td>
<td></td>
<td>B. Within A above: Tests/Inspection/witness audit/measured quantity or Instrument</td>
<td>Minimum of 15% depending upon associated risk</td>
</tr>
<tr>
<td></td>
<td>Minimum number of Sites for each Assessment (MSS) = $0.8\sqrt{n}$ rounded off to the next whole number, where n represents the number of sites</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>MSS</td>
<td>n</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>1</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>2</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>2</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>2</td>
<td>50</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>3</td>
<td>100</td>
</tr>
<tr>
<td>Re-assessment</td>
<td>100% sites</td>
<td>A. Scope of accreditation/Field/Discipline/Scheme (e.g. Chemistry, Microbiology, Mass Metrology, QMS) 100%</td>
<td>Pers = $0.8\sqrt{n}$ where n represents the number of technical staff</td>
</tr>
<tr>
<td></td>
<td>However experiences gained during the previous assessment shall be taken into account when determining the final percentage to be assessed</td>
<td>B. Within A above: Tests/Inspection/witness audit/measured quantity or Instrument</td>
<td>Subject to the past performance of the Facility, a minimum of 30%</td>
</tr>
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9 Risk

9.1 MAURITAS may increase the sample size depending on the risks identified. The type of risks may include the following:

a) Operating in a region or country that MAURITAS has identified as representing a significant risk area in terms of maintaining accreditation requirements or in terms of political or safety reasons;
b) Formal complaint under investigation by MAURITAS;
c) 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) Technical staff turnover at the accredited CAB;
g) Inability to cover part of the scope due to extraordinary circumstances (example: pandemic, riots, flooding, etc) during a planned assessment

9.2 MAURITAS may decrease the sample size depending on the risks identified. The type of risks may include the following:
   a) Good performance in previous assessments;
   b) Continued stability in the system;
   c) Multiple accreditation by other ILAC/IAF Signatories;
## Appendix A: Amendment Table

<table>
<thead>
<tr>
<th>SN</th>
<th>Section</th>
<th>Amendment</th>
</tr>
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<tbody>
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