ISO Guide 25 Versus ISO 9000 for Laboratories

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Acceptance of test data, nationally or internationally, should be based on the application of Guide 25 to assure the necessary confidence in the data's validity.

Introduction

Internationally, as well as here in the United States, there is considerable debate and confusion about the similarities, differences and relationships between laboratory accreditation (usually performed using ISO/IEC Guide 25, "General Requirements for the Competence of Calibration and Testing Laboratories") and quality system certification (or registration) to one of the three ISO 9000 series of quality system models, usually 9001, 9002 or 9003. For a laboratory, quality system certification is normally performed using ISO 9002.

Quality system certification has become a popular method of providing assurance of product quality. But does it? The large number of organizations offering certification to ISO 9000 series has created, perhaps accidentally but certainly deliberately in some cases, the scenario that certification to ISO 9000 assures product quality, and for laboratories, validity of specific test (and calibration) results. To the well informed, this is misleading.

There are several significant differences between laboratory accreditation using Guide 25 and quality system certification, but the key difference can be summarized by the fact that the essence of Guide 25 is to ensure the validity of test data, while technical credibility is not addressed in ISO 9002.

Why is there so much confusion? First, there is a significant problem of semantics. Second, the purposes of each standard are different and thus examination against them gives different levels of assurance. The ISO 9000 series of standards provide a generic system for quality management of an organization, irrespective of the product or service it provides.

Guide 25 is a document developed specifically to provide minimum requirements to laboratories on both quality management in a laboratory environment and technical requirements for the proper operation of a laboratory. To the extent that both documents address quality management, Guide 25 can be considered a complementary document to ISO 9002 written in terms most understandable by laboratory managers.

There is, however, a view being expressed that the application of ISO 9002 is sufficient for the effective operation of a laboratory, and thus ensures the validity of test data. This opinion has caused some confusion in the laboratory community itself and also, more broadly, among users of laboratory services. The problem is compounded when accreditation of the laboratory by a third party is required.

The Semantics Problem

Terminology used in this area of conformity assessment is in a state of flux, and is confusing or even misleading. The three "tion" words – accreditation, certification and registration – are often used interchangeably. For example, the U.S. EPA talks about accredited asbestos workers and certified drinking water laboratories when others in the same agency talk of certifying laboratory personnel and accrediting laboratories.

The problem is compounded by some very specialized bodies using the words in a different context altogether. For example, U.S. building code groups refer to accredited products rather than certified products and Underwriters Laboratories (or UL) uses the term "listed" instead of "certified" partly because the word "certified" carries with it the connotation of a guarantee, which according to UL representatives is misleading and goes beyond what UL product safety certification actually is.

The ISO Council Committee on Conformity Assessment (CASCO) has attempted to resolve the semantics problem by standardizing the following definitions:

- Accreditation: procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.
- Certification: procedure by which a third party gives written assurance (certificate of conformity) that a product, process or service conforms to specified requirements.
- Registration: procedure by which a body indicates relevant characteristics of a product, process or service, or particulars of a body or person, in an appropriate, publicly available list.

Internationally, certification has become the dominant term. However, the common use in the United States is not always in harmony with this

international guidance, particularly with European practice. The European approach is to label both quality system registrars and product certifiers as certification bodies. There is very little, if any, use of the term registration in Europe. So we have certification bodies performing either or both product certification and quality system registration.

There seems to be some agreement in the U.S. that "accreditation" is a formal recognition that a body is competent to carry out specific tasks, while "certification" is either self-declaration by a supplier (also known as self-certification, a term CASCO discourages, preferring the term "supplier declaration") or a formal evaluation by a third-party that a product conforms to a standard.

"Registration" is the term commonly used in the United States when referring to certification of quality systems. So we have laboratory accreditation defined as a formal recognition that a laboratory is competent to carry out specific tests or specific types of tests, and quality system registration being defined as a formal attestation that a supplier's quality system is in conformance with an appropriate quality system model (i.e., either ISO 9001, 9002 or 9003). Thus, the ASQ's (American Society for Quality) Registrar Accreditation Board (RAB) accredits quality system certification bodies.

Traditionally, certification in the U.S. has related to products, processes or services, but because of the European influence we are hearing more references to the certification of quality systems, or the very misleading short-hand, "ISO certified" seen in many advertisements. ISO is vigorously discouraging this type of reference as inappropriate, inaccurate, and possibly an infringement on the ISO trademark. Unfortunately, this type of advertising is largely to blame for perpetuating the confusion and hyping quality system registration beyond that which it can honestly deliver.

Differing Purposes

ISO 9000 SERIES

The primary aim of the ISO 9000 standards is defined in the Scope section of ISO 9001:

> *". . . specifies quality-system requirements for use where a supplier's capability to design and supply conforming product needs to be demonstrated."*

The standards' primary purpose is, therefore, to provide a management model suitable for the supply of a conforming product or service between two parties – a supplier and the customer. However, the focus on the use of the ISO 9000 standards as two-party models has shifted greatly as more and more use is made of them for third-party certification purposes. In today's complex world, there are limited opportunities for all customers to have direct relationships with their suppliers, so third-party certification bodies are, in effect, taking on the roles of representatives of multiple second parties (all the customers which rely on independent certification for their reassurance about a supplier). It is important, therefore, that users of third-party certification understand what form of reassurance is provided when an organization is certified against a quality system standard.

Since the ISO 9000 standards are generic, it is often a significant challenge to interpret their use in different industry sectors, or in organizations of different sizes or technical complexities. Quality system certification does not, however, certify the quality of a particular product or service for compliance with specific technical specifications, but only the management system's compliance with a defined model (ISO 9001, 9002, or 9003).

The introduction to the ISO 9001 standard makes this distinction between systems and product conformance, where it states: "It is emphasized that the quality-system requirements specified in this International Standard, ISO 9001, are complementary (not alternative) to the technical (product) specified requirements." Essentially, the ISO 9000 standards are reminding customers that they need to consider whether assurance is required not only on the compliance of a supplier's management system, but also on the technical compliance of the products provided by the supplier. This product assurance may be provided through a range of mechanisms such as product certification, product or process audits by the purchaser and vendor-supplied test data.

ISO/IEC GUIDE 25-1990

Unlike the ISO 9000 series, ISO/IEC Guide 25 was not established primarily as a contractual model for use between suppliers and their customers. Its aims are to:

- Provide a basis for use by accreditation bodies in assessing competence of laboratories;
- Establish general requirements for demonstrating laboratory compliance to carry out specific calibrations or tests; and
- Assist in the development and implementation of a laboratory's quality system.

Historically, Guide 25 was developed within the framework of third-party accreditation bodies. Its early drafting was largely the work of participants in the International Laboratory Accreditation Conference (ILAC) and the latest edition was prepared in response to a request from ILAC in 1988.

To understand the significance and purpose of Guide 25 and its relationship to ISO 9002, it is essential that it be viewed in light of its development history: it was initially designed to promote the harmonization of criteria for laboratory accreditation. Guide 25 is now being used by laboratory accrediting bodies throughout the world and is the basis for mutual recognition agreements among accrediting bodies.

Laboratory accreditation is defined

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in ISO/IEC Guide 2 as "formal recognition that a testing laboratory is competent to carry out specific tests or specific types of tests." The key words in this definition are "competent" and "specific tests." Each accreditation recognizes a laboratory's technical capability (or competence) defined in terms of specific tests, measurements, or calibrations. In that sense, it should be recognized as a stand-alone form of quite specialized technical certification – as distinct from a purely quality management system certification – as provided through the ISO 9000 framework.

Laboratory accreditation may also be viewed as a form of technical underpinning for a quality system in much the same way that product certification could be considered as another form of complementary underpinning for a certified quality management system.

Similarities/Differences

Both the ISO 9000 series and ISO/IEC Guide 25 are used as criteria by third-party certification bodies, and both contain quality systems elements. The systems elements of ISO 9000 are generic; those of the ISO/IEC Guide are also generic but more specific to laboratory functions. The textual differences between ISO 9002 and Guide 25 are obvious, but when interpreted in a laboratory context, it is generally accepted that the system elements of the two documents are closely compatible. This is acknowledged in the introduction of Guide 25 which states: "Laboratories meeting the requirements of this Guide comply, for calibration and testing activities, with the relevant requirements of the ISO 9000 series of standards, including those of the model described in ISO 9002, when they are acting as suppliers producing calibration and test results."

It is not true, however, that laboratories meeting the requirements of ISO 9002 will thus meet the requirements or the intent of Guide 25. In addition to its system requirements (which are compatible with ISO 9002), Guide 25 emphasizes technical competence of personnel for their assigned functions, addresses ethical behavior of laboratory staff, and requires the use of well-defined test and calibration procedures and participation in relevant proficiency testing programs. Guide 25 also provides more relevant equipment management and calibration requirements, including traceability to national and international standards for laboratory functions; identifies the role of reference materials in laboratory work; and provides specific guidance relevant to the output of laboratories – the content of test reports and certificates – together with the records requiring management within the laboratory.

Although Guide 25 contains a combination of systems requirements and those related to technical competence, for laboratory accreditation purposes the Guide is normally used only as a starting point. Guide 25 recognizes in its introduction that ". . . for laboratories engaged in specific fields of testing such as the chemical field . . . the requirements of this Guide will need amplification and interpretation . . . "

In the American Association for Laboratory Accreditation (A2LA) system of laboratory accreditation, these additional technology-specific criteria are contained in special program requirements documents such as the "Environmental Program Requirements."

However, there is another level of technical criteria which must be met for the accreditation of laboratories: the technically-specific requirements of the individual test methods for which the laboratories' competence is publicly recognized. So the hierarchy of criteria which must be met for laboratory accreditation purposes is as follows:

- ISO/IEC Guide 25
- Any field-specific criteria
- Technical requirements of specific test methods and procedures

Apart from comparisons on the similarities and differences between the purposes of ISO 9000 and Guide 25 and their use for third-party conformity assessment purposes, it is important to examine the differences in skills and emphasis of assessors involved in quality system certification and laboratory accreditation assessments.

For quality system certification, emphasis is traditionally placed on the qualifications of the assessor to perform assessment against the systems standard. The system assessor (often referred to as the Lead Assessor) is expected to have a thorough knowledge of the requirements of that standard. In current international practice, a quality system assessment team may or may not include personnel who have specific technical backgrounds or process familiarity relevant to the organizations being assessed.

For laboratory accreditation, the assessment team always involves a combination of personnel who have expert technical knowledge of the test or measurement methodology being evaluated for recognition in a specific laboratory, together with personnel who have specific knowledge of the policies and practices of the accreditation body and the general systems applicable to all accredited laboratories. Thus, the laboratory accreditation assessment includes a technical peer review component plus a systems compliance component.

There are some other elements of difference in the respective assessment processes. For example, laboratory accreditation involves appraisal of the competence of personnel as well as systems. Part of the evaluation of a laboratory includes evaluation of supervisory personnel, in many cases leading to a recognition of individuals as part of the laboratory accreditation. The technical competence and performance of laboratory operators may also be witnessed as part of the assessment process. The loss of key personnel may affect the continuing accredita-

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tion of the laboratory by the accrediting body. For example, A2LA recognizes key staff whose absence would reduce the laboratory's technical competence and may prompt a reassessment before it would normally be scheduled.

The final product of a laboratory is test data. In many cases, laboratory accreditation assessments also include some practical testing of the laboratory through various forms of proficiency testing (inter-laboratory comparisons or reference materials testing).

Quality system certification is not normally linked to nominated key personnel. The technical competence of managers and process operators is not a defined activity for quality system assessment teams. It is through the documented policies, job descriptions, procedures, work instructions, training requirements of organizations and objective evidence of their implementation that quality system certifiers appraise the personnel component of a system. Staff turnover is not an issue in maintaining certification.

Complementary Functions

Recognizing that there are differences in the purposes, criterion and emphases of ISO 9000 and Guide 25 and their uses for conformity assessment purposes, it is worthwhile to consider how the roles of quality system certification and laboratory accreditation can best interact.

Quality system certification for a laboratory should be viewed as a measure of a laboratory's capability to meet the quality expectations of its customers in terms of delivery of laboratory services within a management system model as defined in ISO 9002 or 9001 – a "quality" job. Secondly, laboratory accreditation should be viewed by customers as an independent reassurance that a laboratory is technically and managerially capable to perform specific tests, measurements or calibrations – a "technically competent" job.

If satisfaction is needed on both these characteristics, then a combination of quality system certification and laboratory accreditation may be appropriate. If a laboratory's function is purely for internal quality control purposes within an organization and it does not present any formal output in terms of certificates or reports to either external customers (or internal customers within a larger organization requiring formal test reports), it may be appropriate for the laboratory to operate within the overall ISO 9002 framework of the parent company. Nevertheless, such laboratories and their senior management may also benefit from the external, independent appraisal provided by the technical assessors used in laboratory accreditation. However, if a laboratory issues certificates or reports certifying that products, materials, environmental conditions, or calibrations conform to specific requirements, they may need to demonstrate to their clients or the general community that they are technically competent to conduct such tasks. Laboratory accreditation provides the independent measure of that competence.

Scope of Accreditation/ Certification

Organizations may be certified to a quality system standard within very broad industry or product categories. Naturally, organizations with a very narrow product range are certified in these terms.

Laboratories, on the other hand, are accredited for quite specific tests or measurements, usually within specified ranges of measurement with associated information on uncertainty of measurement, and for particular products and test specifications.

Accreditation bodies encourage laboratories to endorse test reports in the name of the accreditation body to make a public statement that the particular test data presented has been produced by a laboratory which has demonstrated to a third party that it is competent to perform such tests.

The ISO 9000 series of standards are not intended to be used in this way. They address the quality system, not specific technical capability. A quality system certification body's logo should not be used as a certification mark or endorsement as to the conformity of a particular product with its specified requirements. Similarly, it should not be used to endorse the competent performance of tests, calibrations or measurements reported by laboratories. Only a logo or endorsement showing accreditation to Guide 25 or equivalent for specific calibrations or tests denotes technical credibility and an expectation of valid results. Laboratories certified to ISO 9000 cannot make the same claim.

Role of Accredited Calibration Laboratories

For more general interaction between certified quality systems and laboratory accreditation, one very significant area is the role that accredited calibration laboratories play in demonstrating traceability to national and international standards of measurement. The ISO 9000 series require that

> *". . . suppliers shall . . . calibrate ... inspection, measuring and test equipment . . . against certified equipment having a valid known relationship to nationally recognized standards."*

Many calibration certificates presented to quality system auditors contain statements that the measurements or calibrations are "traceable to national standards." Some auditors also insist that suppliers' calibration documents provide cross-references to the other reference standards used to calibrate their own devices and to provide a documented chain of traceability back to their own country's or international standards of measurement. There may be multiple steps, involving various

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calibration devices, required to demonstrate traceability back to a national standard. This can therefore become a very complex and, in some perceptions, bureaucratic demonstration of traceability by a supplier. The supplier may also have no direct access to information, or influence over, the provider of calibrations for its equipment.

Concentration by auditors on documented statements of traceability of measurements can be viewed as an exercise in "paper traceability, "not "technical traceability," i.e., the calibrations performed on their equipment have been performed by personnel competent to undertake the measurements, under controlled environmental conditions (where appropriate), using other higher accuracy equipment that is maintained and recalibrated within appropriate intervals and backed up by records and other management systems which meet the principles of good laboratory practice embodied in Guide 25. Accreditation of the laboratory providing a specialist calibration service offers such reassurance of technical traceability.

As it is a fundamental requirement for accredited calibration laboratories to have their own equipment traceable to national and international standards, both the interest and spirit of the ISO 9000 requirements are thus met when accredited calibration laboratories are used by suppliers. This principle has been recognized in the recently issued ISO Standard 10012.1-1992 where Clause 4.15, "Traceability," states that

> *". . . the supplier may provide the documented evidence of traceability by obtaining his calibrations from a formally accredited source."*

Fundamental Difference

Quality system registration (ISO 9000) asks:

- Have you defined your procedures?
- Are they documented?
- Are you following them?

Laboratory accreditation asks the same questions but then goes on to ask:

- Are they the most appropriate test procedures to use in the circumstances?
- Will they produce accurate results?
- How have you validated the procedures to ensure their accuracy?
- Do you have effective quality control procedures to ensure ongoing accuracy?
- Do you understand the science behind the test procedures?
- Do you know the limitations of the procedures?
- Can you foresee and cope with any technical problems that may arise while using the procedures?
- Do you have all the correct equipment, consumables and other resources necessary to perform these procedures?

The registration of a laboratory's quality management system is a com-

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ponent of laboratory accreditation – not a substitute. Quality system registration of a laboratory to ISO 9000 misses a key element – technical validity and competence.

Unfortunately, quality system registration of laboratories is already being seen as an easier route to some form of recognition for a laboratory than full accreditation.

European Position

In an April 1992, statement issued by the European Organization for Testing and Certification (EOTC):

> *". . . the only acceptable stand is to state that QS certification cannot be taken as an alternative to accreditation, when assessing the proficiency of testing laboratories. Not trying to underrate the QS certification procedure, it should nonetheless be underlined that, by being intended as a systematic approach to the assessment of an extremely broad scope of organizations and field of activity, it cannot include technical requirements specific to any given domain."*

Conclusion

Before laboratories jump on the ISO 9000 bandwagon, they should understand whether this type of third-party recognition is really appropriate for the needs of their customers. From the point of view of the user of test data, the quality management systems approach to granting recognition to laboratories is deficient in that it does not provide any assessment of the technical competence of personnel engaged in what can only be described as a very technical activity, nor does it address the specific requirements of particular products or measurements. The ISO 9000 series states explicitly that they are complementary, not alternatives to specified technical requirements. Users of test data, therefore, should be concerned with both the potential for performing a quality job (quality system) and technical competence (ability to achieve a technical result). The best available method of achieving these two objectives is through laboratory accreditation bodies, operating themselves to best international practice, requiring laboratories to adopt best practices and by engaging assessors who are expert in the specific tests in which the customer is interested. Acceptance of test data, nationally or internationally, should therefore be based on the application of Guide 25 to assure the necessary confidence in the data's validity.

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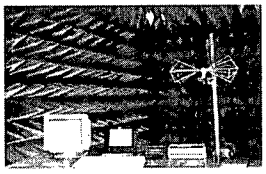

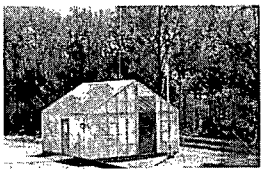

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