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| **DETAILS OF ASSESSMENT** |
| **ORGANISATION** |  |
| **LABORATORY REFERENCE NUMBER** |  |
| **TYPE OF ASSESSMENT** | **Preliminary Visit Initial Assessment** **Assessment Extension****Extraordinary visit Re-assessment***(Specify:…………………………….)* |
| **LABORATORY REPRESENTATIVE** |  |
| **DOCUMENTATION USED** | **Quality Manual Procedures Manual** **Work Instructions Records****Standard Operating Procedures**  |
| **NAME OF TEAM LEADER** |  |
| **SIGNATURE**  |  |
| **DATE OF REVIEW** |  |
| **DATE(S) OF ASSESSMENT** |  |

***NOTE: 1****. Compliance = C, Non-compliance = NC, Not Applicable =NA*

**2. MAURITAS R DOCUMENTS REQUIREMENTS**

**Assessors need to check conformance of the laboratory with respect to the requirements of MAURITAS R1, R2, R3 and R4 Regulations:**

**MAURITAS R1 – Regulations to be met by certification bodies, inspection bodies and calibration and testing laboratories**

|  |  |  |  |
| --- | --- | --- | --- |
| **Clause** | **MAURITAS R1 Requirement** | **C/NC/****NA** | **Evidence checked** |
| **7.1 d** | TL to check whether the laboratory makes reference to accreditation in such a manner so as not to bring MAURITAS into disrepute nor in a misleading manner?  |  |  |
| **7.1 g** | TL to check contracts between labs and clients.  |  |  |
| **7.1 i** | TL to check how lab ensures that its clients do not reproduce part of the test/calibration reports?  |  |  |
| **9.2** | TL to check whether there has been any changes with respect to: ‘legal, commercial or organisational status’, ‘organisation and management e.g key managerial or technical’, ‘policies or procedures’, ‘premises’, ‘equipment, facilities, working environment or other resources’, ‘technical signatories’ and ‘compliance with MAURITAS requirements’ within the organisation since the last visit of MAURITAS? Did the laboratory inform MAURITAS within 1 week of these changes?  |  |  |
| **9.3** | TL to check whether lab has been able to comply with the new Regulations and relevant criteria of competence within the deadline given by MAURITAS? |  |  |

**MAURITAS R2 – Regulations to be met by applicant and accredited CABs**

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| --- | --- | --- | --- |
| **Clause** | **MAURITAS R2 Requirement** | **C/NC/NA** | **Evidence checked** |
| **10** | Assessment team to confirm whether all documents and access were provided during the assessment. |  |  |
| **17.6** | Assessment Team to check in case of a recent previous suspension of accreditation, whether the laboratory discontinued making any reference to accreditation with MAURITAS after suspension. |  |  |

**3. REVIEW: ISO/IEC 17025:2017**

| **CLAUSE** | **MANAGEMENT REQUIREMENTS** |  **C/NC/** **NA** | **EVIDENCE CHECKED** |
| --- | --- | --- | --- |
| **4**  | **General requirements:** |  |  |
| **4.1** | **Impartiality** |  |  |
| **4.1.1** | Are the laboratory activities undertaken impartially and structured and managed so as to safeguard impartiality? |  |  |
| **4.1.2** | Is the laboratory management committed to impartiality? |  |  |
| **4.1.3** | Is the laboratory responsible for the impartiality of its laboratory activities and does it allow commercial, financial or other pressures to compromise impartiality?  |  |  |
| **4.1.4** | Does the laboratory identify risks to its impartiality on an on-going basis? |  |  |
| **4.1.4** | Does this include those risks that arise from its activities, or from its relationships, or from the relationships of its personnel?  |  |  |
| **4.1.5** | If a risk to impartiality is identified, is the laboratory able to demonstrate how it eliminates or minimizes such risk? |  |  |
| **4.2** | **Confidentiality** |  |  |
| **4.2.1** | Is the laboratory responsible, through legally enforceable commitments, for the management of all information obtained or created during the performance of laboratory activities? |  |  |
|  | Does the laboratory inform the customer in advance, of the information it intends to place in the public domain? |  |  |
| Except for information that the customer makes publicly available, or when agreed between the laboratory and the customer (e.g. for the purpose of responding to complaints), Are all other information considered proprietary information and regarded as confidential? |  |  |
| **4.2.2** | When the laboratory is required by law or authorized by contractual arrangements to release confidential information, is the customer or individual concerned, unless prohibited by law, notified of the information provided? |  |  |
| **4.2.3** | Is information about the customer obtained from sources other than the customer (e.g. complainant, regulators) kept confidential between the customer and the laboratory? Is the provider (source) of this information kept confidential to the laboratory and when it is shared with the customer, is there agreement by the source? |  |  |
| **4.2.4** | Do the personnel, including any committee members, contractors, personnel of external bodies, or individuals acting on the laboratory’s behalf, keep confidential all information obtained or created during the performance of laboratory activities? |  |  |
| **5** | **Structural requirements** |  |  |
| **5.1** | Is the laboratory a legal entity, or a defined part of a legal entity, that is legally responsible for its laboratory activities? |  |  |
| **5.2** | Does the laboratory identify management that has overall responsibility for the laboratory? |  |  |
| **5.3** | Does the laboratory define and document the range of laboratory activities for which it conforms with this document? |  |  |
| **5.3** | Does the laboratory claim only conformity with this document for this range of laboratory activities, which excludes externally, provided laboratory activities on an ongoing basis? |  |  |
| **5.4** | Are the laboratory activities carried out in such a way so as to meet the requirements of this document, the laboratory’s customers, regulatory authorities and organizations providing recognition?Does this 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? |  |  |
| **5.5** | Does the laboratory: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;
 |  |  |
| **5.5** | 1. document its procedures to the extent necessary to ensure the consistent application of its laboratory activities and the validity of the results.
 |  |  |
| **5.6** | Does the laboratory 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?
 |  |  |
| **5.7** | Does laboratory management ensure that:1. communication takes place regarding the effectiveness of the management system and the importance of meeting customers’ and other requirements;
2. the integrity of the management system is maintained when changes to the management system are planned and implemented?
 |  |  |
| **6** | **Resources requirements** |  |  |
| **6.6** | **Externally provided products and services** |  |  |
| **6.6.1** | Doesthe laboratory ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services:1. are intended for incorporation into the laboratory’s own activities;
2. are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider;
3. is used to support the operation of the laboratory?
 |  |  |
| **6.6.2** | Does the laboratory 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?
 |  |  |
| **6.6.3** | Does the laboratory communicate its requirements to external providers for:1. the products and services to be provided;
2. the acceptance criteria;
3. competence, including any required qualification of personnel;
4. activities that the laboratory, or its customer, intends to perform at the external provider’s premises?
 |  |  |
| **7** | **Process requirements** |  |  |
| **7.1**  | **Review of requests, tenders and contracts** |  |  |
| **7.1.1** | Does the laboratory have a procedure for the review of requests, tenders and contracts? |  |  |
| **7.1.1** | Does the procedure 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?
 |  |  |
| **7.1.2** | Does the laboratory inform the customer when the method requested by the customer is considered to be inappropriate or out of date? |  |  |
| **7.1.3** | Arethe specification or standard, and the decision rule clearly defined when the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance)?Is the decision rule selected communicated to and agreed with, the customer unless inherent in the requested specification or standard? |  |  |
| **7.1.4** | Areany differences between the request or tender and the contract resolved before laboratory activities commence?Areeach contract acceptable both to the laboratory and the customer?Dodeviations requested by the customer impact the integrity of the laboratory or the validity of the results? |  |  |
| **7.1.5** | Is the customer informed of any deviation from the contract? |  |  |
| **7.1.6** | If a contract is amended after work has commenced, is the contract review repeated and are any amendments made communicated to all affected personnel? |  |  |
| **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?Example by:1. providing reasonable access to relevant areas of the laboratory to witness customer-specific laboratory activities;
2. preparation, packaging, and dispatch of items needed by the customer for verification purposes?
 |  |  |
| **7.1.8** | Are records of reviews, including any significant changes, retained?Are records also retained of pertinent discussions with a customer relating to the customer’s requirements or the results of the laboratory activities? |  |  |
| **7.9** | **Complaints** |  |  |
| **7.9.1** | Doesthe laboratory have a documented process to receive, evaluate and make decisions on complaints? |  |  |
| **7.9.2** | Is description of the handling process for complaints available to any interested party on request?Upon receipt of a complaint, does the laboratory confirm whether the complaint relates to laboratory activities that it is responsible for?Isthe laboratory responsible for all decisions at all levels of the handling process for complaints? |  |  |
| **7.9.3** | Does the process for handling complaints include at least the following elements and methods:1. description of the process for receiving, validating, investigating the complaint, and deciding what actions are to be taken in response to it;
2. tracking and recording complaints, including actions undertaken to resolve them;

 c) ensuring that any appropriate action is taken? |  |  |
| **7.9.4** | Isthe laboratory receiving the complaint responsible for gathering and verifying all necessary information to validate the complaint? |  |  |
| **7.9.5** | Whenever possible, does the laboratory acknowledge receipt of the complaint, and provide the complainant with progress reports and the outcome? |  |  |
| **7.9.6** | Arethe outcomes to be communicated to the complainant made by, or reviewed and approved by, individual(s) not involved in the original laboratory activities in question? |  |  |
| **7.9.7** | Whenever possible, does the laboratory give formal notice of the end of the complaint handling to the complainant? |  |  |
| **7.10** | **Nonconforming work** |  |  |
| **7.10.1** | Does the laboratory have a procedure that is 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)? |  |  |
| **7.10.1** | Does the procedure 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?
 |  |  |
| **7.10.2** | Does the laboratory retain records of nonconforming work and actions as specified in 7.10.1, bullets b) to f)? |  |  |
| **7.10.3** | Where the evaluation indicates that the nonconforming work could recur, or that there is doubt about the conformity of the laboratory’s operations with its own management system, does the laboratory implement corrective action? |  |  |
| **7.11** | **Control of data and information management** |  |  |
| **7.11.1** | Does the laboratory have access to the data and information needed to perform laboratory activities?  |  |  |
| **7.11.2** | Isthe laboratory information management system(s) used for the collection, processing, recording, reporting, storage or retrieval of data validated for functionality, including the proper functioning of interfaces within the laboratory information management system(s) by the laboratory before introduction?Whenever there are any changes, including laboratory software configuration or modifications to commercial off-the-shelf software, are they authorized, documented and validated before implementation? |  |  |
| **7.11.3** | Is the laboratory information management system(s):1. protected from unauthorized access;
2. safeguarded against tampering and loss;
3. 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;
4. maintained in a manner that ensures the integrity of the data and information;
5. include recording system failures and the appropriate immediate and corrective actions?
 |  |  |
| **7.11.4** | When a laboratory information management system is managed and maintained off-site or through an external provider, does the laboratory ensure that the provider or operator of the system complies with all applicable requirements of this document? |  |  |
| **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** | Are calculations and data transfers checked in an appropriate and systematic manner? |  |  |
| **8** | **Management system requirements** |  |  |
| **8.1** | **Options** |  |  |
| **8.1.1** | **Generals**Does the laboratory establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results?In addition to meeting the requirements of Clauses 4 to 7, does the laboratory implement a management system in accordance with Option A or Option B? |  |  |
| **8.1.2** | **Option A**Does the management system of the laboratory address the following:* management system documentation (see 8.2);
* control of management system documents (see 8.3);
* control of records (see 8.4);
* actions to address risks and opportunities (see 8.5);
* improvement (see 8.6);
* corrective action (see 8.7);
* internal audits (see 8.8);
* management reviews (see 8.9).
 |  |  |
| **8.1.3** | **Option B**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. |  |  |
| **8.2** | **Management system documentation (Option A)** |  |  |
| **8.2.1** | Does laboratory management establish, document, and maintain policies and objectives for the fulfilment of the purposes of this document and does it ensure that the policies and objectives are acknowledged and implemented at all levels of the laboratory organization? |  |  |
| **8.2.2** | Do the policies and objectives address the competence, impartiality and consistent operation of the laboratory? |  |  |
| **8.2.3** | Does the laboratory management provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness? |  |  |
| **8.2.4** | Are all documentation, processes, systems, records, related to the fulfilment of the requirements of this document included in, referenced from, or linked to the management system? |  |  |
| **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? |  |  |
| **8.3** | **Control of management system documents (Option A)** |  |  |
| **8.3.1** | Does the laboratory control the documents (internal and external) that relate to the fulfilment of this document? |  |  |
| **8.3.2** | Does the laboratory ensure that:1. documents are approved for adequacy prior to issue by authorized personnel;
2. documents are periodically reviewed, and updated as necessary;
3. changes and the current revision status of documents are identified;
4. relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;
5. documents are uniquely identified;
6. the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose?
 |  |  |
| **8.4** | **Controls of records (Option A)** |  |  |
| **8.4.1** | Does the laboratory establish and retain or maintain legible records to demonstrate fulfilment of the requirements in this document? |  |  |
| **8.4.2** | Does the laboratory implement the controls needed for the identification, storage, protection, back-up, archive, retrieval, retention time, and disposal of its records?Does the laboratory retain records for a period consistent with its contractual obligations? Is access to these records consistent with the confidentiality commitments?Are records readily available? |  |  |
| **8.5** | **Actions to address risks and opportunities (Option A)** |  |  |
| **8.5.1** | Does the laboratory consider the risks and opportunities associated with the laboratory activities in order to:1. give assurance that the management system achieves its intended results;
2. enhance opportunities to achieve the purpose and objectives of the laboratory;
3. prevent, or reduce, undesired impacts and potential failures in the laboratory activities;
4. achieve improvement?
 |  |  |
| **8.5.2** | Does the laboratory plan:1. actions to address these risks and opportunities;
2. how to:
* integrate and implement the actions into its management system;
* evaluate the effectiveness of these actions?
 |  |  |
| **8.5.3** | Are actions taken to address risks and opportunities proportional to the potential impact on the validity of laboratory results? |  |  |
| **8.6** | **Improvement (Option A)** |  |  |
| **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?Are the feedback analysed and used to improve the management system, laboratory activities and customer service? |  |  |
| **8.7** | **Corrective action (Option A)** |  |  |
| **8.7.1** | When a nonconformity occurs, does the laboratory:1. react to the nonconformity and, as applicable:
* take action to control and correct it;
* address the consequences;
1. evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
* reviewing and analyzing the non-conformity
* determining the causes of the non-conformity
* determine if similar non-conformities exist or could potentially occur
1. implement any action needed;
2. review the effectiveness of any corrective action taken;
3. update risks and opportunities determined during planning, if necessary;
4. make changes to the management system, if necessary?
 |  |  |
| **8.7.2** | Are corrective actions appropriate to the effects of the nonconformities encountered? |  |  |
| **8.7.3** | Does the laboratory retain records as evidence of:1. the nature of the nonconformities, cause(s) and any subsequent actions taken;
2. the results of any corrective action?
 |  |  |
| **8.8** | **Internal audits (Option A)** |  |  |
| **8.8.1** | Does the laboratory 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?
 |  |  |
| **8.8.2** | Does the laboratory: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;
 |  |  |
| **8.8.2** | 1. define the audit criteria and scope for each audit;
2. ensure that the results of the audits are reported to relevant management;
3. implement appropriate correction and corrective actions without undue delay;
4. retain records as evidence of the implementation of the audit programme and the audit results?
 |  |  |
| **8.9** | **Management reviews (Option A)** |  |  |
| **8.9.1** | Does the laboratory management 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? |  |  |
| **8.9.2** | Are the inputs to management review recorded?Does the information include 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;
 |  |  |
| **8.9.2** | 1. corrective actions;
2. assessments by external bodies;
3. changes in the volume and type of the work or in the range of laboratory activities;
4. customer and personnel feedback;
5. complaints;
6. effectiveness of any implemented improvements;
7. adequacy of resources;
8. results of risk identification;
9. outcomes of the assurance of the validity of results; and
10. other relevant factors, such as monitoring activities and training?
 |  |  |
| **8.9.3** | Do the outputs from the management review record all decisions and actions related to, at least:1. the effectiveness of the management system and its processes;
2. improvement of the laboratory activities related to the fulfilment of the requirements of this document;
3. provision of required resources;
4. any need for change?
 |  |  |

🗆**The Team Leader has performed review of the documentation of the laboratory prior to the assessment.**

**Verified by:**

**Name:……………………….. Signature:……………………… Date:………………**