Name of Lab:………………………………………………………………………………

File no:………………………………….

| **No.** | **Clause** | **PART A: Procedure(s) required** | **Reference to laboratory documents[[1]](#footnote-1)** | **Remarks by Team Leader[[2]](#footnote-2)** | **Corrective Action by Laboratory / Confirmation by Team Leader[[3]](#footnote-3)** |
| --- | --- | --- | --- | --- | --- |
| **6.2 PERSONNEL** |  |  |
| 1 | 6.2.5 | The laboratory shall have procedure(s) and retain records for:1. determining the competence requirements; (see 6.2.2)
2. selection of personnel;
3. training of personnel;
4. supervision of personnel;
5. authorization of personnel;
6. monitoring competence of personnel.
 | E.g. SOP XXXClause |  | Corrective action by Lab:Confirmation by Team Leader: |
| **6.4 EQUIPMENT** |  |  |
| 2 | 6.4.3 | The laboratory shall have a procedure for handling, transport, storage, use and planned maintenance of equipment. | E.g. SOP XXX |  | Corrective action by Lab:Confirmation by Team Leader: |
| 3 | 6.4.10 | When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure. (See 7.7.1 e) |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| **6.6 EXTERNALLY PROVIDED PRODUCTS & SERVICES** |  |  |
| 4 | 6.6.2 | The laboratory shall have a procedure and retain records for:1. defining, reviewing and approving the laboratory’s requirements for externally provided products and services;
2. defining the criteria for evaluation, selection, monitoring of performance and re-evaluation of the external providers;
3. ensuring that externally provided products and services conform to the laboratory’s established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer;
4. taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.
 |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| **7.1 REVIEW OF REQUESTS, TENDERS & CONTRACTS** |  |  |
| 5 | 7.1.1 | The laboratory shall have a procedure for the review of requests, tenders and contracts. The procedure shall ensure that:1. the requirements are adequately defined, documented and understood;
2. the laboratory has the capability and resources to meet the requirements;
3. where external providers are used, the requirements of 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;
4. the appropriate methods or procedures are selected and are capable of meeting the customers' requirements.
 |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| 7.2.1 SELECTION AND VERIFICATION OF METHODS |  |  |  |
| 6 | 7.2.1.1 | The laboratory shall use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.NOTE “Method” as used in this document can be considered synonymous with the term “measurement procedure” as defined in ISO/IEC Guide 99. |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| **7.2.2 VALIDATION OF METHODS** |  |  |
| 7 | 7.2.2.4 | The laboratory shall retain the following records of validation:1. the validation **procedure** used;
2. specification of the requirements;
3. determination of the performance characteristics of the method;
4. results obtained;
5. a statement on the validity of the method, detailing its fitness for the intended use.
 |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| 7.3 SAMPLING |  |  |  |
| 8 | 7.3.1 | The laboratory shall have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling method shall address the factors to be controlled to ensure the validity of subsequent testing or calibration results. The sampling plan and method shall be available at the site where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical method.  |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| 9 | 7.3.3 | The laboratory shall retain records of sampling data that forms part of the testing or calibration that is undertaken. These records shall include, where relevant:reference to the sampling method used;  |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| **7.4 HANDLING OF TESTS OR CALIBRATION ITEMS** |  |  |
| 10 | 7.4.1 | The laboratory shall have a procedure for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items, including all provisions necessary to protect the integrity of the test or calibration item, and to protect the interests of the laboratory and the customer. |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| **7.7 ENSURING THE VALIDITY OF RESULTS** |  |  |
| 11 | 7.7.1 | The laboratory shall have a procedure for monitoring the validity of results. The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:1. use of reference materials or quality control materials;
2. use of alternative instrumentation that has been calibrated to provide traceable results;
3. functional check(s) of measuring and testing equipment;
4. use of check or working standards with control charts, where applicable;
5. intermediate checks on measuring equipment;
6. replicate tests or calibrations using the same or different methods;
7. retesting or recalibration of retained items;
8. correlation of results for different characteristics of an item;
9. review of reported results;
10. intralaboratory comparisons;
11. testing of blind sample(s).
 |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| **7.9 COMPLAINTS** |  |
| 12 | 7.9.1 | The laboratory shall have a documented process to receive, evaluate and make decisions on complaints. |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| 13 | 7.9.2 | A description of the handling process for complaints shall be available to any interested party on request. Upon receipt of a complaint, the laboratory shall confirm whether the complaint relates to laboratory activities that it is responsible for and, if so, shall deal with it. The laboratory shall be responsible for all decisions at all levels of the handling process for complaints. |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| 14 | 7.9.3 | The process for handling complaints shall include at least the following elements and methods: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. |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| **7.10 NONCONFORMING WORK** |  |  |
| 15 | 7.10.1 | The laboratory shall have a procedure that shall be implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures or the agreed requirements of the customer (e.g. equipment or environmental conditions are out of specified limits, results of monitoring fail to meet specified criteria). The procedure shall ensure that:1. the responsibilities and authorities for the management of nonconforming work are defined;
2. actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;
3. an evaluation is made of the significance of the nonconforming work, including an impact analysis on previous results;
4. a decision is taken on the acceptability of the nonconforming work;
5. where necessary, the customer is notified and work is recalled;
6. the responsibility for authorizing the resumption of work is defined.
 |  |  | Corrective action by Lab:Confirmation by Team Leader: |

| **No** | **Clause** | **PART B: Other type of documents required** | **Reference to laboratory documents1** | **Remarks by Team Leader2** | **Corrective Action by Laboratory / Confirmation by Team Leader3** |
| --- | --- | --- | --- | --- | --- |
| **4 GENERAL REQUIREMENTS** |  |  |
| 1 | 4.2.4 | Personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory’s behalf, shall **keep confidential** all information obtained or created during the performance of laboratory activities, except as required by law. |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| **5 STRUCTURAL REQUIREMENTS** |  |  |
| 2 | 5.1 | The laboratory shall be a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities.NOTE: Evidence of legal entity e.g. Register of Company (ROC), Memorandum of Association (MoA), Government Act or Regulation. |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| 3 | 5.2 | The laboratory shall identify management that has overall responsibility for the laboratory. |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| 4 | 5.3 | The laboratory shall **define and document** the range of laboratory activities for which it conforms with this document. The laboratory shall only claim conformity with this document for this range of laboratory activities, which excludes externally provided laboratory activities on an ongoing basis.NOTE: Laboratory to define scope of testing and/or calibration and relevant activities carried out. |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| 5 | 5.4 | Laboratory activities shall be carried out in such a way as to meet the requirements of this document, the laboratory’s customers, regulatory authorities and organizations providing recognition. This shall include laboratory activities performed in all its permanent facilities, at sites away from its permanent facilities, in associated temporary or mobile facilities or at a customer's facility.NOTE: The laboratory to provide information on related regulatory requirements (if any). |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| 6 | 5.5 | The laboratory shall:1. define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between management, technical operations and support services;
2. specify the responsibility, authority and interrelationship of all personnel who manage, perform or verify work affecting the results of laboratory activities;
3. document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.
 |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| 7 | 5.6 | The laboratory shall have personnel who, irrespective of other responsibilities, have the authority and resources needed to carry out their duties, including:1. implementation, maintenance and improvement of the management system;
2. identification of deviations from the management system or from the procedures for performing laboratory activities;
3. initiation of actions to prevent or minimize such deviations;
4. reporting to laboratory management on the performance of the management system and any need for improvement;
5. ensuring the effectiveness of laboratory activities.
 |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| **6.2 PERSONNEL** |  |  |
| 8 | 6.2.2 | The laboratory shall **document** the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience.  |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| 9 | 6.2.4 | The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities. |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| 10 | 6.2.6 | The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:development, modification, verification and validation of methods;analysis of results, including statements of conformity or opinions and interpretations;report, review and authorization of results. |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| **6.3 FACILITIES & ENVIRONMENTAL CONDITIONS** |  |  |
| 11 | 6.3.2 | The requirements for facilities and environmental conditions necessary for the performance of the laboratory activities shall be documented. |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| **6.4 EQUIPMENT** |  |  |
| 12 | 6.4.7 | The laboratory shall establish a calibration programme, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.NOTE: Calibration programme to be submitted. |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| **7.3 SAMPLING** |  |  |
| 13 | 7.3.1 | The laboratory shall have a sampling plan and method when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling method shall address the factors to be controlled to ensure the validity of subsequent testing or calibration results. The sampling plan and method shall be available at the site where sampling is undertaken. Sampling plans shall, whenever reasonable, be based on appropriate statistical methods. | If applicable |  | Corrective action by Lab:Confirmation by Team Leader: |
| **8.1.3 OPTION B** |  |  |
| 14 | 8.1.3 | A laboratory that has established and maintains a management system, in accordance with the requirements of ISO 9001, and that is capable of supporting and demonstrating the consistent fulfilment of the requirements of Clauses 4 to 7, also fulfils at least the intent of the management system requirements specified in 8.2 to 8.9.NOTE: Laboratory that implement Option B to submit relevant documents that address the requirements of Option A. |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| **8.2 MANAGEMENT SYSTEMS DOCUMENTATION (OPTION A)** |  |  |
| 15 | 8.2.2 | The policies and objectives shall address the competence, impartiality and consistent operation of the laboratory.NOTE: The laboratory to establish measureable objectives in order to comply with Clause 8.9.2 b) - fulfilment of objectives. |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| 16 | 8.2.4 | All documentation, processes, systems, records, related to the fulfilment of the requirements of this document shall be included in, referenced from, or linked to the management system. |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| **8.3 CONTROL OF MANAGEMENT SYSTEM DOCUMENTS (OPTION A)** |  |  |
| 17 | 8.3.1 | The laboratory shall control the documents (internal and external) that relate to the fulfilment of this document. |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| 18 | 8.3.2 | The laboratory shall ensure that:documents are approved for adequacy prior to issue by authorised personnel;1. documents are periodically reviewed, and updated as necessary;
2. changes and the current revision status of documents are identified;
3. relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;
4. documents are uniquely identified;
5. the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose.
 |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| **8.8 INTERNAL AUDIT (OPTION A)** |  |  |
| 19 | 8.8.1 | The laboratory shall conduct internal audits at planned intervals to provide information on whether the management system:1. conforms to:
* the laboratory’s own requirements for its management system, including the laboratory activities;
* the requirements of this document;
1. is effectively implemented and maintained.
 | To be verified during on-site assessment. |  | Corrective action by Lab:Confirmation by Team Leader: |
| 20 | 8.8.2. | The laboratory shall:1. 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;
2. **define the audit criteria** and **scope for each audit**;
3. ensure that the results of the audits are reported to relevant management;
4. implement appropriate correction and corrective actions without undue delay;
5. retain records as evidence of the implementation of the audit programme and the audit results.
 |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| **8.9 MANAGEMENT REVIEW (OPTION A)** |  |  |
| 21 | 8.9.1 | The laboratory management shall review its management system at planned intervals, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document. | To be verified during on-site assessment. |  | Corrective action by Lab:Confirmation by Team Leader: |
| 22 | 8.9.2 | The inputs to management review shall be recorded and shall include information related to the following:1. changes in internal and external issues that are relevant to the laboratory;
2. fulfilment of objectives;
3. suitability of policies and procedures;
4. status of actions from previous management reviews;
5. outcome of recent internal audits;
6. corrective actions;
7. assessments by external bodies;
8. changes in the volume and type of the work or in the range of laboratory activities;
9. customer and personnel feedback;
10. complaints;
11. effectiveness of any implemented improvements;
12. adequacy of resources;
13. results of risk identification;
14. outcomes of the assurance of the validity of results; and
15. other relevant factors, such as monitoring activities and training.
 |  |  | Corrective action by Lab:Confirmation by Team Leader: |

| **No** | **Clause** | **PART C: Requirement related to risk** | **Reference to laboratory documents1** | **Remarks by Team Leader2** | **Corrective Action by Laboratory / Confirmation by Team Leader3** |
| --- | --- | --- | --- | --- | --- |
| **4.1 IMPARTIALITY** |  |  |
| 1 | 4.1.4 | The laboratory shall identify risks to its impartiality on an on-going basis. This shall include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. However, such relationships do not necessarily present a laboratory with a risk to impartiality. |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| 2 | 4.1.5 | If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk. |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| **8.5 ACTIONS TO ADDRESS RISKS AND OPPORTUNITIES** |  |  |
| 3 | 8.5.2 | The laboratory shall plan:1. actions to **address these risks** and opportunities;
2. how to:
* integrate and implement these actions into its management system;
* evaluate the effectiveness of these actions.
 |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| 4 | 8.5.3 | Actions taken to address risks and opportunities shall be proportional to the potential impact on the validity of laboratory results.NOTE: Laboratory to provide relevant records |  |  | Corrective action by Lab:Confirmation by Team Leader: |
| **8.9 MANAGEMENT REVIEW (OPTION A)** |  |  |
| 5 | 8.9.2 | The inputs to management review shall be recorded and shall include information related to the following:m) **results of risk identification**; |  |  | Corrective action by Lab:Confirmation by Team Leader: |

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| --- |
| **Prepared by (Laboratory authorised personnel)**Name: Date: |

**To be completed during assessment:**

|  |  |
| --- | --- |
| **Reviewed by Team Leader**Name:Date: | **Acknowledge by Laboratory authorised personnel**Name: Date: |

Note:

* Team Leader to upload the completed LA 201-7 in the e-Accreditation system.
1. **Note:**

 To be completed by laboratory prior submission of accreditation application [↑](#footnote-ref-1)
2. To be completed by Team Leader during Adequacy Audit [↑](#footnote-ref-2)
3. To be filled up by laboratory after Adequacy Audit and submit to Standards Malaysia. Team Leader to review and confirm on the acceptance of corrective action taken by the laboratory [↑](#footnote-ref-3)