



Laboratory Accreditation or ISO 9001 Certification?

LABORATORY ACCREDITATION OR ISO 9001 CERTIFICATION?

When selecting a supplier to fulfill your testing, calibration or measurement needs, you need to 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/inspection procedures
- accurate recording and reporting of data
- appropriate testing environment

Whilst a laboratory can reassure you that they have the above attributes, or you can attempt to evaluate the service yourself, neither provides you with confidence that you have selected a technically competent service.

WHAT IF THE LABORATORY HAS ISO 9001 CERTIFICATION?

Laboratories can be audited and certified to an international management systems standard called ISO 9001. This standard is widely used in manufacturing and service organisations to evaluate their system for managing the quality of their product or service.

Whilst effective as a management evaluation tool, ISO 9001 *does not* evaluate the technical competence of a supplier. This means that 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 THEN CAN YOU BE SURE THAT A LABORATORY IS TECHNICALLY COMPETENT?

Throughout the world, many countries now rely on a process called Laboratory Accreditation as a means of independently evaluating laboratory competence.

Unlike ISO 9001 certification, laboratory accreditation uses criteria and procedures specifically developed to determine technical competence. Specialist technical assessors conduct a thorough evaluation of all factors in a facility that affect the production of technical data. The criteria are based on an international standard called ISO/IEC 17025, which is used for evaluating laboratories throughout the

world. This standard 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;
- the testing environment;
- sampling, handling and transportation of test items;
- quality assurance of test, inspection or calibration data.

Laboratory accreditation also covers the relevant quality systems elements addressed in ISO 9001 certification. To ensure continued compliance, accredited facilities are regularly re-examined to ensure 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 on-going demonstration of their competence.

HOW CAN YOU TELL IF A LABORATORY IS ACCREDITED?

Accredited laboratories usually issue test or calibration reports bearing some type of logo or endorsement indicating their accreditation. You should also check with the laboratory as to what specific tests or measurements they are accredited for, and for what ranges or uncertainties. This is normally specified in their Scope of Accreditation, which may be supplied by the laboratory upon request.

Accreditation bodies in many countries publish lists or directories of the laboratories they have accredited, together with laboratories' contact details and information on their testing capabilities. If necessary, you can contact the accreditation body and find out whether there are any accredited laboratories that can perform the tests or calibrations you require.

To find out if your country has one or more laboratory accreditation bodies, try contacting your national standards body or your ministry for industry or technology. Alternatively, if you have access to the internet, you can visit the website of the International Laboratory Accreditation Cooperation (ILAC) at www.ilac.org and use the directory of laboratory accreditation bodies available on this website. You will also find directories of accredited laboratories for certain countries on this website.

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Whilst effective as a management evaluation tool, ISO 9001 does not evaluate the technical competence of a supplier

WHAT ABOUT DATA FROM OVERSEAS LABORATORIES?

Many countries around the world have one or more organisations responsible for the accreditation of their nation's laboratories. Most of these accreditation bodies have now adopted ISO/IEC 17025 as the basis for accrediting their country's 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, where possible.

This uniform approach allows countries to establish agreements among themselves, 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 these countries. In effect, each partner in such arrangements recognises the other partner's accredited laboratories as if they themselves had undertaken the accreditation of the other partner's laboratories.

Some 45 laboratory accreditation bodies have now signed a multi-lateral mutual recognition arrangement, called the ILAC Arrangement, which greatly enhances the acceptance of data across the national borders of the signatory countries. Full details for the ILAC Arrangement and the list of signatories can be found on the ILAC website 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 on overseas markets. This effectively reduces costs for both the manufacturer and the importers, as it reduces or eliminates the need for products to be retested in another country.

Countries without viable accreditation systems can seek to have their laboratories accredited by established accreditation systems, so that their test data and associated goods can be accepted on foreign markets. These countries can also endeavour to develop their own accreditation system based on the structure and experience of established systems.

CONCLUSION

There are differences between the purpose, criteria and emphasis of the ISO 9001 quality system standards 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. Similarly,

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 want, for other reasons, to also maintain a certified ISO 9001 management system. For example, many laboratory-based organisations undertake activities additional to the generation of test, measurement and calibration data. Laboratory accreditation does not address these ancillary activities of a laboratory. If an organisation's quality system covers non-testing functions such as accounting, marketing, information services, education etc, it may be necessary or desirable to seek to have such activities recognised through an ISO 9001 certification process.

WHERE CAN I GET MORE INFORMATION?

For more information on laboratory accreditation, you can contact your local ILAC member. ILAC members in each country can be found in the Directory on the website of the International Laboratory Accreditation Cooperation (ILAC) at www.ilac.org.

MORE INFORMATION ABOUT ILAC

ILAC is the peak international authority on laboratory accreditation, with a membership consisting of accreditation bodies and affiliated organisations throughout the world. It is involved with the development of laboratory accreditation practices and procedures, the promotion of laboratory accreditation as a trade facilitation tool, the assistance of developing accreditation systems, and the recognition of competent test and calibration facilities around the globe. ILAC actively cooperates with other relevant international bodies in pursuing these aims.

ILAC also publishes a range of literature on topics covering accreditation, testing, trade facilitation and related subjects. Its internet site at www.ilac.org can provide a range of information on laboratory accreditation, as well as the location of its members world-wide. A brochure, entitled *What Is ILAC?*, provides detailed information on ILAC and its activities, and is available on request.

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