

Laboratory Accreditation

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What We'll Cover

- ◆ Definitions
- ◆ History of Accreditation
- ◆ Why Accreditation?
- ◆ Current Accreditation Requirements
- ◆ Improvements to System

Definitions

◆ Accreditation:

- Procedure by which an authoritative body gives *formal recognition* that a body or person is competent to carry out *specific* tasks.

◆ Conformity:

- Fulfillment by a product, process or service of specified requirements.

Definitions

- ◆ **Conformity Assessment:**
 - Any activity concerned with determining directly or indirectly that relevant requirements are fulfilled.
- ◆ **Conformity Assessment Body:**
 - Body that conducts conformity assessment.

Definitions

◆ Mutual Recognition Arrangement:

- An agreement between two or more parties by which each party accepts the accreditations granted by other signatories.

History of EMC Accreditation in the USA

◆ 1985

- In January of 1985, Retlif was the first laboratory to petition the US Government to develop a laboratory accreditation program in EMC.
- As a result, NIST expanded its NVLAP program to include EMC.

History of EMC Accreditation in the USA

- ◆ 1989
 - NAVAIR requires NVLAP accredited test facilities.

History of EMC Accreditation in the USA

◆ 1996

• FCC General Docket 95-19

- ◆ FCC deregulates approvals process for PCs and PC Peripherals.
- ◆ Manufacturers Declaration of Conformity (“DoC”) added as an option to Commission Certification.
- ◆ Requires use of a NVLAP accredited test facility.
- ◆ Adopted May 9, 1996.

• A2LA expands scope to include EMC in response to newly opened market by FCC.

History of EMC Accreditation in the USA

◆ 1998

- The US Department of Commerce designates EMC Directive CABs under the US-EU MRA.
 - ◆ Laboratory Accreditation Required.
- FCC General Docket 98-68
 - ◆ FCC Privatizes Equipment Approval
 - ◆ TCBs required to be Accredited to both ISO Guide 58 and ISO Guide 25 (17025)
 - ◆ Adopted December 17, 1998
- NACLA formed

History of EMC Accreditation in the USA

- ◆ 2000
 - Big 3 Automakers rely on AEMCLRP for EMC test data. (Automotive EMC Laboratory Recognition Program)
 - The US Department of Commerce designates R&TTE Directive CABs under the US-EU MRA.
 - ◆ Laboratory Accreditation Required.

Why Become an Accredited Laboratory?

- ◆ Required by Regulator
- ◆ Required by a Trade Agreement
- ◆ To Gain Access to or Recognition in a Market
- ◆ Desire for an Independent Audit
- ◆ Marketing Tool

Why Use an Accredited Laboratory?

- Required by Government Agency
- Required by Customer
- To Enhance Customers Confidence
- To Complement in House Quality Systems
- Decrease Time to Market
- Improve Acceptance of Test Data

Why Use an Accredited Laboratory?

- ◆ What do you consider when selecting a laboratory?
 - Staff
 - Equipment
 - Adequate QA procedures
 - Appropriate test procedures & methods
 - Traceability
 - Reporting procedures
 - Facilities

ISO/IEC 17025:1999

- ◆ General Requirements for the Competence of Testing and Calibration Laboratories
 - Replaced
 - ◆ IEC Guide 25
 - ◆ EN 45001

Scope of 17025

- ◆ 17025 is applicable to:
 - All organizations performing tests and/or calibrations.
 - ◆ Including 1st, 2nd and 3rd Party Laboratories
 - ◆ Regardless of:
 - Number of Personnel
 - Scope of Testing Services

What About ISO 9000?

- ◆ Testing and calibration laboratories that comply with ISO/IEC 17025 meet the requirements of:
 - ISO 9001
 - ◆ When performing tests using non-standard methods (Developed or designed within the laboratory)
 - ISO 9002
 - ◆ When using standard test methods (Industry accepted methods)

17025 Contents

- ◆ 1 Scope
- ◆ 2 Normative References
- ◆ 3 Terms and Definitions
- ◆ 4 Management Requirements
- ◆ 5 Technical Requirements

17025 Section 4

Management Requirements

- ◆ 4.1 Organization
- ◆ 4.2 Quality System
- ◆ 4.3 Document Control
- ◆ 4.4 Review of Requests, Tenders and Contracts
- ◆ 4.5 Sub Contracting of Tests and Calibrations
- ◆ 4.6 Purchasing services and Supplies

17025 Section 4

Management Requirements

- ◆ 4.7 Service to the Client
- ◆ 4.8 Complaints
- ◆ 4.9 Control of Non-Conforming Testing and/or Calibration Work
- ◆ 4.10 Corrective Action
- ◆ 4.11 Preventive Action
- ◆ 4.12 Control of Records

17025 Section 4

Management Requirements

- ◆ 4.13 Internal Audits
- ◆ 4.14 Management Reviews

17025 Section 5

Technical Requirements

- ◆ 5.1 General
- ◆ 5.2 Personnel
- ◆ 5.3 Accommodation and Environmental Conditions
- ◆ 5.4 Test and Calibration Methods
- ◆ 5.5 Equipment
- ◆ 5.6 Measurement Traceability

17025 Section 5

Technical Requirements

- ◆ 5.7 Sampling
- ◆ 5.8 Handling of Test and Calibration Items
- ◆ 5.9 Assuring the Quality of Tests and Calibrations
- ◆ 5.10 Reporting the Results

The Process

- ◆ Application to Accreditation Body (AB)
- ◆ Self Audit
 - Submit Results to AB
 - Resolve any deficiencies
- ◆ On Site Assessment
 - Resolve any Deficiencies
- ◆ Accreditation Granted or Denied
- ◆ Yearly Surveillance

Problems?

- ◆ US is unique in that Accreditation Bodies are in competition.
- ◆ Multiple Accreditation Bodies in the same sector results in inconsistencies in laboratory assessments.
- ◆ The proliferation of standards, especially within the EU.
- ◆ Lack of “Buy In” from Regulators and Specifiers.

Improvements

- ◆ Competition
- ◆ Inconsistencies in laboratory assessments
- ◆ Proliferation of standards
- ◆ Buy In

Why Accreditation?

- ◆ Laboratories:
 - Determines, Recognizes, Promotes and Maintains Technical Competence
- ◆ Specifiers:
 - Establishes and Ensures Confidence
- ◆ Users:
 - Identifies Sources of Reliable Testing Services

Thank You

◆ For More Information:

- <http://ts.nist.gov/ts/htdocs/210/214/214.htm>
- www.acil.org
- www.a2la.org
- www.nacla.net
- www.ilac.org

