ACCREDITED LABORATORY
SAC-SINGLAS

ACCREDITATION SCHEME FOR LABORATORIES

SAC-SINGLAS 002

Requirements for the Application of ISO/IEC 17025

SAC-SINGLAS 002, 15 February 2017
The SAC Accreditation Programme is managed by SPRING Singapore

	CONTENT	PAGE

1. INTRODUCTION

1.1 This document SAC-SINGLAS 002, *"Requirements for the Application of ISO/IEC 17025"* provides the policies and guidance for laboratories in their application of ISO/IEC 17025: 2005.

1.2 This document forms part of the SAC-SINGLAS criteria for accreditation of laboratories for all fields of testing and calibration using ISO/IEC 17025. The 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.**

2. MANAGEMENT REQUIREMENTS

Clause 4.1.4 Organisation – Conflict of Interest

2.1 For key laboratory personnel, who may also have production or marketing related responsibilities, clear policies must be available to define how impartiality is assured for their testing/calibration responsibilities. For departments having conflicting interests, the laboratory should ensure that organisation arrangements should not adversely affect the laboratory's compliance with ISO/IEC 17025.

Clause 4.1.5 (b) Organisation – Undue Influence and Pressure

2.2 All laboratory personnel should be free from undue influence and pressure which would compromise the quality of work. The source of undue pressure may be internal (eg management pressure, deadlines) or external (eg customer complaints, priority requests). Management has to determine the type of undue influence and pressure the staff might encounter and implement clear policy and instruction for countering them. Precaution should be taken to ensure that there is no conflict of interests between staff and clients. If relevant, the laboratory should have a written policy against acceptance of gifts and gratuities from customer.

Clause 4.1.5 (h) Organisation - Technical Management

2.3 The technical management may be a designated technical manager or may consist of a combination of designated technical managerial personnel who are responsible for specified testing/ calibration area. All technical issues relating to testing and calibration activities shall be fully covered by the technical management.

Clause 4.2 Management System

2.4 Quality documentation shall include or make reference to approved signatories, terms of accreditation and the policy on the use of the SAC-SINGLAS endorsement.

Clause 4.4 Review of Requests, Tenders and Contracts

2.5 When reviewing requests, tenders and contracts, laboratories should be aware that customers may not always understand their own needs. As far as practicable, laboratories should give advice to customers and help them to determine the suitability of the test or calibration needs. During contract review, calibration laboratories should specifically discuss their measurement uncertainty with their customers to ensure they can meet the customers' specifications.

Clause 4.5 Subcontracting of tests and calibrations

2.6 Laboratories shall document their policies and procedures for engaging subcontractors. Accredited laboratories using the services of subcontracting laboratories are responsible to their customers for ensuring that the subcontracting laboratory has a satisfactory management system and is competent to perform the required test / calibration. Use of SAC-SINGLAS accredited laboratories or laboratories accredited by SAC-SINGLAS mutual recognition arrangement partners is sufficient to ensure competence. All results reported by the subcontractor shall be covered by an accredited report.

2.6.1 When a subcontractor is not accredited by SAC-SINGLAS or another organisation recognised as equivalent, the laboratory shall record its assessment of that laboratory's capability to meet ISO/IEC 17025 requirements. As an example, the laboratory should require the following subcontractor records to demonstrate the compliance with ISO/IEC 17025 for the work in question, prior to the subcontracting:

- A copy of the subcontractor's quality manual that meet the requirements of ISO/IEC 17025,
- A copy of the subcontractor's procedure(s) for the work in question,
- A copy of training records for the personnel responsible for performing the subcontracted work, and
- A format of a test report or calibration certificate for the testing / calibration intended to be subcontracted.
- The results of the subcontracted work shall not be expressed in a SAC-SINGLAS accredited report.

2.6.2 The accreditation status of subcontractors should be regularly reviewed to ensure currency.

Clause 4.6 Purchasing Services and Supplies

2.7 Purchasing of supplies and services include consumables and perishable items, equipment and calibration services. When purchasing calibration services, laboratories should refer to the SAC-SINGLAS 006 – *Traceability of Measurement* to ensure that traceability requirements are met.

Clause 4.7 Service to Customers

2.8 Feedback of all clients, including internal clients, should be sought.

Clause 4.8 Complaints

2.9 Laboratories shall inform SAC-SINGLAS when a complaint, involving any technical competency or integrity of test or calibration result relating to the scope of accreditation, is not resolved within 90 days from the date of receipt of the complaint.

Clause 4.10 Improvement

2.10 Laboratories should be able to show evidences on how continuous improvement are sought in the workplace.

Clause 4.12 Preventive Action

2.11 Preventive action is a proactive process to identify improvement opportunities, rather than a reaction to the identification of problems or complaints. Total quality management tools such as brainstorming, flowcharting, Pareto charts etc may assist this process. Consideration should also be given to provide staff with a formal mechanism for contributing suggestions for improvement.

Clause 4.14 Internal Audits

2.12.1 The internal audit schedule shall cover all elements of the management system over a twelve-month period. The audit should determine if:

- procedures described in the management system are being followed;
- objectives (as defined in the management system) are being achieved;
- designated duties are being carried out satisfactorily and
- there are opportunities for improvements.

2.12.2 The laboratory is encouraged to use LAFM03, Laboratory Assessment Checklist, to ensure all aspects of ISO/IEC 17025 are covered during the Internal Audit. It is also a good practice to record accordingly all evidences audited.

2.12.3 The corrective actions submitted to address the findings of internal audit shall be verified and accepted by the relevant internal auditor.

Clause 4.15 Management Reviews

2.13 The effectiveness of the management system shall be reviewed by the laboratory's management at least once every twelve months.

3. TECHNICAL REQUIREMENTS

Clause 5.2 Personnel

3.1 The evaluation of personnel is a major part of laboratory assessments. This criterion is evaluated based on the range, complexity and frequency of performing of calibrations or tests for which accreditation is sought.

3.1.1 A laboratory shall have proper procedures for training new technical personnel and for developing the expertise of existing technical personnel in new or rarely used techniques. The criteria used to assess the competence of trainees shall form an integral part of the procedures. Records of training and assessments of competence shall be kept. These shall include or refer to records of test or calibration results performed during training and assessment of competence. The validity of results produced by technical personnel, particularly in the early stages after completion of training in new techniques shall be monitored.

3.1.2 Vision deficiencies may prevent some people from performing some work satisfactorily (eg textile, non-destructive, chemical or microbiological testing). It is the responsibility of the laboratory management to ensure in such cases that vision problems shall not affect validity of results.

3.1.3 For approved signatories including nominees, the requirements stated in clause 5 of SAC-SINGLAS 001 Accreditation Process shall be met.

3.1.4 Personnel responsible for giving opinions and interpretations as specified in SAC 02 clause 2.3.1.6shall have in-depth knowledge of the relevant technical discipline. They should comply with the additional aspects of the competence given in Note 2 of clause 5.2.1 of the ISO/IEC 17025.

3.1.5 Any testing/calibration conducted away from the base laboratory (such as site laboratories, in a mobile testing laboratory or in the field) should also be under adequate technical control. This would normally require either the location of an approved signatory at each facility or having an approved signatory at each facility at least once a week, the maintenance of a logbook recording the dates and relevant activities of each visit. Involvement of an approved signatory in the setting up of a site laboratory is recommended.

Clause 5.3 Accommodation and Environmental Conditions

3.2 When testing in the field, testing 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 5.4 Test and Calibration Methods and Method Validation

Clause 5.4.1 General

3.3 A formalised system shall be in operation for issuing, reviewing and updating of methods and specifications. The system shall enable the laboratory to be aware of any new editions of published standards. Methods shall be reviewed regularly with respect to the publications of new editions of standards, development in the testing or calibration technology and other relevant information.

3.3.1 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 show records of test or calibration which are done infrequently to demonstrate the competence of the laboratory's staff. 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 5.4.2 Selection of Methods

3.4 Whilst standard methods have been validated by the standard writing bodies for their intended scope, the capability of the laboratory to conduct the test must be confirmed. This may include, for example, verification of performance of the equipment against test standard requirements, availability of the required reference materials and/or standard, suitability of the laboratory environment, skills and competence of testing staff, as well as the overall ability of the laboratory to achieve the required precision detection limits and other performance characteristics of the methods. Proficiency testing may also be used to confirm the laboratory's capability in performing the test method.

Clause 5.4.6 Measurement Uncertainty

3.5 For calibration laboratories, they shall calculate the measurement uncertainty in accordance to 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.

3.5.1 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*.

Clause 5.4.6.1 In-house Calibration

3.6 Where the laboratory chooses to establish an in-house calibration programme for its testing or measuring equipment, the requirements of ISO/IEC 17025 need to be met. The laboratory should have suitable qualified personnel, procedures, equipment and a traceability programme to perform its in-house calibration. Specifically, the following requirements shall be met:

a. Methods or procedures employed for the purpose of in-house calibration should be either published standards or consensus methods which are fit for their intended purpose.

b. Measurement uncertainty shall be reported in the in-house calibration report.

c. To ensure the technical competence of staff performing in-house calibration. (eg appropriate training course in the area of metrology, demonstrate understanding on the principle of measurement uncertainty, etc).

d The in-house calibration report shall include information where appropriate as listed in clause 5.10.2 and clause 5.10.4 of ISO/IEC 17025. It shall include detailed information on but not limited to:

i. The intended use of the calibrated equipment
ii. The specification limits of the calibrated equipment
iii. The measurement range of the calibrated equipment
iv. A statement of compliance of the calibrated equipment whether it meets the specified requirements.
v. The traceability of the reference standard to International System of Units (SI)

e. Though in-house calibration will be assessed during the assessment, the laboratory should note that this would not constitute part of the Terms of Accreditation. However, a full/partial suspension may be made against the laboratory for any or all tests included in the terms of accreditation if the validity of the test/calibration results obtained through equipment calibrated in-house are affected.

3.6.1 Laboratories performing in-house calibrations are encouraged to seek accreditation for calibration work.

Clause 5.4.6.2 Uncertainty of Measurement for testing

3.7 Testing laboratories shall estimate uncertainty of measurement for all quantitative tests**.**

3.7.1 The laboratory shall report uncertainty of measurement for borderline results where the uncertainty may affect compliance to a specification limit.

3.7.2 When using a test method the following cases may apply:

a. For a test method that has no guidance on uncertainty of measurement, the laboratory shall estimate the uncertainty of the test using procedures as detailed in Section 3.5 of this document.

b. For a standard test method which contains guidance to the uncertainty estimation, testing laboratories are not expected to do more than to follow the uncertainty evaluation procedure as given in the standard.

c. For a standard test method that gives a typical estimation of uncertainty of measurement for test results, laboratories are allowed to quote this figure if they can demonstrate full compliance to the test method.

d. For a test method that has published data on some component of uncertainty of measurement data eg inter-laboratory reproducibility, the laboratory shall use these values as a guide only and consider them together with other pertinent uncertainty contributors such as sample homogeneity, stability, reference materials etc, to estimate its own uncertainty of measurement.

The degree of rigour of uncertainty of measurement estimation may be different for different technical fields.

3.7.3 When estimating uncertainty of measurement of test methods, the laboratory shall evaluate all sources of uncertainty. If calculations of certain components proved to be insignificant, the laboratory may choose to disregard the component. However, all records of such evaluations shall be documented.

3.7.4 Applicant laboratory shall work towards estimation of measurement uncertainty for all the parameters under its scope.

Clause 5.5.2 Equipment

3.8.1 A monitoring system shall be in operation to alert the laboratory staff of the due dates of calibration, verification and maintenance for all items of equipment.

3.8.2 The laboratory needs to show that calibration reports are reviewed after calibration of equipment.

Clause 5.6 Measurement Traceability

3.9 Where traceability to International System of Units (SI) is required, the laboratory shall refer to the policies in SAC-SINGLAS 006 – *Traceability of Measurement*.

3.9.1 Where the laboratory undertakes calibration of equipment using certified reference materials or reference standards, it is the responsibility of the laboratory to ensure that traceability of the reference materials or reference standards is established.

Clause 5.6.2.2 Measurement Traceability for Testing

3.10 Reference standards and equipment shall be calibrated over the intended range and to the appropriate level of accuracy specified in relevant test methods.

3.10.1 A laboratory performing its own calibration will also be subjected to technical assessment to ensure that all the relevant requirements of ISO/IEC 17025 are met (eg adequately documented procedures, procedure to estimate the uncertainty, complete records of calibration data). The laboratory is encouraged to verify its own calibration of equipment through proficiency testing, where available.

3.10.2 There may be instances where the technical assessment of in-house calibration will require the expertise of a metrologist.

Clause 5.6.3.2 Reference Materials

3.11 For laboratories using reference materials, all precautions have to be taken to match the matrices of the reference materials to those encountered in the laboratory's test samples. The effects of any non-matching matrices shall be determined.

Clause 5.7 Sampling

3.12 The extent to which laboratories are involved in sampling varies greatly. Some laboratories have no involvement whatsoever, others have over-viewing responsibility, and some take charge of the total process. In the last case, laboratories are encouraged to gain accreditation to cover sampling as well as testing. The following conditions apply to accreditation for sampling.

a. The laboratory shall have documented sampling procedures. These may be national or international standard. If in-house methods are used, the validity for the intended purpose must be demonstrated by the appropriate data.
b. The sampling method must be cited on the test report whenever the laboratory wishes to extend the test results to an entire batch.

3.12.1 When the laboratory has partial or no control over sampling the following issues shall be addressed:

a. Test records must include details of the supplier of the sample and other relevant historical information such as condition on receipt, reported date of sampling. If a sample has a characteristic that cast doubt on its validity, but is not possible to reject the sample, a clear statement of the perceived deficiency must be made on the report.

b. When customers, suppliers or factory personnel take samples, they should be provided with written sampling instructions. It may be necessary for the laboratory to supply appropriate clean and labeled sampling containers and/or training in sampling technique. Sample containers shall be free from any source of contamination;

c. If a test method specifies the use of a particular sampling method, and the laboratory has no evidence as to whether the sampler followed the method, this fact must be acknowledged on the report.

Clause 5.9 Assuring the quality of test and calibration results

3.13 Each SAC-SINGLAS accredited laboratory shall adopt an appropriate set of quality control procedures suitable for the range of work done and to the number of testing staff available. The adequacy of the quality control procedures will be examined critically during assessments.

Some of the quality control procedures commonly adopted by laboratories are:

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.

f. Participation in proficiency testing programmes or other forms of inter-laboratory comparisons. This allows the laboratory to compare its performance and comparability of its data to those broader groups involved in the same tests. It provides a useful alert mechanism to any fault 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 5.10 Reporting the results

Clause 5.10.2 Test reports and Calibration Certificates

3.14.1 In general, approved signatories 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 or names of signatories, approval in writing to the SAC-SINGLAS shall be obtained. The laboratory shall demonstrate that its system is safeguarded and the identity of the person taking responsibility for the report is clearly identified.

3.14.2 Non-accredited reports and the associated work on tests/calibration within the terms of accreditation are expected to be of the same standard as accredited reports.

Clause 5.10.4 Calibration Certificates

3.15 The measurement uncertainties associated with the measurand shall be reported with the expanded uncertainty, coverage factor k and level of confidence of approximately 95%.

3.15.1 The numerical value of the uncertainty of measurement shall be given to at most two significant figures.

3.15.2 The numerical value of the measurement result should in the final statement normally be rounded to the least significant figure in the value of the expanded uncertainty assigned to the measurement result.

Clause 5.10.5 Opinions and Interpretations

3.16 Laboratories can provide opinions and interpretations in an accredited report for areas defined in SAC 02 clause2.3.1.6. 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.