

Press release for GTMA

Making the climb to ISO/IEC 17025

Accreditation - IndySofts' Calibration software can help calibration labs scale this standards summit.

Like dedicated mountain climbers who carefully plan their expeditions to the summits of Everest or Kilimanjaro, quality professionals who work in calibration, inspection and testing laboratories must also prepare before they lead their organizations up the slopes of ISO standards registration.

They won't be selecting ropes and ice picks, but these quality management system "mountaineers" must select the gear that will underwrite the success of their businesses and ensure the precision required by their industry. Successful products, the viability of the labs and even the safety of human lives depend upon careful preparation and the right tools.



As the guidelines for ISO standards become more stringent, calibration management software increasingly offers the most reliable tools to catalogue, organize, guide and evaluate a calibration lab's progress through specific procedures. Software is invaluable in helping to establish a systematic, predictable approach to lab operations. Auditors understand the necessity of reliable software solutions and value data from such systems, especially when they're integrated into a lab's

daily activities. A virtual Swiss army knife loaded with features, quality software is a vital tool for companies attempting to achieve registration to various ISO standards.

Historically, labs have looked to ISO 9001 for guidelines on ensuring quality processes in calibration, inspection and testing. The increased acceptance of the ISO/IEC 17025 standard has introduced a new level of complexity in the "ascent" to registration. These standards address aspects of lab competency as well as reliability in calibration procedures and results. Labs that set excellence as their goal must move beyond the procedural competence demanded by ISO 9001 and demonstrate competence through the "technically valid data and results" required by ISO/IEC 17025. Accurate measurement estimations, competent lab technicians, and traceability of methods and equipment are vital parts of the standard's requirements.

The right software product can sustain day-to-day lab operations while allowing maximum flexibility for ISO/IEC 17025 accreditation challenges. Labs that research the standard as well as the required tools for the journey will be assured of success. ISO/IEC 17025's

section 5 regarding technical requirements represents the first leg of the ascent, and it can be conquered almost entirely by a properly constructed software solution. Let's look at some specific situations.

Certificates of calibration

The process for creating certificates of calibration (or "certs") must be extremely flexible to allow for modifications required by ISO/IEC 17025 specifications. Make sure your calibration management software can generate unique cert numbers and that it offers plenty of options to display data collected from calibrations or tests on the certificate. Section 5.10 provides a comprehensive list of the minimal characteristics for certs or test reports. These items include (but aren't limited to) title, lab address, calibration location, custom information, equipment calibrated, date and time, methods used, test point findings and technician's signatures.

Custom certs for customer and/or equipment type should also be available to allow for specifications in section 5.10.1, which emphasizes that customer requirements must be fulfilled. Also check that additional riders can be included with the cert, and that outsourced certificates can be added to the system so that complete documentation is made available.

Charts, trend analysis and process workflow

Look for software that supports charts and calibration trend reports. These data support statistical analysis of the overall calibration system and allow technicians to visualize the effects of procedural changes.

Software that tracks equipment through the lab reduces the chance of mishandling at any step. This functionality is generally referred to as "workflow" (or "process modelling") and it ensures, through a system of data checks, that employees follow exact procedures as equipment moves through the lab. Systems that provide visual feedback or enforce rules for the use of equipment reduce training costs and ensure reproducibility of lab policies. When evaluating the process provided by any system, ask yourself if the software will force you to radically alter your existing workflow or allow you to maintain your existing in-house procedures. The difference here can mean reduced training and deployment times.

Tracking

Keeping a record of "tracks" is valuable for both mountaineers and quality professionals. A reliable calibration management package should allow for entry and tracking of any equipment used for testing or calibration. Ensure that equipment records meet at least the minimum requirements of section 5.5.5, which includes such items as unique identifiers, manufacturer and model number, equipment documentation, historical records, and calibration and/or maintenance procedure scheduling.

Software should clearly identify reference standards, traceable to the International System of Units, and allow for tracking and calibration in addition to scheduled or impromptu checks. Off-site calibration of references should be logged and marked "unavailable" until they're returned and validated for use. A powerful system will allow you to scan and attach all relevant documents to complete your paper trail.

Document storage in a central location or database isn't required by the standard, but it does offer greater control. Just make certain that a complete record of the equipment's calibration history can be stored or referenced in some manner.

Preventive maintenance

In a lab or manufacturing environment, preventive maintenance is important to ensure

timely upkeep of internal equipment and compliance with section 5.5.6. If any equipment is allowed outside the lab, the system should log its exit and prompt you to perform required performance checks upon its return. Systems that schedule maintenance procedures reduce the chance of missing an important cycle that might be uncovered during an audit.

Validations of methods are also essential to a quality management system. Search out packages that allow for scheduled or on-demand studies of the measurement system. Often referred to as gauge studies, these options provide statistical data on the overall accuracy of your measurement methods and the technicians who perform them. In a study, data are collected through a series of performed measurements, then compiled into results based on one of various standardized industry calculations. Historical charting or trending of these results for statistical analysis and refinement adds linearity to your analysis.

Security and validation

For a lab or manufacturing environment, security is essential to survival and is addressed in section 5.4.7.2. This specifies not only that your data should be secured, but also that there are checks for validity in data entry and collection. Further, the specification refers to software validation, the process of ensuring that software meets or exceeds its intended use. Look for systems that lock down the database and allow customization of the security system to reflect users' needs.

This decreases the chance of individuals modifying data or performing tasks that are beyond their experience, job scope or capabilities.

Certainty in uncertainty

Allowing for estimated uncertainty is one of the most important--and most stringent--components of ISO/IEC 17025. By definition, estimated uncertainty implies the degree of confidence in a measurement result's validity. Because of the complexity surrounding estimated uncertainty calculations, it's also a definitive dividing point when evaluating calibration management systems that can help achieve compliance to the standard.

A variety of factors (referred to as "parameters" or "contributors") come together to form an estimated uncertainty value. The lower the number, the higher the confidence in the measurement results. The best systems will meet the requirements of the guide to the expression of uncertainty in measurement (GUM) and incorporate all elements of the calibration process to deliver a high level of confidence in the estimated uncertainty value. Fully automating the correlation of contributors, environmental factors and other lab-provided variables provides a nearly effortless means of calculating values for busy technicians. Modern systems that allow lab managers or uncertainty specialists to administer uncertainty budgets for the entire lab keep the process in control while not impeding technicians' progress.

Performing a calibration

ISO/IEC 17025 requires proper documentation of the calibration process. Any oversight can create a nonconformance during lab assessments. It's important to have a complete record of the events before, during and after the calibration procedure. Procedures used during the calibration should be connected to the calibration data record--not cross-linked from a global pool where they could be accidentally deleted. A complete calibration record with full traceability will find favour with auditors.

Analyzing the process

After calculated, well-planned climbs, mountaineers document their expeditions and pass the information on to their peers. Similarly, quality managers must ensure that the calibration process is documented and show their teams the best route to compliance. In conjunction with the ideal calibration management software package, an internal quality manual dictating procedures for complying to ISO/IEC 17025 can allow managers to retrace steps and calculate the methods used for achieving their labs' goals.

Planning for the future

Even after a lab has achieved ISO/IEC 17025 accreditation, continual improvements are necessary as standards change or customers' demands increase. The best tool for any quality software system is one that expands with a lab's changing needs. Flexible certificates, charts and trend analysis, workflow control, equipment tracking, preventive maintenance, security and estimated uncertainty are all addressed in ISO/IEC 17025 and supply critical guidelines for selecting the ideal system.

In the future, calibration management software systems will continue to improve. Innovations such as automated evaluation of technicians' training, vendor qualification and other processes will expand to meet the full requirements of ISO/IEC 17025. Because the standard's specifications are broad, you won't find a software package that covers everything in minute detail. The challenge is to find a balance--a product that helps your lab meet the guidelines while maximizing efficiency in quality assurance. IndySoft Calibration Software is just such a product.

For more information on IndySoft or to request an on-site demo, visit www.indysoft.co.uk