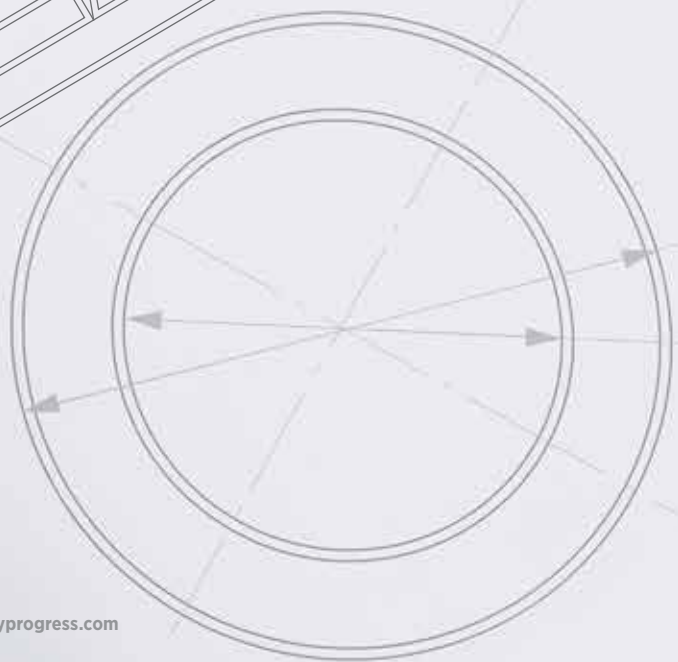


The importance
of ISO/IEC 17025
accreditation
and its
relationship to
ISO 9001

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MEASURED ACCURACY





Just the Facts

ISO/IEC 17025:2017 is considered the preeminent standard for calibration and testing labs throughout the world.

Organizations certified to ISO 9001:2015 must pay close attention to calibration requirements and must use an accredited ISO/IEC 17025 metrology lab or assess the metrology lab's conformance to ISO/IEC 17025 using competent personnel.

These organizations must exercise caution and due diligence when selecting a testing lab and a calibration lab to ensure these labs are ISO/IEC 17025:2017 accredited and qualified.

International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) 17025:2017—General requirements for the competence of testing and calibration laboratories is the preeminent global standard for calibration labs (CL) and testing labs (TL) worldwide. ISO/IEC 17025 requires specific processes and procedures to ensure that measurement certainty is correctly evaluated.

Independent validation and verification of the effectiveness of these processes and procedures are achieved through accreditation. Without third-party accreditation or second-party (that is, supplier) audits performed by competent personnel, a metrology or testing lab cannot demonstrate independent validation and verification

of the effective compliance of its quality management system (QMS) to ISO/IEC 17025. Getting accredited to ISO/IEC 17025 remains the most popular method of ensuring conformance to this standard.

Many metrology and testing labs worldwide will make statements on calibration or testing certificates issued to clients such as: “calibrated in accordance with ISO/IEC 17025” or “ISO/IEC 17025-compliant metrology laboratory.” This misleading information is further complicated by the fact that ISO/IEC 17025-accredited testing and metrology labs have a defined scope of accreditation covering specific types of devices or tests and calibrations. The lab may not have an unlimited scope of accreditation covering all types of calibration for devices or all types of tests.

The aforementioned statements give customers a false sense of security. Without independent accreditation or independent validation (that is, without QMS assessments performed by personnel competent to audit against the ISO/IEC 17025 standard) and a scope of accreditation that includes the device being calibrated or test performed, these statements are meaningless and cannot ensure that calibration or testing has been performed to national or international standards that are traceable.

Organizations certified or registered to ISO 9001:2015—in which calibration is a requirement—must ensure that such equipment is “calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards.”¹ ISO 9001-certified organizations perform calibration internally, externally using a metrology lab, or both.

To ensure traceability to a national or international standard, the organization must use an accredited ISO/IEC 17025 metrology lab or assess the metrology lab’s conformance to ISO/IEC 17025 using competent personnel. Organizations that do not choose either of these options cannot claim legitimately that they are meeting the requirements of ISO 9001 *Clause 7.1.5.2—Measurement traceability*.

Accreditation to ISO/IEC 17025

The term “accreditation”² means that a test or calibration lab has a QMS that includes required documented information (including documents and records), required processes and effective implementation of that QMS, which will be assessed and examined by an accreditation body (AB).

To become accredited to ISO/IEC 17025:2017, a TL or CL must undergo an assessment of its QMS as well as a technical assessment (TA), done by an AB. To become certified to ISO 9001:2015, an organization must undergo an audit or assessment of its QMS, conducted by a certification body (CB). There is no TA in this case.

The QMS assessment to ISO/IEC 17025:2017 ensures that the lab’s documentation system

and organizational structure conform to the requirements of ISO/IEC 17025:2017. This involves a review that includes the required quality documents, including testing or calibration procedures, organizational charts, management of conflict of interest issues, internal audits, management reviews, handling of customer complaints and competence of personnel, to name a few.

This portion of the assessment—to evaluate compliance with ISO/IEC 17025—is similar to the ISO 9001:2015 stage-one assessment. However, the ISO/IEC 17025 assessment also includes a TA.

The TA includes:

- + Witnessing the lab’s testing or calibration activities.
- + Reviewing calibration and maintenance records of its measuring and testing equipment.
- + Reviewing the lab’s ability to accurately compute measurement uncertainty (MU).
- + Reviewing the lab’s program and methods to ensure compliance with proficiency testing/interlaboratory comparison testing (or equivalent steps shown in ISO/IEC 17025:2017).

Metrological traceability (MT) of the measurements taken by the lab is a significant issue reviewed by the AB and is addressed in section 6.5 of ISO/IEC 17025:2017. MT can be illustrated as follows:

If a test technician from a lab measures a length using a caliper, the accuracy of his readings depends on the accuracy of the caliper. If the caliper is calibrated by an accredited calibration lab, the technician’s measurements are traceable to the calibration lab, which in turn, by virtue of its accreditation, is traceable to the international system of units (SI).

To achieve accreditation, CLs must demonstrate conformance with the use of National Institute of Standards and Technology (NIST)-certified reference standards or reference materials.³ The CL uses validated calibration procedures (VCP) to perform its calibrations. Validation ensures the calibration procedure has been used by numerous

professional experts, and the procedure provides consistent results.

Methods to ensure a CL-VCP is validated include one of the following:

- + The VCP is directly derived from or based on a published national standard, such as the American Society for Testing and Materials (ASTM) E-4 for force calibrations.
- + The VCP is directly derived from or based on a published manufacturer's manual (a.k.a. owner's manual) that shows a procedure for the equipment's calibration.
- + The VCP is directly derived from or based on a calibration procedure contained in a U.S. Department of Defense (DoD) publication (for example, the U.S. Navy's standard operating procedure for a specific calibration).

In all cases, the procedure would have been used by many different professional experts through ASTM, through the manufacturer, or through the DoD's calibration experts.

If these options are not available, the CL has the option to do its own round robin project⁴ to ensure its VCPs are properly validated.

To be accredited, a CL must comply with the items stated earlier. A TL, which performs its own in-house calibrations, also must comply with the TA requirements.

ABs

In the United States, an AB typically is a private company that must pass an external audit for conformance to ISO 17011:2017 performed by a nominee of the International Laboratory Accreditation Cooperation (ILAC). ILAC nominates a randomly selected peer evaluation team consisting of personnel from different ABs to perform an external audit of any given AB. By passing such an audit and complying with other ILAC requirements, the AB becomes a full signatory member of the ILAC Mutual Recognition Agreement. An AB must be a member if its accreditations are to be accepted worldwide.

The AB's logo, along with the ILAC logo and the tagline, "ISO/IEC 17025 Accredited," will appear on calibration or testing certificates

issued by accredited metrology or testing labs. These accredited labs cannot put these logos on certificates when equipment calibration or tests performed are not within the scope of their ISO/IEC 17025 accreditation.

ISO 9001:2015

ISO 9001:2015 is the world's most popular QMS model. The thematic requirements of ISO 9001 include leadership and top management commitment, planning, support, operational control, performance evaluation and improvement. Certification to ISO 9001 is achieved by retaining the services of an accredited CB. The CB performs an initial certification audit (conducted in two stages) and issues a certificate of conformance to ISO 9001 valid for three years, contingent upon no less than annual surveillance audits. Organizations pursuing conformance and certification to ISO 9001 will see improvements to customer satisfaction, product and service reliability, and consistency in its processes.

ISO and IEC permit a TL (which must have its own QMS in strict adherence to ISO/IEC 17025:2017) to use a QMS based on ISO 9001:2015. In addition, the TL must undergo an additional TA. To become accredited to ISO/IEC 17025:2017, a TL must undergo an assessment, which will include the TA. It should be noted that even if the TL or CL is certified to ISO 9001:2015, it still must have a TA. In addition, not all ISO/IEC 17025:2017 QMS requirements are met by meeting the requirements of ISO 9001:2015.

If the TL wishes to become accredited to ISO/IEC 17025:2017, it must have metrologically traceable calibrations in accordance with section 6.5 of ISO/IEC 17025:2017. This section requires an unbroken chain of calibrations, which establishes traceability to the SI system of units.

Measurement uncertainty

MU is an estimate of the error associated with the numerical test results generated by a TL or CL. Theoretically, there is no such thing as a

perfect measurement. All measured values have some error associated with them. An accredited TL or CL must make a reasonable estimate of the MU associated with its numerical results.

A test result in which no numbers are involved (such as a go/no-go gauge used to accept or reject and determine passing or failure) has no MU that can be computed. MU estimation involves the mathematical computation of the errors introduced into the test or calibration.

Variability of the testing or calibration process

When statistically computed (that is, when it is computed as a standard deviation of the test results), it is called Type A MU. A standard deviation generated by an accredited proficiency test provider can be used as a Type A MU for that test. Variability and error are introduced by each measuring instrument used by a TL.

A TL takes the MU of each instrument from its calibration certificate issued by an ISO/IEC 17025:2017-accredited CL. Typically, this is called a Type B MU. For example, if five measuring instruments are used, a TL may have five MUs, one for each measuring instrument—for instance, B1 through B5. A CL also considers the MU of its reference standards or reference materials. The CL gets this information from the calibration certificates issued by the National Measurement Institute, such as NIST in the United States.

When numerically possible, the TL or CL must account for environmental factors—such as the effect of temperature, relative humidity and all other factors, such as human variability—in the MU estimate. A vector sum (usually a root mean square) value of the earlier MUs results in combined, expanded MU. A table that lists the earlier MUs—item by item—is called an MU budget.

ISO/IEC 17025:2017-accredited TLs and CLs must compute MU. For a TL, a nonnumerical result exempts it from computing MU. A CL typically has no numerical results, and it must compute MU for every calibration it performs

(per ISO/IEC 17025:2017). If the margin by which a product passes or fails a test is extremely wide, a TL may state that the computation of MU for that test is not relevant.

For example, in a given test, assume that the maximum test sample temperature (allowed by the test standard) for the test sample in one hour is 300° C. The test standard also states that the test specimen fails the tests if the temperature rises above this limit. If in this test, the actual temperature reached by the specimen was only 100° C, the specimen passes by such a wide margin that the influence of the MU of the thermometer (typically less than 1° C) on the test result is irrelevant. Similarly, if the actual temperature reached is 325° C, the MU of the thermometer (typically less than 1° C) is irrelevant.

However, if the actual temperature reached is 299.5° C (very close to the limit stated in the test standard), the computation of MU and its influence on the test result is most relevant. If the test is on a naturally occurring material (for example, wood) that has huge test specimen variability, or the test method is known to have a huge variability (for example, a spread of flame test as described in ASTM E-84),⁵ a TL may state that the computation of MU for that test is irrelevant.

As a general requirement, a decision rule (a rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement) must be met in accordance with clause 7.13 of ISO/IEC 17025:2017. This clause states:

“When the customer requests a statement of conformity to a specification or standard for the test or calibration (for example, pass/fail, in tolerance/out of tolerance), the specification or standard and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer.”⁶

This requirement means that if the TL or CL has contracted with the customer that it will perform a test (or calibration) per a given standard,

it is required to follow the pass/fail criteria given in that standard. If it is not clearly stated in the standard, the accredited TL/CL must get prior written agreement from its customer.

It is well known that most accredited labs perform tests in accordance with legally enforceable contracts to test and calibration standards that are clearly stated in the contract. Because these test and calibration standards are published with clear criteria for passing or failing, the TL or CL would be complying with the decision rule (in accordance with clauses 3.7 and 7.13 of ISO/IEC 17025:2017), as long as it follows the test/calibration standard, which may or may not require any computation of MU.

Due diligence recommended

Organizations attempting to achieve conformance to ISO 9001, along with those organizations already certified to this standard, should exercise caution and due diligence when selecting a TL or CL. As part of the vendor selection process, always request a copy of the lab's accreditation certificate and verify the equipment you will be sending to the lab or the test they are performing is covered by their scope of accreditation.

If the lab is not ISO/IEC 17025:2017-accredited, a second party or supplier audit must be conducted using competent personnel to determine the level of compliance to this standard. Records of these audits must be maintained.

In addition, if the logo of the AB is included in the calibration or testing certifications, it indicates the lab is ISO/IEC 17025-accredited and not just compliant. Without this vital information (or in its absence, the evidence of successful supplier audits), it will not be possible for any organization to ensure that the calibration of its equipment is traceable to national or international standards. Such a test or calibration, performed by an accredited TL or CL, has traceability to the SI system of units.

What this means to the customer is that the CL or TL's competence to perform the work has been competently evaluated and the results of the lab's work have an acceptable margin

of error (usually very small). As mentioned earlier, this is achieved by having an unbroken chain of calibrations, as independently verified by the ABs. [QP](#)

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EDITOR'S NOTE

References and notes listed in this article can be found on the article's webpage at qualityprogress.com.



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