ISO/IEC 17025 quality program for captive laboratories

In any production facility there are many hurdles and challenges to produce our customers' products whether these be chemical valves, automobiles, frying pans, raw forgings or castings. These products come in all shapes, configurations, requirements, materials and specifications. To handle all of these variables as well as the business, most modern companies endure an ISO 9001:2015 audit and accreditation. A logical next step is to achieve third party certification of ancillary operations. One of these operations is laboratory and inspection functions. All manufacturers perform inspection and testing of their raw materials and finished products to ensure consistency and quality to design or regulatory requirements. Following a structure of a standard such as ISO/IEC 17025 gives laboratory (captive or independent) direction, management commitment requirements and most importantly competence of analysis, testing and inspection to ensure quality. This abstract looks to justify the rational to having a captivity certified ISO/IEC 17025 accreditation for a manufacturer.

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Definition, history and evolution of ISO/IEC 17025

To get going we need to understand a few definitions. Let's start with guideline. A guideline is an outline of policy. A standard is defined as something set up and established by authority as a rule for the measure of quantity, weight, extent, value, or quality. We are dealing with quality as the original, modern era ISO laboratory guidance document was ISO/IEC Guide 25 as well as EN45001. These documents were a great framework for evolution to demonstrate the technical competence and operational transparency of conformity assessment bodies as they related in certifying testing laboratories. In 1999, 2005 and to the current revision of the standard 2017, ISO/IEC 17025 has offered more structure in topics such as reliability, uncertainty of techniques, validation of methods, work instructions, approved providers as well as enhanced training.

Value of an ISO/IEC 17025 program

There are so many benefits to a program that follows ISO/IEC 17025 so let's start out with the disadvantages. Cost of certifying a program will range from $5,000.00 to $15,000.00 USD. There is the hard work that it takes to develop the program and the creation of the uncertainty budgets, CRMs for validation as well as implementation time. If there is not lab or inspection staff that is well versed in the standard things will take longer.

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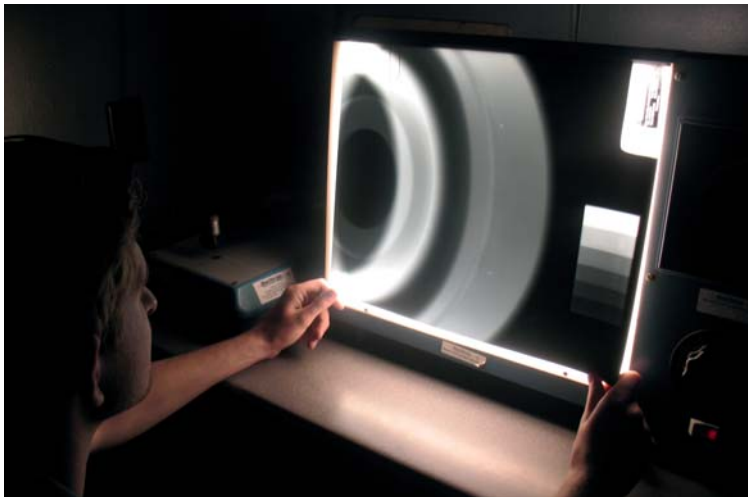
There are some lets say inconvenient truths – Things you find in your journey that you wish you hadn't seen. Seeing some of the areas that don't meet your requirements for repeatability of let's say specific elements analyzing chemical analysis of a certified Reference Material (CRM). If you find that your chemical range from the CRM that you are working to not on target consistently this needs to be addressed and problem solved. This is part of the continuous improvement circle (plan, act, do, check). This is moving you into the direction of positive direction and formalization.

Some of the immediate benefits to the program are having great documentation control of results, work instructions, endorsed material or product certifications, calibration structure and corrective action mechanisms. The ISO/IEC 17025 standard dovetails into your corporate ISO 9001:2015. There is also the opportunity for the use of the achieved activities listing of approved methods on your scope to be used as a marketing tool allowing for growth possibly into new markets. In the end you

Metal being poured into air set molding sand.



A film review of production castings for volumetric soundness by a certified Level II RT technician.

are looking to gain accuracy, consistency and customer satisfaction.

Validation and verification activities

There are so many advantages to know that there is order, repeatability, gage R&R as well as higher order training of the qualified personnel. This will include all levels of your program. ISO/IEC 17025 requires order, compliance and repeatability of testing and inspection activities. These must be well developed via work instructions and repeatable as far as data outputs are concerned. This allows organizations the ability to trend data after validations to a CRM have been performed and verify compliance through documented methods.
In the below table the elements of validation of tests conducted, verification methods used and the advantages of this type of testing in a proper and comprehensive manner.

Risk management considerations for captive laboratories

Understanding a few key definitions for this element of risk as specified in ISO/IEC 17025 is quite necessary. In the future of all quality system standards the understanding and abatment of risk is beginning to overshadow many elements of new standards. We will discuss it here to offer a brief understanding and some counter measures that can be applied.
Here are definitions as specified in ISO/IEC Guide 73; Risk Management Vocabulary[1], as well as the quality assurance community:

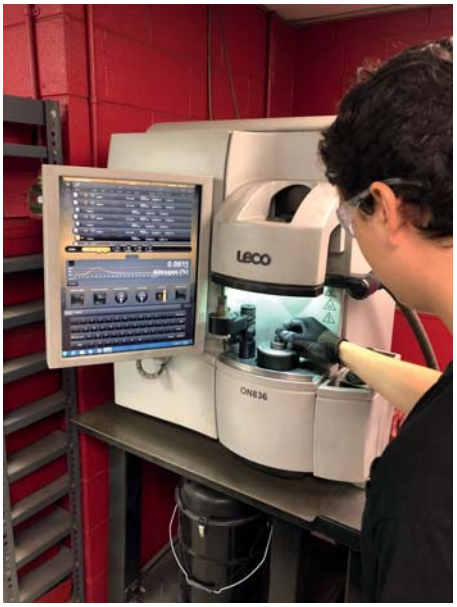
- *Risk* is defined as the effect of uncertainty on objectives.
- *Risk management* is coordinated activities to direct and control an organization with regard to risk.
- *Uncertainty* states, even partial, of the deficiency of information related to our understanding or knowledge of an event.

The above terms are logical, fair and driven by data and goals. In a testing or inspection world understanding of consistency (procedures), repeatability (control) and direction (goals) are all good things. These definitions allow for a plan which will lead to coordination and finally success within the laboratory. Keeping all of the laboratory quality systems in working order requires a knowledgeable staff that keeps up with changes to the community, equipment, specifications and standards. Speaking to the laboratory and inspection community within your own facility is a good place to listen. Listening to trusted personnel will open opportunities for corrective measures and continuous improvement. Your customers will offer avenues that you can possibly go down to assist your organization in abating risk.

Testing Technique	Verification method	Advantage of the demonstration of ISO/IEC 17025 due to verification activities have been performed
Metal Lab – Chemical analysis	Certified Reference Materials (CRMs) and proficiency testing	Understanding the limits of your capabilities of elemental analysis in numerous matrices of alloy families.
Metal Lab – Mechanical testing	Performed via software evaluations	Having a solid verification data that can be trended offering trust of material properties.
Metal Lab – Microstructure evaluation	Verified by review of standard photomicrographs	Library of photomicrographs to use as reference of acceptable and unacceptable structures.
Metal Lab – Ferrite determination	Performed via software evaluations and/or physical measurements	Chemistry and heat treatment vs. ferrite percentage reference data.
Inspection – Hardness testing	Verified by testing on a certified test reference material block	Hardness ranges verifications allows for tables to reference heat treatment or pouring temperature vs. reference material hardness.
Inspection – Magnetic permeability via Severn Gage	Verified by testing on a certified ferrite block reference material	Having the magnetic permeability data verified against a test verification block offers confidence in the magnetic signature of tested materials.
Inspection – Liquid penetrant inspection – color contrast, water washable	Verified by use of certified tamp handle certified reference block	Having a clear discrimination of required sensitivity of the technique

Testing a production casting for hardness with a Rockwell testing unit.

Testing of material strength via tensile testing with a universal testing machine.



Chemical analysis - specifically nitrogen and oxygen - with a gas fusion analyzer.

These customer discussions such as an improperly formatted material certifications, error on a nondestructive testing report or an error in the review of a calibration report will in most instances will be an opportunity to have your quality program to possibly issue a corrective action which when performed properly begins the risk process.
In the developed of the risk abatement standard it has been structured for companies' quality policies within both ISO/IEC 9001:2015 and ISO 31000:2018 frameworks and methodologies to involve the proper personnel to rectify and problem solve issues. Following the standard approach for risk abetment drives profitability within the context of analysis and problem solving. Performing and applying problem solving tools such as value stream mapping or five why these preceding

Chemical analysis being performed using an OES-DR analyzer.

concepts are outputs to improvement to the ISO process. ISO/IEC 17025 embraces these comments and will drive the thinking with risk in mind for all problems but the everyday standard operation practices of your laboratory and inspection areas.

Future direction and standard recap

There is no crystal ball on the future direction of ISO/IEC 17025.
Its current structure has made the process of testing and inspection accuracy more robust. The gap in the revision of the standard from its last cycle (12 years) has addressed so many topics that it may be a long stretch in the revision committee. This last long revision stretch really added only a few components such as risk, more uncertainty budgeting, competence verification and other topics. ILAC (International Laboratory Accreditation Cooperation) requested that the process be entered into revision in 2013 to move us to the 2017 revision primarily that the referenced standards within ISO/IEC 17025 were no longer current.
The current standard at the 2017 revision has numerous older standards reference that will drive a revision in the future such as ISO/IEC Guide 99 of metrology vocabulary, ISO/IEC 17043 of interlaboratory comparison and ISO Guide 31 discussing CRM labeling and certification requirements. There are dozens of other ISO standards referenced that will become in need of revision, transferred to other standards or renamed. It is felt that risk abetment will also become more of a process model in advanced thinking taking a greater role. We will just have to see where this will be going.

Conclusion

Constant vigilance is what it takes to have a successful ISO/IEC 17025 program. The proactive environment, management support and a supportive infrastructure to the quality systems are the core of the program and its approach. Creating an evolving QA structure and living in the mode of communication is key to continuous improvement and constant validation. Develop of key personnel who will be the future leaders of the organization in the technical areas is extremely important to be able to embrace change and new velocities as laboratory needs increase. The next decade will me really exciting for compliant and accredited laboratories both captive and independent third party laboratories!

Bibliography

1. ISO Guide 73: 2008, Risk Management

About Michael Porfilio

Michael has been in and servicing the foundry industry since 1985. His background is in the fields of Metallurgy, Quality Management, Sales and Marketing as well as Operations Management. He currently is a Certified Nuclear Quality Systems Auditor and NDT Level III. He is employed at Stainless Foundry & Engineering, Inc. as the Director of Quality.