QUALITY SYSTEMS

ISO/IEC 17025:2005

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"For Training Purposes Only"

What is ISO 17025 ?

- ISO/IEC 17025:2005 is an international standard for calibration and testing labs. It takes relevant parts of ISO 9001 and adds the former ISO Guide 25 to form the standard.

- Requires labs to demonstrate that they:
  - **Operate a quality system**– that is applicable to all fields of testing and activities
  - All policies, systems, programs, procedures and instructions are documented
  - Documents are communicated, understood, available and implemented by appropriate personnel

WHAT IS ISO 17025 ?

- Requires labs to demonstrate that they:
  - **Generate technically valid results**– technical management ensures that Section 5.0 of ISO 17025 is implemented and maintained
  - By maintaining traceability- everything in the lab
  - Methodology – lab developed, standard, non standard, validation
  - Equipment – measurement traceability
  - Personnel – training, competency
  - Sampling – handling, chain of custody
  - Reporting of Results – test reports, opinions, interpretations, electronic results

Who uses ISO 17025?

- All National Accreditation Bodies have adopted ISO 17025

- Several industries and countries have incorporated it into their industry-specific or application-specific regulations

What is ACCREDITATION ?

- **Accreditation** is a formal recognition process where an authoritative body
  - **a:** reviews and approves a quality system
  - **b:** recognizes or assures as conforming with a standard

- One example of accreditation is the accreditation of testing laboratories and certification specialists that are permitted to issue official certificates of compliance with established standards.

Why do we need a Quality System?

"The purpose of your Quality Management System is to ensure that all services and products satisfy the customer's requirements and have been designed, manufactured, and delivered under controlled conditions." ISO 17025

Quality System

- **The Quality Management System is structured in three levels of documentation:**
  - The Quality Manual
  - Standard Operating Procedures and Test Methods
  - Records

  ISO Section 4.0

Quality Manual

"The laboratory's quality system, policies and objectives shall be defined in a Quality Manual" ISO 17025

Quality Manual - objective

- The objective of your Quality Manual is to document the compliant policies and associated procedures that are integrated into your daily activities.

- Continual improvements are established, implemented, and locked into the management system.

Quality Manual

- This Quality Manual and associated documents (including procedures) and records serves as the quality plan for the laboratory. Other documents include
  - Standard Operating Procedures (SOPs)
  - Quality Control Plans in test methods
  - Organizational Charts
  - Proposals
  - Project Management Outlines

How do you know the Quality System is Effective?

- The Quality Management System should be assessed to confirm it is effective
  - by planned internal/external audits, covering all aspects of the operation (lab)
  - by regular management reviews, with continual improvements
  - by customer complaints

How do you know the Quality System is Effective?

- Additional measures:
  - By establishing the level of the laboratory's performance
  - Participating in proficiency testing or inter-laboratory tests
  - Ensuring that all personnel are trained to a level associated with the quality management system
  - Validating laboratory methodologies
  - Establishing and reporting quality data

Summary

Remember the following terms

- ISO17025 – international standards
- Accreditation- process of approval for conformity to standards
- Quality Management System – is to ensure all products and services are designed, manufactured and delivered under controlled conditions
- Quality Manual – lab's quality system is defined in this document

QUESTIONS

ABOUT "The Quality System"

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