



ACCREDITATION SCHEME FOR LABORATORIES

SAC-SINGLAS 002 (JUNE 2018)

**Guidelines for the Application of
ISO/IEC 17025: 2017**

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1. INTRODUCTION

- 1.1 This document SAC-SINGLAS 002, “*Guidelines for the Application of ISO/IEC 17025: 2017*” provides the guidance for laboratories in their application of ISO/IEC 17025: 2017.
- 1.2 This document should be read in conjunction with ISO/IEC 17025, SAC 01 “***Terms and Conditions for Accreditation***” and SAC 02 Rules for Use of SAC Accreditation Marks and Mutual Recognition Arrangement (MRA) Marks. **Additional field specific requirements are found in the relevant technical notes.**
- 1.3 This document is to be used when conformity assessment bodies are considering to transit, or have transited to ISO/IEC 17025:2017.

2. GENERAL REQUIREMENTS

Clause 4.1.1 Impartiality – Structure

- 2.1 The management of the laboratory should have clear documented policies to define the impartiality of their testing/calibration/sampling responsibilities. The laboratory management should also be responsible for communicating these policies to their staff on an on-going basis.

Clause 4.1.4 Impartiality – Risks to impartiality

- 2.2 Risks to impartiality may be identified through various means, e.g. employee declarations of financial liabilities, whistleblowing policies, management evaluation of risk etc. It is recommended that the identification of risks to impartiality should be reviewed for relevance at least once every 12 months.

3. STRUCTURAL REQUIREMENTS

Clause 5.6 (b), (c) Deviations from Management System

- 3.1 Deviations from the management system can be identified through audits, feedback from employees, customers or interested parties, etc.

4. RESOURCE REQUIREMENTS

Clause 6.2 Personnel

- 4.1 Vision deficiencies, e.g. colour blindness, blurred vision etc, may prevent some people from performing some work satisfactorily (e.g. textile, non-destructive, chemical or microbiological testing). It is the responsibility of the laboratory management to ensure that vision deficiencies and problems shall not affect validity of results.

Clause 6.3.5 Facilities and environmental conditions

- 4.2 Involvement of an approved signatory in the setting up of a site laboratory is recommended.
- 4.3 When performing tests/calibration/sampling in the field, sites must be chosen to minimise the effects of environmental conditions and contamination. All relevant environmental conditions should be recorded and retained with other test data.

Clause 6.4.1 Equipment

- 4.4 It is not necessary for a laboratory to own the equipment as long as it has adequate records that the equipment meets the requirements of the test methods.

Clause 6.6 Externally provided products and services

- 4.5 Accredited laboratories using externally provided products and services are responsible to their customers for ensuring that these providers have a satisfactory management system and are competent to perform the required test / calibration / sampling. Use of SAC-SINGLAS accredited laboratories or laboratories accredited by SAC-SINGLAS mutual recognition arrangement partners is one method to ensure competence. All results reported by such providers shall be covered by an accredited report.

As an example, the laboratory may review the following documents to evaluate the external provider's competency, prior to the engagement of the external provider:

- A copy of the external provider's quality manual
- A copy of the external provider's procedure(s) for the work in question,
- A copy of training records for the personnel responsible for performing the work, and
- A sample of a test/sampling report or calibration certificate for the testing / calibration/sampling intended to be externally provided.

5. PROCESS REQUIREMENTS

Clause 7.1.1 (c) Use of external providers and client approval

- 5.1 As a good laboratory practice, it is recommended that the laboratory informs their clients on the use of external providers and gain approval in writing, prior to carrying out the testing/calibration.

Clause 7.1.3 Statement of conformity and decision rule

- 5.2 The decision rule should also take into consideration regulatory requirements as well as safety factors. The decision rule shall also take into account the measurement uncertainty as required by clause 3.7 of ISO 17025:2017. However, the extent of consideration of the measurement uncertainty is to be decided by the laboratory.

Clause 7.2.1.5 Verification of methods

- 5.3 The laboratory is to verify that it can perform the methods prior to introducing them as required by clause 7.2.1.5 of ISO 17025:2017. Verification can be in the form of verifying the accuracy of measuring or testing equipment, qualifications of staff, consistency of environmental conditions etc.
- 5.4 Accreditation will normally be given only for tests and calibration which are performed regularly, particularly if they are considered to be experience dependent. Laboratory may be required to produce records of test or calibration which are done infrequently to demonstrate competence. In such cases, the laboratory will be required to set up a regular schedule of performance checks to verify and demonstrate their continuing competence.

Clause 7.3.2 Sampling methods

- 5.5 Laboratories can consider taking reference from relevant sampling techniques published in well-established literature to develop their sampling plans.

Clause 7.6 Evaluation of Measurement Uncertainty

- 5.6 For calibration laboratories, the measurement uncertainty shall be calculated in accordance with ISO "Guide to the Expression of Uncertainty in Measurement" (ISO GUM). The laboratory may use SAC-SINGLAS Technical Guide 1 – "Guidelines on the Evaluation and Expression of Measurement Uncertainty" for guidance.
- 5.7 For testing laboratories, the laboratory may choose to use procedures in ISO GUM, ISO 5725, SAC-SINGLAS Technical Guide 2 – *A Guide on Measurement Uncertainty in Chemical Analysis* or other international documents eg Eurachem Guide – *Quantifying Uncertainty in Analytical Measurement*.
- 5.8 For reporting of measurement uncertainty in test reports, laboratories can refer to the APLAC-TC-005 - *Guidelines for Evaluation and Report of Measurement Uncertainty in Testing* or ILAC G17 – *Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025*
- 5.9 For qualitative tests, the evaluation of measurement uncertainty is not required.

Clause 7.7. Ensuring the validity of results

- 5.10 Clause 7.7.1 of ISO/IEC 17025:2017 refers to the internal monitoring of results. These are methods which the laboratory may utilize to ensure validity of their results.
- a. Programmed usage of certified reference materials and other materials of known characteristics during the course of routine sets of analyses. This practice, done routinely, also allows for the use of analytical control charts and for the monitoring of the ongoing level precision being achieved in the laboratory, and if sufficient reference materials are available, for evaluation of the accuracy being achieved at various concentration levels.
 - b. Regular testing of replicate samples by the same operator. This allows for an ongoing estimate of the reproducibility being achieved by an individual operator. It may be done either fully known to the operator or by programmed re-submission of previously tested samples suitably re-identified.
 - c. Regularly testing of the same sample or calibration of the same item by two or more operators. This allows for the estimation of between-operator precision being achieved in the laboratory and for identifying any significant biases evident in an individual operator's results.
 - d. Programmed testing of the same sample by different analytical techniques or two different items of the same apparatus type. For calibration, the same items may be measured by different instruments or using different techniques. This allows for estimation of any technique-dependent bias or equipment bias in the laboratory's results.
 - e. Recording and monitoring of results obtained from the same sample by the laboratory's clients or suppliers. This allows, given sufficient data, for control charts to be established to monitor the between-laboratory precision achieved between the two laboratories concerned. The data obtained may also be compared with any available published data on reproducibility for the tests concerned, if both laboratories are using the same test method.
- 5.11 Clause 7.7.2 of ISO/IEC 17025:2017 refers to the external monitoring of results. The following are suggested methods which the laboratory may utilize.
- a. Participation in proficiency testing programmes or other forms of inter-laboratory comparisons. This allows the laboratory to compare its performance results with a broader group involved in the same tests. It provides a useful alert mechanism to any fault or inconsistency in technique, operators or equipment which may not be otherwise evident. Such programmes also provide a mechanism for estimation of reproducibility for specific tests.

Clause 7.8.2 Common requirements for reports

- 5.12 In general, approved signatories (if applicable) are expected to apply their signatures in manuscript. However, if the laboratory chooses the use of photographic, electronic and mechanical means of reproduction of signatures, the laboratory shall demonstrate that its system is safeguarded and the identity of the person taking responsibility for the report is clearly identified.
- 5.13 Unendorsed non-accredited reports and the associated work on tests/calibration within the terms of accreditation are expected to be of the same standard as endorsed accredited reports.

Clause 7.8.6 Reporting statements of conformity

- 5.14 Laboratories may refer to APLAC TC 004 or ILAC G8 for guidance on Decision rules and reporting statements of conformity.

Clause 7.8.7 Opinions and Interpretations

- 5.15 Laboratories can provide opinions and interpretations in an endorsed accredited report for areas defined in SAC 02 clause 2.3.1.6. For inclusion of opinions and interpretations other than those specified in the above clause, the laboratory can issue them as a separate attachment without SAC-SINGLAS endorsement.

6. MANAGEMENT SYSTEM REQUIREMENTS

Clause 8.1 Options

- 6.1 Laboratories may select Option A or B for the implementation of the management system. Selection of Option B does not absolve the laboratory of the responsibility to ensure that the requirements of Option A are met.
- 6.2 For laboratories who select Option B, SAC assessors may request for the necessary ISO 9001 documents to verify the laboratory's compliance to ISO/IEC 17025: 2017.

Clause 8.5 Actions to address risks and opportunities

- 6.3 It is recommended that the laboratory undertakes this risk assessment at periodic intervals. A recommended timeframe for this risk assessment is at least once every 12 months.
- 6.4 It is recommended that laboratories use a matrix format to present the risks and opportunities analysis.

Clause 8.8 Internal audits

- 6.5 The recommended interval for internal audit is at least once every 12 months and should cover all aspects of the management system.

Clause 8.9 Management reviews

- 6.6 The recommended interval for management review is at least once every 12 months.