

OBTAINING ISO17025 ACCREDITATION FOR YOUR LABORATORY

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ACCREDITATION

The process of officially recognizing [...] as [...] qualified to perform a particular activity.

- *OxfordDictionaries ... <https://www.oxforddictionaries.com/>*

ISO17025:2005

General Requirements for the Competence of Testing and Calibration Laboratories

- *www.iso.org > ISO Store (download the standard from here)*

ISO – International Standards Organization

To determine if the pursuit of an ISO17025:2005 accredited testing laboratory is a reasonable allocation of monetary and human resources for your organization can be reasonably evaluated. The standard, along with all definitions and requirements, must be clearly understood when determining what gaps exist between your current system and the path towards accreditation.

ISO17025:2005 is the internationally recognized standard focused on the competence of your laboratory, independent of the overall organization. Accreditation indicates that the company has voluntarily, without coercion nor influence, agreed to a third-party review of your testing quality systems = audit. Certification can be applied to either calibration and, or testing sites. It is the SCOPE of activity which is audited.

This paper will focus on testing laboratories and not calibration facilities.

ISO17025 is the Quality Management System (QMS) for the laboratory. For instance, if the company already manages an ISO9001 compliant facility, then the laboratory is ISO9001 compliant. The gap between ISO9001 and ISO17025 then becomes the Technical Requirements needed for accreditation.

As you decide to explore laboratory accreditation, you must identify which Accrediting Body¹ (AB) to work with. Your AB will provide you a Quality Audit checklist, which will enable you to understand your existing QMS. The checklist will minimally distinguish the following necessary requirements for certification:

Quality Manual

Internal Audits

Management Review Requirements

Document Controls

Nonconformance

Sampling

Corrective and Preventative Actions and Records

Risks

Measurement Systems

Quality Objectives

Scope of Testing

Equipment

Methods

Resources

Proficiency Testing (Inter Laboratory Comparison – ILC)

If the facility is already involved in testing practices within the laboratory, then the Scope of your Accreditation must be defined by the interested parties. The interested parties are represented as your AB, your laboratory, the company and management, as well as all internal and external customers.

SCOPE of Accredited TESTING

Before initiation of testing activities you have identified to be audited to, the plan must be defined and known – What will be tested and what will not be tested. Information should also be available on what accountable deliverables are desired. Defining the scope of the testing for accreditation is critical for the organization, project manager (s) and all management as well. If the scope is properly defined, there will be a clear understanding of what is tested, along with capable test methods, technicians and equipment.

It is recommended when identifying your scope, that you begin with publically recognized standards. You may pursue certification for non-standard or laboratory developed methods, as well; however, this could require additional resource load as the testing facility would become responsible for identifying the statistical measurement of uncertainty for these methods. A **standard method** will have readily available methods of uncertainty published.

Examples of Standard Methods:

- Pressure Sensitive Tape Council (**PSTC**)
- American Society for Testing & Materials (ASTM)
- American National Standards Institute (ANSI)
- Technical Association of the Pulp and Paper Industry (TAPPI)
- Society of Automotive Engineers (SAE)
- Military Specifications (MIL-SPEC)

Once the scope of testing is defined, the AB chosen and Quality Checklist in hand, you are prepared to schedule your pre-audit on-site visit.

1. Examples of ILAC recognized ABs to support your ISO17025 accreditation process:

- American Association for Laboratory Accreditation (A2LA)
 - o www.a2la.org
- National Voluntary Laboratory Accreditation Program (NVLAP)
 - o www.nist.gov/nvlap
- ANAB ANSI-ASQ National Accreditation Board (was ACLASS)
 - o www.anab.org
- Perry Johnson Laboratory Accreditation, Inc. (PJLA)
 - o www.pjllabs.com

Cost of the accreditation is dependent on the Scope of Testing and number of employees that must be witnessed for competency. It is up to you to define your scope, to make the costs as big or small as you design. The AB will quote on the supplied scope, days to witness the technicians and the testing and size of your management system.

If the organization's laboratory is managed to ISO17025 competency, your value as a supplier has increased, enabling the laboratory to provide confident, reliable and repeatable testing to your internal and external customers. This also ensures robustness in testing and allow the company to market its technical competence.

Once you are ISO17025 accredited, your certification and Scope of Testing is publically available. Your AB maintains an available listing of labs and scopes that they have audited to compliance. You will be able to provide your management updates on your competition, suppliers', customers' and others' laboratory competencies.

Some customers even require an organization to be accredited. For instance, the Automotive QMS – ISO/TS 16949 – requires that their Tier 1 suppliers must be accredited to report certified testing data.

If you are not currently an accredited laboratory, and rely on outside testing, the costs for testing can grow quickly. In addition, external customers typically require testing reports and data to be updated annually. If you maintain an onsite accreditation, you can control these annual maintenance costs and deliver certified, updated reports more expeditiously than rely on an outside vendor. Rather than budgeting updated testing with outside laboratory services, your annual budget can be focused on updating and maintaining your QMS of the lab, allowing your scope of testing to grow - providing an advantage in your current market space while simultaneously supporting the development and expanding your marketed testing footprint competitively. ISO17025 will provide you the demonstrated, technical confidence and leverage to necessitate closing new business or closing quality opportunities.

While the benefit to external customers is more tangible, your accredited testing lab will also deliver enhanced perception to internal customers, as well. Competence in testing may provide management the needed confidence for further infrastructure investments to the testing site, such as new and more complex equipment, updated controls (environment, i.e.), laboratory IT and much more. Accreditation will also allow the company to mitigate risk with certified testing data.

Typically, the laboratory testing is identified for internal consumption and benefit; however, pending Scope of Testing of accreditation, your lab can also be used as a source of revenue or profit center if outside testing is pursued.

The internal support of Senior Management will feed the continuous improvement all quality systems drive towards.

An on-site reassessment audit occurs every two years. Some ABs require on-site surveillance visits every other year. These audits may also deliver a much softer benefit of enhanced test technician discipline and engagement, especially via the ILC requirements when internal, mature data can be utilized. Your organization may also enjoy longer technician retention with the structure and confidence in place due to the externally accredited and supported program.

Lastly, the Proficiency Testing requirements of ISO17025 help your organization network with other accredited laboratories to the extent which your lab would like to participate.

While the standard may be intimidating at first read, it is readily executable with your company's sound business practices and Senior Management support. Implementation and management to the standard is defined by you and your authored Quality Manual. You make your lab scope as broad or as narrow as you need to support your organizational goals and objectives. Pursuing the laboratory specific QMS demands you to evaluate metrics to help the company understand such things as project close rates, timelines, testing capacity, technician skill sets and overall asset utilization. The overall return on investment can be calculated.

You have the equipment.

You have the methods.

You have the technicians.

You have the management.

Identify the right Accrediting Body for the organization and go get certified.

Laboratory accreditation is growing. ISO17025 certification will provide all stakeholders the assurance that your lab is delivering consistent, quality and repeatable results – reflective of a best in class, first in quality product or service for all of your customers.

Definitions and Acronyms to know:

Accreditation – Defined in Paper

ISO – International Organization for Standardization

ILAC – International Laboratory Accreditation Cooperation

AB – Accrediting Body

MRA – Mutual Recognition Arrangement

Scope of Testing – Defined in Paper

QMS – Quality Management System