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ISO 17025 COMPLIANCE AND PRACTICAL GUIDELINES

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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

ISO 17025
PROCESS REQUIREMENTS

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

ISO 17025
PROCESS REQUIREMENTS

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

ISO 17025
PROCESS REQUIREMENTS

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 Manger 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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