

CAP TODAY

C O L L E G E O F A M E R I C A N P A T H O L O G I S T S

Making the leap to ISO 15189—what leaders have learned

Anne Ford

Four months after his laboratory received CAP 15189 accreditation, Leo Serrano, administrative director of Avera McKennan Hospital and University Health Center, Sioux Falls, SD, is still riding high. “Here we are in South Dakota, where people think it’s nothing but snow and soybeans, and we’re the first hospital laboratory in the nation to be accredited by the CAP for ISO 15189,” he says. “Our level of elation is immeasurable.”

Likewise, the party’s still going on at Piedmont Medical Laboratory, Winchester, Va., a standalone lab that received its CAP 15189 accreditation in November. “Even though the economy’s supposed to be reducing realization, we came off our best month ever in February,” says Joe Skrisson, Piedmont CEO and executive director. “You could extrapolate that from what ISO [accreditation] has done.”

As the first two laboratories to receive ISO 15189 accreditation through the CAP, Avera McKennan and Piedmont have paved the way for other institutions to pursue this highly challenging—and prestigious—accreditation. Those institutions include Blanchard Valley Hospital, Findlay, Ohio, which, at CAP TODAY press time, was awaiting the CAP’s decision on the lab’s accreditation under CAP 15189.

Cordelia Sever, MD, chair of the CAP 15189 Accreditation Committee and director of clinical pathology at Pathology Associates of Albuquerque, reports that an additional five laboratories are in the process of becoming accredited, including her own as well as a LabCorp location in Tampa, Fla. Another 20 are in the pipeline. “Especially now, with a new [U.S. political]

known as ISO 15189:2007, and based on ISO/IEC 17025 and ISO 9001, the standard was developed with the CAP’s input and introduced in 2003.

Since then it’s become mandatory in several countries, including Australia and many European nations, but remains optional in the United States. It complements, rather than replaces, the CAP’s Laboratory Accreditation Program, and emphasizes operational systems improvement, risk mitigation, and quality management. Avera McKennan and Piedmont have cited its applicability as a quality-management system as one of the standard’s biggest draws, while Dr. Sever and

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administration that wants to transform health care, a lot of people believe that in order to stay in the game, you really need to reach a new level of excellence,” Dr. Sever says. “And to make a real significant leap, you have to have a good management system that’s going to be nimble. The ISO program is a good way to achieve that.”

A quick refresher: Last fall, the CAP began offering CAP 15189, a program that accredits laboratories to the International Organization for Standardization’s 15189 standard, which details quality-management and competency requirements for medical labs. (Avera McKennan, Piedmont, and Blanchard Valley were part of the program’s pilot stage, which was launched in January 2008.) Formally

others have said that CAP 15189 accreditation can help laboratories maintain gains they may have made with Lean or Six Sigma, or both.

Now that Avera McKennan and Piedmont have been accredited to the standard, with Blanchard Valley likely to follow soon, representatives from all three laboratories weigh in with stories about their experiences and advice to others who are considering following in their footsteps—including feedback on what it takes to keep CAP 15189 accreditation after you’ve achieved it.

The answer: “The same amount of momentum” that it took to get the accreditation in the first place, says Benita Haines, corporate compliance and

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quality process manager for Valley Health Laboratories, a shareholder of Piedmont. In her previous position as Piedmont's quality management, compliance, and education coordinator, Haines oversaw the implementation of the 15189 standard there. Even now that Piedmont has been accredited, "we still have to keep up with all of the quarterly internal audits and submit our paperwork," she says. "The nice thing is that now the staff know the language of the standard better and are living it day to day. But it's taking the same amount of momentum, because we're digging deeper into different issues."



Haines

Some of those issues entail the use of root-cause analysis. This part of 15189 requires laboratories to uncover the fundamental origins of errors, rather than simply blame an employee. For example, Piedmont recently began performing root-cause analysis on errors that had arisen during the pre-analytical stage, particularly those related to data entry, to determine which factors were leading to those errors: "Is it a particular day? A particular shift? Requisition design? Environment? Design of workstations? Productivity of staff?" Haines says. "The staff is able to identify trends and drill down better. I think that's thanks to the ISO standard."

Blanchard Valley's root-cause analysis experience has been similarly rewarding. "Before we started this ISO journey, we did not do internal root-cause analysis," says laboratory director Bonnie Van Schoik. "I didn't want to be part of a root-cause analysis because it was always negative. That is totally not what we want to be about. We want to promote the proactive engagement of the staff." To that

end, when they have a problem now that could have potential serious adverse effects on a patient's outcome, anyone who might have affected that patient result is brought together and asked to bring ideas to the table to help improve that process. "That really does empower the associate. We try very diligently to make this not a punitive action," Van Schoik says. The analyses performed at Blanchard Valley thus far have revealed, among other things, that the way the laboratory information system functions could enhance



Van Schoik

the timeliness of contacting an appropriate caregiver with critical values, and that stat turnaround time could be shortened simply with a minor process change.

Another benefit of ISO 15189 accreditation, Haines says, is the continued increase in staff buy-in that it has sparked, particularly when it comes to understanding the importance of document control—that is, making sure no one is using an outdated version of a policy or procedure (which often happens in the form of pinning up a "cheat sheet" in one's work area rather than consulting the most current official version). Getting to this point at Piedmont took some doing. "Time and time again, we would have an internal audit, and we always had nonconforming documents hanging up," Haines says. "Recently I walked through and did not find any nonconforming documents displayed. I mentioned to staff, 'Great job; there are no hanging documents,' and they replied, 'Oh, no, we know what is expected,' instead of asking,

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'Why can't I have a document hanging up?' It is part of their culture now."

As Van Schoik has learned, culture change is perhaps the most challenging aspect of the entire process. To help snag staff buy-in at Blanchard Valley, early in the accreditation process a form was developed to allow any staff member to report any nonconformance he or she had spotted and help revise the policy or procedure in question. "We are trying to empower our associates to believe in themselves and question processes," she explains. In addition, several laboratory employees have been trained as "scouts" and asked to lead small groups with other staff members to review new procedures. On a more whimsical note, Van Schoik and her colleagues developed an ISO-themed game, in which employees earned game pieces for various accreditation-related tasks, then traded the pieces in for treats like movie tickets or fast-food gift cards "as a token of appreciation that they were getting onboard with our ISO 15189 journey."

Then, too, staff buy-in at Blanchard Valley was inadvertently boosted by the ISO requirements themselves, says Doug Hughes, laboratory information services coordinator: "In the beginning, when we were asking people to document what they do and how they do it, many people would say, 'Why do I have to write this down? I already know what I do.' But once we've gotten all those things on paper, I've seen a lot of people express pride in what they do, with the realization: 'Boy, I really do a lot.' It's kind of amazing."

Documentation, as it happens, is one of the most difficult aspects of ISO 15189. Electronic document control systems (Piedmont uses one from Par-

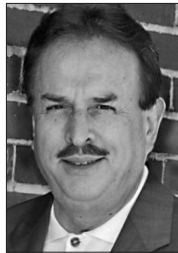
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adigm Software), though expensive, simplify the process. "The document control was incredibly difficult to get under control," Haines says. "But once we did, it became a lot easier. Once we imported our documents, maintenance of the system was simple. It is set up for annual review with reminders via e-mail to the owner of the document. We are reminded to archive documents once the retention period is reached. General staff only have access to the current version."

Was it pricey? Skrisson estimates the cost of Piedmont's electronic document control system at about \$20,000, and hastens to add, "It's a very small investment for the commitment you get from your people."

Van Schoik agrees, saying, "We had well over 85 policy and procedure manuals that were binders on shelves that are now being put into the system"—in Blanchard Valley's case, the SoftTech Health Lab QMS. "It is costly—we're not going to sit here and tell you it's not—but you have to invest on the front end to really reap the benefits," she adds.

That's not to say, however, that document control can't be achieved without purchasing such a system. Avera McKennan, for example, decided to use Excel. "We had significant financial constraints, so we did it very fru-



Skrisson



Serrano

gally," Serrano says. "You don't have to spend tons of money. You just have to be prepared to be creative." That said, he adds, "if we'd had the money, I would have gotten the software."

As for the money Avera McKennan did spend, Serrano waxes enthusiastic about its return on investment. "We're already seeing the financial benefits pay off," he says. "We have a very strong research arm, the Avera Research Institute, and they are actually using our ISO accreditation to help them garner grants, because we do the testing for their clinical trials. That has gotten them some very nice grants. We've also been able to use it to our advantage as we have discussions with payers. When you can show them that your laboratory is a 15189-accredited laboratory, that definitely gets their attention."

And then there are the nonfinancial rewards, Serrano continues: "It gives us a significantly more powerful platform from which to tout the laboratory and its contributions to patient care and to quality. While we

have consistently had world-class turnaround times, world-class error rates, we still had physicians on our medical staff who emphasized the outliers. This achievement confirms what we had been telling them."

Laboratories that are considering pursuing ISO 15189 accreditation through the CAP should keep an eye out this summer for a series of webinars that the College will hold to help educate potential participants about the standard, and to give them the chance to hear the early-adopting laboratories speak about their experiences.

Dr. Sever is encouraged by the number of laboratories that have inquired about and are gearing up for 15189 accreditation, despite the state of the economy and the scrutiny every expense item is getting. "It takes a while and we are pretty confident that it will evolve," she says. Meanwhile, in the words of Serrano: "If you have a quality laboratory, and you want to set yourself apart from the herd, this is the way to go." □



Dr. Sever

Anne Ford is a writer in Chicago.

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