Laboratory Accreditation—Impact on Society

Speaker/Author
John A. Wehrmeyer, Principal Consultant
Quality Consultants of New York
2334 Sir Edward Lane
Maryville, TN 37803
Tele: (865) 379-8434
FAX: (865) 379-8508
E-Mail: qc@charter.net

Abstract

Laboratory accreditation has had a growing and significant influence on the world of calibration and testing. Over the past decade, there has been a major increase in the number of laboratories which have sought and achieved accreditation of their services. In addition, a number of new accrediting bodies have been founded.

This presentation takes a critical look at the impact of laboratory accreditation and how it has affected the quality of the services delivered. It addresses such issues as the cost/benefit ratio of accreditation, the strengths and weaknesses of the process, and how accreditation might be improved.

Accreditation has grown over the last decade

During the past decade, the number of accredited calibration laboratories in the United States has quadrupled. There is no doubt that accreditation of calibration laboratories is a reality that has taken root in America. Now that there is an appropriate sample size of calibration laboratories to examine, perhaps it is time to ask some important questions.

Are the objectives of accreditation being realized? Which aspects of accreditation seem to be working well and where might improvements be needed?

Since my experience is in the field of calibration, I would like to restrict my remarks to calibration laboratories, in spite of the fact that there are four to five times as many accredited testing labs. Secondly, I should like point out that I am approaching this topic as one who has been doing calibration assessments and consulting for a major U.S. accrediting body. Although I have tried to gather input from some of the relatively new accrediting bodies, I am certainly not qualified to speak for all of them. Therefore, I hope to leave adequate time at the end of this presentation for comments and additional insight from those in attendance.

Objectives of accreditation

So lets return to the question, “Are the objectives of accreditation being realized?”, and by the way, “What are those objectives?” In a few words, the objectives of accreditation are to support

trade and to minimize redundant activity. Put in more technical terms, accreditation should make it possible for one to use a service with a quantitatively defined degree of quality and limits of uncertainty at a known level of confidence in a way that is universally recognized and at the lowest possible cost.

Are the objectives being realized?

As evidenced by the increasing numbers of customers, agencies, and various organizations, both private and public, I would have to say yes! Although there are still some departments of the U.S. government, for example, which still appear to be reluctant to accept accreditation as an alternative to doing their own assessment of supplier quality, the tide is definitely turning. Consider the Department of Defense for example. Two of the three major divisions are now using the accreditation approach, yet the third branch shows few signs of converting.

Looking at private industry reveals even greater progress. When the first commercial laboratories were becoming accredited in the U.S. it was difficult for them to find services to have their reference standards receive accredited calibrations. In many instances, they had to use the services of NIST, another national metrology institute or seek services outside the U.S. Due to this situation, accrediting bodies were more liberal about waiving this requirement. Today, with hundreds of U.S. laboratories holding accreditation, the requirement to have their reference standards calibrated by an accredited lab is being more rigorously enforced. At this time, in the area of the major metrological services, such as physical, dimensional, electrical or thermodynamic, accredited calibration services exist in this country with only a handful of exceptions.

Growth drivers

You might ask, "What has been the cause of this growth?" For the most part, accreditation was originally driven by international trade. Then, within the U.S., it was the automobile industry followed by other international businesses. In response to these industries, their suppliers were being required to use accredited services, and so it spread throughout the supply chain. A few calibration laboratories chose to become accredited as a means of improving their quality or to attract new business, but most were driven by customer demand for it.

The impact on quality

With all this growth in the number of accredited calibration laboratories, the next question is, "What has been the impact of the quality of services?" According to a recent survey, the responses have been varied, but in general, most of the remarks have been positive. Eighty-seven percent (87%) of respondents who work in the calibration laboratories have indicated that the quality of their services has significantly improved. Forty-one percent (41%) of users of calibration services said that they also saw improvement. But thirty-eight (38%) detected no difference, and eleven percent (11%) were undecided. Three percent (3%) felt that the quality of service actually was worse.

Although the majority of users saw improvement in quality, many of the customers were also concerned about the increased cost. In fact, many customers today are using services offered by accredited calibration laboratories, either because of their customers requirements or as a matter of choice, but they are electing the non-accredited service when a choice is offered at a lower price.

Ways in which quality has improved

Actually, most customers are not in a good position to judge the technical quality of a calibration service. If they were in such a position, they usually would have calibrated their instruments themselves. Therefore, customers usually judge a service but peripheral factors such as cost, speed of service, convenience factors, and the apparent quality of the documentation.

On the other hand, accreditation assessors are in a much better position to observe the technical competence of a calibration laboratory. In fact, in large part that is their assignment. As one who has served in this role for that last six years, I am pleased to report to the competence of most laboratories has improved through the process of accreditation.

There have been several aspects of the calibration processes where improvement has occurred, but in my opinion, the most outstanding improvement has been in the laboratories' ability to estimate their measurement uncertainties. This is not to say that there is universal and detailed understanding of this topic at this point of time. In fact, the authors of the ISO Guide to the Expression of Uncertainty in Measurement could probably find some fault with most estimates, but it has been my observation that significant progress is being made. It is not that the estimates are so important in themselves, although they certainty add value. The greater importance is that in order to calculate a reasonable estimate one has to come to a more complete understanding of the measurement process itself. With this new knowledge comes a better understanding of the measurement processes capabilities and limitation, not to mention the areas where potential improvements may lie.

In the past, many laboratories relied upon techniques such as Test Accuracy Ratios, or TARs, typically of four to one or greater. This approach seemed to work fairly well, especially since "Accuracy Specifications" were readily available from the original equipment manufacturers (OEMs). There were some weaknesses to this approach, however. For example, consider cases where standards with a four times better accuracy are not available or situations where significant uncertainty components are not captured in the "Accuracy Spec".

Another area of major improvement has been that of documentation. Most laboratories applying for accreditation have sound measurement practices in place, but these same organizations had not instituted the appropriate documentation. This problem usually becomes remedied by the accreditation process. I guess, like most of us, the laboratory's staff enjoys the technology more than the paper work.

Opportunities for improvement

In spite of the improvements which accreditation fostered, there are some aspects of the current system which lend themselves to improvement.

One of the inherent features of accreditation is that it sets forth a minimum set of requirements. This means that once a laboratory has achieved accreditation, they do not need to improve much beyond the minimum. This issue has been somewhat addressed by the new ISO/IEC 17025:2005 standard which encourages continual improvement, but this still appears to be a weakness in the system. I recall the frustration of laboratories that preferred to send their standards to the "best", often OEM laboratories, but could not because those laboratories were not accredited. The frequency of this frustration has diminished as many of these OEM laboratories have achieved accreditation, but still it does point out a weakness of accreditation.

Attitude of the laboratories

I have observed that laboratories tend to fall into one or two groups which I call the "Minimalist" and the "Quality Motivated" laboratories. The difference between the two groups hinges on attitude, usually of the management or at least the quality manager. The attitude of the minimalists does not embrace the spirit of the standard. There goal seems to be to become accredited while making as few changes as possible and to do as little as possible to meet the requirements of the standard. The Quality Motivated laboratories, on the other hand, gladly embrace change as long as they can envision that the quality of their services might be improved.

Potential conflicts of interest

There seems to be a potential risk for a systemic conflict of interest.

The risk lies in the fact that competition could encourage an Accrediting Body (AB) to lower it standards to gain market share. Keep in mind that an AB usually imposes requirements on the laboratories which it accredits beyond those of the international standards. Generally these are needed to more clearly define areas where the standard are vague or where good metrology practice require it. But these additional requirements are usually applied under the direction of each AB and can be modify them within certain limitations are their discretion. There is the possibility that in an effort to become "more appealing" to laboratories seeking accreditation, these requirements could be diminished. To date, I have not witnessed that this is the case. At least the major ABs in the United States have stood by their standards, and the laboratories which they have accredited, for the most part, have been loyal to them. But how would the ABs react if this loyalty disappears?

The assessors working for the ABs can face the same problem. There is a risk that the assessors who do the most thorough job could become known as "tough" and become avoided. This has not been an extensive problem thus far and may be offset by the fact that these same "tough" assessors often offer the most suggestions regarding laboratory improvement. So, as previously mentioned, the laboratories with the "quality attitude" may not avoid a "tough" assessor as they

realize more value from what the assessor has to offer them. On the other hand, a "minimalist" laboratory may try to steer clear of a "tough" assessor.

Uniform qualification of assessors

As you might suspect, one of the major challenges for the ABs is to find qualified assessors. In addition, there is the issue of training the assessors in such as way as to provide uniform assessments. The ABs work very hard at this, but with the diversity of laboratories as well as the backgrounds of the assessors, perfectly uniform assessments will continue to be an ideal goal which will never be realized.

In some ways, the assessment process seems inefficient

Generally, a laboratory is reassessed every two years. Each time the topics covered during the assessments are the same. Of course, between assessments, there may be some changes in the requirements. In addition, because the quality system may have been working well in 2002 does not guarantee that it will be fine in 2004, not to mention possible changes in personnel, equipment, and so forth. Still, I have observed that a considerable amount of time is spent during an assessment repeatedly examining elements where there has never been a problem.

Typically, in order to touch upon all the elements of the standard plus the additional AB's requirements in a limited amount of time, the assessor must cover the breadth of the requirements and only go into the depth probe deeper when a problem has been detected. I wonder if it would be possible, by design, if each assessor were assigned to focus on a few elements in depth trusting that other assessors will concentrate on other areas. It may take eight years to cover all the elements, but at the end of that period, an assessment process that covers the breadth and depth of all areas will have been accomplished. This approach would require more planning on the part of the ABs, but it might result in a more efficient assessment process.

Summary

In summary, it is the opinion of the author that due to accreditation, there has been a marked improvement in the calibration laboratories within the U.S. This has been illustrated in the shrinking number of deficiencies which I find as I assess laboratories that have been previously accredited as well as an increased understanding of laboratory staff on subjects such as measurement uncertainty. On the other hand, there is still ample opportunity for continuous improvement in the accreditation system.