

Requirement as ISO 17025 for accreditation of laboratory



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- It include mainly two important clauses for accreditation is given below:
 - Management requirement (4 to 4.15)
 - Technical requirement (5 to 5.10)

4. Management requirement



- 4.1 Organization
 - Legally authorized
 - Responsibility to carry out valid testing as per ISO
 - Laboratory facility should cover all works
 - Laboratory shall have managerial and technical personnel who has irrespective of other responsibilities
 - Management and personnel are free from any under internal and external commercial, financial and other pressures. Etc.

4.2 Management system



- laboratory shall document its policies, systems, programs, procedures and instructions to the extent necessary to assure the quality of the test and/or calibration results
- Top management shall provide evidence of commitment to the development and implementation of the management system and to continually improving its effectiveness.
- quality manual

4.3 Document control



- establish and maintain procedures to control all documents that form part of its management system (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.
- reviewed and approved for use by authorized personnel prior to issue.

4.4 Review of requests, tenders and contracts



- Establish and maintain policy and procedures for the review of requests, tenders and contracts.
- Requirements should adequately defined, documented and understood
- laboratory has the capability and resources to meet the requirements
- The appropriate test and/or calibration method is selected and is capable of meeting the customers requirements

4.5 Subcontracting of tests and calibrations



- unexpected reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a competent subcontractor.

4.6 Purchasing services and supplies



- laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations.
- ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations

4.7 Service to the customer



- laboratory shall be willing to 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, provided that the laboratory ensures confidentiality to other customers.

4.8 Complaints



- The laboratory shall have a policy and procedure for the resolution of complaints received from customers or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory.

4.9 Control of nonconforming testing and/or calibration work



- laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer.
- correction is taken immediately.

4.10 Improvement



- laboratory shall continually improve the effectiveness of its management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

4.11 Corrective action



- laboratory shall establish a policy and a procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations have been identified.

4.12 Preventive action



- When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.

4.13 Control of records



- laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records. Quality records shall include reports from internal audits and management reviews as well as records of corrective and preventive actions

4.14 Internal audits



- laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities to verify that its operations continue to comply with the requirements of the management system and this International Standard.
- carried out by trained and qualified personnel.

4.15 Management reviews



- the laboratory's top management shall periodically conduct a review of the laboratory's management system and testing and/or calibration activities to ensure their continuing suitability and effectiveness, and to introduce necessary changes or improvements.

5 Technical requirements



- 5.1 General
- Many factors determine the correctness and reliability of the tests and/or calibrations performed by a laboratory. These factors include contributions from:
 - human factors
 - accommodation and environmental conditions
 - test and calibration methods and method validation
 - equipment
 - measurement traceability
 - sampling
 - the handling of test and calibration items

5.2 Personnel



- laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates.

5.3 Accommodation and environmental conditions



- Laboratory facilities for testing and/or calibration, including but not limited to energy sources, lighting and environmental conditions, shall be such as to facilitate correct performance of the tests and/or calibrations.

5.4 Test and calibration methods



- laboratory shall use appropriate methods and procedures for all tests and/or calibrations within its scope.
- These include sampling, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test and/or calibration data.
- laboratory shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing and/or calibration, or both.

5.4.1 Validation of methods



- Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled.
- laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use.

5.4.2 Estimation of uncertainty of measurement



- Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. In certain cases the nature of the test method may preclude rigorous, metrological and statistically valid, calculation of uncertainty of measurement. In these cases the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation.
- Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.

5.5 Equipment



- laboratory shall be furnished with all items of sampling, measurement and test equipment required for the correct performance of the tests and/or calibrations (including sampling, preparation of test and/or calibration items, processing and analysis of test and/or calibration data).

5.6 Measurement traceability



- All equipment used for tests and/or calibrations, including equipment for subsidiary measurements (e.g. for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The laboratory shall have an established Programme and procedure for the calibration of its equipment.
- Calibration
- Testing
- Reference standards and reference materials

5.7 Sampling



- The laboratory shall have a sampling plan and procedures for sampling when it carries out sampling of substances, materials or products for subsequent testing or calibration. The sampling plan as well as the sampling procedure shall be available at the location where sampling is undertaken.

5.8 Handling of test and calibration items



- laboratory shall have procedures for the transportation, receipt, handling, protection, storage, retention and/or disposal of test and/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.

5.9 Assuring the quality of test and calibration results



- laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken.

5.10 Reporting the results



- results of each test, calibration, or series of tests or calibrations carried out by the laboratory shall be reported accurately, clearly, unambiguously and objectively, and in accordance with any specific instructions in the test or calibration methods.