



Should Laboratories Be Accredited to ISO/IEC 17025 or Certified to ISO 9001?

When selecting a supplier to fulfill your testing, calibration, or measurement needs, you must be sure that they can supply you with accurate and reliable results. The technical competence of a laboratory depends on a number of factors, including:

- The qualifications, training, and experience of the staff
- The right equipment – appropriately calibrated and maintained
- Adequate quality assurance and quality control procedures
- Appropriate sampling practices
- Sound testing and/or inspection procedures
- Accurate recording and reporting of data
- Appropriate testing environment

While a laboratory can reassure you that it has these attributes, or you can attempt to evaluate the service yourself, neither approach provides you with confidence that you have selected a technically competent service. Relying on third-party accreditation assessments, however, does provide such confidence.

What if a Laboratory has ISO 9001 Certification?

Laboratories can be audited and certified to the international management systems standard ISO 9001, which is widely used in manufacturing and service organizations to evaluate their systems for managing the quality of their products and services.

While effective as a management evaluation tool, ISO 9001 is not appropriate for evaluating the technical competence of a supplier's laboratory. The evaluation of a supplier against ISO 9001 does not assure you or your customers that the test, inspection, or calibration data are accurate and reliable.

How to Be Sure a Laboratory is Technically Competent

In the United States and throughout the world, many rely on the process called *laboratory accreditation* as a means to independently evaluate laboratory competence.

Unlike ISO 9001 certification, laboratory accreditation uses criteria and procedures specifically developed to determine the technical competence of laboratories. Specialist technical assessors conduct a thorough evaluation of all factors in a facility that affect the production of technical data. They use criteria based on the international standard ISO/IEC 17025, which is used for evaluating laboratories throughout the world. ISO/IEC 17025 specifically addresses factors relevant to a laboratory's ability to produce precise, accurate test and calibration data, including:

- Technical competency of staff
- Validity and appropriateness of the methods
- Traceability of measurements and calibrations to national standards
- Appropriate application of measurement uncertainty
- Suitability, calibration, and maintenance of test equipment
- Testing environment
- Sampling, handling, and transportation of test items
- Quality assurance of test, inspection, or calibration data

Accreditation to ISO/IEC 17025 also covers the quality systems elements addressed in ISO 9001 certification that are specifically relevant to laboratories. To ensure continued compliance, accredited facilities are regularly re-examined to ensure that they maintain their standards of technical expertise. These facilities may also be required to participate in regular proficiency testing programs or inter-laboratory comparisons as an ongoing demonstration of their competence.

How to Tell if a Laboratory is Accredited

Laboratories accredited to ISO/IEC 17025 usually issue test or calibration reports bearing some type of logo (or symbol) or other endorsement indicating their accreditation. A laboratory maintains a publicly available scope of accreditation. This scope of accreditation indicates the specific tests and/or measurements to which the laboratory is accredited. It also indicates ranges and the laboratory's best measurement capability.

Accreditation bodies throughout the world publish lists or directories of the laboratories they have accredited, including contact information and information on the capabilities of those laboratories. You can contact the accreditation body to find out if there are any accredited laboratories that can perform the tests or calibrations you require.

International Acceptance of ISO/IEC 17025 Laboratory Accreditation

In many countries, one or more organizations are responsible for accrediting of that country's laboratories. These accreditation bodies have adopted ISO/IEC 17025 as

the basis for accrediting their countries' testing and calibration laboratories. This has helped countries employ a uniform approach to determining laboratory competence. It has also encouraged laboratories to adopt internationally accepted testing and measurement practices.

This uniform approach allows countries to establish agreements based on mutual evaluation and acceptance of each other's laboratory accreditation systems. Such international agreements – called mutual recognition arrangements (MRAs) – are crucial in enabling test data to be accepted between countries. In effect, each partner in such an arrangement recognizes the other partner's accredited laboratories as if they themselves had undertaken the accreditation of the other partner's laboratories.

More than 50 laboratory accreditation bodies have signed the ILAC Arrangement, a multi-lateral mutual recognition arrangement that greatly enhances the acceptance of data across the borders of the signatory countries. Full details of the ILAC Arrangement and a list of signatories can be found on the ILAC Web site at www.ilac.org.

This developing system of international arrangements between accreditation bodies has enabled accredited laboratories to achieve a form of international recognition, and allowed data accompanying exported goods to be more readily accepted in foreign markets. This reduces costs for both manufacturers and importers, as it reduces or eliminates the need for products to be retested in another country.

Conclusion

There are differences in the purpose, criteria, and emphasis of the ISO 9001 quality system standard and those of the accreditation standard ISO/IEC 17025.

For laboratories concerned with demonstrating technical competence underpinned by a quality system, ISO/IEC 17025 is the appropriate standard. Suppliers seeking competent testing facilities should ensure that those facilities are accredited to ISO/IEC 17025, with a scope of accreditation appropriate for the testing or calibration required.

A testing facility accredited to ISO/IEC 17025 may have reason to also maintain a certified ISO 9001 management system. For example, many laboratory-based organizations undertake activities additional to the generation of test, measurement, and calibration data. Laboratory accreditation does not address these ancillary activities. If an organization's quality system covers non-testing functions such as accounting, marketing, information services, education, etc., it may be necessary or desirable to have such activities recognized through an ISO 9001 certification process.

Where to Get More Information

For more information on laboratory accreditation, contact ACLASS Accreditation Services, an ANSI-ASQ National Accreditation Board Company, at 877-344-3044 or info@aclasscorp.com.

For more information on management systems accreditation to ISO 9001, contact ANSI-ASQ National Accreditation Board (ANAB) at 800-606-5394 or info@anab.org.

ACLASS and ANAB

ACLASS Accreditation Services, now an ANSI-ASQ National Accreditation Board company, provides laboratory accreditation for testing and calibration laboratories to ISO/IEC 17025, reference material producers (RMPs) to ISO Guide 34, and inspection bodies to ISO/IEC 17020. ACLASS is a signatory to the ILAC, APLAC, and IAAC multilateral recognition arrangements for ISO/IEC 17025.

ANAB is the U.S. accreditation body for management systems. ANAB accredits certification bodies for ISO 9001 quality management systems (QMS), ISO 14001 environmental management systems (EMS), ISO 27001 information security management systems, ISO 22000 food safety management systems, ANSI/AIHA Z10 occupational health and safety management systems, and numerous industry-specific requirements. ANAB is a member of the International Accreditation Forum (IAF) and a signatory of the IAF multilateral cooperative arrangements (MLAs) for QMS and EMS.

More Information About ILAC

The International Laboratory Accreditation Cooperation (ILAC) is the global authority on laboratory accreditation, with a membership of accreditation bodies and affiliated organizations throughout the world. It is involved with the development of laboratory accreditation practices and procedures, promotion of laboratory accreditation to facilitate trade, assistance in developing accreditation systems, and recognition of competent test and calibration facilities around the globe. ILAC cooperates with other international bodies in pursuing these aims. ILAC publishes a range of literature on accreditation, testing, trade facilitation, and related subjects. For more information, visit www.ilac.org.

More Information About IAF

The International Accreditation Forum, Inc. (IAF) is the world association of conformity assessment accreditation bodies for management systems, products, services, personnel, and similar programs. Its primary function is to develop a single worldwide program of conformity assessment to reduce risk for business and its customers by assuring the validity of accredited certificate. Accreditation assures users of the competence and impartiality of the body accredited. IAF members accredit certification bodies that issue certificates attesting that an organization's management, products, or personnel comply with a specified standard. For more information, visit www.iaf.nu.