Technical Management?
We Don't Need No Technical Management!

Speaker/Author: Dr. Henrik S. Nielsen
HN Metrology Consulting, Inc.
HN Proficiency Testing, Inc.
10219 Coral Reef Way
Indianapolis, Indiana, USA
Email: hsnielsen@HN-Metrology.com
Phone: (317) 849 9577; Fax: (317) 849 9578

Abstract

ISO 17025 requires that laboratories "have technical management which has overall responsibility for the technical operations." However, the standard does not specify any requirements for the background and education of those assigned to this role. This is disconcerting as they presumably are tasked with ensuring the quality of the measurement results produced by the laboratory as well as "the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates," as the standard also requires. In the absence of competent technical management, the responsibility for ensuring the integrity of the measurements performed by the laboratory can move in one of two different directions: It can be left to the laboratory technicians, as suggested by the Certified Calibration Technician credentials offered by ASQ, or it can be handed off to assessors or proficiency testing providers. The problem with the first approach is that while a technician may be very good at applying a measurement or calibration procedure, he or she often does not have the necessary background in mathematics and physics to account for all the potentially significant sources of uncertainty in a measurement and properly quantify their influence on the measured value in each particular case. The problem with relying on third parties to determine a laboratory's measurement capabilities (as opposed to merely evaluating or confirming the laboratory's own determination of its capabilities), is that it takes away the laboratory's ownership and responsibility for its own measurement processes.

1. Introduction

Laboratory accreditation is a formal recognition of an organization's technical competency to perform specific tests, types of tests, or calibrations. This differs from quality system registration in that the latter only verifies that the organization in question follows a documented quality system in accordance with the quality system elements of a particular standard, e.g. ISO 9000 or even ISO/IEC 17025. The quality system registration process is generally not designed to assess for technical competency.

Looking at calibration laboratories specifically, one could define a "technically competent organization" as one that by independent design can consistently provide measurement results that are correct within their stated uncertainties.

The caveat “by independent design” is an important one. It may be possible for a laboratory to provide measurement results that are correct within their stated uncertainties by following processes and procedures of external origin, that the laboratory’s technicians have been trained to follow, if these processes and procedures are technically sound. But if the laboratory does not have the capability to evaluate on its own whether this is the case, then it is merely by luck that the laboratory provides correct measurement results.

If a laboratory does not have the ability to evaluate the technical soundness of measurement processes and procedures, it will also be unable to distinguish between those provisions of a process or procedure that are merely issues of convenience or facility and those that are crucial to the correctness of the measurement results. Consequently, it will be as likely to modify the latter as the former and again it will be merely by luck when the laboratory provides correct measurement results.

2. ISO 17025

ISO 17025 states in its introduction that: “This International standard … contains all of the requirements that testing and calibration laboratories have to meet if they wish to demonstrate that they operate a quality system, are technically competent, and are able to generate technically valid results.” [1]

This would suggest that if all the requirements of the standard are met, the laboratory will be technically competent and be able to generate technically valid results, as defined above. However, there seems to be one fundamental requirement lacking from the standard, and this carries over into a number of other requirements and, depending on how the requirements are interpreted, renders many of the technical competency requirements moot.

In the change from ISO Guide 25 to ISO 17025, the technical management requirement was changed from requiring a technical manger to be appointed to:

“4.1.5.h: The laboratory shall have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations.”[1]

The change was presumably made in recognition of the situation where a laboratory has a broad scope and different people have the necessary expertise within different parts of this scope, e.g. dimensional and electrical measurements.

However, where ISO Guide 25 section 6.1 required: *“The laboratory shall have sufficient personnel, having the necessary education, training, technical knowledge and experience for their assigned functions.”* [2] ISO 17025 has no corresponding requirement as it relates to the technical management. In other words, there is no requirement in ISO 17025 that the technical management has any skills whatsoever!

I believe this is a fundamental flaw in the standard. I would suggest that the writers of the standard took it as a given that the people assigned as technical management would have the necessary background to carry out this role and never thought it necessary to make this an explicit requirement.

The problem is compounded in requirements such as ISO 17025 section 5.2.5:

The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. [1]

This requirement appears to be the replacement of the requirement in ISO Guide 25 section 6.1. However, note that where the Guide 25 requirement appears to apply to all staff and be based on a global standard for what is "necessary", the ISO 17025 requirement is limited to personnel who "*perform particular types of sampling, test and/or calibration, issue test reports and calibration certificates, give opinions and interpretations and operate particular types of equipment.*" [1] Note that there is no requirement to the management itself, nor is there a requirement that defines what these authorizations shall be based upon. In other words there is no requirement that the technical management is competent and there is no requirement that the criteria used for personnel authorization are meaningful relative to the authorized activities!

There are several other requirements in ISO 17025 that clearly presupposes that the technical management is competent and become meaningless when this is not the case.

3. Quality Weasels

One could take the position that even though ISO 17025 does not explicitly require the technical management to be competent, any reasonable reader of the standard would come to the conclusion that this is what was intended with the standard.

However, the problem for accreditation bodies in taking this approach is that not all readers are reasonable and the laboratories that are the least reasonable are often also the most litigious.

The path of least resistance therefore tend to be to interpret the requirements in the standard literally as written and allow any requirement that is open to interpretation to be interpreted to mean as little as possible.

Words that allows for interpretation of requirements are often referred to as weasel words, because they allow laboratories that are so inclined to weasel out of these requirements. Over time more and more laboratories and consultants find more and more requirements that can be creatively interpreted to be meaningless. In the case of ISO 17025 the most common interpretation of what it requires has been diluted substantially over the 5 years since its publication. One might suggest that this trend alone is reason enough to have a substantial rewrite of requirement standards on a regular basis.

The losers in this trend are the laboratories that genuinely live up to the spirit of the standard and want their accreditation to reflect this fact, as well as users of accredited services that rely on accreditation to ensure that the laboratories they contract with "operate a quality system, are technically competent, and are able to generate technically valid results," as the introduction to ISO 17025 states.

4. Calibration Technicians

With the lack of requirements to the technical management, the skills of the calibration technicians become critically important, as that is what is left to ensure the technical validity of the results produced.

A significant proportion of the people working in metrology laboratories in the United States entered into the field through the military. So it may be useful to look at the structure of the military metrology infrastructure to understand the background of the typical US metrology person.

Each branch of the US military operates a significant number of laboratories. Each branch also has a centralized location where procedures are developed and validated and where it is determined what equipment can be used for what procedures. As far as I am aware, not much of the process of developing and validating measuring and calibration procedures is public, but we still assume that this validation takes place and some level of uncertainty estimation is applied to determine the suitability of the procedures and the equipment listed in them.

In essence, this means that the technical management for these laboratories resides in these centralized locations. The focus for the personnel in the laboratories and their training is therefore to ensure that they have the skill to carry out the measuring processes and procedures as written and emphasize the need to follow these procedures to the letter. It is not to create new procedures or evaluate the validity of the procedures provided.

In this context it must also be noted that the military has a vast amount of metrology equipment and a key interest is to ensure the interchangeability of this equipment. Military calibration procedures generally appear to be designed with this goal in mind. It means than any piece of equipment of a certain make and model with a valid calibration sticker can be expected to perform as all others in its population, in part because they have all been calibrated the same way using the same procedures to the same tolerances. Civilian users of calibration services usually do not have this type of need. Therefore, a procedure that is appropriate for military purpose may not be appropriate for industrial use and even if it has been validated for military use, this validation may not take into account the industrial needs.

The experience of working in military calibration laboratories therefore, while being an excellent background for a calibration technician, does not necessarily qualify someone to meaningfully fill the technical management role in a commercial laboratory.

Another source of laboratory personnel, especially in the areas of field calibration of e.g. CMMs and optical comparators, is factory service technicians. These technicians are generally trained to follow the manufacturers' procedures, which are developed and validated at the factory. These technicians are also not encouraged to create new procedures or question the technical validity of the procedures provided to them.

In this case the procedures are generally geared towards troubleshooting and adjusting the equipment to perform within the manufacturer's specifications in the shortest possible amount of time. This is a very different aim than ensuring traceability, documenting as-found conditions and demonstrate performance in strict accordance with standards, as is generally required for the user of this equipment, if the user in turn wants to maintain accreditation for the measurements subsequently performed on this equipment.

As with the military technician, the former factory service technicians are generally excellent calibration technicians, but their background does not necessarily qualify them to fill the technical management role in an independent laboratory or develop and validate procedures aimed at establishing and maintaining traceability for the equipment they are calibrating.

5. Technical Management

ISO 17025 is written based on the paradigm that a laboratory has two separate staff functions: Technical management which is made up of one or more people who together have the necessary knowledge to develop and validate measurement processes and procedures and estimate uncertainty for all the areas on the laboratory scope and a number of technicians who carry out the actual measurements.

Technical management may also function as technicians, but unless the laboratory is quite small it is not optimal to have all technicians be part of technical management. However, if the technical management is de facto eliminated by the lack of meaningful requirements to its background and skills, then one approach could be to in essence require all technicians to also perform the technical management functions, e.g. validate methods and procedures and estimate uncertainty. But ISO 17025 does not require this and currently few laboratories seem to be taking this route.

The ASQ Certified Calibration Technician program seems to be aimed at increasing the theoretical knowledge of calibration technicians and could be seen as a means of bridging the gap between the typical background a calibration technician usually has and the requirements that would be relevant for a technical manager. However, since the body of knowledge is very broad, it requires much knowledge that is irrelevant to a technician who is specialized in one particular field of calibration. It is also questionable whether pushing this level of know-how out to each individual technician is optimal from a business perspective.

6. The Assessor as Technical Management

The alternative in the case of accredited laboratories is that the laboratory assessors in a way fill the technical management role by issuing a laundry list of deficiencies for every instance in the laboratory's calibration procedures and the calibrations demonstrated during the assessments that are not technically correct and items that are missed in the uncertainty estimates.

The obvious problem with this approach is that at some stage the line is crossed from where the assessor merely observes the laboratory's performance to in essence function as the laboratory's technical management and consultant. A laboratory that has no competence in a certain measurement discipline could apply for accreditation in this discipline and in essence through the deficiency report get a checklist of what they need to put in place to claim competence in this discipline.

This is, of course, not the purpose of the accreditation process, but without a meaningful requirement for technical management competence, there is really no mechanism to allow the assessor and the accreditation body to of merely note the lack of technical management qualifications as the root cause of these types of problems and disallowing accreditation in the areas where the qualifications are lacking

7. Proficiency Testing as a Substitute for Technical Management

Over the last several years accreditation bodies have put more and more emphasis on proficiency testing requirements and made these requirements more specific.

It is tempting to look at proficiency testing as proof of technical competence and think that with enough proficiency testing there is no real need for specific requirements to the competence of a laboratory's technical management. One could also conclude that the technical expertise of the assessor is less critical.

These are wrong conclusions for several reasons: Firstly, as the requirements stand today, proficiency testing is only a very sparse sampling of the laboratory's work. Secondly, proficiency testing is not necessarily designed to test the most difficult or challenging items on a laboratory's scope or the extremes of the range where competency is claimed. Thirdly, proficiency testing does not observe the measurements the laboratory makes or evaluate the content of the laboratory's uncertainty analysis; proficiency testing only evaluates the stated measurement results and claimed uncertainties as results of black box processes.

Proficiency testing is designed to be a double check of a managed process of creating credible measurement results. It is not designed to be a substitute for having competent technical management in place.

8. Conclusion

It is necessary to establish some meaningful requirements to the background and education of an accredited laboratory's technical management. This will ensure the continued credibility of the laboratory accreditation system.

It is also necessary to be able to distinguish between isolated errors and omissions in an otherwise functioning system managed by competent technical management and the symptoms of a lack of competent technical management and handle the two differently in the accreditation process.

Finally there is a need to change the way ISO 17025 requirements are interpreted. Unfortunately, this is quite difficult to do. One approach could be for accreditation bodies to create interpretation guides that elaborate what the requirements mean and define a "passing grade" for each requirement. This would be quite a daunting task and such a document would probably be subject to frequent revisions. However, it might be possible to at least issue interpretations for the weasel words to define meaningful interpretations for those requirements that do not apply in all cases. Raising the bar for technical management might render some of these issues moot, since competent technical management would be less likely to try to avoid meaningful interpretations of the ISO 17025 requirements.

The beneficiaries of such changes would be the laboratories that have genuinely competent technical management in place for the types of measurements in their scope and who wish for their accreditation to truly signify that they "are technically competent, and are able to generate technically valid results".

Customers of accredited laboratories that rely on accreditation to ensure the correctness of the results they receive and who rely on the credibility of accreditation to ensure that one test or calibration can be accepted everywhere will also benefit from such changes.

9. References

1. ISO/IEC 17025:1999: "General requirements for the competence of testing and calibration laboratories."

2. ISO/IEC Guide 25:1990: "General Requirements for the Competence of Calibration and Testing Laboratories."