‘We wanted to be the best we could possibly be’: CAP ISO 15189-accredited labs on the difference it makes

Anne Ford

September 2018—Ten years ago, Richard J. Zarbo, MD, was feeling pretty proud of his laboratory. As system chairman of pathology and laboratory medicine at Detroit-based Henry Ford Health System, over the previous few years he’d seen his team rigorously implement Lean practices, practices that had paid off in greater safety and efficiency. “Setting the bar higher was important because that’s the culture here,” he says. “This is what we do.”

Then he encountered his first CAP 15189-accredited laboratory, and knew the game had changed: “We thought we were pretty good at what we did, until we saw what Leo did.”

That would be Leo Serrano, then the administrative director of Avera McKennan Hospital and University Health Center, Sioux Falls, SD—the first hospital laboratory in the nation to be accredited by the CAP for ISO 15189. “I was just blown away with the level of discipline that I saw there, and that’s what prompted me to bring the vision of 15189 as a systemwide stretch goal to my own team,” Dr. Zarbo says.

Ten years later, Henry Ford is just one of 67 laboratories that have achieved CAP 15189 accreditation, with more than a dozen others having applied or in process. In the decade since the CAP introduced the program, which accredits laboratories to the International Organization for Standardization’s 15189 standard, it has gained a rock-solid reputation as the premier method for reaching excellence in medical laboratories.

As Dr. Zarbo puts it: “ISO is really the status of the few. Anybody can buy and drive a Cadillac, but very few get to drive a Porsche. When you’re doing ISO as a laboratory, you’re driving a Porsche. There are not many other people on the highway with you.”

On the 10th anniversary of the CAP 15189 program, three institutions share how undertaking this rigorous program has changed their practices and outcomes for the better.

A decade after his then-laboratory achieved 15189 accreditation, Serrano calls it “the highlight of my career.”

“It’s a long road, a trying road, and an extremely rewarding road,” says Serrano, who is now clinical and operational consultant and operations manager for FirstPath, a Fort Lauderdale-based pathology group. “The lessons you learn from 15189, you carry forth into all of your future efforts.”

Like Henry Ford Health System, Avera McKennan had already implemented Lean practices before it ever considered adding 15189. “Because we were Lean fanatics, if you will, our turnaround times were very tight and very consistent, and those kinds of metrics that Lean and Six Sigma labs like to use were already in place,” Serrano explains.

So why add 15189? “The way we sold the concept to our administration was that it would validate the quality of our laboratory,” he says. “We had participated in a number of quality surveys, and we always came out as a shining star. But that’s just somebody else’s opinion. Having 15189 accreditation meant that an outside independent neutral arbiter had come in and said: ‘You meet the highest standard possible.’”

In addition to the considerable bragging rights that accompanied becoming the first U.S. hospital laboratory to be CAP 15189 accredited (for that he credits the full Avera lab team, particularly Cheryl Wildermuth, laboratory quality management manager), the accreditation did several things for Serrano’s staff. First, it motivated and unified them in a tremendous way. “As we explained what 15189 was going to do for us, everybody bought into it, and it became the glue that bonded the entire laboratory,” says Serrano. “Organizationally, emotionally, and in many other ways.”

‘Our research institute was immediately awarded a half-million-dollar contract.
And as we improved, that translated into better marketing tools, which helped us get even more outreach work.’ — **Leo Serrano**

The accreditation brought unexpected business benefits as well. “As soon as people saw that we were the first ISO 15189 hospital laboratory, our research institute was immediately awarded a half-million-dollar contract,” he says. “And as we improved, that translated into better marketing tools, which helped us get even more outreach work. Because of that, we were able to keep the ‘blood brothers’ from really having any impact whatsoever in our market area.” Avera recently achieved CAP 15189 reaccreditation for the third time.

Though his current institution, FirstPath, is not 15189 accredited, it’s just a matter of time, Serrano says. “The things that I’ve learned from when we did them at Avera, we have applied a great many of those at FirstPath. The owners of FirstPath have bought into the whole thing, lock, stock, and barrel. So we have started gearing in that direction.”

Until then, he has a memento to help keep the 15189 inspiration alive. When the Avera McKennan laboratory personnel first learned they had achieved ISO accreditation, they all streamed onto the hospital grounds for a group picture. A copy of it still sits in Serrano’s home office.

“That’s a constant reminder,” he says. “We wanted to be number one above all. We wanted to be the best we could possibly be. And if you have that same drive, then 15189 is what you want to achieve, because that’s the ultimate designator of a top-quality laboratory.”

After Dr. Zarbo saw the freshly 15189-accredited Avera McKennan laboratory, he returned to his Henry Ford team and told them: “We have to go another notch up.”

For example? Lean-saturated as it was, the laboratory already documented defects in the workplace via a deviation management system. “In our first year, I think we documented about 8,000 things that were defective in the work or didn’t please the customer or didn’t go well and had to be reworked and redone,” he recalls. After HFHS achieved CAP 15189 accreditation (becoming, at the time, the largest entity to do so) in 2013, the laboratory continued and amplified those efforts. “So we now document over 70,000 defects annually,” he says. “And we do it in a defined manner that starts to document the root cause, documents the corrective action, and documents the preventive action. So think about how this laboratory looks now, as compared to six or eight years ago.”

Quality systems manager Ruan Varney knows exactly how it looks. “We started with 125 subclassification codes in the first year and consistently grew to over 300 in 2018. Each manager is equipped with a monthly summary chart

of their most frequent deviations to engage their staff as well as their external supplier for improvement opportunities." They recently began an improvement process with the emergency department in hopes of reducing the number of clinical blood samples submitted to the laboratory that are categorized as "quantity not sufficient" and "clotted" by sharing data from the deviation management system.

"The latest enhancement in the deviation management system is to be able to narrow down to the phlebotomist who drew that specimen to understand the underlying root causes for improvements. This is huge for us and very exciting," Varney says, explaining that the hope is to expand the pilot to other areas of the hospital. "We monitor the ongoing progress of this pilot with a daily metric board shared with the ED. While reducing the risk to patients, we have also earned a higher level of respect from our customers."

Dr. Zarbo points to document control as another example of an area in which 15189 has made a big difference. "The College required us to have document control, and that was usually a paper-based system," he says. "But if you're going to do things so that all your policies and procedures are standardized across all laboratories in a system of almost 1,000 people, you have to be electronic. We realized that unless we had an electronic document system we could not pursue ISO."

Since implementing that electronic document control as part of the 15189 accreditation requirements, the laboratory now has more than 10,000 documents in its EDS. All of the laboratory manuals are kept on the lab's intranet, so that any employee anywhere in the system can consult them or print them out at any time. "This is a direct result of our quest for ISO," Dr. Zarbo says.

One undertaking that was completely new to the laboratory at the time it began the 15189 accreditation process was the internal audits requirement. "The goal is to find things that people who do the work take for granted and don't see as deficiencies," he explains. "So we do this auditor work throughout the year of all laboratories in the system. And what has been the outcome? Almost every single laboratory under our direction has had a 90 percent decrease in Laboratory Accreditation Program deficiencies since we began this process."

Varney says the laboratory has also seen a vast improvement in turnaround times since becoming 15189 accredited. "Previously, a prostate resection, for example, would have taken up to seven days to result; now it takes two days from receipt in the laboratory," she says. "We also receive breast biopsy specimens the same day or next morning from our affiliate hospitals. That very same day the breast specimens are accessioned and processed and glass slides are delivered to the pathologists." The significantly shorter turnaround times are monitored at each stage with a daily metric board. "We know when it was packaged for delivery from the site, when it was taken off the delivery log, when it was grossed and delivered to the pathologist. We have our clinicians complimenting us: 'I don't know what you guys do, but it is amazing—we have our results, we can expedite the patient appointments, and get them to the clinic faster for their management.'"

'Almost every single laboratory under our direction has had a 90 percent decrease in

Laboratory Accreditation Program deficiencies since we began this process.' — **Richard Zarbo, MD**

There are improvements in clinical pathology as well. Before 15189, it wasn't unusual for a critical value phone call to be made to a physician at 2 AM regarding a specimen from a patient who had been seen at 10 AM that day. "Because of multiple continuous process improvements, we now call the clinician within about four hours of specimen collection," Varney says. "When the call is made earlier in the same day, the clinician has a chance to attend to the patient earlier rather than our waking up the clinician in the middle of the night and the patient being sent to the ER."

The 15189 standard requires management review. "We actually had a number of consultants with us years ago," Dr. Zarbo says. "Their advice was to focus on only a certain aspect of management and just do a deep dive on that. We thought: That's not really good enough for us as a system laboratory, so we're going to do our own reflective self-inspection of every single management system that we have and whether it delivers on the goal of quality and human engagement, year after year after year." It's this approach, he says, that has led to a 35 percent drop in the rate of most common deficiencies.

To those intimidated by the 15189 accreditation process, Dr. Zarbo says, "This is hard work. But eventually, when it becomes the only way you work, it's no longer hard; it just becomes the manner in which you work." And to those who don't see why such a lengthy and rigorous accreditation is worth it, he quotes the late quality management expert W. Edwards Deming: "Learning is not compulsory, and neither is survival."

"This is really a survival mode," he argues. "There's going to be a lot of change going forward in health care, and not everybody's going to be on the playing field. There's going to be a lot of consolidation going forward, so this [15189 accreditation] is also a survival strategy, frankly. This is a competitive business strategy."

When the Joint Pathology Center in Silver Spring, Md., earned 15189 accreditation last year, it became the first federal laboratory to do so. It was the culmination of a journey that began when director Clayton D. Simon, MD, was in a meeting with his boss. "The topic came up that we at the Joint Pathology Center say we produce a quality product," he recalls. "And my boss was like: How do you know?"

Taken aback as he was by the question, Dr. Simon admitted it was a valid one. In response, he decided, "Fine. The best way to know is to get an outside organization to come in, you open your doors and your books, and you ask them, 'How are we doing?' So that's what we did."

How did he get buy-in from staff? "We're the military—we can order people to do stuff," he says tongue-in-cheek. "No, really, we explained to our personnel what we're trying to do and why. If we're going to tell people we're a premier lab, we have to act like it. We represent ourselves to be the consultants to pathologists across the entire Department of Defense and Veterans Administration, and all of those hospitals are required by law to be CAP certified. If we're going to be a step above, then we probably should take the next step."

Quality assurance manager Grace M.B. Deneke, MA, MT(ASCP), was on the front lines of that step and all the steps that followed it. "To get buy-in, I think that was a delicate balance," she says. "We created a quality manual that engaged all aspects of our organization. We had to create policies and procedures for the quality systems so they could gradually understand the value of addressing nonconformities. Just slowly entrenching the organization with quality provided us a buy-in. And then they could develop their quality indicators or performance indicators, which they would share during our monthly meetings and take pride in their accomplishment."

The process of converting document control from a manual to an electronic system also helped achieve buy-in among staff. "It was very ambitious, it took lots of hours, but we got it down," she says. "The beauty now is that everybody has access to the same document and they can quickly update it and see who's in compliance, so they

saw the benefit of having a system. It became, ‘OK, we can do this.’”

‘Everybody’s process now is visible, so everybody’s paying attention to their section and how they contribute to the overall turnaround time.’ — **Grace Deneke, MA, MT(ASCP)**

Early in the process, Deneke brought in an outside ISO consultant to lead the team through a value stream mapping process, “so everybody could see the flow of work and how much waste there was,” she says. “They were like, ‘Oh, we definitely need to stop doing that.’ Everybody’s process now is visible, so everybody’s paying attention to their section and how they contribute to the overall turnaround time.”

Dr. Simon’s favorite part of the accreditation process has been watching the gradual decrease in that turnaround time. Before 15189, an average of slightly more than seven days elapsed between the time the laboratory received a case to the time its customer received the diagnosis. Post-15189, that has gone to an average of slightly more than three days. That has helped keep the Joint Pathology Center competitive.

Dr. Simon explains: “See, if the JPC is taking too long, in a pathologist’s opinion, they’ll send it to somebody on the outside. If they send it to us, we do it for free, because that’s our job in the military. If they send it to someone else, like Mayo Clinic, they pay for it. Some of our customers were thinking, ‘Hmm, free in seven days or $300 in three days.’ Sometimes when you’re trying to get a patient diagnosed and treated, it’s worth the money spent. I needed to make the JPC competitive with other organizations that were charging for it. Now, 10 percent of our cases get signed out the same day we receive them. And they get them for free. You can’t put a price on that.”

Of course, success often has a flip side, though in this case it’s one Dr. Simon gladly accepts. “We track how many customers call us with a question, such as asking where their case is,” he says. “We have more and more people calling us asking us where their case is, and we’ve had it less than five days. That tells me they’re so used to cases coming out faster that they’re already missing their case at four or five days. When our average was seven days, they’d wait till 10 days, 12 days, two weeks. Now they’re calling us three days in. That, to me, is a success story. Yes, we’re fielding more questions, but in my view that is a positive thing because we’re meeting their expectations.”

To laboratories that are considering undergoing the 15189 process, he says, “I think they need to go into it with their eyes open, knowing this is not going to be easy. It’s like turning a very large ship with a very small rudder. The better your processes already are, the easier it will be to go through it. If your processes are less than good, it requires larger changes, and people are resistant to that.

“Now, people are resilient,” he continues. “Once you demonstrate why those changes need to happen, it becomes

a whole lot easier for people to buy into it. It's like watching your child grow. You don't see the changes day to day, but if you take a picture when they're two years old, and then a picture when they're three years old, you see a huge difference."

When the JPC received its 15189 accreditation, it held a ceremony so all of the employees could share in the moment. Dr. Simon asked his boss—a major general—to give a speech. "He started looking at what ISO 15189 actually is, and he was stunned," Dr. Simon recalls. "He goes, 'You people are underplaying this. This is a huge accomplishment.' Well, to us working in a laboratory, it didn't seem that huge. It was just the next logical step."

After nearly 10 years as a member of the CAP 15189 Committee, Frank Schneider, MD, assistant professor in the Department of Pathology and Laboratory Medicine at Emory University School of Medicine, now chairs the committee. What has he witnessed during that time? "What we have seen and learned is that a small laboratory can do this just as well as a big laboratory can do it," he says.

Small or big, even after 10 years one of the most common questions the committee gets about the CAP 15189 program is: Where's the checklist?

"Most people are used to the Laboratory Accreditation Program, which is very checklist based," he explains. "But the ISO program doesn't have a checklist. It's based on this international standard 15189. The first advice I always give people is, go online and buy yourself the standard. There is no checklist; it's a collection of requirements that a laboratory should meet. The goal of ISO is not to develop or publish accreditation documents. They publish standards, and it is up to you how you want to meet the requirements. So it is not prescriptive, like certain CLSI documents that tell you exactly how to do things."

Dr. Schneider

The other common question he hears: Why would we do this? One answer he often gives: "We have learned over the years that many laboratories benefit from it in terms of constant inspection readiness and deficiency reduction. When you look at the outcomes of LAP inspections, a lot of problems laboratories have are document control, and ISO labs perform pretty well in those inspections."

In the end, what drives people into the program, in his view, is the vision of "not stomping out fires when they run into problems"—that is, "not struggling anymore with these recurrent issues."

Juan C. Millan, MD, whose laboratory system recently achieved 15189 accreditation, agrees. "The important thing is that you have to look at everything that really is not coming out right. You cannot just simply say, 'Well, it's a random error.' You need to look and do root cause analysis where you see what is required, and then you change the processes." Dr. Millan is clinical vice president of diagnostics, director of chemistry services, and medical director of Legacy Laboratory Services, Portland, Ore.

Dr. Schneider elaborates: "ISO is a wonderful complement to a very technical driven Laboratory Accreditation Program in that it provides this overarching process-oriented look at the laboratory from beginning to the end. It's

designed in a way that it improves the operation of the whole laboratory. For that, you need the right culture in the laboratory. I think laboratories do better if they want it. I recommend that labs don't look at this as something that they *have* to do, and it usually doesn't work as well if it gets handed down from the top as, 'Someone should do this.'"

"What laboratories should know is that this is easier than you think," he concludes. "And there's no reason to shy away from it."

Anne Ford is a writer in Evanston, Ill.

Laboratories interested in ISO 15189 accreditation, or those that are already ISO 15189 accredited but wish to exchange information with peers, can request a tour of Henry Ford Health System laboratories, which are an ISO 15189 Center of Excellence and Learning. To request a tour, contact Caroline Maurer, director of CAP 15189 Laboratory Improvement Programs, at cmaurer@cap.org *or 847-832-7451.*