



Laboratory Accreditation

1. Introduction

In response to the global growth of wine trade, a set of principles has been endorsed by FIVS that are closely aligned with those of the World Wine Trade Group (WWTG).

One of these principles is that analyses of wine required for demonstration of compliance in international trade should be generated by laboratories complying with international standards.

Throughout the world most government, regulatory, and industry laboratories rely upon a process called accreditation as a means of confirming the technical competence of analytical laboratories.

2. Accreditation Defined

ISO/IEC 17025 accreditation requires compliance with management and technical criteria, policies, and procedures specifically developed to determine technical competence.

Laboratories that are accredited to this international standard have demonstrated that they are technically competent and are able to produce accurate and precise test data within a stated range of uncertainty.

Upon a satisfactory external assessment and successful completion of proficiency testing, the laboratory is issued a clear statement of its Accreditation along with a Scope of Accreditation listing the test methods that the laboratory is accredited to perform.

ISO/IEC 17025 requires continual improvement. Regular internal audits are expected to indicate opportunities to make the test or calibration better than it was.

Accreditation is a voluntary, third party-reviewed process. As part of accreditation, a laboratory's entire quality management system must be thoroughly evaluated on a regular basis to ensure continued technical competence and compliance with ISO/IEC 17025.

3. Origins and Evolution of the Standard

ISO/IEC Guide 25 was first issued in 1990 and replaced by the International Standard ISO/IEC 17025 in 1999 by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

Today, ISO/IEC 17025 has become the competency standard for testing laboratories throughout the world.

4. Accreditation Bodies

Laboratory accreditation can only be granted by an Accreditation Body, or AB.

Such bodies include the nonprofit, non-governmental American Association for Laboratory Accreditation (A2LA) in the United States, COFRAC in France, NATA in Australia, UKAS in the United Kingdom, and many others.

Laboratories should choose an AB that has a mutual recognition agreement (MRA) with the International Laboratory Accreditation Cooperation (ILAC).

Accreditation Bodies are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) and the International Accreditation Forum (IAF) Multilateral Recognition Arrangement (MLA). This “recognition” is provided as a result of successful audits performed by Regional Accreditation Groups such as the Asia Pacific Laboratory Accreditation Conference (APLAC) and the Inter-America Accreditation Cooperation (IAAC) using another international standard, ISO/IEC 17011.

Such “recognition” determines the technical competence, reliability and integrity of accreditation bodies.

Using “recognized” Accreditation Bodies is one tool that is helping laboratories and their customers not only to comply efficiently and effectively with regulations and standards around the globe, but also to expand into new markets, including those overseas.

5. International Recognition of Accreditation Bodies

Multilateral arrangements between member accreditation bodies are based on mutual evaluation and acceptance of each other’s accreditation systems.

In this way, the acceptance of products and services across national borders is made easier by removing the need for them to undergo additional tests, inspections or certification in each country into which they are sold. The short concept is “one test, one accreditation — accepted everywhere”.

Here are some mutual recognition agreements in place for A2LA, NATA, COFRAC, and UKAS.

International Laboratory Accreditation Cooperation (ILAC)

The Mutual Recognition Arrangement (MRA) entered into force on January 31, 2001. The original arrangement was signed by 36 laboratory accreditation bodies from 28 economies worldwide.

Asia Pacific Laboratory Accreditation Cooperation (APLAC)

The Mutual Recognition Arrangement was originally signed on November 19, 1997 and establishes cooperation among many accreditation bodies throughout the Asia-Pacific Region.

Inter-American Accreditation Cooperation (IAAC)

The Inter-American Accreditation Cooperation is an association of accreditation bodies and other organizations interested in conformity assessment in the Americas. The first three signatories were A2LA, INMETRO of Brazil

and SCC of Canada. A2LA, SCC and INMETRO agreed to formally recognize and promote the equivalency of each other's laboratory accreditations.

Trans-Pacific Partnership (TPP) – (Not yet ratified)

Accreditation recognized by existing regional and international mutual recognition arrangements (ILAC and IAF) is referenced as being a key measure to support trade through the removal of technical barriers to trade.

The eleven Pacific Rim countries included are: New Zealand, Mexico, Australia, Brunei, Chile, Singapore, Canada, Japan, Malaysia, Peru, and Vietnam.

6. Importance to International Authorities and Regulators

Accreditation and Mutual Recognition Arrangements provide governments and regulators with a credible and robust framework upon which to further develop and enhance government-to-government bilateral and multilateral international trade agreements.

Multilateral arrangements between national accreditation bodies have also helped make accreditation an internationally recognized 'stamp of approval' to demonstrate compliance with agreed standards and requirements.

With confidence in the conformity assessment process underpinned by accreditation, standards can be used to support a lighter touch approach to regulation.

As an additional benefit, accreditation and mutual acceptance agreements free governments and economies from the demands of cross evaluating and auditing redundant and unique programs saving financial and human resources.

7. The Role of Accreditation Bodies

The accreditation body may not prescribe how a laboratory is run or how analyses are carried out.

The standard lays out a set of requirements for developing the basic components of a robust quality management system and the laboratory is expected to address each of those components, in their own way, with data quality objectives appropriate for the needs of the end user.

The laboratory must "say what they do and do what they say".

8. Costs and Applicability

For the laboratory with a comprehensive quality management system in place, the additional expense would be the cost of the initial and recurring assessments which could typically be a few thousand US dollars (or less) per year.

For a laboratory operating without a quality management system, or only a minimal one, a significant investment in ensuring ongoing data quality would be required.

Accreditation can be a sound investment for any laboratory that operates, or wishes to operate, under a solid quality management system and has a need to demonstrate the reliability of their data to others.

Accreditation is applicable for laboratories of any size. There are one and two person accredited laboratories throughout the world. Clearly, the decision of whether to become accredited must not be dependent upon the size or scope of the laboratory.

9. Accreditation and Certification

Though it may appear to be a matter of semantics at first glance, Accreditation and Certification and are quite different.

Laboratories are accredited under ISO/IEC 17025, rather than Certified or Registered as in the ISO 9000 series.

Accreditation is a “third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks,” as defined by ISO/IEC 17011.

Certification is a “third-party attestation related to products, processes, systems or persons,” as defined by ISO/IEC17000.

ISO 9001, for example, is a certification that applies to an entire organization. While effective as a management evaluation tool, this standard does not attempt to provide assurance of competency, (that test data are accurate and reliable).

In short, accreditation differs from certification by adding the concept of a third party Accreditation Body attesting to technical competence specific to a Scope of Accreditation within a laboratory, in addition to its adherence and operation under a documented quality system.

There are some “non-recognized” entities such as registrars that are providing “evaluations” of laboratories and giving them “certificates” that they are “compliant” with ISO/IEC 17025. The laboratories that receive these “certificates” have no international standing, and their results would not meet the concept of “one test, one accreditation — accepted everywhere”.

Several programs exist to issue “Certified” Analyst credentials in, for example, the field of water and wastewater analysis. Such programs typically require some specified level of education, practical experience, and successful performance on an examination related to the field of practice. Such programs do not provide assurance of the underlying quality systems of the laboratory involved, or of the laboratories competence in producing defensible analytical data.

10. Conclusions and Comments

The existence of a single international laboratory quality framework, and mutual recognition agreements covering most of the world, have been decades in the making. Enormous numbers of competent people from around the world have toiled both on the domestic and international diplomatic and scientific fronts to make such a framework a reality.

Many laboratories throughout the world previously suffered under a regime with redundant requirements and audits from local, county, state, and federal authorities as well customers and clients. ISO/IEC 17025 accreditation has not eliminated, but has greatly reduced, that burden.

All of the major economies have spoken regarding accreditation by acceptance of mutual recognition agreements such as those by ILAC, APLAC, and IAAC.

Laboratories throughout the world now have available a common system that assures recognition of their accredited analyses by both customers and governments.

This common system fulfills the goal of the FIVS endorsed principle that analyses of wine required to demonstrate compliance in international trade should be generated by laboratories complying with international standards.

[FIVS](#) is an international federation serving trade associations and companies in the alcohol beverage industry from around the world. It provides a forum for its members to work collaboratively on legal and policy issues and communicates Federation views to national governments and international organisations.