VERTICAL ASSESSMENT ISO/IEC 17025:2017

FOR TESTING AND CALIBRATION LABORATORIES

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| **Name of Laboratory** | | |  | |
| **Assessment Type**  *(Initial Assessment, Assessment, Re-Assessment, Extension of Scope, etc..)* | | |  | |
| **Name of Assessor / Technical Expert / MAURITAS Staff** | | |  | |
| **Date(s) of Assessment** | | |  | |
| **Field of Testing / Calibration** | | |  | |
| **Laboratory Representative** | | |  | |
| **Certificate or Report** *(Select one or more final Report / Certificate)*  *Record at least the report number, date & the parameter(s), as on the Schedule of Accreditation / draft schedule.* | | | | |
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| **Name of analyst(s) & Qualifications** | | | | |
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| ***Clause*** | **REQUIREMENTS AND COMMENTS**  *\*Compliance = C, Non-compliance = NC, Not applicable = NA*  *Notes:*   1. *Indicate WHAT has been checked and HOW requirements have been implemented.* 2. *The order of assessment need not follow the order of the checklist. Assessors are expected to know & have the standard when carrying out the vertical assessment; this checklist is designed as guidance to prompt detailed recording of the process.* 3. *Where a clause is marked as NA, reason must be provided as to why it is not applicable.*   ***REFER TO ISO/IEC 17025:2017 FOR DETAILS*** | | | **C NC**  **NA\*** |
| **7.5** | **Data recording and Technical Records** *(state which data and calculations were checked)* | | | |
| 7.5.1 -  7.5.2 | Records include the date and the identity of personnel responsible for each activity.  Records contain results, report and sufficient information to enable identification of factors affecting measurement results.  Amendments to technical records traceable to previous versions or to original observations.  Original, amended data and files are kept, including the date of alteration and person responsible. | | |  |
| ***Comments:*** | | | | |
| **6.2** | **Personnel** | | | |
| 6.2.1 - 6.2.6 | Analyst deemed as competent to perform the work and to evaluate significance of deviations; Is proof of competence available?  Personnel competence documented for each activity.  Duties, responsibilities and authorities communicated to personnel.  Records retained for: training; supervision; authorisation; monitoring of competence.  Personnel authorized to perform specific function. | | |  |
| ***Comments:*** | | | | |
| **6.3** | **Facilities and environmental conditions** | | | |
| 6.3.1 -  6.3.5 | Suitability of facilities and environmental conditions for the laboratory activities.  Requirements for facilities and environmental conditions documented.  Environmental conditions monitored, controlled and recorded.  Measures for access control, cross-contamination prevention and effective separation implemented; monitored and reviewed periodically.  Suitability of facilities or sites outside laboratory’s permanent control. | | |  |
| ***Comments:*** | | | | |
| **7.2.** | **Selection, Verification and Validation of Methods** | | | |
| 7.2.1.1 -  7.2.2.4 | Proof of confirmation of proper operation of standard methods, laboratory developed methods, non-standard methods.  Documented methods up-to-date and available to personnel.  Validation done for non-standard and laboratory-developed methods & methods used outside their validated scope; planning, development, periodic reviews and authorities.  Methods validated and availability of performance capability.  Modifications to the validation development plan approved and authorized.  Validation records retained (procedure; requirements; performance characteristics; results & statement of validity of the method). | | |  |
| ***Comments:*** | | | | |
| **7.6** | **Uncertainty of Measurement** | | | |
| 7.6.1 - 7.6.3 | Contributions to measurement uncertainty identified.  Calibration laboratories (including in-house calibration) - evaluate the measurement uncertainty for all calibrations.  Testing laboratories - evaluate measurement uncertainty (refer to Notes in Standard). | | |  |
| ***Comments:*** | | | | |
| **7.3** | **Sampling** | | | |
| 7.3.1 - 7.3.3 | Have a sampling plan and method addressing the factors to be controlled to ensure the validity of subsequent testing or calibration results. The sampling plan and method is available at the site where sampling is undertaken.  The sampling method described selection of samples or sites, the sampling plan, the preparation and treatment of sample(s) from a substance, material or product to yield the  required item for subsequent testing or calibration.  Records of sampling data retained. | | |  |
| ***Comments:*** | | | | |
| **6.4** | **Equipment** | | | |
| 6.4.3 - 6.4.13 | Procedure for handling, transport, storage, use, maintenance.  Verification of conformity to requirements/commissioning before use.  Equipment achieves measurement accuracy or measurement uncertainty required.  Measuring equipment are calibrated ***(Refer to MAURITAS R3 and MAURITAS F3.37)***.  Appropriateness of calibration and verification programmes cover operating range.  Calibrated equipment and equipment due for calibration correctly labelled, coded or identified.  Handling / transport / storage / use to prevent contamination / unintended adjustment / deterioration of equipment  Records of calibration and verification complete, tolerances appropriate.  Intermediate checks - standard/reference materials, reference, primary, transfer and working standards ***(Refer to MAURITAS R3 and MAURITAS F3.37)***.  Calibration and reference material data are updated and implemented. Reference values  and Correction factors updated.  Equipment records; identity, software, firmware, etc. as specified in 6.4.13 a) – h) | | |  |
| ***Comments:*** | | | | |
| **6.5** | **Metrological Traceability** | | | |
| 6.5.1 - 6.5.3 | Establish and maintain metrological traceability of its measurement results.  Traceability to national standards.  Metrological traceability to an appropriate reference e.g. CRMs, Consensus standards.  ***(Refer to MAURITAS R3 and MAURITAS F3.37)*** | | |  |
| ***Comments:*** | | | | |
| **6.6** | **Externally provided products and services** | | | |
| 6.6.1 - 6.6.3 | Only suitable externally provided products and services that affect laboratory activities are used.  A procedure available and records retain for 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 this document, 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.  The laboratory communicated its requirements to external providers for 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. | | |  |
| ***Comments:*** | | | | |
| **7.4** | **Handling of test or calibration items** | | | |
| 7.4.1 - 7.4.4 | A procedure is available for the transportation, receipt, handling, protection, storage, retention, and disposal or return of test or calibration items.  A system is in place for the unambiguous identification of test or calibration items.  Deviations from specified conditions are recorded upon receipt of the test or calibration item, including consulting the customer for further instructions before proceeding. An item tested or calibrated acknowledging a deviation from specified conditions, a disclaimer is included in the report indicating which results may be affected by the deviation.  Environmental conditions are maintained, monitored and recorded when items need to be stored or conditioned under specified environmental conditions. | | |  |
| ***Comments:*** | | | | |
| **7.7** | **Ensuring the validity of results** | | | |
| 7.7.1 – 7.7.3 | Indicate how the laboratory monitors results and if the monitoring is planned and reviewed.  Monitoring data suitably recorded (e.g. control charts, statistical techniques, trends analysis etc.), evaluated and reviewed.  Monitor its performance by comparison with results of other laboratories; Proficiency Testing and Interlaboratory Comparison.  Frequency of participation in PT for the selected parameter determined by taking into consideration the risk assessment pertaining to the parameter.  Monitoring data analysed (through trend analysis). This analysis is used to control and/or improve the laboratory’s activities.  Actions taken for results found outside pre-defined criteria | | |  |
| ***Comments:*** | | | | |
| **7.8** | | **Test Report / Certificate** | | |
| 7.8.1.1 –  7.8.2.2 | | Results reviewed and authorized prior to release.  Simplified report issued with the agreement of the customer  Report/certificate include the requirements as specified in 7.8.2.1 a) – p), unless the laboratory has valid reasons for not doing so (e.g. title, name and address, method, date of issue etc.).  Data provided by a customer clearly identified.  A disclaimer is put on the report when the information is supplied by the customer and can affect the validity of results.  If the laboratory is not responsible for the sampling stage, it is stated in the report that the results apply to the sample as received. | |  |
| **MAURITAS R4** | | **Rules for the Use of MAURITAS Accreditation Symbol and Combined Mark** | | |
| Sections:  5 & 6  6.10.2.3 | | The use of MAURITAS symbol/Combined Mark /disclaimer on test/calibration report.  The use of disclaimers when the laboratory makes use of opinions and interpretations.  Assessor to check calibration labels affixed on equipment after calibration (for calibration laboratories only) | |  |
| **7.8.3** | | **Specific requirements for test reports** | | |
| 7.8.3.1 | | In addition to 7.8.2, do test reports, where necessary for Interpretation of test results, include information as specified in 7.8.3.1 a) – e) (e.g. environmental conditions, measurement uncertainty, authorities etc.) ? | |  |
| **7.8.4** | | **Specific requirements for calibration certificates** | | |
| 7.8.4.1 –  7.8.4.3 | | In addition to the requirements listed in 7.8.2, do calibration certificates include the requirements as per 7.8.4.1 a) – f)?  Is the laboratory responsible for sampling?  Calibration certificate or calibration label shall not contain any recommendation on the calibration interval except where this has been agreed with the customer. | |  |
| ***Comments:*** | | | | |
| **7.8.5** | | **Reporting sampling – specific requirements** | | |
|  | | Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, do reports include requirements as per 7.8.5 a) – f), where necessary for the interpretation of results (e.g. date of sampling, unique ID, location of sampling, environmental conditions etc.)? | |  |
| ***Comments:*** | | | | |
| **7.8.6** | | **Reporting statements of conformity** | | |
| 7.8.6.1 –  7.8.6.2 | | Decision rule documented when statement of conformity to a specification or standard is provided.  Statement of conformity clearly identifies:   1. to which results the statement of conformity applies 2. which specifications, standards or parts thereof are met or not met 3. the decision rule applied (unless it is inherent in the requested specification or standard). | |  |
| ***Comments:*** | | | | |
| **7.8.7** | | **Reporting opinions and interpretations** | | |
| 7.8.7.1 - 7.8.7.3 | | Only authorised personnel express opinions and interpretations. (Notes in Standard)  Opinions and interpretations expressed are based on the results obtained from the tested or calibrated item and clearly identified.  Record of the dialogue with the customer retained. | |  |
| ***Comments:*** | | | | |
| **7.8.8** | | **Amendments to reports** | | |
| 7.8.8.1 - 7.8.8.3 | | Any change of information clearly identified and, where appropriate, the reason for the change included in the report.  Amendments to a report after issue only made in the form of a further document, or data transfer which includes the statement “Amendment to Report, serial number or an equivalent form of wording.  A complete new report is uniquely identified and contain a reference to the original that it replaces. | |  |
| ***Comments:*** | | | | |
| **7.11** | | **Control of data** | | |
| 7.11.1 –  7.11.6 | | Access to the data and information needed to perform laboratory activities.  LIMS validated for functionality before introduction.  Competence of external service provider.  Calculations and data transfers checked in an appropriate and systematic manner. | |  |
| ***Comments:*** | | | | |

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| **Additional Assessor Notes** *(This may be used for rough notes as well)* |

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| **Signed by:**  **Assessor**  **Technical Expert and/or**  **MAURITAS Staff** | **Signature Date:** | |
| **Team Leader** |  | **Date:** |