

Simplistic Approach in Achieving ISO/IEC 17025 Certification

Speaker/Author: Baskar Kotte

President, Quality Systems Enhancement, Inc.

American Society for Quality (ASQ)

American National Standards Institute (ANSI)

1790 Woodstock Road Roswell, Georgia 30075

Phone: 770 518 9967; Fax: 770 518 9968

www.enhancequality.com Email: consult@enhancequality.com

ISO (The International Organization for Standardization) and IEC (The International Electrotechnical Commission), which formulate international standards through technical committees, have formulated ISO/IEC 17025 on “General requirements for the competence of testing and calibration laboratories”. This standard was prepared by ISO/CASCO, Committee on Conformity Assessment and was published on December 15, 1999. This standard replaces and cancels ISO/IEC Guide 25.

The current publication covers all of the requirements of ISO/IEC Guide 25 and important management requirements of ISO 9001: 1994.

The standard has not yet been synchronized with the ISO 9001: 2000.

This standard covers the performance requirements of Test and Calibration for:

- Competence
- Standard methods
- Non-standard methods
- Laboratory developed methods

Application of this standard includes all activities of Testing and Calibration that can be used by:

- Any organization of any size
- First/Second/Third Party Certification Laboratories
- Organizations involved in product certification

Applicability/traceability requirements can be addressed using accreditation matrices for calibration and testing

Calibration:

Calibration Category/Scope

Item

Manufacturer

Model #

Calibration-Internal

Maintenance-Internal

Calibrated By

Testing:

Type of Field Testing/Testing

Test Technology

Range

Test Methods and Full Title of Test

Equipment Used

Limitations

Application of this standard is a real value addition for all the testing and calibration laboratories. When the certification is a requirement, compliance to this standard is mandatory. Regulatory and Accreditation bodies use this standard as performance monitoring tool.

All the automotive industries and other organizations willing to demonstrate the competence of the testing and calibration activities are required to comply with the requirements of this standard. This standard cover various testing and calibration activities in the filed of:

Calibration:

- Physical/Instruments Calibration:
 - Dimensional
 - Mechanical
 - Thermodynamics
 - Electromagnetics
 - Radiation
 - Time and Frequency
- Chemical Calibration
 - Proficiency Testing
 - Spectrophotometric NTRMs (NIST Traceable Reference Materials)
 - Other Reference Materials

Testing:

- Radiation
- Electromagnetic Compatibility
- Telecommunications
- Environments
- Fasteners & Metals
- Information Technology
- Security Testing
- Product Testing

This standard consists of 14 Management requirements and 10 Technical requirements:

Management Requirements:

1. Organization
2. Quality Systems
3. Document Control
4. Review of Requests, Tenders and Contracts
5. Subcontracting of Tests and Calibrations
6. Purchasing Services and Supplies
7. Service to the Client
8. Complaints
9. Control of Nonconforming Work
10. Corrective Action
11. Preventive Action
12. Control of Records
13. Internal Audits
14. Management Reviews

Technical requirements:

1. General
2. Personnel
3. Accommodation and Environmental
4. Test and Calibration Methods
5. Equipments
6. Measurement Traceability
7. Sampling
8. Handling of Test and Calibration Items
9. Assuring the Quality of Test and Calibration results
10. Reporting the Results

An organization that intends to get certified to ISO/IEC 17025 is required to establish and maintain the documented procedures and ensure the implementation through various monitoring and measuring activities such as internal audits, corrective and preventive actions and regular management reviews.

Comprehensive, simplified, value added documentation helps in smooth implementation of these requirements. It is important to meet all the requirements of the standard while specifying the exclusions and limitations in the scope of the certification.

Application of effective audit methods such as process approach and functional approach, depending on the type of activity, would benefit the organization in effective monitoring of the implementation process. Evidence-gathering interview techniques would yield the desired results of the auditing process.

Selection of accredited registrar, Top management Interface in certification process and good preparation to face the third party audit helps in smooth and value adding certification.

A disciplined approach would help any organization to achieve the certification through seamless and painless process. Following are the steps required to ensure successful certification.

1. ISO/IEC 17025 Awareness Training to All employees
2. Document Development
3. Document Review & Corrections
4. Internal Quality Auditor Training
5. Procedure Implementation
6. Pre-Assessment
7. Deficiency Correction
8. Readiness Evaluation
9. Coaching Prior to Audit
10. Defending the System During the Audit

References: ISO/IEC 17025:1999

Baskar Kotte, *Ten step Approach™ for successful certification, QSE publication, 1992*