Should I pursue ISO/IEC 17025 certification & why is accreditation important when selecting a Testing Laboratory?

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ISO/IEC 17025

- Why isn't ISO 9001 or AS9100 enough?
- Critical Requirements for ISO/IEC 17025
- ISO/IEC 17025 Accreditation Scheme
- Qualifications of ISO/IEC 17025 Accreditation Bodies
- How is ISO/IEC 17025 referenced in the AS6081 and AS6171

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ISO/IEC 17025

General requirements for the competence of testing and calibration laboratories

- Quality Management Standard
  - Quality System
  - Technical Requirements

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SAE Aerospace G-19 Committee

- Chartered to address aspects of preventing, detecting, responding to and counteracting the threat of counterfeit electronic components.
- Two Standards reference ISO/IEC 17025
    - AS6081 - Counterfeit Electronic Parts Avoidance – Distributors
    - AS6171 - Test Methods Standard; Counterfeit

Why isn't ISO 9001 or AS9100 enough?

Typical verbiage on an ISO 9001 certificate

Your Company Name Here

has been found to conform to the Management System Standard:

ISO 9001:2008

This Certificate is valid for the following product or service ranges:

Your Product or Services Here

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Why isn't ISO 9001 or AS9100 enough?

Typical verbiage on an ISO/IEC 17025 certificate

Your Laboratory Name Here

This laboratory is accredited in accordance with the recognized International Standard ISO/IEC 17025:2005 *General Requirements for the Competence of Testing and Calibration Laboratories.* This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system

Your Laboratory Scope Here

Why isn't ISO 9001 or AS9100 enough?

"Conforms to a Management System Standard"

versus

"This accreditation demonstrates technical competence for a defined scope and the operation of a laboratory quality management system."

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Technical Competence

Factors which will be included in the audit

- The Qualifications, training and experience of the staff
- The Right equipment, properly calibrated and maintained
- Appropriate Test Methods
- Suitable Testing facilities

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Technical Competence

Why is technical competence important to you?

- Protect your company's reputation
- Avoid expensive retesting
- Increase your customers' confidence
- Minimize Risk

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Laboratory Scope

Each Laboratory must define their scope of work

- Test Type
- Test Parameters
- Test Methods (specific MIL STD, industry standards, customer-specific standards, etc.)
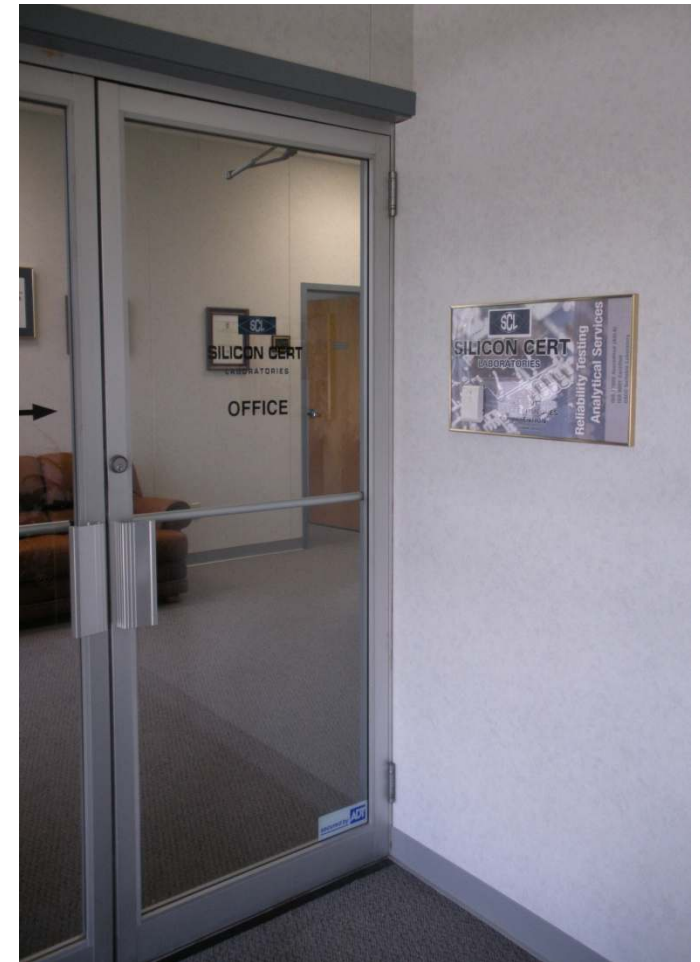
If a test is NOT included in a laboratory's scope of work, it is NOT accredited.

ISO/IEC 17025 vs. ISO 9001, AS9100, AS9120

Similar Requirements

- Management Responsibility, authority and communications
- Document Control
- Resource Management
- Management Review
- Internal Audits
- Corrective Action
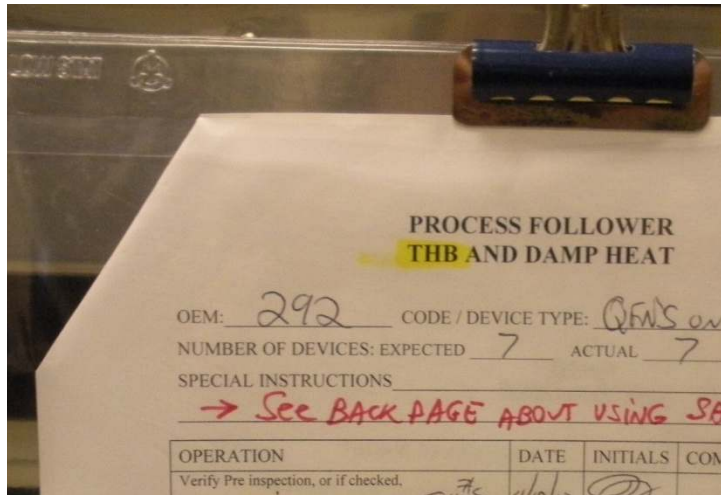- Control on Nonconforming product

Additional Requirements of ISO/IEC 17025

- Controlled access of the lab
- Protection of Customer Property
- Protection of Customer Data

Additional Requirements of ISO/IEC 17025

- Policies and procedures for confidentiality
- Ethics Policy

Additional Requirements of ISO/IEC 17025

- Document competence of personnel through proficiency testing
- Procedure for Test Method Validation

Additional Requirements of ISO/IEC 17025

- Must have most current revision of all standards
- Advise customers if inappropriate methods are requested
- Advise customers of subcontracted work

Accreditation to ISO/IEC 17025

International Laboratory Accreditation Cooperation

an international cooperation of laboratory and
inspection accreditation bodies
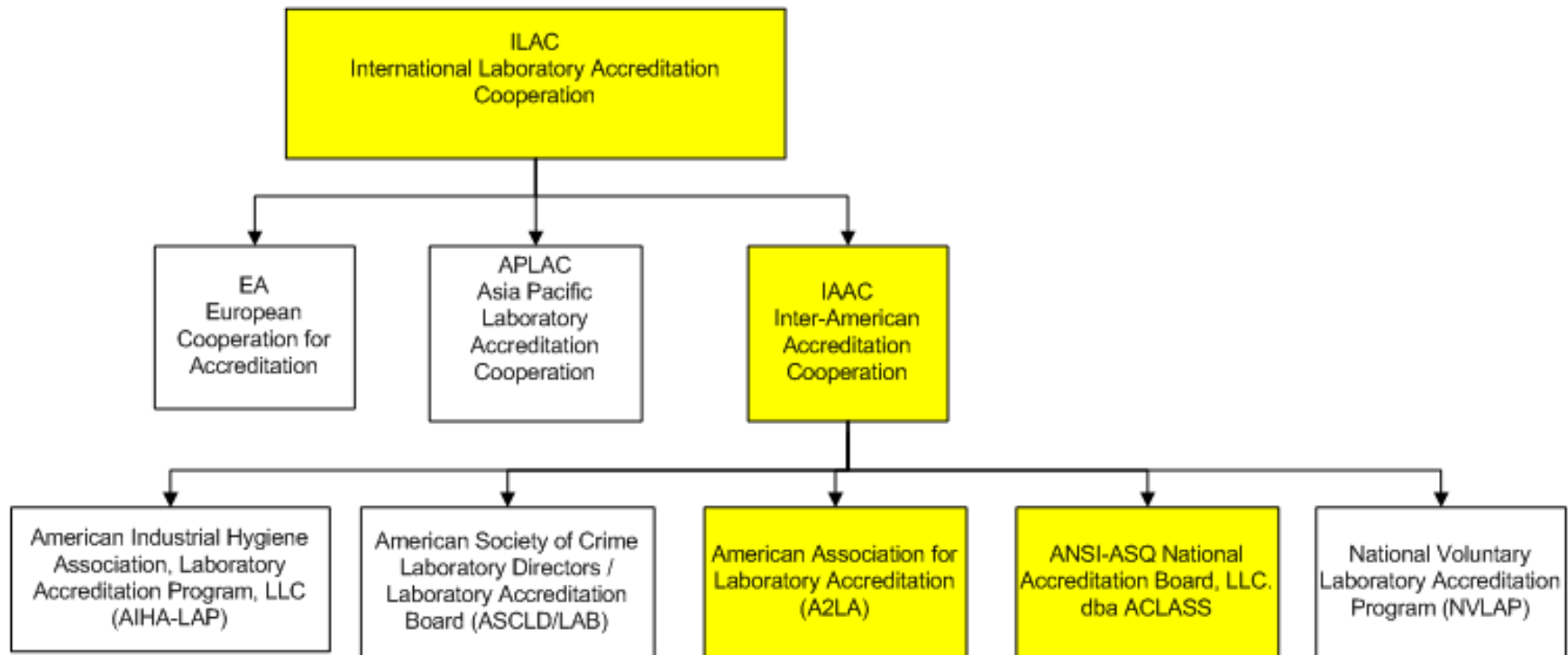to help remove technical barriers to trade

Accreditation to ISO/IEC 17025

Inter American Accreditation Cooperation

an association of accreditation bodies
in the Americas and other organizations
interested in conformity assessment

Accreditation Scheme

Accreditation Bodies

- For each test that Accreditation Bodies for ISO/IEC 17025 are authorized to audit and accredit to the standard; they must have Subject Matter Experts

- ILAC will audit the Accreditation Bodies to ensure that they have the knowledge required to audit the test method.

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ISO/IEC 17025
and
Counterfeit Detection

SAE AS6081 – Aerospace Standard

Counterfeit Electronic Parts Avoidance – Distributors	
Purpose	standardizes practices to: a. procure parts from reliable sources, b. assess and mitigate risk of distributing counterfeit parts, c. control suspect or confirmed counterfeit parts, d. report suspect and confirmed counterfeit parts to other potential users and Authority Having Jurisdiction, e. and assess, mitigate, control, and report parts which have been used, refurbished, or reclaimed, but represented as new product.
Target Audience	Distributors of Electronic Components
Uses	• Requirements for a Counterfeit Mitigation program • **Intended to be used for certification of Distributors (ANAB)**
Status	•Ballot completed in April.

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AS6081 Requirements

AS6081 requires that laboratories performing counterfeit detection are either

- *Accreditation to ISO/IEC 17025 by an ILAC-recognized accrediting body (e.g. ANSI-ASQ National Accreditation Board/ACLASS, A2LA, etc.) and to the specific tests and inspections must be included on the laboratory scope of accreditation;*

- *Participation in the DLA Land and Maritime Laboratory Suitability List for comparable tests (e.g. MIL-STD test methods);*

- *Documented approval by the Customer through on-site audit*

AS 6171 - Aerospace Standard

Test Methods Standard; Counterfeit Electronic Parts	
Purpose	Standardize practices to detect suspect counterfeit electronic parts and to ensure consistency of test techniques and requirements across the supply-chain
Target Audience	Independent Testing Facilities Distributors (in-house testing capability)
Uses	• Definition of Test Methods for counterfeit detection • Accreditation • **Intended to be used for accreditation of Independent Test Laboratories or Distributors (ILAC, through ACLASS, A2LA,etc.)**
Status	• In Draft

AS6171 Requirements

- AS6171 will contain a number of Test Methods
- These Test Methods can be included on the scope of accreditation of a test lab
    - A lab can include only those methods for which they are capable in their scope of accreditation
- If the test method is on the scope of accreditation, a subject matter expert from the Accreditation Body will have audited the lab to confirm their competence.

Should I pursue ISO/IEC 17025?

- Game Changers
    - Proficiency Testing
    - Secure facility (even if you are part of a larger organization)
    - Environmental Controls
    - Ethics Policy
    - Conflict of Interest

Thank you

Any Questions?

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