ACCREDITED LABORATORY
SAC-SINGLAS

ACCREDITATION SCHEME FOR LABORATORIES

SAC-SINGLAS 001

Accreditation Process

SAC-SINGLAS 001, Oct 2010
The SAC Accreditation Programme is managed by SPRING Singapore

1. The Scheme

1.1 The Singapore Laboratory Accreditation Scheme (SINGLAS) is the national laboratory accreditation scheme of the Singapore Accreditation Council (SAC) which is managed by the Standards, Productivity and Innovation Board (SPRING Singapore). The said scheme will be referred to as "SAC-SINGLAS".

1.2. The primary objectives of SAC-SINGLAS are as follow:

a) to operate the accreditation of laboratories in accordance to international criteria, such as ISO/IEC 17011 and requirements for mutual recognition arrangements

b) to provide by means of assessment, the assurance that the professional practice by accredited laboratories are in accordance to international standards, such as ISO/IEC 17025 and ISO 15189

c) to ensure that the accreditation processes are carried out with professionalism and integrity

d) to strengthen and develop accreditation schemes to meet the needs of stakeholders

e) to facilitate trade and market access by establishing and maintaining mutual recognition arrangements (MRA) with overseas and regional / international accreditation bodies, such as APLAC, EA and ILAC

1.3 SAC-SINGLAS gives formal recognition to laboratories that have been independently assessed and found to comply with the criteria established by SAC. Accreditation is granted for specific calibration or testing activities of a laboratory, and is not a blanket approval for its total operations.

1.4 SAC accredits calibration and testing laboratories in specific fields of science or technology which can demonstrate that they comply with currently accepted standards of good laboratory practice and management, in particular the requirements of ISO/IEC 17025 *"General Requirements for the Competence of Testing and Calibration Laboratories"* and the specific requirements of each field.

1.5 This document should be read in conjunction with SAC 01 *Terms & Conditions for Accreditation*, ISO/IEC 17025 and any specific requirements that may be published as SAC-SINGLAS Technical Notes relating to specific calibration, testing and measurement activities.

1.6 Medical testing laboratories and medical imaging facilities should refer to SAC-SINGLAS 001 Med/MI for the accreditation process pertaining to their scope.

2. Definitions

2.1 Accreditation criteria:
Requirements of SAC-SINGLAS expressed in general terms, which address organisation, human and material resources, operating procedures, calibration and quality assurance practices of a laboratory. Such requirements are specified in the documents and technical notes as stipulated in Annex 1.

2.2 Accredited laboratory:
A calibration or testing laboratory to which SAC-SINGLAS accreditation has been granted.

2.3 Approved signatory:
A person recognised under SAC-SINGLAS to sign SAC-SINGLAS endorsed calibration or test reports issued by an accredited laboratory.

2.4 Branch Laboratory:
A calibration or testing facility at a different location from the parent accredited laboratory established permanently with the same management system as parent accredited laboratory to perform calibrations or tests.

2.5 Calibration:
The set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realised by standards.

2.6 Classification of laboratory under SAC-SINGLAS:
A distinct entity either an organisation or a department within an organisation having a specific field of accreditation.

2.7 Field of calibration or testing:
A broad sphere of science, engineering, or technology used to describe a general area of calibration or testing for SAC-SINGLAS classification purposes. In addition, for accreditation purposes, fields of calibration or testing are subdivided into specific calibrations or tests, groups of calibration or tests or product types.

2.8 Interlaboratory comparisons:
Organisation, performance and evaluation of test on the same or similar test items by three or more laboratories in accordance with predetermined conditions.

2.9 Laboratory accreditation:
A formal recognition that a calibration or testing laboratory is competent to carry out specific calibrations, tests or types of tests.

2.10 Laboratory assessor:
An individual who carries out some or all functions related to laboratory assessment under SAC-SINGLAS.

2.11 Management representative:
A person nominated by a calibration or testing organisation to represent it in all matters relating to SAC-SINGLAS accreditation.

2.12 Non-conformity:
Non-fulfillment of a requirement.

2.13 Critical Non-conformity:
A *critical* non-conformity or a series of non-conformities which seriously threatens the credibility of the laboratory accreditation scheme. Gross lack of technical competence, persistent violation of SAC Terms & Conditions, regulations, gross lack of commitment of the organisation to quality or compliance with accreditation criteria and existence of serious doubt on the integrity and impartiality of the organisation. A management system breakdown, as indicated by a series of *significant* non-conformities which seriously threaten the quality of all activities under the system, warrants a *critical* non-conformity.

Note:
Gross lack of competence may arise from lack of competent staff for critical activities, inappropriate environment for critical activities, lack of critical equipment, lack of critical traceability, totally invalid test, calibration or inspection method, total breakdown of the record or documentation system, lack of or totally ineffective quality assurance procedures or other causes.

2.14 Significant Non- conformity:
A *significant* non-conformity has serious adverse effect on the validity of an activity, its results or the competence of the organisation or a violation of SAC Terms & Conditions for accreditation.

The existence of a serious doubt on the technical validity of an activity or its results, as indicated by a series of related *minor* non-conformities is a *significant* non-conformity. Furthermore, persistence of a *minor* non-conformity for an extended period of time and without any plausible explanation may be a violation of SAC Terms & Conditions for accreditation, warrants is a *significant* non-conformity.

2.15 Minor Non-conformity:
A minor non-conformity has no serious adverse effect on the validity of the activity, its results or the competence of the organisation.

Note:
Minor non-conformities have a tendency to grow into significant non-conformities if not addressed appropriately at the time.

2.16 Observation:
An assessment finding that does not warrant non-conformity but is identified by the assessment team as an opportunity for improvement.

2.17 Reference material:
A material or substance with one or more of whose property values are sufficiently homogeneous and well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.

2.18 SAC-SINGLAS endorsed calibration or test report:
A report that includes a statement by the laboratory that it is accredited for the calibration or test conducted and that the calibration or test has been performed in accordance with the terms and conditions for accreditation under SAC. It shall include the SAC-SINGLAS mark and the Certificate Number.

2.19 Schedule of Accreditation:
A schedule issued with the Certificate of Accreditation listing the specific tests, calibrations and measurements for which accreditation have been granted.

2.20 Site Laboratory:
A calibration or testing facility at a different location from the parent accredited laboratory established temporarily to service a particular project to perform calibrations or tests that are within the terms of accreditation of the parent accredited laboratory.

2.21 Surveillance:
Routine examination of a calibration or testing laboratory to evaluate its continued compliance with SAC-SINGLAS requirements, normally every twelve month period.

2.22 Suspension of Accreditation:
Process of temporarily making accreditation invalid, in full or for part of the terms of accreditation.

2.23 Terms of Accreditation:
The measurements, examinations, calibrations or tests for which a laboratory is accredited under SAC-SINGLAS including any qualifications such as calibration or test methods, range of measurements and measurement uncertainty.

2.24 Withdrawal of Accreditation:
Process of cancelling accreditation in full.

3. SAC-SINGLAS Organisational Structure

3.1 Council Committee for Laboratory Accreditation

3.1.1 The Council Committee for Laboratory Accreditation (CCLA) is a specialist committee appointed by the SAC Council. The CCLA is responsible for the formulation of policies, provides guidance and oversees the operation of the Laboratory Accreditation Scheme.

3.1.2 The CCLA is authorised by the SAC Council to review, evaluate and approve assessment reports for accreditation of laboratories through its Review Committee. The CCLA may also co-opt individuals with relevant technical or management expertise as advisors for the review of assessment reports.

3.1.3 The term of office for members of the Council Committee for Laboratory Accreditation is three years with provision for reappointment.

3.2 Technical Committees

3.2.1 Technical Committees are established for each field of calibration or testing under SAC-SINGLAS.

3.2.2 Technical Committee members are appointed by the Council Committee for Laboratory Accreditation. The basis of appointment is the member's knowledge and expertise in the respective technical field. The Technical Committees are to recommend detailed technical criteria in their respective fields of calibration or testing and to review, evaluate and approve each assessment reports, on a selected member basis.

3.2.3 The term of office for members of the Technical Committees is three years with provision for reappointment.

3.3 Technical Assessors / Experts

3.3.1 Each Technical Committee maintains a panel of technical assessors/experts who are appointed from the ranks of government departments, associations & societies, academic institutions, research organisations, industrial and commercial laboratories. The assessors/experts are chosen on the basis of their professional knowledge and expertise in a particular area of calibration/testing technology and their ability to examine and evaluate a laboratory's standard of management and practices.

3.3.2 The assessors, upon assignment by the Technical Committee, conduct on-site assessments of applicants and accredited laboratories based on the criteria established under SAC-SINGLAS.

3.3.3 The assessment team submits assessment report to the Review Committee under the CCLA for approval after the assessment.

4. Accreditation Process

4.1 Introduction

4.1.1 Enquiries regarding SAC-SINGLAS may be made at the **Singapore Accreditation Council**.

4.1.2 Laboratories interested to be accredited under SAC-SINGLAS may obtain the relevant documents (except ISO/IEC Standards) and application form from SAC or download them from SAC website.

4.1.3 A laboratory is advised to study in detail the SAC Terms and Conditions to ensure that it can substantially meet the accreditation criteria before it lodges an application for accreditation.

4.1.4 The management system of the laboratory shall be operational for at least two months before SAC carries out an assessment of the laboratory.

4.2 Application

4.2.1 All applications shall be made in the form provided by SAC and be supported with documents containing sufficient information regarding its staff, management system, equipment, calibration, laboratory practices, or other information necessary or requested by SAC from time to time for the assessment of the laboratory.

4.2.2 The applicant shall nominate a management representative to liaise with SAC on all matters relating to accreditation and the applicant shall keep SAC informed of any changes in the representative.

4.3 Preliminary Assessment

4.3.1 Upon receipt of a duly completed application form and satisfactory supporting documents relating to its management system, equipment, calibration and laboratory practices, SAC will arrange for a preliminary assessment unless otherwise requested by the applicant.

4.3.2 SAC makes recommendations to the laboratory on the nonconformities noted and upon full rectification of the nonconformities may recommend the laboratory to proceed with the initial assessment.

4.4 Initial Assessment

4.4.1 This is an on-site evaluation of the applicant to determine whether it conforms with the accreditation criteria before an accreditation is awarded.

4.4.2 SAC will appoint an appropriate assessment team comprising Lead Assessor, and Technical Assessor/Expert to assess the applied scope for accreditation.

4.4.3 The applicant shall make available personnel such as management representative, key technical staff and all nominees for signatory approval of the laboratory for interviews during the assessment.

4.4.4 The applicant shall conduct or demonstrate various calibrations and/or tests, undertake calibrations or tests on samples provided by SAC or participate in interlaboratory comparison programmes as recommended by the assessment team.

4.4.5 The applicant will be advised on the assessment findings which include comments on competence and conformity. During the assessment, non-conformities are categorised as "Critical", "Significant" or "Minor". The management representative should ensure that the non-conformities and observations raised are fully understood and acknowledged.

4.4.6 The applicant with "critical non-conformities" will not be granted accreditation for the specific test/calibration. However, the laboratory may request to be re-assessed after rectification of the critical non-conformities. Applicant laboratory will be re-assessed after it has rectified the critical non-conformities.

4.4.7 The applicant with "significant" and "minor" non-conformities is four weeks to submit the corrective action.

4.4.8 As part of the corrective action, the laboratory shall submit the relevant evidences and a form that capture information on investigation and root cause analysis (e.g. Corrective/ Preventive Action Report or Corrective Action Report).

4.4.9 Once the applicant has taken the necessary corrective actions, the assessment team shall review the corrective actions and if necessary, conduct a verification visit to verify the actions taken.

4.4.10 A Review Committee comprises appropriate members from the Council Committee for Laboratory Accreditation and members from the relevant Technical Committee.

4.4.11 Appropriate technical experts may be co-opted by the Review Committee in its evaluation of the assessment reports.

4.5 Award of Accreditation

4.5.1 The Council Committee for Laboratory Accreditation grants accreditation to the applicant upon being satisfied that the laboratory meets the criteria for accreditation.

4.5.2 All decisions of the Council Committee for Laboratory Accreditation on the granting of accreditation, extension, reduction, renewal or suspension or withdrawal of the same shall, unless expressly provided herein, be final and not called into question by the laboratory.

4.5.3 A Certificate of Accreditation will be issued to the accredited laboratory together with a Schedule giving details of its terms of accreditation. Laboratory may request for an additional certificate and a nominal fee will be charged (please refer to SAC-SINGLAS 003). The SAC-SINGLAS Certificate of Accreditation is valid for a period of three years with provision for renewal on expiry.

4.5.4 The accredited laboratory shall pay SAC an annual certificate fee and other assessment and administrative fees as determined by SAC from time to time.

4.5.5 All accredited laboratories will be listed in a Directory published by SAC and in the SAC website.

4.6 Routine Surveillance and Renewal Assessment

4.6.1 SAC shall conduct surveillance assessments on accredited laboratories to ensure that the standard of practice complying with criteria is maintained. A surveillance assessment shall be conducted normally once every twelve months.

4.6.2 A renewal assessment shall be conducted prior to the expiry of the Certificate of Accreditation. The Certificate shall be renewed on the condition that the accredited laboratory has been found to have maintained the necessary standard of practice during the validity of the Certificate and is capable of maintaining the standard established.

4.6.3 All accredited laboratories shall submit a copy of the internal audit report to SAC prior to the assessment. The laboratories may submit the report three months before the date of assessment.

4.6.4 The laboratories may request for an extension or reduction in the terms of accreditation for consideration during the surveillance and renewal assessment. For such requests, the laboratories shall write formally to SAC at least 1 month before the date of assessment. Upon approval by the CCLA, a revised Schedule will be issued to the laboratories to reflect any changes in the terms of accreditation.

4.6.5 The laboratory will be advised on the assessment findings which include comments on competence and conformity. During the assessment, non-conformities are categorised as "Critical", "Significant" or "Minor". The management representative should ensure that the non-conformities and observations raised are fully understood and acknowledged.

4.6.6 The laboratory with "critical non-conformities" may have the laboratory's scope of accreditation suspended or withdrawn. The laboratory is given one week to submit a corrective action plan which includes the investigation made, specific actions to be taken, the timeliness for completion of corrective actions. Once the assessment team is satisfied with the corrective action plan, the corrective actions shall be completed four weeks from the last day of assessment.

4.6.7 The laboratory with "significant non-conformities" and "minor non-conformities" is given four weeks to submit the correction action.

4.6.8 The laboratory shall submit the corrective action as described in clause 4.4.8 of this document.

4.6.9 Once the laboratory has taken the necessary corrective actions, the assessment team shall review the corrective actions and if necessary, conduct a verification visit to verify the actions taken.

4.7 Non-routine Assessment

4.7.1 The non-routine assessments will include visits made to consider requests for extension in the terms of accreditation or in signatory approvals, or to investigate complaints made against the accredited laboratories on areas within the scope of SAC-SINGLAS accreditation, if these could not be conducted during the routine surveillance visits.

4.7.2 Unannounced assessments are conducted for special reasons such as to investigate a complaint against a laboratory. SAC reserves the right to conduct unannounced visits when the need arises.

4.7.3 SAC may conduct non-routine assessment for reinstatement of accreditation for laboratories whose accreditation has been suspended or inoperative due to various reasons such as change of premises or loss of all signatories.

4.8 Suspension and Withdrawal of Accreditation

4.8.1 A suspension or withdrawal may be made against an accredited laboratory for any or all of the calibrations or tests included in the terms of accreditation for such period as the Council Committee for Laboratory Accreditation may determine if it is satisfied that:

(a) the laboratory has not maintained a standard of practice complying with the accreditation criteria;

(b) the laboratory has violated the terms and conditions for the accreditation stipulated in SAC 01;

(c) the laboratory has failed to provide reasonable resources for the assessors to discharge their duties;

(d) the laboratory has failed to rectify the nonconformities that have an effect on the validity of the test / calibration results one month after the given time frame. These may include retrieval and re-issuing of the affected calibration / test reports;

(e) the laboratory has failed to submit the corrective actions within the agreed time frame without valid reason; or

(f) the laboratory has failed to pay all necessary fees levied by SAC from time to time.

4.8.2 Where any failure to comply with any accreditation criteria is, in the opinion of the Council Committee for Laboratory Accreditation, of a temporary nature and rectification will not be immediate, SAC may retain accreditation on a suspended basis for any or all of the tests covered in the terms of accreditation of that laboratory.

4.8.3 SAC shall withdraw the accreditation when departures from the accreditation criteria, which lead to suspension of accreditation, are not rectified within the stipulated timeframe, normally not more than a year.

4.8.4 SAC shall inform the accredited laboratory in writing of the suspension or withdrawal and the reasons for the suspension or withdrawal. The calibration or testing laboratory shall have the right to appeal to the SAC Council.

4.8.5 No accreditation shall be suspended or withdrawn unless SAC:

(a) has served at least two weeks' written notice to the accredited laboratory, stating the grounds for the suspension or withdrawal; and

(b) has considered any written appeal from the accredited laboratory received during these two weeks.

4.8.6 During the two weeks' notice, the status of accreditation of the calibration or testing laboratory is considered to be in temporary suspension and no SAC-SINGLAS endorsed reports shall be issued.

4.8.7 If a written appeal has been received, the SAC Council shall convene an Appeal Committee chaired by a SAC Council member and comprising members not involved in the evaluation of the laboratory to consider the explanations given, and if the accredited laboratory so wishes, shall provide an opportunity for the accredited laboratory to be heard as soon as possible. When necessary, appropriate technical experts may be co-opted to assist in hearing the appeal.

4.8.8 If no appeal has been received by the SAC Council against the notice of suspension or withdrawal, or if in the opinion of the SAC Council the explanations submitted are not satisfactory, SAC shall, on the expiry of the notice, suspend or withdraw the accreditation and inform the laboratory in writing.

4.8.9 Any accredited laboratory may voluntarily withdraw its accreditation by giving two weeks' written notice to SAC.

4.8.10 A laboratory whose accreditation has been voluntarily withdrawn, withdrawn by SAC or suspended shall not issue SAC-SINGLAS endorsed reports or represent or imply in any way to any party that its accreditation under SAC-SINGLAS is operative.

4.8.11 A laboratory whose accreditation has been withdrawn shall return the Certificate of Accreditation and all other appropriate documents to SAC immediately.

4.9 Reinstatement of Accreditation

4.9.1 A laboratory whose accreditation has been suspended in part or in full may be reinstated subject to a re-assessment. The laboratory shall satisfy all the criteria of a formal assessment and the award of accreditation as per clauses 4.4 and 4.5.

4.10 Re-Application

4.10.1 A laboratory whose accreditation has been withdrawn by SAC may re-apply one year after its date of withdrawal and shall be considered as fresh applicant.

4.10.2 A laboratory that has withdrawn its accreditation may re-apply and shall be considered as fresh applicant.

5. Approved Signatories

5.1 The nominees for signatory approval shall be competent to make a critical evaluation of calibration and/or test results and be a staff occupying a position in the organisational structure which is responsible for the adequacy of results.

5.2 The status of approved signatory shall be granted only to persons nominated by the calibration or testing organisation.

5.3 The status of approved signatory may be granted to a nominee for specific calibrations, tests or all calibrations or tests for which the laboratory is accredited.

5.4 As the status of approved signatory is granted in the context of the tests being performed in a particular laboratory, it shall not be considered as a personal qualification.

5.5 The nominee for signatory approval shall be thoroughly familiar conversant with SAC Terms and Conditions together with other relevant criteria.

5.6 The nominee for signatory approval should have worked in the organisation for more than 12 months and have the relevant qualification and experience in the related field.

5.7 No approval will be granted to a nominee without being interviewed by the assessment team. If the nominee for signatory approval is not present in the assessment, a separate visit or interview is required.

5.8 In addition to the interview, the nominee, at the discretion of the assessment team, may be required to sit for a written test.

5.9 Approved signatory shall be:

- Diploma holder of relevant discipline and a minimum of 3 years related working experience.
- GCE "A" level and below, with a minimum of 8 years related working experience.

5.10 The approved signatory shall ensure the reliability and completeness of the calibration or test reports for which responsibility is taken on behalf of the accredited laboratory concerned.

5.11 All approved signatories shall be subjected to review during assessment. It is the responsibility of the accredited laboratory to ensure that existing approved signatories are present when their areas are being assessed. Otherwise their signatory approval may be withdrawn, or a separate visit or interview may be required.

6. Site and Branch Laboratories

6.1 An accredited laboratory shall seek approval from SAC if it wishes to set up a site laboratory to conduct calibrations or tests covered in the terms of accreditation. The accredited laboratory shall not issue SAC-SINGLAS endorsed reports for calibrations or tests conducted in the site laboratory unless accreditation has been extended to cover the work performed in the site laboratory.

6.2 If an accredited laboratory wishes to seek accreditation for its branch laboratory, it shall apply formally to SAC to request for an extension of the accreditation to the branch laboratory.

6.3 SAC may consider on a case to case basis the accreditation of overseas branch laboratories with Headquarters (HQ) in Singapore, if they meet the following:

- The HQ oversees and controls the management system and its implementation in the branch laboratories; and
- The branch laboratories must operate to the same management system and technical procedures as the HQ.

7. Safety

7.1 Safe working conditions are essential to good laboratory practice and management. The laboratory shall observe all necessary safety precautions to ensure that it has a safe working environment.

7.2 SAC will not arrange for on-site assessment if it considers the laboratory to be unsafe.

7.3 It is the laboratory's responsibility to comply with relevant health and safety requirements.

Annex 1 - Listing of Accreditation Criteria Documents

a) ISO/IEC 17025 - General Requirements for the Competence of Testing and Calibration Laboratories

b) SAC 01 - Terms and Conditions for Accreditation

c) SAC-SINGLAS 001 - Accreditation Process

d) SAC-SINGLAS 002 - Requirements for the Application of ISO/IEC 17025

e) SAC-SINGLAS 006 - Traceability of Measurement

f) PROF Note 001 - Policies on Proficiency Testing

g) Field Specific Technical Notes

- C & B 001 - Specific Requirements for Chemical & Biological Testing Laboratories
- C & B 002 - Quality Assurance of Equipment commonly used in Chemical & Biological Testing Laboratories
- CE 001 - Specific Requirements for Civil Engineering Testing Laboratories
- CE 002 - Specific Requirements for Non-Destructive Testing for Concrete
- ENV 001 - Specific Requirements for Environmental Testing Laboratories
- ENV 002 - Quality Assurance of Equipment commonly used in Environmental Testing Laboratories
- EL 001 - General Requirements for Electrical Testing Laboratories
- EL 002 - Specific Policy for Uncertainty of Measurement for Electrical Testing Laboratories
- EL 003 - General Requirements for the Accreditation of Information Technology Security Testing
- GT 001 - Specific Requirements for Gaming Testing
- MET 001 - Specific Requirements for Calibration & Measurement Laboratories
- MET 002 - General Requirements and Criteria of documenting the Best Measurement Capability
- MECH 001 - Specific Requirements for Mechanical Testing Laboratories
- NDT 001 - Specific Requirements for Non-Destructive Testing Laboratories
- NDT 002 - Guidelines for the Recognition of Non-Destructive Testing (NDT) Personnel Certifications for SAC-SINGLAS Assessments
- NDT 003 - Quality Assurance of Equipment Commonly used in Non-Destructive Testing Laboratories