ISO 17025 - In a nutshell

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.

Management Requirements
- Organization
- Quality system
- Document control
- Review of requests, tenders and contracts
- Subcontracting of tests and calibrations
- Purchasing services and supplies
- Service to client
- Complaints
- Control of nonconforming testing and/or calibration work
- Corrective action
- Preventive action
- Control of records
- Internal audits
- Management reviews

Technical Requirements
- General
- Personnel
- Accommodation and environmental conditions
- Test and calibration methods and method validation
- Equipment
- Measurement traceability
- Sampling
- Handling of test and calibration items
- Assuring the quality of test and calibration results
- 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 Organization

Laboratory must be legally identifiable.
Identify and eliminate potential conflicts of interest within the overall organization.
Identify and eliminate departures from the quality system.
Protect confidential and proprietary information.
Avoid activities that would diminish confidence in the laboratory.
Define the organization of the laboratory and the inter-relationships within the laboratory.
Have technically competent management.
Appoint a quality manager for the laboratory.
Appoint deputies for key managerial personnel.

4.2 Quality System

Establish a quality system and document all policies, systems, procedures, and instructions.
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;
- management roles and responsibilities.

Ensure records are kept of all activities supporting your quality system.

4.3 Document Control

Write procedures that are valuable to the end user.
Control all procedures and identify and track all documents.
Create and maintain a Master 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 only competent subcontractors who comply with ISO 17025.
Notify the customer that subcontractors are being used.
Subcontractors must be approved by the customer, whenever possible.

4.6 Purchasing Services and Supplies
Evaluate suppliers of goods and services that are critical to the quality of testing and calibration.
Inspect 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.

4.8 Complaints
Have a procedure for resolving complaints.
Record all complaints 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 corrective action.
Notify the customer of non-conforming work.

4.10 Corrective Action
Find the "root cause" of all non-conforming work produced by the laboratory.
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.
Schedule an audit of the laboratory if the nonconformity brings laboratory integrity into question.

4.11 Preventive Action
Identify needed improvements and potential non-conformities.
Plan preventive action.
Ensure effectiveness of the preventive action.

4.12 Control of Records

Keep records of the quality system and of technical activity.
Store the records suitably.
Establish retention times.
Keep complete records of calibration results, made at the time of the tests.
Mistakes in recording results will be crossed out and initialed, but not erased.

4.13 Internal Audits

Audit the laboratory's activities at least annually.
Auditors should be independent of the audited facility.
Take timely corrective action if problems are found.
Follow up on corrective action to ensure its effectiveness.

4.14 Management Reviews

Laboratory executive management will periodically review the laboratory's quality system and activity.

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.

5.2 Personnel

Only competent, qualified personnel can execute procedures.
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 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.
Prevent cross-contamination by incompatible 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.

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
Protect calibration/testing items.
Identify all items, to prevent confusion with similar items.
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:
- certified 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

5.10 Reporting Results
Report the results of each test or calibration.
Include all information requested by the customer.
Test reports and calibration certificates shall include a list of the items tested.
Test reports shall include measurement uncertainty and a statement of pass/fail with respect to requirements/specifications.
Calibration certificates shall include test conditions, measurement uncertainty and traceability.
Calibration certificates shall not recommend a calibration interval.
If possible, calibrate an instrument before and after an adjustment or repair.
Subcontractors doing calibrations will issue calibration certificates for their work.