

Graduate to an Accredited Laboratory

By Gillian Campbell

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Many manufacturers rely heavily on outside metrology laboratories to tell them that their processes are where they should be. So you've found a lab that offers a good price, but how do you know that the lab is doing a good job? Maybe it is time that your company graduated to using an accredited metrology laboratory.

Not all labs are the same. When a lab says that it has obtained quality systems registration or certification, it conveys that the organization is following a documented quality system in accordance with the quality system element of standards. But these processes do not normally assess technical competency. Often, auditors used for this process have experience in the business being audited, but they are typically not technical experts.

When a lab says it has received accreditation from a recognized accreditation body, on the other hand, that communicates a stronger message--namely, that the lab has undergone a rigorous process through which an independent, third party has verified the organization's technical competence to perform specific tests, types of tests or calibrations. The preeminent accreditation bodies include the American Association for Laboratory Accreditation (A2LA, Frederick, MD), and the National Voluntary Laboratory Accreditation Program (NVLAP, Gaithersburg, MD). Both of these organizations are signatories to the National Cooperation for Laboratory Accreditation Mutual Recognition Arrangement, having demonstrated compliance with ISO/IEC Guide 58 through peer assessment, and both are internationally recognized.

When evaluating labs as potential business partners, it is important for companies to ask each lab for its scope of accreditation. If a lab is not accredited in your area of interest, then its technical competence in that area has not been assessed by an accrediting body.

Jerry Harris, Oak Ridge Metrology Center quality manager at BWXT Y-12 LLC (Oak Ridge, TN), the company operating the Department of Energy's (DOE) Y-12 National Security Complex, says, "From the perspective of our lab and doing work for the DOE, there are times when we have to use a commercial laboratory in an area where we don't particularly have the expertise or equipment. We look for accredited laboratories, because if we use labs that aren't accredited, we have to go in and perform an audit of the organization, which costs taxpayer money."

But there is more to selecting a lab than accreditation. "Accreditation is great, but you have to make sure you're dealing with an ethical lab with a good reputation. You have to call and make sure a lab has customers that are really satisfied and happy with its work," says Mohamed Abdelhafiz, director of metrology services at

CEJohansson (Livonia, MI), a supplier of metrology solutions.

Both Abdelhafiz and Harris agree that it is important to look for labs with staff who have history and experience with accreditation. "Someone who's just gotten accredited is not the same as someone who has been accredited for 10 or 12 years," Abdelhafiz contends.

No cakewalk

Although newly accredited labs may have less tenure than the veterans, all labs go through the same rigorous process to maintain accreditation. From the lab's perspective, "the benefits of accreditation force you to take a hard look at your quality program, operating procedures, technical competence and all of the general things that we sometimes tend to look at in our day-to-day activities, and make sure they work correctly," says Harris.

The time it takes a lab to get accredited, from beginning to end, depends mainly on completeness of the application and the laboratory's readiness for the on-site assessment. The backlog at the accreditation body also can play a role. Earning accreditation from A2LA can take anywhere from three to eight months, on average, says Ramona Saar, A2LA quality manager.

Harris explains that as a DOE laboratory, his team is used to a rigorous and well-documented system. When his lab first became accredited in the mid-1990s, six months were spent reviewing the system. During that time, the system was compared to the standards the accrediting body would use. The result was a team that was comfortable and ready for the accreditation process.

Saar notes that measurement uncertainty issues and measurement uncertainty budgets are important considerations for potential users of a calibration laboratory's services. "That really involves quite a bit because they [labs] have to understand their measurements very well, and understand the Guide to the Expression of Uncertainty in Measurement (GUM)," she says. "Of course, this depends on the precision of the measurements that they want to be doing. Consistent with the GUM, we don't require detailed uncertainty budgets if they're not claiming very tight measurement uncertainty. The higher the level of the lab, the more detail they have to go into. But that seems to be the stumbling block for the smaller labs--measurement uncertainty."

When a lab has received accreditation, users can generally feel confident about that lab's technical competence and compliance to ISO/IEC 17025, General Requirements for the Competence of Testing and Calibration Laboratories, the internationally agreed upon standard for laboratory accreditation.

In addition, depending upon the accreditation body used by a lab, accreditation also signifies that the lab conforms to certain requirements beyond ISO 17025. Accreditation bodies may have their own set of policies by which laboratories must abide. For example, A2LA has additional policies regarding traceability, site-testing calibration and proficiency testing.

Saar explains, "These are all additional requirements that have been agreed upon at the international level and if a lab really wants to meet accreditation and be the equivalent of what everyone else is doing, they should meet these additional items beyond the standard."

The process

Users can gain a better appreciation of using accredited laboratories by understanding the rigorous process they

go through. The first step in the formal accreditation procedure is for the lab to obtain a full application from an accrediting body. A2LA provides checklists for self-audits with its applications. Once the laboratory has completed the paperwork--including information on the scope, or breadth of capabilities for which it is seeking accreditation, as well as the self-audits it has performed--the application is returned to A2LA and processed. A2LA then identifies an assessor or team of assessors "that we think would do a good job covering the scope technically and quality system wise," Saar explains.

Scope is by far the determining factor as to how many assessors will audit an organization, according to Saar. The more capabilities the laboratory wants to be accredited for, the larger the number of assessors who are needed. A lab has the right to refuse any individual assessor that it believes could present a conflict of interest or be otherwise problematic.

When the Oak Ridge Metrology Center began the accreditation process, Harris and his team reviewed the resumes of the assessors "to be sure they would be confident in the areas they were assessing." He was surprised by the competency of the assessors provided by the NVLAP. "They were extremely knowledgeable about the areas they looked at--more so than we had been used to. They asked better questions. They asked more penetrating questions. They probably looked more thoroughly than previous assessors at our methods and techniques," Harris observes.

What happens next varies based on the accreditation body, but in the case of A2LA, the laboratory provides the lead assessor with the quality system documentation for an initial quality system review. If there are gaps, the assessor notifies the lab, so corrective action can be taken before the assessor sets foot in the laboratory. This allows the assessor to focus on an opening interview, tour the facility, look at accommodations, review records and observe the actual tests being done once he or she reaches the laboratory, says Saar.

If the lab does on-site calibrations for clients, a visit to a client facility is arranged. Saar says on-site calibrations raise unique problems because technicians who do not have direct management support at a facility might run into difficulties.

Upon completion of the A2LA assessor's on-site review of the lab and its capabilities, the assessor gives the lab a report of noncompliant areas, as well as compliant areas. The lab then must respond to A2LA headquarters within 30 days with documented evidence of compliance or corrective action on the noncompliant items. The 30-day time frame is not absolute, Saar says. "Sometimes there are things that take longer. If a lab needs to have something recalibrated and needs to provide an actual calibration certificate, it might take six to eight weeks. We don't let more than six months go by or they have to be reassessed, because the assessment is time-dependent as well," she explains.

Once all issues have been resolved, Saar says three members of A2LA's 50-member, independent accreditation council of technical experts receive the necessary information. The three experts review the information and then vote independently.

If any of the experts vote negatively, the reasons for the claim must be substantiated and documented. Accreditation is then withheld until the issues are resolved.

If the ballots come back affirmative, the lab gets accredited for a two-year period, and after one year, an on-

site surveillance is conducted. "We check on internal audits and management review--things that help a lab that's recently been accredited keep on track," Saar explains.

The council also has the option of shortening the time between the accreditation and the on-site surveillance visit to less than one year. Saar explains that while the council may think that overall, a lab is doing a good job, some noncritical problems might be noticed.

We'll be back

All labs are reassessed every two years after the initial accreditation. "The renewal process is almost like starting over because the labs have to be fully reassessed," observes Saar.

The years between reassessments do not mean that laboratories can sit back and relax. Every year between the two-year assessment period, and after the first year's on-site surveillance, labs must undergo proficiency testing, both internally and externally. Abdelhafiz says the internal proficiency tests are administered to measure the capabilities of lab technicians and engineers to ensure that "they're truly well versed in their field."

Saar says that labs must notify A2LA of changes in personnel between reassessment periods, because if turnover occurs, a lab might lose its expert in a particular area. If a person of equal competence is not found, that capability may have to be pulled from the lab's scope until the previous level of expertise is reached.

The external proficiency tests "make sure your laboratory, in comparison to other laboratories, is proficient in providing the scope of work that's on the accreditation," says Abdelhafiz. To accomplish this, he says, a master or artifact of a certain shape is sent to a minimum of three laboratories. In addition to measuring the item, each of the labs checks that the accuracy and integrity of the item was not jeopardized during transportation. The results are then compared, and if a lab's results differ from the other labs, it is the offending lab's responsibility to find the discrepancy.

Abdelhafiz says the time needed to correct the situation depends on the problem. "If it's a typo or machine input, then a procedure should be implemented to keep it from happening again. But if it's something like the machine's calibration is out, it takes a little bit more assessment and little bit more of countermeasure so that doesn't happen in the future."

AUTHOR INFORMATION

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