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**CONFIDENTIAL**

**SINGAPORE ACCREDITATION COUNCIL**

**SINGAPORE LABORATORY ACCREDITATION SCHEME (SAC-SINGLAS)**

|  |  |  |  |
| --- | --- | --- | --- |
| **Laboratory Assessment Checklist** | | | |
|  |  |  | |
| Type of Assessment | : | Preliminary / Initial / Renewal / Surveillance / Non-Routine / Verification | |
|  |  |  | |
| Laboratory | : |  | |
|  |  |  | |
| Address | : |  | |
|  |  |  | |
| Tel / Fax | : |  | |
|  |  |  | |
| Names of persons seen | : |  | |
|  |  |  | |
| Field | : |  | |
|  |  |  | |
| Date of visit | : |  | |
|  |  |  | |
| Technical Assessor(s)/Expert(s) | : |  | |
|  |  |  | |
| Lead Assessor | : |  |  |
|  |  | Name & Signature | Date |

References

ISO/IEC 17025: 2017, SAC-01, SAC-02, SAC-SINGLAS 001, SAC-SINGLAS 002, SAC-SINGLAS 006,

PROF 001

|  | **Description** |
| --- | --- |
| To Produce | Mandatory to meet the requirement |
| To Consider | Guidance to meet the requirement |

| **Clause No.** | **Description** | **Yes** | **No** | **N.A.** | **Remarks** |
| --- | --- | --- | --- | --- | --- |
| **4.** | **General Requirements** | | | | |
| **4.1** | **Impartiality** | | | | |
| 4.1.2 | Does the laboratory demonstrate management commitment to impartiality?  To consider   * Management review * Code of conduct * Declaration forms relating to confidentiality / impartiality |  |  |  |  |
| 4.1.4 | Does the laboratory identify risks to its impartiality on an ongoing basis?  - Risk from activities  - Risk from its relationships  - Risk from the relationships of its personnel  To consider   * Risk assessment * Risk matrix |  |  |  |  |
| 4.1.5 | Does the laboratory eliminate or minimize the risks identified? |  |  |  |  |
| **4.2** | **Confidentiality** | | | | |
| 4.2.1 | How is the laboratory responsible for the confidentiality of information obtained or created during the performance of laboratory activities, and proprietary rights of its customers?  To consider   * Code of conduct * Contractual agreement |  |  |  |  |
| 4.2.2 | Does the laboratory notify its customers when the laboratory is legally obliged to release confidential information of its customers? |  |  |  |  |
| 4.2.3 | Does the laboratory ensure that information about its customers received from sources other than the customers are kept confidential?  Does the laboratory ensure that the source(s) of information about its customers is not revealed to the customers unless agreed by the source(s)? |  |  |  |  |
| 4.2.4 | How does the laboratory ensure that personnel keep confidential all information obtained or created during the performance of laboratory activities? |  |  |  |  |
| **5.** | **Structural Requirements** | | | | |
| 5.1 | Is the laboratory or the organization legally responsible?  To produce   * Valid ACRA Certificate * Company registration number |  |  |  |  |
| 5.2 | Does the laboratory identify management that has overall responsibility for the laboratory?  To consider   * Job description * Organisation chart |  |  |  |  |
| 5.3  5.4 | Does the laboratory define and document the range of laboratory activities which conforms to ISO 17025:2017?  Does it cover work carried out in:   * permanent facilities? * sites away from its permanent facilities? * associated temporary facilities? * mobile facilities? * customer’s facilities?   Do these activities conform to customer and regulatory requirements? |  |  |  |  |
| 5.5  a)  b)  c) | Does the laboratory:  define the organization and management structure of the laboratory  specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results  document necessary procedures to ensure consistent application of its activities and the validity of its results?  To consider  Job description, Organisation chart, Roles and Responsibilities, Standard Operating Procedures |  |  |  |  |
| 5.6  a)  b)  c)  d) | Does the laboratory have authorized and sufficient personnel to:  implement, maintain and improve the management system?  Identify deviations and initiate actions to minimize or prevent such deviations?  Report to management on the performance of the management system and any need for improvements?  Ensure the effectiveness of laboratory activities? |  |  |  |  |
| 5.7 | Does the laboratory communicate to staff about the effectiveness and integrity of the management system when changes are made to it? |  |  |  |  |
| **6.** | **Resource Requirements** | | | | |
| **6.1** | **General** | | | | |
|  | Does the laboratory have sufficient personnel, facilities, equipment, systems and support services necessary to manage and perform its laboratory activities? |  |  |  |  |
| **6.2** | **Personnel** | | | | |
| 6.2.2 | Does the laboratory document the competence requirements for each function that may influence the results of laboratory activities?  - Education  - Qualification  - Training required  - Technical knowledge  - Skills  - Experience  To consider   * Training and Competency Matrix * Job description * Training records * Curriculum vitae |  |  |  |  |
| 6.2.4 | Are the duties, responsibilities and authorities of laboratory personnel communicated to them? |  |  |  |  |
| 6.2.5  a)  b) to f) | Does the laboratory have procedures and retain records for:  Determining the competence requirements?  Selection, training, supervision, authorization, and monitoring of competence of personnel performing laboratory activities?  To produce   * Procedures of the above * Records of the above |  |  |  |  |
| 6.2.6  a)  b)  c) | Does the laboratory authorize personnel to perform laboratory activities pertaining to:  development, modification, verification and validation of methods?  analysis of results, including statements of conformity or opinions and interpretations?  report, review and authorization of results? |  |  |  |  |
| **6.3** | **Facilities and environmental conditions** | | | | |
| 6.3.1  6.3.2 | Does the laboratory document and ensure control of the facilities and environmental conditions necessary for the performance of the laboratory activities?  To produce   * Procedures of the above |  |  |  |  |
| 6.3.3 | Does the laboratory monitor, control and record the environmental conditions?  To produce   * Records of the above |  |  |  |  |
| 6.3.4 | Does the laboratory monitor and periodically review the measures to control facilities? For example:  - Access to and use of laboratory areas?  - Prevention of contamination, interference or other adverse influences?  - Effective separation between areas with incompatible laboratory activities? |  |  |  |  |
| 6.3.5 | Does the laboratory ensure compliance to Section 6.3 of ISO 17025:2017 when laboratory activities are performed at sites or facilities outside its permanent control? |  |  |  |  |
| **6.4** | **Equipment** | | | | |
| 6.4.1 | Does the laboratory have access to equipment required for the correct performance of laboratory activities, and which can influence results? |  |  |  |  |
| 6.4.2 | Does the laboratory ensure compliance to Section 6.4 of ISO 17025:2017 when using equipment outside its permanent control? |  |  |  |  |
| 6.4.3 | Does the laboratory have a procedure for handling, transport, storage, use and planned maintenance of equipment?  To produce   * Procedures of the above |  |  |  |  |
| 6.4.4 | Does the laboratory verify that equipment conforms to specified requirements before being placed or returned into service? |  |  |  |  |
| 6.4.5  6.4.6 | Does the laboratory ensure that measuring equipment is calibrated and capable of achieving the measurement accuracy or measurement uncertainty required to provide a valid result? |  |  |  |  |
| 6.4.7 | Does the laboratory have an established calibration programme and review the suitability and frequency of calibration?  To produce   * Calibration programme * Records of review of calibration programme   To consider   * Equipment Master List |  |  |  |  |
| 6.4.8 | Is there a system of labelling, coding or identification of all equipment requiring calibration or which has a defined period of validity? |  |  |  |  |
| 6.4.9 | Does the laboratory have a process of handling equipment that no longer meets specified requirements?  Does the process include examining the effect of the deviation from specified requirements? |  |  |  |  |
| 6.4.10  6.4.11 | Does the laboratory perform periodic checks or updates to maintain confidence in the performance of its equipment?  Note: This includes reference values or correction factors. |  |  |  |  |
| 6.4.12 | Does the laboratory take practicable measures to prevent unintended adjustments of equipment from invalidating results? |  |  |  |  |
| 6.4.13  a)  b)  c)  d)  e)  f)  g)  h) | Does the laboratory retain records for equipment which can influence laboratory activities? For example:  the identity of equipment, including software and firmware version;  the manufacturer’s name, type identification, and serial number or other unique identification;  evidence of verification that equipment conforms with specified requirements;  the current location;  calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;  documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;  ﻿  the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;  details of any damage, malfunction, modification to, or repair of, the equipment.  To produce   * Records of the above |  |  |  |  |
| **6.5** | **Metrological traceability** | | | | |
| 6.5.1 | Does the laboratory establish and maintain metrological traceability of its measurement results by means of a documented unbroken chain of calibrations, each contributing to the measurement uncertainty, linking them to an appropriate reference? |  |  |  |  |
| 6.5.2  6.5.3 | Does the laboratory ensure that measurement results are traceable to the International System (SI) of Units where possible?  To consider   * Calibration provided by competent laboratory * Certified reference materials by competent producer * Direct realization of SI units |  |  |  |  |
| **6.6** | **Externally provided products and services** | | | | |
| 6.6.1 | Does the laboratory ensure the suitability of externally provided products and services? |  |  |  |  |
| 6.6.2  a)  b)  c)  d) | Does the laboratory have procedures and records for the following?  defining, reviewing and approving the laboratory’s requirements for externally provided products and services;  defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;  ensuring that externally provided products and services conform to the laboratory’s established requirements, or when applicable, to the relevant requirements of Section 6.6 of ISO 17025:2017, before they are used or directly provided to the customer;  taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.  To produce   * Procedures of the above * Records of the above |  |  |  |  |
| 6.6.3  a)  b)  c)  d) | Does the laboratory communicate its requirements to external providers for the following?  the products and services to be provided;  the acceptance criteria;  competence, including any required qualification of personnel;  activities that the laboratory, or its customer, intends to perform at the external provider’s premises.  To Consider   * Tenders * Contracts * Specifications * Purchase Orders |  |  |  |  |
| **7.** | **Process Requirements** | | | | |
| **7.1** | **Review of requests, tenders and contracts** | | | | |
| 7.1.1  a)  b)  c)  d) | Does the laboratory have a procedure for the review of requests, tenders and contracts? The procedure shall ensure that:  the requirements are adequately defined, documented and understood;  the laboratory has the capability and resources to meet the requirements;  where external providers are used, the requirements of Section 6.6 are applied and the laboratory advises the customer of the specific laboratory activities to be performed by the external provider and gains the customer’s approval;  the appropriate methods or procedures are selected and are capable of meeting the customers’ requirements. |  |  |  |  |
| 7.1.2  7.1.4 | Does the laboratory notify the customer of any inappropriate or outdated methods, and ensure that the contract shall be acceptable to both the laboratory and the customer?  Does the laboratory ensure that deviations requested by the customer do not impact the integrity of the laboratory or the validity of the results? |  |  |  |  |
| 7.1.3 | Is the decision rule clearly defined, communicated, and agreed by both the laboratory and the customer when a statement of conformity is required to be appended on the test/calibration/sampling report? |  |  |  |  |
| 7.1.5  7.1.6  7.1.8 | Does the laboratory notify customers of any deviations from the contract and, if the deviations occur after work has commenced, repeat the contract review and notify all affected personal?  To produce   * Records of contract review * Records of any changes and pertinent discussions on customer’s requirements |  |  |  |  |
| 7.1.7 | Does the laboratory cooperate with customers or their representatives in clarifying the customer’s request and in monitoring the laboratory’s performance in relation to the work performed? |  |  |  |  |
| **7.2** | **Selection, verification and validation of methods** | | | | |
| **7.2.1** | **Selection and verification of methods** | | | | |
| 7.1.2.1  7.2.1.2 | Are all methods, procedures, and supporting documentation appropriate to laboratory activities, relevant, up to date, and readily available to personnel? |  |  |  |  |
| 7.2.1.3 | Does the laboratory ensure that it uses the most appropriate version of a method? |  |  |  |  |
| 7.2.1.4 | Does the laboratory select and inform the customer of the method chosen if the customer does not specify the method? |  |  |  |  |
| 7.2.1.5 | Has the laboratory verified that it can properly perform the methods and achieve the required performance before introducing them?  To produce   * Records of verification |  |  |  |  |
| 7.2.1.6 | Does the laboratory have a formal plan for method development, performed by competent personnel with adequate resources?  Are periodic reviews carried out to ensure that the needs of the customer are fulfilled? |  |  |  |  |
| 7.2.1.7 | Does the laboratory document, justify, authorize and seek acceptance from the customer for any deviations to methods prior to performing them? |  |  |  |  |
| **7.2.2** | **Validation of methods** | | | | |
| 7.2.2.1  7.2.2.2  7.2.2.4 | Does the laboratory validate any non-standard methods, laboratory developed methods, standard methods used outside their intended scope, or any validated methods that have since been modified?  To produce  Records of validation   * validation procedure used * specification of the requirements; * ﻿determination of the performance characteristics of the method; * results obtained; * a statement on the validity of the method, detailing its fitness for the intended use |  |  |  |  |
| 7.2.2.3 | Are the performance characteristics of validated methods relevant to customer’s needs and consistent with specified requirements? |  |  |  |  |
| **7.3** | **Sampling** | | | | |
| 7.3.1  7.3.2 | Does the laboratory have a sampling plan and method for performing of sampling activities?  Is the sampling plan and method available at the site where sampling is performed?  Does the sampling method address the factors to be controlled to ensure the validity of subsequent testing or calibration results?  To Produce  Sampling method describing:   * selection of samples or sites * the sampling plan (where reasonable, this shall be based on statistical methods) * preparation and treatment of sample(s) from a substance, material or product to yield the required item for subsequent testing or calibration |  |  |  |  |
| 7.3.3  (a) to (h) | Does the laboratory retain records of sampling data that forms part of the testing or calibration that is undertaken?  To produce   * Sampling records |  |  |  |  |
| **7.4** | **Handling of test or calibration items** | | | | |
| 7.4.1 | Does the laboratory have procedures for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items?  Does the procedure document the necessary measures to protect the integrity of the test or calibration item, and the interests of the laboratory and the customer?  To produce  Procedures for the above |  |  |  |  |
| 7.4.2 | Does the laboratory have a system for unambiguous identification of test or calibration items that ensures no physical confusion or when referred to in records or documents?  Is the identification retained whilst under the responsibility of the laboratory? |  |  |  |  |
| 7.4.3 | Upon receipt of test or calibration items which have deviated from specified conditions, does the laboratory record these deviations?  Are the deviations notified to customers for their instructions and the results of this consultation recorded?  To produce   * Records for the above |  |  |  |  |
| 7.4.4 | For items requiring storage under specific environmental conditions, does the laboratory maintain, monitor and record these conditions?  To produce   * Records for the above |  |  |  |  |
| **7.5** | **Technical records** | | | | |
| 7.5.1 | Does the laboratory retain and maintain technical records containing sufficient information to enable repetition of the laboratory activity under conditions as close as possible to the original?  To produce  Records for the above containing (but not limited to):   * date and identity of personnel responsible for the laboratory activity and checking of data and results * factors affecting measurement results and its associated measurement uncertainty * Evaluation of measurement uncertainty |  |  |  |  |
| 7.5.2 | Are amendments to technical reports trackable to previous versions or original observations?  Are the original and amended data and files kept?  To produce  Records for the above containing:   * Date of alteration * Indication of altered aspects * Personnel responsible for the alterations |  |  |  |  |
| **7.6** | **Evaluation of measurement uncertainty** | | | | |
| 7.6.1 | Does the laboratory identify the contributions to measurement uncertainty using appropriate methods of analysis, including those arising from sampling? |  |  |  |  |
| 7.6.2 | For laboratories performing calibrations, including of its own equipment, is the  measurement uncertainty for all calibrations evaluated? |  |  |  |  |
| 7.6.3 | For laboratories performing testing, has the measurement uncertainty been evaluated?  *NB: If it is not possible to evaluate the measurement uncertainty, an estimation of the uncertainty must be made.* |  |  |  |  |
| **7.7** | **Ensuring the validity of results** | | | | |
| 7.7.1 | Does the laboratory have a procedure for monitoring the validity of results?  Is the monitoring planned and reviewed periodically? |  |  |  |  |
| 7.7.2 | Does the laboratory compare its results with other laboratories, for example through participation in proficiency testing or inter-laboratory comparisons? |  |  |  |  |
| 7.7.3 | Does the laboratory analyse the data or results of the monitoring activities and take appropriate actions when these results fall outside pre-defined criteria? |  |  |  |  |
| **7.8** | **Reporting of results** | | | | |
| **7.8.1** | **General** | | | | |
| 7.8.1.1  7.8.1.2 | Does the laboratory review and authorize the results prior to release? Are any results not reported to the customer made readily available? |  |  |  |  |
| **7.8.2** | **Common requirements for reports** | | | | |
| 7.8.2.1  a)  b)  c)  d)  e)  f)  g)  h)  i)  j)  k)  l)  m)  n)  o)  p) | Does the report contain at least the following information?  A title (e.g. “Test Report”, “Calibration Certificate” or “Report of Sampling”);  Name and address of the laboratory;  Location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory’s permanent facilities, or in associated temporary or mobile facilities;  Unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;  Name and contact information of the customer;  Identification of the method used;  A description, unambiguous identification, and, when necessary, the condition of the item;  Date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results;  Date(s) of performance of the laboratory activity;  Date of issue of the report;  Reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results;  A statement to the effect that the results relate only to the items tested, calibrated or sampled;  The results with, where appropriate, the units of measurement;  Additions to, deviations, or exclusions from the method;  Identification of the person(s) authorizing the report;  Clear identification when results are from external providers. |  |  |  |  |
| 7.8.2.2 | When applicable, does the laboratory clearly identify in its reports which information and/or sample is provided by the customer? |  |  |  |  |
| **7.8.3** | **Specific requirements for test reports** | | | | |
| 7.8.3.1  a)  b)  c)  d)  e) | Does the test report issued by the laboratory contain the following where necessary?  Information on specific test conditions, such as environmental conditions;  Where relevant, a statement of conformity with requirements or specifications;  ﻿  Where applicable, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent) when:  — it is relevant to the validity or application of the test results;  — a customer’s instruction so requires, or  — the measurement uncertainty affects conformity to a specification limit;  Where appropriate, opinions and interpretations;  Additional information which may be required by specific methods, authorities, customers or groups of customers. |  |  |  |  |
| **7.8.4** | **Specific requirements for calibration reports** | | | | |
| 7.8.4.1  a)  b)  c)  d)  e)  f) | Does the calibration report issued by the calibration laboratory contain the following:  The measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent);  The conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;  A statement identifying how the measurements are metrologically traceable;  The results before and after any adjustment or repair, if available;  Where relevant, a statement of conformity with requirements or specifications;  Where appropriate, opinions and interpretations |  |  |  |  |
| 7.8.4.3 | Does the calibration laboratory ensure that calibration certificates or labels issued do not contain any recommendation on the calibration interval?  If a certificate or label contains any recommendation on the calibration interval, has this been agreed with the customer? |  |  |  |  |
| **7.8.5** | **Specific requirements for sampling reports** | | | | |
| a)  b)  c)  d)  e)  f) | Does the sampling report contain the following information?  The date of sampling;  Unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers as appropriate);  The location of sampling, including any diagrams, sketches or photographs;  A reference to the sampling plan and sampling method;  details of any environmental conditions during sampling that affect the interpretation of the test results;  ﻿  Information required to evaluate measurement uncertainty for subsequent testing or calibration. |  |  |  |  |
| **7.8.6** | **Reporting statements of conformity** | | | | |
| 7.8.6.1 | Does the laboratory document the decision rule employed when making statements of conformity in the report? |  |  |  |  |
| 7.8.6.2  a)  b)  c) | When reporting on the statement of conformity, does the statement clearly identify:  to which results the statement of conformity applies?  which specifications, standards or parts thereof are met or not met?  the decision rule applied? |  |  |  |  |
| **7.8.7** | **Reporting opinions and interpretations** | | | | |
| 7.8.7.1 | Does the laboratory ensure that opinions and interpretations are made and released by authorized personnel?  Does the laboratory document the basis on which the opinions and interpretations are made? |  |  |  |  |
| 7.8.7.2 | Is it clearly identifiable in the reports when the laboratory makes opinions and interpretations based on the results obtained from the tested or calibrated item? |  |  |  |  |
|  |  |  |  |  |  |
| 7.8.7.3 | Does the laboratory keep records of any communications of opinions and interpretations with the customer? |  |  |  |  |
| **7.8.8** | **Amendments to reports** | | | | |
| 7.8.8.1 | When the laboratory makes any changes to a report, is this clearly identified in the report?  Where appropriate, are the reasons for the changes clearly identified? |  |  |  |  |
| 7.8.8.2 | When changes are made to a report after it has been issued, does the laboratory issue it as a further document which includes the statement “Amendment to report, serial number or other equivalent form of wording? |  |  |  |  |
| 7.8.8.3 | When issuing a completely new report, does the laboratory issue a unique identification to this report and include a reference to the original report? |  |  |  |  |
| **7.9** | **Complaints** | | | | |
| 7.9.1  7.9.3  a)  b)  c) | Does the laboratory have a documented process to receive, evaluate and make decisions on complaints?  Does the process for handling complaints contain at least the following elements?  description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;  tracking and recording complaints, including actions undertaken to resolve them;  ensuring that any appropriate action is taken. |  |  |  |  |
| 7.9.2  7.9.4 | Is the handling process for complaints available to any interested party upon request?  When receiving the complaint, does the laboratory gather and verify all action to validate the complaint, and take action to deal with any complaints that it is responsible for?  To produce   * Handling process for complaints |  |  |  |  |
| 7.9.5 | Does the laboratory, where possible, acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome? |  |  |  |  |
| 7.9.6 | Is the individual(s) who reviews, approve or communicate the outcomes of the complaint investigation to the complainant involved in the original laboratory activities? |  |  |  |  |
| 7.9.7 | Does the laboratory (where possible) give formal notice of the end of the complaint handling to the complainant?  To produce   * Records for Clauses 7.9.5 to 7.9.7 |  |  |  |  |
| **7.10** | **Nonconforming work** | | | | |
| 7.10.1  a)  b)  c)  d)  e)  f)  7.10.2 | Does the laboratory have a procedure for dealing with nonconforming work?  Does the procedure ensure that:  The responsibilities and authorities for the management of nonconforming work are defined;  actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;  an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;  a decision is taken on the acceptability of the nonconforming work;  where necessary, the customer is notified and work is recalled;  the responsibility for authorizing the resumption of work is defined.  To produce  Records for Clause 7.10.1 (b) to (f) |  |  |  |  |
| 7.10.3 | Does the laboratory take corrective action when it is found that nonconforming work could recur or that there is doubt about the conformity of the laboratory’s operations with its own management system? |  |  |  |  |
| **7.11** | **Control of data and information management** | | | | |
| 7.11.1 | Does the laboratory have access to necessary data and information to perform its laboratory activities? |  |  |  |  |
| 7.11.2 | Does the laboratory validate its laboratory information management systems for functionality and proper functioning of interfaces before introduction?  Does the laboratory authorize, document and validate any modifications to its laboratory software? |  |  |  |  |
| 7.11.3  a)  b)  c)  d)  e) | Is the laboratory information management system  protected from unauthorized access?  safeguarded against tampering and loss?  operated in an environment that complies with supplier or laboratory specifications or, in the case of non-computerized systems, provides conditions which safeguard the accuracy of manual recording and transcription?  maintained in a manner that ensures the integrity of the data and information?  able to record system failures and the appropriate immediate and corrective actions? |  |  |  |  |
| 7.11.4 | Does the laboratory ensure that external providers or operator of the laboratory information management system complies with the requirements of section 7.11 if it is managed offsite? |  |  |  |  |
| 7.11.5 | Does the laboratory ensure that instructions, manuals and reference data relevant to the laboratory information management system(s) are made readily available to personnel? |  |  |  |  |
| 7.11.6 | Does the laboratory ensure that calculations and data transfers are checked in an appropriate and systematic manner? |  |  |  |  |
| **8.** | **Management system requirements** | | | | |
| **8.1** | **Options** | | | | |
| 8.1.2  8.1.3 | **Option A**  The management system of a laboratory shall address the following:  - management system documentation (8.2)  - control of management system documents (8.3)  - control of records (8.4)  - actions to address risks and opportunities (8.5)  - improvement (8.6)  - corrective action (8.7)  - internal audits (8.8)  - management reviews (8.9)  **Option B**  The laboratory has established and maintained a management system in accordance to ISO 9001:2015, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Sections 4 to 7, also fulfils at least the intent of the management requirements specified in 8.2 to 8.9. |  |  |  |  |
| **8.2** | **Management system documentation** | | | | |
| 8.2.1  8.2.2 | Does the laboratory establish, document and maintain policies and objectives for the fulfillment of ISO 17025:2017 and ensure that these policies are acknowledged and implemented at all levels of the laboratory organization?  Do the policies and objectives address he competence, impartiality and consistent operation of the laboratory? |  |  |  |  |
| 8.2.3 | How does the laboratory provide evidence that the management is committed to the development and implementation of the management system and continually improving its effectiveness  To consider  ISO 9001:2015 clause 5.1  - communicating to the organisation the importance of meeting customer as well as statutory and regulatory requirements  - establishing the quality policy  - ensuring that quality objectives are established  - conducting management reviews  - ensuring the availability of resources |  |  |  |  |
| 8.2.4 | Are all documentation, processes, systems, records, etc included, referenced or linked to f the management system?  To consider  ISO 9001:2015 clause 4.2.1 |  |  |  |  |
| 8.2.5 | Do all personnel involved in laboratory activities have access to the parts of the management system documentation and related information that are applicable to their responsibilities?  To consider  Doc control, access rights to inspectors and contracted inspectors |  |  |  |  |
| **8.3** | **Control of management system documents** | | | | |
| 8.3.1, 8.3.2  a)  b)  c)  d)  e)  f) | Does the laboratory have procedures to control the documents (internal and external)?  Does the laboratory ensure that:  documents are approved for adequacy prior to issue by authorized personnel;  documents are periodically reviewed, and updated as necessary;  changes and the current revision status of documents are identified;  relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;  documents are uniquely identified;  the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.  To produce   * Procedures on control of documents   To consider   * Documentation can be in any form or any type of medium (include propriety and in-house developed software). * ISO 9001:2015 Clause 4.2.3 |  |  |  |  |
| **8.4** | **Control of records** | | | | |
| 8.4.1 8.4.2 | Does the laboratory establish and retain legible records to demonstrate fulfilment to Section 8.4?  Does the laboratory implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time and disposal of its records?  Is access to these records readily available and consistent with the confidentiality arrangements?  To consider   * As a guide, important records should be kept at least through 1 accreditation cycle. * ISO 9001:2015 Clause 4.2.4 |  |  |  |  |
| **8.5** | **Actions to address risks and opportunities** | | | | |
| 8.5.1  8.5.2  a)  b) | Does the laboratory consider the risks and opportunities associated with laboratory activities?  Does the laboratory plan  actions to address these risks and opportunities;  How to:  - integrate and implement the actions into its management system;  - evaluate the effectiveness of these actions.  To produce  Records of identification of risks and opportunities and associated action plans |  |  |  |  |
| 8.5.3 | Are the actions taken to address risks and opportunities proportional to the potential impact on the validity of laboratory results? |  |  |  |  |
| **8.6** | **Improvement** | | | | |
| 8.6.1 | Does the laboratory identify and select opportunities for improvement and implement any necessary actions? |  |  |  |  |
| 8.6.2 | Does the laboratory seek feedback, both positive and negative, from its customers?  Does the laboratory analyse the feedback for purposes of improving the management system, laboratory activities and customer service? |  |  |  |  |
| **8.7** | **Corrective Action** | | | | |
| 8.7.1  a)  b)  c)  d)  e)  f) | In the event of a nonconformity, does the laboratory  react to the nonconformity and, as applicable:  - take action to control and correct it;  - address the consequences;  evaluate the need for action to eliminate the cause(s) of the nonconformity, to prevent recurrence or occurance elsewhere, by:  - reviewing and analysing the nonconformity;  - determining the causes of the nonconformity;  - determining if similar nonconformities exist, or could potentially occur;  implement any action needed;  review the effectiveness of any corrective action taken;  update risks and opportunities determined during planning, if necessary;  make changes to the management system, if necessary. |  |  |  |  |
| 8.7.2  8.7.3 | Are the corrective actions appropriate to the effects of the nonconformities encountered?  To produce   * Records of nonconformities, cause(s) and any subsequent actions taken * Records of the results of any corrective action |  |  |  |  |
| **8.8** | **Internal audits** | | | | |
| 8.8.1  a)  b) | Does the laboratory conduct internal audits to determine if the management system  conforms to:  - the laboratory’s own requirements for its management system, including the laboratory activities;  - the requirements of ISO 17025;  is effectively implemented and maintained. |  |  |  |  |
| 8.8.2  a)  b)  c)  d)  e) | Does the laboratory  plan, establish, implement and maintain an audit programme including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits;  define the audit criteria and scope for each audit;  ensure that the results of the audits are reported to relevant management;  implement appropriate correction and corrective actions without undue delay;  retain records as evidence of the implementation of the audit programme and the audit results.  To produce   * Records of Internal audits |  |  |  |  |
| **8.9** | **Management reviews** | | | | |
| 8.9.1 | Does the laboratory management review its management system to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of ISO 17025? |  |  |  |  |
| 8.9.2  a)  b)  c)  d)  e)  f)  g)  h)  i)  j)  k)  l)  m)  n)  o) | Does the laboratory record the following inputs to management review?  changes in internal and external issues that are relevant to the laboratory;  fulfilment of objectives;  suitability of policies and procedures;  status of actions from previous management reviews;  outcome of recent internal audits;  corrective actions;  assessments by external bodies;  changes in the volume and type of the work or in the range of laboratory activities;  customer and personnel feedback;  complaints;  effectiveness of any implemented improvements;  ﻿  adequacy of resources;  results of risk identification;  outcomes of the assurance of the validity of results; and  other relevant factors, such as monitoring activities and training. |  |  |  |  |
| 8.9.3  a)  b)  c)  d) | Does the laboratory record the outputs of the management review pertaining to:  the effectiveness of the management system and its processes;  improvement of the laboratory activities related to the fulfilment of the requirements of this document;  provision of required resources;  any need for change. |  |  |  |  |
|  | **Requirements** | | | | |
| **A**  1.  2.  *3.* | Existing Approved Signatory  Do the signatories still occupy appropriate positions in the staff structure to be responsible for the adequacy of test or calibration results?  Do the signatories still retain sufficient contact time with testing/calibration procedures to maintain the ability for critical evaluation of results?  For approved signatories including nominees, are the requirements stated in Clause 5 of SAC-SINGLAS 001 being met? |  |  |  | SAC-SINGLAS 001, Clause 5 |
| **B.**  1.  2.  3.  4. | New Nominees for Signatory Approval  Does/Do the nominee(s) occupy appropriate positions in the staff structure to be responsible for the adequacy of test or calibration results?  Does/Do the nominee(s) spend sufficient time in the laboratory in order to exercise adequate supervision?  Is/are the nominee(s) familiar with the quality system as documented in the quality manual and SINGLAS requirements?  Comments from technical assessor on the  nominee(s) technical qualification, experience, knowledge of test/calibration methods, competency in making critical evaluation of test/calibration results (See requirements in A.3) |  |  |  | SAC-SINGLAS 001, Clause 5 |
| **C.**  3.1(a)  3.1 (b)  (i)  (ii)  (iii)  (iv)  (v)  (vi)  (vii)  (viii)  3.1(c)  3.1(e)  3.1(f)  3.1(g)  3.1(h)  3.1(i)  3.1 (j)  3.1 (k) | **Obligations of the accredited laboratory**  Offer to all customers a standard of service consistent with the SAC terms and conditions and maintain impartiality and integrity in all operations;  Immediately notify SAC-SINGLAS on:  Any change in its legal, commercial or organisational status;  Any changes in organisation, top management and key personnel e.g. key managerial staff, management representative and approved signatories who could affect the performance or competence of the laboratory;  Plans to conduct any accredited activities outside the Republic of Singapore;  Change of resources and premises,  Any lawsuit or criminal investigation of the laboratory or its staff;  Any changes to the scope of accreditation;  Any significant changes in main policies;  Any other matters that may affect the ability of the laboratory to fulfil requirements for accreditation;  Adhere to the rules for the use of the SAC Accreditation Marks and reference to accreditation status as stipulated in SAC 02;  *Is the laboratory using Combined ILAC MRA Mark on accredited report?*  Not to use the accreditation status in such a manner as to bring SAC into disrepute and not make any statement related to the accreditation which SAC may consider misleading or unauthorized;  Provide reasonable facilities, such as accommodation, cooperation, and access to documentation, test/calibration standards, personnel and calibration/testing areas for assessors and SAC staff to discharge their duties throughout assessments and resolution of complaints;  Make prompt payment to SAC of all necessary fees levied by SAC;  Upon the withdrawal of accreditation forthwith discontinue its use of reference to accreditation and withdraw all advertising materials which contains any reference to accreditation;  Make a clear and unequivocal statement in all contacts with its customers that a certificate of accreditation in no way implies that the product or service is approved by SAC; and  Not represent or hold itself out as being the agent or partner of SAC or make any representations on behalf of SAC.  Ensure the standard of service and integrity of reports are maintained during relocation. Accredited reports can continue to be issued prior to SAC verification of continual compliance at the new location.  (NB: Should subsequent findings from SAC during the reassessment show the accreditation requirements are compromised, this may warrant for recall of reports issued.) |  |  |  | SAC 01, clause 3.1 |

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| D. | Follow up on last year findings |
| E. | Other Observation and Comments  Safety (SAC-SINGLAS 001, Clause 8) |
| F. | Additional Notes |