Inter American Accreditation Cooperation

ACCREDITATION VS. CERTIFICATION OF LABORATORIES

THE ROLES OF ISO/IEC 17025 AND ISO 9001

IAAC COMMENTS

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ACCREDITATION VS. CERTIFICATION OF LABORATORIES

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1 Background

As a result of some misunderstandings in the general community about the roles and significance of accreditation or certification with respect to laboratories and their quality management systems, the Inter-American Accreditation Cooperation (IAAC) wishes to clarify the issue. The confusion has partly arisen due to the publication of a new International Standard for laboratory competence, ISO/IEC 17025:1999, and the emergence of a new version of ISO 9000(1) in 2000.

There is a particular need to explain the differences between accreditation and certification when laboratories require some independent **recognition of their competence** in accordance with ISO/IEC 17025 or of **compliance of their quality management system** with ISO 9001. Users of laboratories' services also need to understand the different purposes of the two Standards and the significance of specifying compliance with either of them when they commission services from a laboratory.

This information paper outlines the following key issues:

- ISO/IEC 17025: 1999, *General requirements for the competence of testing and calibration laboratories* has a different content and purpose to that of ISO 9001:2000, *Quality management systems – Requirements*;
- Both ISO/IEC 17025 and ISO 9001 have quality management system criteria, so there is some overlap in parts of the two Standards;
- The processes used to assess or audit against ISO/IEC 17025 and ISO 9001 have significant differences and a different emphasis;
- There are valid reasons for **some** laboratories to hold both accreditation to ISO/IEC 17025 and certification to ISO 9001; and
- Accreditation certificates and certification certificates for laboratories should clearly indicate the relevance of ISO 9001 compliance on the two types of certificates.

2 Accreditation and Certification

Certification is defined in ISO/IEC Guide 2 as a procedure by which a third party gives written assurance that a product, process, or service conforms to specified requirements. Its relevance to laboratories is discussed in detail later in this paper.

ISO CASCO - (ISO - Conformity Assessment Committee) has issued Guides/Standards related to *testing* (and calibration) laboratories (ISO/IEC 17025) and *certification* bodies (ISO/IEC Guides 62 and 65).

Accreditation is defined in ISO/IEC Guide 2 as a procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks. (The relevance of accreditation to laboratories is also discussed in detail later in this paper).

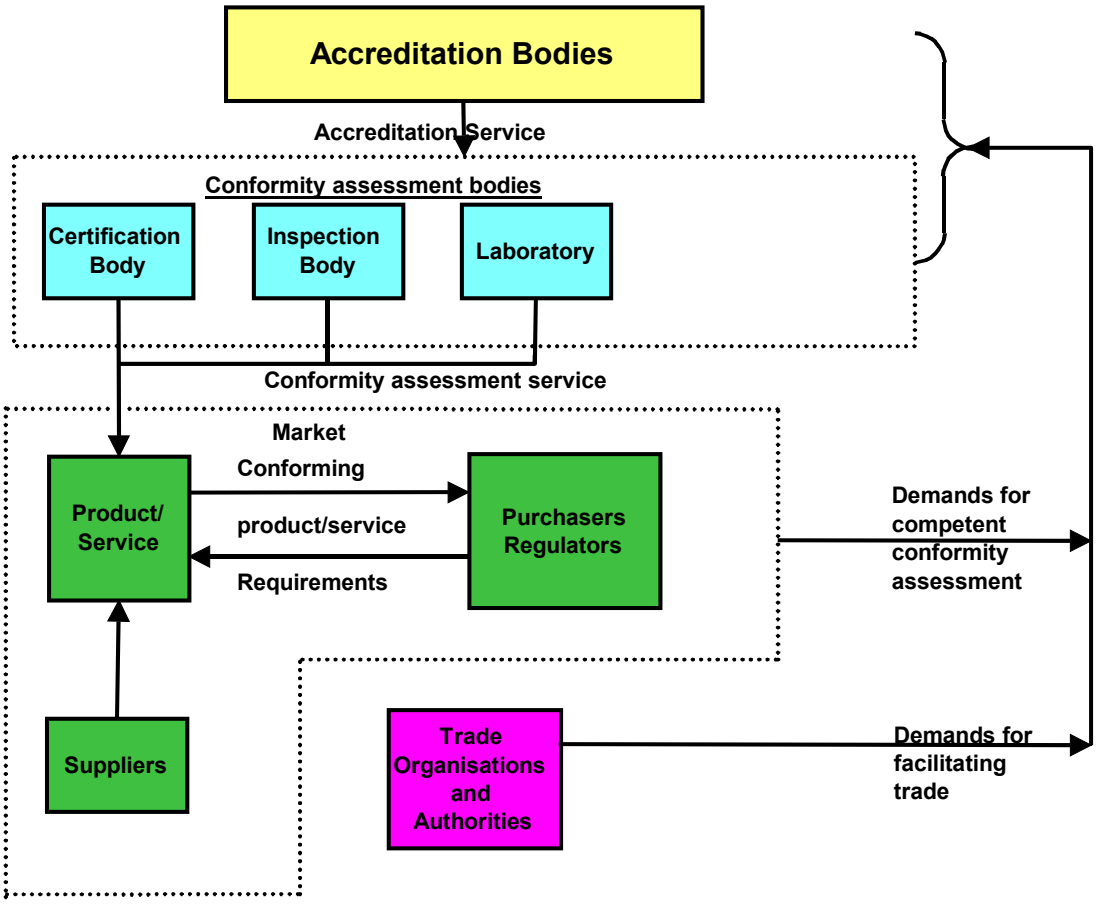
Accreditation of laboratories is perhaps the oldest and most widespread type of accreditation of conformity assessment bodies. Requirements for *laboratory accreditation* bodies are addressed in ISO/IEC Guide 58.

The product of a laboratory is data and is usually presented on a certificate or report, so the type of recognition given to such data, through either a supplier's declaration, accreditation of the competence of the laboratory, or through certification of its management system is an important issue for end users of such data.

Figure 1 depicts the relationships of conformity assessment and accreditation to the marketplace exchange between first and second parties.

Figure 1

Accreditation, Certification and Conformity Assessment



Ideally, all elements of the global market will be served.

3 How are Laboratories Accredited or Certified?

For ISO 9001 certifications the emphasis is to assess compliance with *management systems.* The *personnel* used by certification bodies to assess such compliance are expected, therefore, to be appropriately qualified to audit against their management system requirements and the *primary* emphasis is on management systems' expertise of such auditors. Normally, however, they would be expected to have some familiarity with the products, processes etc operated by the organization being certified or they may need to use technical experts in their audit teams to interpret the validity of application of the organization's quality management system to its specific range of products or services.

The expectations for auditor qualifications, or for the combined expertise of audit teams, are normally specified by the IAF member bodies which accredit management systems certification (registration) bodies.

For accreditation of laboratories against ISO/IEC 17025, the primary emphasis is to establish the *specific technical competence* of laboratories. As such, an essential feature of laboratory accreditation assessments is that the assessment team has sufficient technical experts or assessors with detailed knowledge of the types of tests, calibrations, measurements, etc. performed by the laboratory under its scope of accreditation.

Because ISO/IEC 17025 also includes management systems' requirements, the assessment team must also include assessors with appropriate knowledge of those system requirements. In most cases, this system's expertise comes from the permanent staff of the accreditation body, while the specific technical expertise is provided by external specialists. In some cases the technical experts may also have the relevant management systems expertise and they can be used for evaluation of both specific technical competence and management systems compliance of the laboratories.

In addition to assessments by technical experts, laboratory accreditation often also involves the use of proficiency testing and measurement audits, to confirm the competence of laboratories for specific tests, measurements or calibrations. Proficiency testing and measurement audits involve interlaboratory comparisons with products, materials or artifacts of known composition or values, where an individual laboratory's performance is compared with a reference group or to reference values. They provide tangible evidence of an accredited laboratory's capability and are becoming even more frequently used by accreditation bodies, as one part of the accreditation process.

The other difference between ISO/IEC 17025 accreditation processes and ISO 9001 certification processes is that laboratory accreditation is not only laboratory-specific, but is often also people-specific.

In assessments of laboratories, examination of the technical knowledge and competencies of specific staff members is a fundamental feature of accreditation assessments. Usually, the witnessing of performance of a representative number of tests or key parts of tests forms a part of the assessment process, and many accreditation bodies only recognise certain named members of staff as approved to sign test certificates or reports issued under an accreditation body's logo. If such people leave the laboratory, the accreditation body may discontinue accreditation until a suitable replacement is found and is assessed to have the appropriate qualifications and testing experience for the tests covered by accreditation.

In the case of ISO 9001 certifications it is not normally required that specific, named personnel are identified as a component of the certification. Rather, the "people" component of the management system is normally assessed via the organisation's documented policies and procedures for assignment of tasks and for specifying and implementing appropriate qualifications, experience, training and skills for such tasks.

In summary, the major differences between laboratory accreditation and certification, when applied to a laboratory, are shown in Table 2.

Table 2

• Certification	- Means compliance with a standard or specification (eg systems or product standards). - Uses management systems auditors who are qualified by an independent body as meeting internationally agreed criteria. - Can cover more than the activities or tests which have been accredited through laboratory accreditation. - May be general in the scope of certification. - Considers the total business including strategy and planning.
• Laboratory Accreditation	- Is the recognition of specific technical competence. - The scope of accreditation is normally highly specific. - Evaluates people, skills and knowledge. - Provides formal recognition that a testing laboratory is competent to carry out specific tests or specific types of tests. - Uses technical assessors who are recognised specialists in their field. - Also evaluates management systems compliance. - May involve practical tests (proficiency testing and measurement audits).

4 Laboratory Accreditation, ISO 9001 Certification or Both?

The question may be asked whether there are benefits for an organization to maintain both ISO/IEC 17025 accreditation and ISO 9001 certification for it's quality system.

The answer to this question is based on an analysis of the overall needs of the organization, the expectations of the laboratory's clients and the costs and benefits or their respective recognitions through either accreditation or certification.

ISO 9001 certification for the laboratory's quality system provides a "whole of organization" approval aimed at meeting customer requirements and achieving continual improvement, but does not provide assurance of specific technical competence.

Accreditation to ISO/IEC 17025 provides confidence in the technical competence of a laboratory for specified activities while also evaluating the application of ISO 9001 management systems principles to those activities. Accreditation, however, is restricted to a laboratory's testing, measurement or calibration activities and does not involve recognition of other activities in which the laboratory or its parent organization are involved.

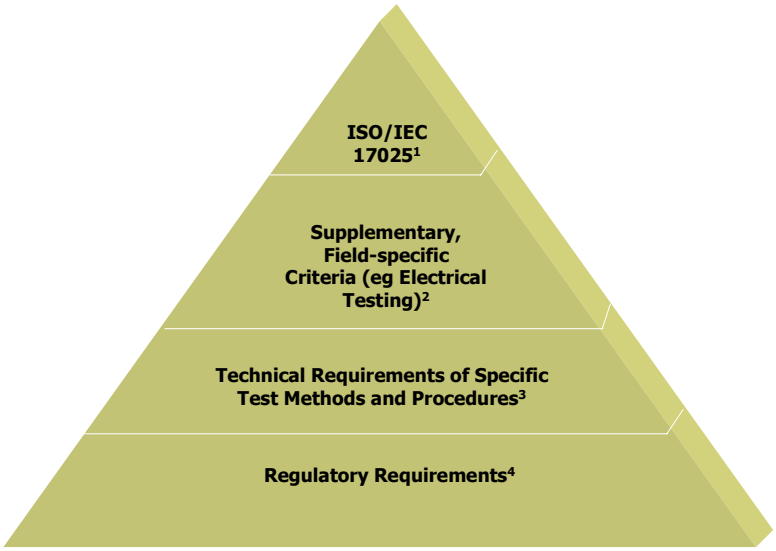
In summary, the decision on the need for ISO/IEC 17025 accreditation and/or ISO 9001 certification of it's quality system, is based on the above analysis of business and customer needs, that is:

- If clients of the organization (including internal clients) require independent assurance of the competence of its laboratory, accreditation to ISO/IEC 17025 may be a necessity;

- If the organization has adopted a "whole of organization" approach to meeting clients' needs, including their needs for assurance of technical competence, then both ISO 9001 certification and ISO/IEC 17025 accreditation should be considered; and

- If the organization has adopted an overall business improvement philosophy, then ISO 9001 should be considered.

Figure 2



1. *General technical competence and systems compliance criteria*
2. *Additional field-specific criteria, eg for emc testing laboratories*
3. *Additional test method criteria*
4. *Additional, regulator-specific criteria (eg reporting formats, labelling etc)*

5 Does Accreditation to ISO/IEC 17025 Include Certification to ISO 9001?

First will be clear that the certification doesn't apply for the laboratory by it self, but to it's quality management system.

Although ISO/IEC 17025 includes the management principles of ISO 9001:1994, laboratory accreditation does not include certification to ISO 9001. As described earlier, the emphasis and processes for laboratory accreditation and the composition of assessment teams are different from ISO 9001 certification processes. Similarly, the processes and emphasis for ISO 9001 certification do not provide an assurance of specific technical competence of a laboratory.

Accordingly, it is essential that Certificates of Accreditation provided by laboratory accreditation bodies do not claim that an accredited laboratory has also been certified to ISO 9001 through the accreditation process. However, because ISO/IEC 17025 does include the principles of ISO 9001:1994 it is appropriate to include on Accreditation Certificates a statement, such as:

(Accreditation Body)

has accredited

(Company XYZ)

following demonstration of its technical competence to operate in accordance with ISO/IEC 17025 (1999) which includes the management requirements of ISO 9001:1994.

Similarly, it is not appropriate for certificates issued to laboratories by bodies certifying their quality management system compliance with ISO 9001:1994 or ISO 9001:2000, to make any claims on certificates about technical competence. Nor should laboratories, whose quality management systems are certified to ISO 9001:1994 or ISO 9001:2000 claim that such certification includes recognition of their technical competence.

Certification of a laboratory quality management system to ISO/IEC 17025 is not appropriate under any circumstances. Accreditation bodies should not accredit QMS certifiers for certification of quality management systems of laboratories. In any case, the accreditation body mark should never be used on a certificate issued by an AB-accredited QMS certifier for the quality management system of the laboratory.

6 Future Direction

IAAC is committed to minimize confusion in the marketplace about certification versus accreditation with respect to laboratories. This includes any needs for amplification of this information paper, if additional guidance is required by end users.

Prepared by IAAC Working Group Task Force (Francisco Monje, Margareth Lafin, Maritza Madriz, Peter Unger) on the Issue of Certification versus Accreditation

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