DECISION TO ACCREDIT

Determine the requirements of the regulator, legislation and customer's needs prior to deciding on the standard to implement.
Process is based on the following:

- Top management's decision to be accredited
- Gap analysis
- Training of personnel
- Design the documentation (incorporate the processes you follow and align to the standard)
- Implement the documentation (ensure you comply to the procedures you write)
- Initiate contact with the accreditation body and start the application process.
- Monitor the process, perform an internal audit and determine gaps.
- Complete corrective action
- Continual implementation and maintenance of records
- Conduct another audit and management review
- Contact accreditation body to complete assessment.

ISO 17025 - IN BRIEF

Summary

The ISO 17025 standard is comprised of 5 elements:

1. Scope
2. Normative References
3. Terms and Definitions
4. Management Requirements
5. Technical Requirements

Elements 4 and 5 contain the actual accreditation requirements.

4. Management Requirements

4.1 Organisation
4.2 Management system
4.3 Document control
4.4 Review of requests, tenders and contracts
4.5 Subcontracting of tests and calibrations
4.6 Purchasing services and supplies
4.7 Service to client
4.8 Complaints
4.9 Control of nonconforming testing and/or calibration work
4.10 Improvement
4.11 Corrective action
4.12 Preventive action
4.13 Control of records
4.14 Internal audits
4.15 Management reviews

5 Technical Requirements

5.1 General
5.2 Personnel
5.3 Accommodation and environmental conditions
5.4 Test and calibration methods and method validation
5.5 Equipment
5.6 Measurement traceability
5.7 Sampling
5.8 Handling of test and calibration items
5.9 Assuring the quality of test and calibration results
5.10 Reporting the results

ISO 17025 is not an easy read for anyone. The following pages summarize the key ideas in each element of the standard.

4.0 Management Requirements

4.1 Organisation

Laboratory must be legally identifiable
Identify permanent site, temporary sites or mobile facility
Identify and outline the approach to eliminate potential conflicts of interest within the overall organization.
Protect confidential and proprietary information pertaining to the customer and organisation
Outline the manner/approach taken to avoid activities that would diminish confidence in the laboratory.
Compile the organogram outlining the flow of responsibility, accountability and the inter-relationships within the laboratory, with the focus from the parent organisation
Discuss the roles and responsibilities of technical personnel and management.
Appoint a quality manager for the laboratory.
Appoint deputies for key managerial personnel.

4.2 Management System

Establish a quality management system and document all policies, procedures, working instructions and forms/records.
Create a Quality Manual, to include:

- a quality policy statement (management commitment to good professional practice, standards of service, objectives, personnel requirements, management commitment to comply with ISO 17025);
- structure of documentation (outline the tiers);
- management roles and responsibilities.

Ensure records are kept of all activities supporting your quality system.
Top management has an imperative role within the QMS and as such there should be proper channels of communication and ensure that there are records of communication pertaining to ensuring the awareness and improvement to the QMS to the personnel

4.3 Document Control

Write procedures that are valuable to the end user.
Control all procedures and identify and track all documents(internal and external source)
Create and maintain a Master List and
distribution list of documents.

Ensure that only authorized documents are in use.
Periodically review all documents and revise as necessary.
Remove invalid or obsolete documents from use immediately.
Uniquely identify each quality system document.
Define and control the document revision process.

4.4 Review of Requests, Tenders, and Contracts

Clearly understand customer requirements.
Keep records of review.
Review sub-contracted work.
Notify customer of any deviations from the contract.
Amend contracts as necessary, repeat the review process, and ensure that amendments are communicated to all affected personnel.

4.5 Subcontracting of Tests and Calibrations

Choose competent subcontractors who comply with ISO 17025 or provide a description of the process followed to audit the companies
Notify the customer that subcontractors are being used.
Subcontractors must be approved by the customer, preferably in writing whenever possible.
Maintain the register of sub contractors and the evaluation documentation

4.6 Purchasing Services and Supplies

Evaluate suppliers of goods and services that are critical to the quality of testing and calibration.
Maintain records of the evaluation and approved suppliers list
Inspect/verify goods and services before use.

4.7 Service to the Client

Understand the customer's needs and keep them informed of delays or deviations.
Seek feedback from the customer and utilize customer surveys.
In most instances the decision to accredit is voluntary based on the requirements of the customer and if one of the key objectives of an organization is to ensure excellent service delivery then the process of evaluation must be designed to ensure that the organization is able to meet/exceed to the client’s needs.

4.8 Complaints

Have a procedure for resolving complaints. Record all complaints, investigations and responsible persons and actions taken.

4.9 Control of non-conforming testing/calibration work

Assign responsibility and authority for handling nonconforming work.
Evaluate the significance of the non-conformity.
Take timely corrective action.
Notify the customer of non-conforming work if necessary.

4.10 Improvement

Based on the evaluation of all the critical areas to allow for the enhancement of the QMS and continuing suitability

4.11 Corrective Action

Find the "root cause" of all non-conforming work produced by the laboratory. Root cause analysis is complex and must be conducted with the aim of identifying the root cause and not superficially such as labeling the incident as “negligence” Select and implement the action most likely to eliminate the cause of the problem.
Corrective action should be appropriate to the magnitude and risk of the problem.
Monitor progress of the corrective action to ensure effectiveness.
Document and implement any changes indicated by the corrective action.
Evaluate the seriousness of the non conformity and schedule an audit of the laboratory if the nonconformity brings laboratory integrity into question.

4.12 Preventive Action

Identify and record needed improvements and potential non-conformities identified during the course of work.
Plan and implement action plans for preventive action.
Ensure effectiveness of the preventive action and monitor process.

4.13 Control of Records

Keep records of the quality management system and of technical activity.
Store, access and dispose the records suitably.
Establish retention times.
Mistakes in recording results will be crossed out and initialed, but not erased or colored over

4.14 Internal Audits

Audit the laboratory's activities at least annually. Ensure that all the clauses/elements of the standard are addressed. Create the audit schedule
If possible auditors should be independent of the audited facility.
Ensure that trained and competent auditors are used.
Keep records
Ensure that the internal audit is conducted internally and is focused. Plan, prepare and conduct the audit to ensure that you identify gaps and correct accordingly.
Take timely corrective action if problems are found.
Follow up on corrective action to ensure its effectiveness.

4.15 Management Reviews

Top management had set the objectives of the organization . Thus top management will periodically review the laboratory's quality system and activity. This will be conducted by reviewing all the critical areas which will allow one to determine if the objectives were met and to conclude on the effectiveness of the QMS and design action plans from the identified areas for improvements.

5.0 Technical Requirements

5.1 General

Many factors contribute to the correctness and reliability of tests and/or calibrations. The laboratory must account for these factors. 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

Only competent, qualified personnel can execute procedures. Ensure all personnel are declared competent

Formulate goals for the education, training, and skills of personnel.

Identify training needs and provide training.

Keep records of authorization, competence, qualifications, training, and experience of personnel.

Maintain updated cv's, job descriptions for all personnel involved in tests or calibrations.

5.3 Accommodation and environmental conditions

Provide proper power, lighting, and environment to facilitate work.

Maintain the specified environment for testing.

Monitor, control and record environmental conditions

Prevent cross-contamination by separation of activities.

Control the access to testing areas.

Ensure good housekeeping.

5.4 Test and Calibration Methods and Method Validation

5.4.1 General

Use appropriate test and calibration methods.

Estimate the uncertainty of measurement where appropriate.

Keep instructions for the use of all equipment up-to-date and readily available.

Deviation from established methods shall be documented and justified.

5.4.2 Selection of Methods

Use validated test methods that are suitable for the task and which meet the needs of the customer.
Methods published in international standards are preferred.
Laboratory-developed methods may be used if they are validated.

5.4.3 Laboratory-developed methods

The introduction of laboratory-developed methods will be planned and effective communication will be ensured.

5.4.4 Non-standard methods

Non-standard methods will be approved by the customer and appropriately validated before use.

5.4.5 Validation of methods

Validation requires objective evidence that the selected method meets the requirements.
All test and calibration methods must be validated.
Record the results of validation and the procedure used for validation.
The range and accuracy of values obtainable from validated methods shall be relevant to the customer's needs.

5.4.6 Estimation of uncertainty of measurement

Calibration and testing laboratories will estimate the uncertainty of all measurements.
Where rigorous uncertainty analysis cannot be done, all relevant uncertainty components will be identified and a reasonable estimation of their magnitude will be made.

5.4.7 Control of data

Calculations and data transfers shall be systematically checked.
Validate and document all software written by laboratory personnel.
Protect the data generated in the laboratory.
Maintain the computers to ensure the integrity of test and calibration data.

5.5 Equipment

Provide equipment that is capable of achieving the required accuracy.
Calibrate equipment before use.
Only authorized personnel will operate equipment.
Maintain a calibration record for each piece of equipment.
Protect and maintain equipment.
Remove defective or questionable equipment from use.
Examine the effect of having used defective or questionable equipment.
Update software to reflect changes in equipment parameters or correction factors.
Calibration status will be displayed on all equipment.
Prevent unauthorized adjustment of equipment.
Maintain the list of equipment and calibration program

5.6 Measurement Traceability

Calibrate equipment before use.
All equipment must have traceability to national standards.

Reference standards shall be calibrated by a suitable agency.

5.7 Sampling

If sampling is employed, the sampling plan must be statistically justified.
Document requests by the customer for deviations from the sampling plan.
Follow procedures for sampling and record the results.

5.8 Handling of Test and Calibration Items

Ensure that the procedure describes the transportation, receipt and handling, protection, storage, retention and disposal of items
Identify all items, ensure unique markings/labeling
On receipt of an item, inspect it for damage, abnormality, and suitability for testing.
Provide safe storage facilities.

5.9 Assuring Quality of Test and Calibration Results Monitor and ensure the validity of tests/calibrations through:

- regular use of certified reference materials and/or internal quality control using secondary reference materials
- participation in inter-laboratory comparisons or proficiency testing programs
- replicate tests or calibrations using the same or different methods
- re-testing or re-calibration of retained items
- correlation of results for different characteristics of an item

Quality control data should be analysed and trends identified, where there are out of limits, investigations and planned actions must be implemented to prevent incorrect results from being reported

5.10 Reporting Results

Identify the process to follow for internal and/or external customers. For internal customers you may report in a simplified manner.
Report the results of each test or calibration, note the relevant disclaimer.
Test reports and calibration certificates shall include a list of the items tested.
Calibration certificates shall include test conditions, measurement uncertainty and traceability.