ACCREDITATION SCHEME FOR LABORATORIES

SAC-SINGLAS 001

Accreditation Process

SAC-SINGLAS 001, 21 Sep 2020
The SAC Accreditation Programme is managed by Enterprise Singapore

	CONTENT	PAGE
1.	**The Scheme**	1
2.	**Definitions**	2
3.	**SAC Organisational Structure**	5
	3.1 Council Committee for Laboratory and Council Committee for Biomedical and Health	5
	3.2 Technical Committees	5
	3.3 Technical Assessors / Experts	5
4.	**Accreditation Process**	6
	4.1 Introduction	6
	4.2 Application	6
	4.3 Preliminary Assessment	6
	4.4 Initial Assessment	7
	4.5 Award of Accreditation	8
	4.6 Routine Surveillance and Renewal Assessment	8
	4.7 Non-routine Assessment	9
5.	**Approved Signatories**	10
6.	**Key Personnel**	11
7.	**Management Representative**	11
8.	**Site and Branch Laboratories**	11
9.	**Safety**	12
Annex 1a	**Listing of Accreditation Criteria Documents**	13
Annex 1b	**Listing of Accreditation Criteria Documents for Medical Testing Laboratories**	14
Annex 1c	**Listing of Accreditation Criteria Documents for Medical Imaging Facilities**	15

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 Enterprise Singapore (ESG). 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 new accreditation fields to meet the needs of stakeholders

e) to facilitate trade and market access by establishing and maintaining mutual recognition arrangements (MRAs) with overseas accreditation bodies through the regional and international bodies, such as Asia Pacific Accreditation Cooperation (APAC) and International Laboratory Accreditation Cooperation (ILAC)

1.3 SAC gives formal recognition to laboratories that have been independently assessed and found to comply with the criteria established. 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 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"* or ISO 15189 "*Medical Laboratories – Particular requirements for quality and competence"* for medical testing laboratories and medical imaging facilities and the specific requirements of each field/ discipline.

1.5 This document should be read in conjunction with SAC 01 *Terms & Conditions for Accreditation*, SAC 02 *Rules for Use of SAC Accreditation Marks and Mutual Recognition Arrangement (MRA) Marks*, ISO/IEC 17025 or ISO 15189 and any specific requirements that may be published as SAC-SINGLAS Technical Notes relating to specific calibration, testing and measurement activities.

2. Definitions

2.1 Accreditation criteria:
Requirements of SAC 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 laboratory to which SAC accreditation has been granted.

2.3 Approved signatory (Not applicable for Medical Testing and Medical Imaging):
A person recognised under SAC to sign SAC accredited calibration or test reports issued by an accredited laboratory.

2.4 Branch Laboratory:
A 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:
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 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 with at least 1 laboratory (where applicable & available) in accordance with predetermined conditions.

2.9 Key Personnel (For Medical Testing and Medical Imaging):
Personnel with responsibility for operating laboratory to monitor all work performed so as to achieve reliable data resulting in quality patient care.

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

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

2.12 Management representative:
A person nominated by a calibration or testing organisation to represent it in all matters relating to SAC accreditation (see clause 7 for details).

2.13 Medical Testing Laboratory:
Laboratory for the biological, microbiological, immunological, chemical, immunohaematological, haematological, biophysical, cytological, pathological or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultancy advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation.

2.14 Medical Imaging Facility
Laboratory for performance of procedures including the use of radiography, ultrasound, mammography, computed tomography, angiography, magnetic resonance, nuclear medicine and/ or bone mineral densitometry.

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

2.16 Critical Non-conformity:
A *critical* non-conformity which seriously threatens the credibility of the laboratory accreditation scheme. Gross lack of technical competence, persistent violation of SAC Terms & Conditions, 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 key activities, inappropriate environment for key activities, lack of critical equipment, lack of 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.

2.17 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 a *significant* non-conformity.

2.18 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.

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

2.20 Reference material:
Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.

2.21 SAC accredited 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.

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

2.23 Site Laboratory:
A 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.

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

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

2.26 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.

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

3. SAC Organisational Structure

3.1 Council Committee for Laboratory (CCL) and Council Committee for Biomedical and Health (CCBH)

3.1.1 The Council Committee for Laboratory (CCL) and Council Committee for Biomedical and Health (CCBH) are specialist committees appointed to support the SAC Council. The CCL is responsible for the formulation of policies, provides guidance and oversees the operation of the Laboratory Accreditation Scheme, based on ISO/IEC 17025. The CCBH is however responsible for the operation of accreditation fields for medical testing and medical imaging based on ISO 15189, and the Good Laboratory Practice (GLP) Compliance Programme.

3.1.2 The CCL and CCBH are authorised to review, evaluate and approve assessment reports for accreditation of laboratories and facilities for their respective areas, through their Review Committees. The CCL and CCBH 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 CCL and CCBH is three years with provision for reappointment.

3.2 Technical Committees

3.2.1 Technical Committees are typically established for each field of calibration or testing as well as for GLP.

3.2.2 Technical Committee members are appointed from different stakeholder groups based on 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 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 its respective Review Committee under the CCL or CCBH 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 may obtain the relevant documents (except ISO/IEC Standards) from SAC website. Online application can be made via SACiNet. For new programme where online application is not yet available in SACiNet, the application form can be downloaded 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 submitted in SACiNet 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 update any changes in the representative in SACiNet.

4.3 Preliminary Assessment

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

4.3.2 SAC makes recommendations to the laboratory on the non-conformities 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 Team Leader, 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.

4.4.7 The applicant with “significant” and “minor” non-conformities is given 1 month to submit the corrective action.

4.4.8 As part of the corrective action, the laboratory shall submit/upload the relevant evidences and root cause analysis (e.g. Corrective/ Preventive Action Report or Corrective Action Report) in SACiNet.

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

4.4.10 A Review Committee comprises appropriate members from the respective Council Committee for Laboratory or Council Committee for Biomedical and Health 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 respective Council Committee for Laboratory and Council Committee for Biomedical and Health 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 and Council Committee for Biomedical and Health on the granting, extension, reduction, renewal, suspension or withdrawal of accreditation 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 four years with provision for renewal on expiry.

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

4.5.5 All accredited laboratories will be listed on 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 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 indicate in SACiNet and upload the supporting documents least 1 month prior to the date of assessment.

4.6.4 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.

4.6.5 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 1 month from the last day of assessment.

4.6.6 The laboratory with “significant non-conformities” and “minor non-conformities” is given 1 month to submit the correction action.

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

4.6.8 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 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 or key personnel.

5 Approved Signatories (Not applicable for Medical Testing and Medical Imaging)

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 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 and above, 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 Key Personnel (for Medical Testing and Medical Imaging)

6.1 The key personnel shall be competent to make a critical evaluation of test results and be a staff occupying a position in the organisation staff structure which is responsible for the adequacy of results.

6.2 The key personnel shall ensure the reliability and completeness of the test reports for which responsibility is taken on behalf of the accredited laboratory concerned.

6.3 The accredited laboratory shall ensure that the key personnel be thoroughly conversant with SAC-SINGLAS terms and conditions together with other relevant criteria.

6.4 The key personnel should have the relevant qualification and experience in the related field.

6.5 All key personnel shall be subjected to review during assessment. It is the responsibility of the accredited laboratory to ensure that key personnel be present when their areas are being assessed, otherwise a separate visit or interview may be required.

7. Management Representative

7.1 The management representative of laboratory shall be a full time staff/permanent employee and will be the contact liaison with SAC.

7.2 The management representative shall understand the workings of the laboratory well and shall be able to make decisions on accreditation matters on behalf of the laboratory.

8. Site and Branch Laboratories

8.1 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 accredited reports for calibrations or tests conducted in the site laboratory unless accreditation has been extended to cover the work performed in the site laboratory.

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

8.3 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.

9. Safety

9.1 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.

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

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

Annex 1a - Listing of Accreditation Criteria Documents and Guidelines

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

b) SAC 01 - Terms and Conditions for Accreditation

c) SAC 02 - Rules for Use of SAC Accreditation Marks and Mutual Recognition Arrangement (MRA) Marks

d) SAC-SINGLAS 001 - Accreditation Process

e) SAC-SINGLAS 002 - Guidelines for the Application of ISO/IEC 17025:2017

f) SAC-SINGLAS 006 - Traceability of Measurement

g) PROF 001 - Policies on Proficiency Testing

h) Field Specific Technical Notes

- C&B 001 - Specific Requirements for Chemical & Biological Testing Laboratories
- C&B and ENV 002 - Quality Assurance of Equipment Commonly Used in Chemical & Biological and Environmental 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
- EL 001 - General Requirements for Electrical Testing Laboratories
- EL 002 - Specific Policy for Uncertainty of Measurement for Electrical Testing Laboratories
- GT 001 - Specific Requirements for Gaming Testing
- IT 001 - General Requirements for the Accreditation of Information Technology Testing Laboratories
- 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

Annex 1b Listing of Accreditation Criteria Documents for Medical Testing Laboratories

a) ISO 15189 - Medical Laboratories - Particular Requirements for Quality and Competence

b) SAC 01 - Terms and Conditions for Accreditation

c) SAC 02 - Rules for Use of SAC Accreditation Marks and Mutual Recognition Arrangement (MRA) Marks

d) SAC-SINGLAS 001 - Accreditation Process

e) SAC-SINGLAS 006 - Traceability of Measurement

f) PROF 001 - Policies on Proficiency Testing

g) Technical Note MED 001 - General Criteria for Medical Testing Laboratories

h) Technical Notes for Discipline Specific Requirements MED 002
   - Clinical Chemistry Section
   - Cytogenetics Section
   - Cytopathology Section
   - Haematology Section
   - Histopathology Section
   - Microbiology Section
   - Molecular Pathology Section
   - Immunology Section
   - Urinalysis Section

Annex 1c Listing of Accreditation Criteria Documents for Medical Imaging Facilities

a) ISO 15189 – Medical Laboratories – Particular Requirements for Quality and Competence

b) SAC 01 – Terms and Conditions for Accreditation

c) SAC 02 - Rules for Use of SAC Accreditation Marks and Mutual Recognition Arrangement (MRA) Marks

d) SAC-SINGLAS 001 – Accreditation Process

e) SAC-SINGLAS 006 - Traceability of Measurement

f) Technical Note MI 001 - Specific Criteria for Medical Imaging