Challenges and Timelines Associated with ISO17025 Lab Accreditation

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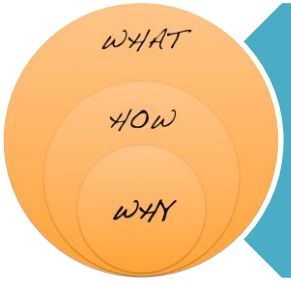
Overview



Background
(What, Why, How)

Our Experience

Life After
Accreditation

What is ISO 17025 Accreditation?

- ISO – International Organization for Standardization
- Single most important standard for calibration and testing laboratories around the world.
- Laboratories accredited to this international standard have demonstrated that they are technically competent and able to produce precise and accurate test and/or calibration data

Why?

Benefits of Laboratory Accreditation

- Formal recognition of testing competency
- Legally defensible data
- Funding Opportunities/Requirement of program participation
- Improved customer satisfaction
- Staff development-training plans
- Ability to share test results across programs

How to Obtain Accreditation

Vision

- Commitment from top management in organization (Quality Policy)
- Determine scope
- Early decisions on document control
- Resource identification
- Staff introduction
- Determine timeline/schedule

Development

What is a Quality Management System? (QMS)

- Formalized system that documents processes, procedures and responsibilities for achieving quality policies and objectives
- Expressed as organizational goals, policies, processes, documented information and resources needed to implement and maintain it
- Focus on continuous improvement and meeting customer requirements
- Sustainability and transparency

What are the components of a Quality Management System?

Management Requirements

Technical Requirements

What are the components of a Quality Management System?

Management Requirements

- Organization
- Management system (Quality Manual)
- Document control
- Review of requests, tenders and contracts; subcontracting
- Purchasing services and supplies
- Customer service and complaints
- Control of nonconforming work
- Corrective Action

Problem Statement:
"The vehicle will not start"

- Why 1 – The battery is dead
- Why 2 – The alternator is not functioning
- Why 3 – The alternator belt has broken
- Why 4 – The alternator belt was well beyond its useful service life and not replaced
- Why 5 – The vehicle was not maintained according to the recommended service schedule

What are the components of a Quality Management System?

Management Requirements

- Improvement and Preventive Action
- Control of Records
- Internal Audits
- Management Review

What are the components of a Quality Management System?

Technical Requirements

- Personnel (PD, training records, IDOCs)
- Accommodation and Environmental Conditions
- Test and Calibration Methods and Method Validation
- Equipment (maintenance, records)
- Measurement Traceability
- Sampling (sampling agreement)
- Sample handling, storage and disposal
- Assuring the quality of test and calibration results
- Reporting of results

Execution

- Select accreditation body
- GAP analysis
- Application process
- Initial assessment
- Deficiencies and corrective actions
- Success ☺

Our Experience

Challenges We Faced

Our Approach Moving Forward

Challenges

- Planning
  - Early decisions on document control
  - Resource identification
- Maintaining overall workload and TAT
- Meeting quarterly deadlines
- Staff Turnover/Training

- New 2017 Standard

The New 2017 Standard

- Main Changes Compared to Previous Edition (2005) – Below taken directly from ISO 17025: 2017 standard (Foreword, pg v).
  - The risk-based thinking applied in this edition has enabled some reduction in prescriptive requirements and their replacement by performance-based requirements;
  - There is greater flexibility than in the previous edition in the requirements for processes, procedures, documented information and organizational responsibilities;
  - A definition of “laboratory” has been added (see 3.6) – “
- Requires the laboratory to plan and implement actions to address risks and opportunities
- Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the management system; achieving improved results and preventing negative effects
- The laboratory is responsible for deciding which risks and opportunities need to be addressed

The New 2017 Standard

- New Numbering System
  - 2005 (5 Sections)
    - Scope, normative references, terms and definitions
    - Section 4 - Management Requirements
    - Section 5 - Technical Requirements
  - 2017 (8 Sections)
    - Scope, normative references, terms and definitions
    - Section 4 – General Requirements
    - Section 5 – Structural Requirements
    - Section 6 – Resource Requirements
    - Section 7 – Process Requirements
    - Section 8 – Management System Requirements

The New 2017 Standard

Section 6 – Resource Requirements

- Personnel
- Facilities and environmental conditions
- Equipment
- Metrological traceability
- Externally provided products and services

Section 7 –Process Requirements

- Review of requests, tenders and contracts
- Selection, verification and validation of methods
- Sampling
- Handling of test or calibration items
- Technical records
- Evaluation of measurement uncertainty
- Ensuring the validity of results
- Reporting of results
- Complaints
- Nonconforming work
- Control of data and information management

Section 8 – Management System Requirements

- Management system documentation
- Control of management system documents
- Control of records
- Actions to address risks and opportunities
- Improvement
- Corrective Actions
- Internal audits
- Management reviews

New Concepts

- Risk and Opportunity
  - ID areas of risk and opportunities for improvement
    - Plan, Do, Check, Act – one tool for continual improvement
- Flexibility
- Focus on outcome of process
- Competence
  - Define
  - Measurable Objectives

Our Approach Moving Forward

- Keep what we have
- Identify new 2017 standard requirements
- Incorporate requirements into system
- GAP analysis
- Make application

Life After Initial Accreditation

- Maintaining accreditation
- Re-assessment and evaluation
- Audits
- Participate in relevant proficiency testing programs between reassessments
  - Further demonstration of technical competence
- Continuous improvement
- Scope expansion

Discussion/Questions?