Should I Have My Lab Accredited to ISO/IEC 17025?

您的实验室是否该有 ISO/IEC 17025 认证？

In 1993 the Automotive Industry Action Group (AIAG) established guidelines for the Production Part Approval Process, commonly known as PPAP. In those early days, the PPAP process was little more than a couple of pages of dimensional and performance test verifications. Thirty years later, a PPAP submission has transformed into a 20 to 30mm thick package full of verifications, certifications, and quality plans. Since many of those documents require some sort of lab or testing verification, the authors of PPAP became concerned about the veracity and quality of the results. For this reason, later revisions to PPAP would include a requirement (Section 2.2.12) that all inspection and testing is conducted by a qualified laboratory.

This is just one example of the importance of having a universal standard available that provides both users and customers guidelines on proper procedures and processes to competently run a laboratory or testing operation that provides consistent and reliable results. Thus, enter ISO/IEC 17025 onto the international stage.

ISO/IEC 17025 is the logical evolution of the third (1990) edition of ISO Guide 25. In essence, the new 17025 standard incorporated the Quality Management System principles of ISO 9000 with the technical lab competency requirements of Guide 25. **ISO/IEC 17025 has evolved several times since its introduction in 1999. The standard was revised a second time in 2005 to become more aligned with the 2000 revision of ISO 9001 and then again in 2017 to align it with the 2015 version of ISO 9001.**

Why is an Accredited Lab Important?

The simple answer to the question is that having a universally accepted standard for laboratory and calibration services gives consumers confidence in the products they are purchasing because testing and verification is done by competent and qualified laboratory sources. This accreditation emphasizes that the lab is using best and consistent technical practices, employs well-trained and competent team members, has verification steps that are traceable back to an established reference, emphasizes continuous improvement practices, and is obtaining accurate, repeatable, and consistent results. Labs that have taken the initiative to rise to the level demanded by this standard and meet its requirements are truly the best in-class. Manufacturers that have an in-house accredited lab or only use accredited labs are able to stand apart from those that do not.

Highlights of ISO/IEC 17025:

ISO/IEC 17025 can be viewed in two parts, a laboratory Quality Management System (QMS) and a technical guide for the tests, processes, and activities conducted by the laboratory. Although different from ISO 9001, many of the QMS aspects of ISO/IEC 17025 are similar or identical to ISO 9001 requirements.

The ISO/IEC 17025 standard is broken into eight sections. They are:

1. Scope
2. Normative References
3. Terms and Definitions
4. General Requirements
5. Structural Requirements
6. Resource Requirements
7. Process Requirements
8. Management System Requirements

The first three sections are common to many standards. The "Scope" is important because it acts as an executive summary and tells the user what the standard is intended to cover and often what it may not cover. The term "normative" means related to or derived from a standard. Therefore, the second section is a list of any standards that the ISO/IEC 17025 standard may reference within its body. There are, in fact, only two standards cited. These contain additional information that may be helpful to the users of this standard. Finally, section three defines a series of terms that are used throughout the standard. A definition section can be extremely helpful because it can educate users on the meaning of terms they may not know or establish a baseline for terms that may have multiple meanings or ambiguity in the marketplace.

Section 4 is the "General Requirements" section. This section addresses two important concepts related to testing labs; impartiality, and confidentiality. Testing labs must be impartial, even if they are an in-house department of a larger organization. The purpose of a test is to without bias assess whether a part meets a requirement or not. It is critical that lab personnel be able to do this without bias or fear of retribution should results be deemed unfavorable. In a similar vein, often multiple customers may be using a lab, and they must have confidence that the lab is not sharing their test results with other parties. Therefore, labs must have strict policies regarding confidentiality and the safeguarding of their customers' information and data.

Section 5 is titled "Structural Requirements". This section defines requirements about the way a lab is set up. It gives requirements for organizational structure, management, and personnel. Most importantly, this section defines requirements emphasizing that the lab has managers and personnel that are aware of what is going on and have authority to conduct the multitude of actions necessary for everyday business.

Section 6 is "Resource Requirements". This section is full of requirements that direct the lab to have the necessary resources to properly and efficiently conduct the activities of the lab. This means that they are required to have the right people in-place, proper conditions and facilities, the right equipment, traceability (measurement results are traceable back to a known reference standard), and that externally provided products and services are available and controlled when necessary.

Section 7 is "Process Requirements". This is the technical section of the document and lays out many requirements for the processes that are necessary from the start to the finish of getting each test sample properly and accurately evaluated, recorded, and results communicated back to the customer.

The final section, Section 8, is "Management System Requirements". This section is the primary bridge to either ISO 9001 or a QMS with similar attributes. This section defines two options; A and B. Option B is for a lab that already has a QMS certified to ISO 9001 (or an equivalent). Option A is for a lab that does not have a registered QMS and sets out some minimum requirements that are otherwise included in an ISO 9001 system. These include:

- That the QMS has certain documentation such as documented policies and procedures.
- That documents, when necessary, are controlled.
- That records, when necessary, are controlled.
- That risks and opportunities are considered, and appropriate actions taken when deemed necessary.
- That the organization is engaged in improvement activities.
- That the organization has a corrective action process.
- That the organization undertakes internal audits.
- That the organization conducts regular management review.

Who Should Have ISO/IEC 17025?

This is a question that every organization must ask themselves and the answer will depend on individual circumstances. Therefore, there is no right or wrong answer. However, in my opinion, any fastener organization that is routinely engaging in metrology, testing, or calibration activities will be much stronger and better with an ISO/IEC 17025 accreditation, than without one.

How do You Get Registered?

On the surface, registration can seem like a daunting task. However, the old adage about "how do you eat an elephant- one piece at a time" is probably the most appropriate answer. It is a process that an organization must take one step at a time. There are many resources that can be obtained to assist in this process from simple guides to hiring an expert consultant. Whichever approach is taken though essentially involves developing the system, assessing the system for gaps, fixing these, proving the system out, and then hiring a registrar partner to come in and independently assess and critique the system.

Once registered to ISO/IEC 17025 the registrar will continue to conduct routine assessments to make sure that your system is maintaining compliance. Usually, these repeated audits will identify gaps not previously discovered or that have gone off-track since the last assessment. As such, these repeated audits should not be seen as burdensome but rather as opportunities to continue to improve the laboratory.

Wrap-up:

Not every fastener organization needs an ISO/IEC 17025 accredited laboratory, however, for organizations that want to be best-in-class, to offer their customers a higher level of value, or engage in a large volume of testing or calibration, having accreditation makes a great deal of sense. ISO/IEC 17025 truly makes a difference and effectively provides confidence that tests, dimensional verifications, and calibrations are being done in a way that they are accurate, traceable, and consistent. ■