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HIGH STANDARDS

TRENDS IN LAB ACCREDITATION AND TRAINING AND TIPS FOR SUCCESS By Rachel Muenz

With ever-tightening government regulations and a closer eye on laboratory tests, accreditation and training aren't likely to lose their importance in the laboratory world anytime soon. Jason Poore, client development coordinator at the American Association for Laboratory Accreditation, says that while accreditation generally doesn't change very often because it's tied to the standards against which organizations choose to be accredited, as tests and measurements are scrutinized more often or there's a desire for international acceptance of results, the need for accreditation becomes more pronounced.

"The concept of third-party accreditation is growing both domestically and internationally, and regulators are increasingly leaning on competent accrediting bodies to establish competency in organizations," he says.

As far as specific trends in lab training go, Poore says that many organizations are starting to realize that over the long term investing in lab training is much less costly than hiring consultants. "Finding an organization with enough knowledge to develop comprehensive training courses with enough substance to facilitate understanding of the content area is absolutely necessary, similar to finding the right consultant," he says.

While accreditation doesn't change very often, Poore says that standards are always being revised to keep up with industry changes and any challenges that come up over time. He adds that currently the major accreditation

standard ISO 17025 is under revision, with a number of changes to the current version of the document proposed. The ISO 17011 standard that governs how accrediting bodies do business is also under review.

"Thankfully these standards will have a generous transition period to allow accrediting bodies to implement the changes along with their accredited organizations," Poore says.

Karen Breckenridge, director of quality systems at the Association of Public Health Laboratories (APHL), notes that a recent trend she's noticed from the public health lab side of things is that more labs are getting ISO 17025 accreditation.

"A lot of that is because they do a lot of environmental work as well, not just clinical testing," she says of public health labs.

"The concept of third-party accreditation is growing both domestically and internationally."

Keys to successful accreditation

For Kathryn Wangsness, chief of the Office of Laboratory Services at the Arizona State Public Health Laboratory, the Food Safety Modernization Act of 2011 was a key reason her lab recently decided to become ISO 17025 accredited. Since Wangsness's lab is part of the nation's Food Emergency Response Network, the U.S. Food and Drug Administration (FDA) recommended completing the accreditation process.

"The FDA was encouraging us to ... become ISO 17025 accredited so that during outbreaks and emergency responses or surveillance activities we would have this accreditation available that would show that we had a quality management system in place and that it had been reviewed by an external entity," she explains.

When it came to choosing an accrediting body, Wangness's lab had to go out for bid, since it is a state lab. She recommends that other government labs that need to go out for bid start the process as soon as possible and be patient.

"It does take a while to go through the standard and figure out all the pieces and parts that are missing that need to be put in place," she says. "If you've got people [who] are dedicated to just doing that, then you could probably get it done fairly quickly, but if you've got limited resources and you're trying to do this, be patient."

For labs that don't need to go out for bid, choosing the right accreditation body is just as important, and, according to Poore, good communication is often the key determiner of which accreditation body to go with.

"All recognized accrediting bodies provide the same basic service: accreditation to a given standard," Poore says. "However, what often sets one accrediting body apart from another is having an open line of communication with knowledgeable staff [who] can help an organization understand the language in the standard and how best to meet the requirements."

Wangness agrees that the knowledge and resources provided by her accreditation body made the ISO 17025 process easier. She adds that many accrediting bodies have a checklist related to the ISO standard that they use for their assessments, which is a helpful tool for any lab completing the accreditation process.

"Downloading that and going through it line by line will really help them in the long run," she says. "With our accreditation body, we're required to go through it every year."

Because the ISO standard involves certain requirements for the facilities and purchasing sides of labs, staff at Wangness's lab who do not perform actual lab work and staff working in the lab had to adopt new systems.

"Everybody was supportive, but it was challenging for them to understand how that all worked and how it was going to fit together," Wangness says. "They had their own processes in place, but now we had to figure out exactly what those processes were, have them available, and make sure that we were doing all the things we needed to do."



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Meetings and good communication were key to how Wangsness's lab dealt with the challenges of switching to ISO 17025. She says that APHL was an important part of the process, as they helped connect her with other labs that had also gone through the accreditation process so she could get tips on and ideas for how to handle any difficulties. They were even able to get an APHL representative to come to their lab and do a walk-through and a one-hour introductory training session on ISO 17025 for all staff involved in the process.

"It does take a while to go through the standard and figure out all the pieces and parts."

"We really used a lot of resources that APHL had available to us," she says, adding that she would recommend other labs get a similar pre-assessment done, whether through a consultant or their accrediting body. "Have an individual come through who's knowledgeable about the standard and will walk through the laboratory and let you know where you might still have gaps."

Poore notes that challenges to labs going through the accreditation process depend on the reasons they are becoming accredited.

"Customer requirements, regulatory requirements, and voluntary participation are all very different reasons to become accredited, and each carries its own set of challenges," he says. "For those organizations [that] must be accredited, getting buy-in from staff or upper management can be daunting. Sometimes assessment findings lead to a need for change, and facilitating that change can be difficult in an organization that is required to be accredited."

For Wangsness, getting that support from upper management right from the start was the key to making the ISO process as smooth as possible.

"We actually went all the way up to the top to make sure that the top individuals understood what their staff [who] actually worked directly with us would be doing, so that we weren't going to run into any issues there," she says, adding that they also had their accreditation body come in and do some on-site training for the entire lab management team. "Having the [whole] management team attend this training and [being] able to ask questions of the accreditation body as we were going through all the different areas and what needed to be put in place [were] really helpful. All the resources [whom] I had talked to highly recommended having the accreditation body provide either off-site or on-site training to staff."

Poore adds that willingness to learn is essential to get the most out of lab training, which is why it's so important for the lab managers to select a training program that's comprehensive and addresses all their needs. He suggests that when deciding on a training program, managers should ask the training provider for as many details on and resources for the course as they can give.

"At a minimum, an organization should want to see learning objectives for a given training course to ensure [that] it is right for them," he says. "Other considerations might be whether the content will be tested at the end of the course, or to request a bio of the trainer to determine an adequate level of experience in the content area."

For Wangsness, most of the benefits of ISO 17025 to her lab have been internal so far, as their accreditation is still fairly recent.

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The image shows a Brookfield DV3T Rheometer, a laboratory instrument used for measuring viscosity. It features a white, boxy design with a large, color touch screen on the front. The screen displays a 'Compare Graph' with two curves, one red and one blue, showing viscosity versus shear rate. Below the graph, there are two tables of data. The first table lists 'Y - Viscosity' and 'X - Shear Rate' for two different samples. The second table lists 'Y - Viscosity' and 'X - Shear Rate' for a single sample. The device is mounted on a stand with a metal probe and a control knob.

"Having to bring on this new accreditation made us really look at our system and clarify things that weren't clear, and put processes in place that just helped streamline how we did things," she says. She adds that though they didn't often have incorrect procedures in the lab, the ISO accreditation has reduced such instances even further. Communication with the nontraditional lab areas, such as facilities and purchasing, has also improved.

"We've learned more about their processes, and they've learned more about ours," she says. "Internally, the benefits have been good. They've really helped give us a better overall system."

Accreditation and training for the future

While the experience of Wangsness's lab shows that traditional training is still alive and well, online training is a growing resource for labs. However, Poore notes, while online training is more convenient, "not all online content is created equal" and there is a "high level of variation between courses and training providers."

For example, he says, prerecorded webinars simply deliver content to listeners with little to no interaction between instructor and learners, though some webinars will have an instructor on standby to answer questions.

"Two-way dialogue is essential in the process of learning many of the nuances involved with accreditation and allows for interaction that cannot always be effectively replicated online," he says. "As training gains popularity, it would be fair to assume that this growth will be both in the online and traditional training course settings."

Breckenridge agrees that traditional training isn't likely to disappear anytime soon.

"We're doing both webinars and teleconferences from our end because many of our members like the opportunity [during] a teleconference to be able to ask some questions," she says of APHL's training options. "A webinar's great for the flexibility of being able to listen to it at your convenience, but sometimes you need someone to answer some questions."

As for accreditation, Poore believes it's an area that will continue to grow.

"As more regulators lean on accreditation as a means of establishing competency, more and more organizations will seek it, whether voluntarily or involuntarily," he says. "It is very likely an area that will see continued growth, especially as accreditation becomes more widely mandated and accepted in the global marketplace and by government entities."

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