A Practical Approach to ISO/IEC 17025

A case study for testing and calibration labs

Henry Troemner LLC has been in the precision measurements and calibration business since 1838. The company's work is done under the strict guidelines prescribed by ISO/IEC 17025—"General requirements for the competence of testing and calibration laboratories," with a view toward providing their customers with the lowest possible measurement uncertainties. Before undergoing the ISO/IEC 17025 registration process, however, Troemner first sought to become an ISO 9001-registered company.

"We were one of the first organizations in the Philadelphia area to achieve ISO 9001 registration," says Tracey Hill, Troemner's quality coordinator and lead internal auditor. "Once the critical step of ISO 9001 registration was successful, the company's focus shifted to the rigorous requirements of ISO/IEC 17025 accreditation. The guidelines make an organization take a critical look at every aspect of performing a calibration."

This resulted in a list of processes that required additional documentation, and procedures that needed to be written for the first time. In addition to the documentation, detailed testing data was required by the National Voluntary Laboratory Accreditation Program (NVLAP) and United Kingdom Accreditation Service (UKAS) to provide evidence that the measurement assurance program had the proper controls in place.

From the first contact with a customer to the delivery of the customer's device with a calibration certificate, every step of the process can have an affect on the quality of the calibration. The requirements of ISO/IEC 17025 provided Troemner with a framework to develop procedures to fully cover all the diverse aspects of the calibration process and the generation of calibration certificates.

However, the development of a documented ISO/IEC 17025 quality system is not enough in the metrology industry. The key to having a successful quality system is to become accredited. In the field of metrology, a third party such as NVLAP, administered through the National Institute of Standards and Technology (NIST), ensures that technically competent individuals are performing the calibrations correctly.

"Accreditation translates to a cost savings in minimizing or even eliminating the need for on-site visits by the customer," says Hill. "If a calibration service provider is not accredited, customers are taking a significant risk with their own quality control program."

Once the decision was made to seek ISO/IEC 17025 accreditation, Troemner's certified ISO 9001 quality management system (QMS) was reviewed, expanded, and enhanced to meet the specific requirements for calibration laboratories. The goal was for Troemner to become ISO/IEC 17025-accredited by both NVLAP

by Nicolette Dalpino

Know & Go

- The development of a documented ISO/IEC 17025 quality system is not enough in the metrology industry. The key to having a successful quality system is to become accredited by the National Voluntary Laboratory Accreditation Program (NVLAP) and United Kingdom Accreditation Services (UKAS).
- Accreditation translates to a cost saving in minimizing or even eliminating the need for on-site visits by the customer.
- Accreditation is a formal recognition by an authoritative entity that an organization or individual is competent to carry out specific tasks.
- The foundation of measurement calculations is the traceability back to nationally recognized standards.
- The contract-review process helps to establish a consistent format for the review and understanding of what customers need.
- Internal audits are an important opportunity to identify opportunities for improvement and implement preventive action.

and UKAS for mass calibrations. Accreditation is a formal recognition by an authoritative entity that an organization or individual is competent to carry out specific tasks. Troemner pursued both of these accreditations to obtain the domestic and international recognition that NVLAP and UKAS carry. By having this double accreditation, Troemner's mass calibration services could be provided all over the world.

Troemner's customer base was keenly interested in their accreditation status. "Recognition from an external body is really what our customers want," says Hill. "We are giving them the peace of mind that they are dealing with somebody who has a system in place and has had that system checked, double checked, and triple checked by external people."

Of the 25 clauses within ISO/IEC 17025 that Troemner met for accreditation, five speak directly to customers: subclause 5.6—"Measurement traceability," subclause 5.3—"Accommodation and environmental conditions," subclause 4.4—"Review of requests, tenders, and contracts," subclause 4.14—"Internal audits," and subclause 5.10—"Reporting the results."

Measurement traceability

Troemner maintains a strong chain of traceability back to nationally recognized standards. To uphold this traceability chain the company performs intralaboratory comparisons of their own standards and interlaboratory comparisons with other accredited facilities. These comparisons demonstrate stability in their standards and laboratory practices.

"For example," explains Hill, "if you need to meet requirements by the FDA, they will tell you that the device that you use in your lab needs to be controlled, and one of the main means of 'control' is knowing the exact value and uncertainty that the device provides."

It starts with the nationally recognized standard device that has a value and uncertainty. That device is measured and compared to Troemner's reference standard, resulting in a value and uncertainty for the Troemner device. Next, in Troemner's calibration laboratory is the measurement of the customer's device that provides a value and uncertainty that is reported on the customer's calibration certificate. This series of measurements completes the traceability chain from national standard to every customer device.

"When we return a product back to a customer with our calibration certificate," says Hill, "they have confidence that the data on the certificate has been generated in accordance with our quality assurance program and the ISO/IEC 17025 requirements, which in turn provide evidence of traceability back to nationally recognized standards."

Accommodation and environmental conditions

Troemner's mass laboratories were specifically constructed to create an environment of stable temperature and humidity, low vibration, and low air velocity, which is suitable for making precise mass measurements. The quality control metrology manager is responsible for monitoring

and maintaining the environment conditions for all calibration services.

To meet the prescribed range of environmental conditions set out by NVLAP, Troemner moved to a new facility in 1999 and specifically constructed a calibration lab as a building-within-a-building design.

"The area that our mass laboratory actually sits on is a separate foundation that is insulated with sand, and has various materials underneath, so it will not be affected by vibrations. The area has its own HVAC system to very precisely control the temperatures and the humidity of the environment," says Hill. "We have alarms build into our software programs so that if something happens we know about it and stop calibrations and fix it. This ensures the accuracy of the measurements and calibrations."

Review of requests, tenders, and contracts

It is critical for the laboratory to fully understand the customer's requirements for the calibration. Contract review by Troemner's inside sales department is where this important activity takes place. The contract-review process helps to establish a consistent format for the review and understanding of what customers need.

"This is our first interface with the customer," states Hill. "We ask 'what do you need?' and try to gain an understanding by having a very detailed and complete contract-review process. ISO/IEC 17025 plays into this, because the standard makes you think of all the different areas that can affect your customer. It give you the tools you need to develop a procedure so that there's consistency among your staff. It's important that everybody is asking the customer the same set of questions and going through the same process to ensure that we receive consistent information."

Internal audits

Under the direction of the lead internal auditor, every section of ISO/IEC 17025 is audited once a calendar year. Any problems that arise during internal audits are treated as corrective actions to ensure that the issue is documented, addressed, resolved, and verified. Internal audits are an important opportunity to identify opportunities for improvement and implement preventive action.

Auditing is a regular activity that keeps a company's finger on the pulse of what's going on. "We have the chance to check up on ourselves to be sure we're in excellent shape for when an external assessor or one of our customers comes in and wants to audit us," says Hill. "It's an opportunity to learn, and to make sure that training has been effective. It lets you sleep at night. You know you're doing everything you can to make sure that the system is operating at its highest level. You know you're identifying problems and nipping them in the bud."

Reporting the results

In the field of calibration, the certificate is everything. It is imperative to present the data properly. ISO/IEC 17025 includes very specific requirements as to what shall be included on the certificate. NVLAP and UKAS look closely at the certificates to make sure that all the requirements are met.

"Say you have a pipette and you want it calibrated," says Hill. "You ship it to Troemner and we perform a series of measurements and perform the calculations. You get your pipette back with a calibration certificate. Then, if you need to have data entered into your programs based on the work that you do with that pipette, the numbers that we give you are hugely important. For example, FDA requirements are critical for our customers. So, those certificates mean that the pipette we calibrated has been assigned a value and an uncertainty, and the quality of the measurement process is ensured."

Since 1995, when Troemner's Mass Calibration Laboratories received accreditation from both NVLAP (Lab Code 105013-0) and UKAS (A UKAS Accredited Calibration Laboratory No. 0516), Troemner has continued to meet and maintain the most rigorous testing and manufacturing standards for all of their calibration services.

Troemner's journey with ISO/IEC 17025 has been essential in maintaining the highest quality standards.

"Each one of the clauses within the standard plays a role in how we look at and pursue quality within our organization," concludes Hill. "Our experience and success with ISO/IEC 17025 for mass services prompted us to expand our calibration labs so that we can now provide accredited calibration services for other measurement disciplines."

About the author

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Comments

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