17025 COMPLIANCE

01 General Requirements
02 Structural Requirements
03 Resource Requirements
04 Process Requirements
05 System Requirements
GENERAL OVERVIEW OF ISO 17025

ISO 17025 - General requirements for the competence of testing and calibration laboratories – 3rd Edition, 2017

• General Requirements
• Structural Requirements
• Resource Requirements
• Process Requirements
• System Requirements
ISO 17025
GENERAL REQUIREMENTS

Impartiality and Confidentiality
- Activities Structured and Managed to Ensure Impartiality
- A stated commitment from top management
- Culture of Integrity

What We Do
- Global Quality Policy Statement
  - Endorsed by top management
  - Reviewed with each new employee
- Code of Ethics
  - Signed by all new employees
  - Renewed each year for existing employees
- Project Reviews
  - The personnel authorizing the report is not the same as the person performing the evaluation; Certification Projects undergo a second review by the Certification Department
ISO 17025
STRUCTURAL REQUIREMENTS

Structure
• Defined Legal Entity
• Roles and Responsibilities of Staff Defined
• Laboratory Scope and Capabilities Defined

What We Do
• Multiple Legal Entities to cover the globe
• Global Quality Policy Statement
  • Defines basic roles and responsibilities
• Organization Charts covering the multiple levels of the laboratory
• Qualifications Database (GSSQ) defines the capabilities of labs and staff
ISO 17025
RESOURCE REQUIREMENTS

Resources
• Personnel
• Facilities and Environmental Conditions
• Equipment
• Metrological Traceability
• External Resources

What We Do
• Personnel must be Trained and Qualified
• Personnel must be properly Managed and Supported
• Personnel records must be Documented and Maintained
• Facilities must be suitable to the tasks
• Facilities must be clean and well organized
• Equipment must be suitable to the task
• Critical Equipment must be Calibrated and NIST Traceable (17025 Calibration Lab)
• Any use of resources outside of the control of the lab must meet the labs procedures and requirements
ISO 17025
PROCESS REQUIREMENTS

Process Requirements
• Contract Review
• Test Methods
• Test Samples
• Measurement Uncertainty
• Validity of Results
• Reporting
• Complaints
• Non-Conforming Work

What We Do
• Sales and Engineering review the request and prepare a Quotation – Shall include a review of the lab’s capabilities to ensure we can meet the customer’s needs
• Appropriate Test Method shall be selected – within the lab’s scope, latest edition, and applicable to the product
• Test Samples shall be controlled while at the lab; shipping database, sample labels, disposition
Process Requirements – cont.  
• Measurement Uncertainty

What We Do
• Measurement Uncertainty Calculations for at least the major testing areas.
• MU is not used to adjust results, it is informative
• MU speaks to the accuracy of the test setup including equipment, personnel, environment, etc.
• A test setup with a large MU value should be investigated for possible improvements
• MU is available upon request but is generally not reported unless required by the customer
• No ‘right’ or ‘wrong’ answer, it is about the process of understanding the sources of uncertainty
Process Requirements – cont.

- Validity of Results

What We Do

- Proficiency Testing Programs are the most common way to ensure the validity of results
- PT’s can take many forms: Inter Lab Comparisons; use of reference material; Proficiency Testing Programs (IFM); Quality Checks; replicate tests
- Use of Data Trending to identify future issues
- Intertek requires each testing category to be checked at least once every 4 years – some programs and customers require much more frequent checks
Process Requirements – cont.

- Reporting

What We Do

- Reporting of the results of an evaluation shall be clear and unambiguous
- Use of Report and Test Data Sheet Templates to control the output
- Some Test Standards will have special reporting requirements (ASTM)
- We do not offer opinions or interpretations related to the results of an evaluation – liability
- We do not offer solutions to failures – liability
ISO 17025
PROCESS REQUIREMENTS

Process Requirements – cont.

- Complaints
- Non-Conforming Work

What We Do

- Complaints can be received by any employee
  - Quality Manager will review any complaints received and determine when further investigation is needed
  - Complaints vs. Complaining (Price too high, unhappy about a failure); we are looking for a violation of our process and procedures

- Non-conforming work relates to results and reports which contained technical errors when issued; usually discovered after the product is in the market place
  - Separate Investigations Manager and database to manage this process
  - Non-conforming work can be a result of Out of Tolerance Calibrations, or internal audits that reveal a problem with the evaluation, etc
ISO 17025
MANAGEMENT SYSTEM REQUIREMENTS

System Requirements
• System Documentation
• Control of Records
• Risk Mitigation
• Process Improvement and Corrective Actions
• Internal Audits and Management Review

What We Do
• Use of Microsoft SharePoint to manage
  • Includes all procedures (Global, Regional, Specific and Local), allows for easy maintenance and distribution
  • Includes all records of system implementation (Training Records, Audit Records, Templates, Etc)
  • Document Control captures identification, storage and maintenance of critical documents
  • Documents are the proof; without the document it didn’t happen
  • Internally developed system for storage and operation of Evaluation Files (EPF); allows document retrieval and review from any location; monitors the progress of the Evaluation
ISO 17025
MANAGEMENT SYSTEM REQUIREMENTS

System Requirements
• Risk Mitigation
• Process Improvement and Corrective Actions
• Internal Audits and Management Review

What We Do
• Complaints System, Internal Audits, Management Reviews contribute to Risk Mitigation
  • We want constant feedback and oversight of the activities to ensure we limit risk to the company
• Corrective Actions taken immediately to fix a known issue – Complaints and Audit Findings
• Process Improvement and Preventive Action – to Ensure the problems don’t happen again
• Annual Internal Audits (both process and technical) involve Quality and Engineering staff
• Annual Management Review summarizes the entirety of the Quality System Implementation and allows the senior management to discuss and identify solutions and improvements
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