

# ProMedica: Getting to the Root of the Problem

By Anne Ford



F. Michael Walsh, MD,  
chair of pathology  
and director of clinical  
laboratories

## Speaking their Language

F. Michael Walsh, MD, knows that if you want to convey something important, you have to couch it in the language your listener speaks. So when he talks about quality indicators with people outside the health care industry, he chooses his acronyms carefully.

“In this region, there’s a lot of people in manufacturing,” says Dr. Walsh, who is chair of pathology and director of clinical laboratories at ProMedica, a 15-site health care system in northwest Ohio and southeast Michigan. “You tell ‘em, ‘We’re CAP-accredited,’ and they look at you like, ‘What’s that?’ But as soon as you say ‘ISO,’ they understand. They know that it’s very structured, very formatted, very procedure-driven, and it’s a way in which you can document your present state and really measure your progress objectively.”

## Ultimate Signifier of Quality

That recognition of ISO accreditation as the ultimate quality signifier is one of the reasons that, in 2009, ProMedica began pursuing ISO 15189 accreditation through the CAP. Nearly three years and a whole lot of work later, the system achieved its goal. As Dr. Walsh and his staff work to maintain accreditation, they share the highs and lows of their journey in hopes of encouraging other, similarly sized institutions—particularly those that, like ProMedica, don’t have a lot of extra financial resources lying around—to consider becoming ISO 15189 accredited themselves.

## Building a Culture First

Because the ProMedica team had already been using Lean tools for some time, the initial prospect of ISO 15189 seemed a little less daunting, says Mark Sattler, administrative director of laboratories. “It was just a very natural



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next step for us,” he says. “We had a number of good things in place and could continue to build on those. An organization beginning ISO and trying to implement Lean at the same time would go through all kinds of culture-changing, but we’d been through that already.” For example, the laboratory staff was already familiar with the notion that, in Sattler’s words, “the people closest to the work know it best,” meaning that they were used to speaking up when they had process improvements to suggest.

## Working on Procedures

But when it came time for ProMedica’s gap assessment (the detailed, CAP-led, on-site evaluation that reveals the scope and nature of the work to be done before accreditation), Sattler and his team got a bit of a shock. “When we had the inspectors out, they helped us realize that yes, we had made great progress on Lean; yes, our associates owned the improvements they had been part of making; yes, we had also made great strides in building a culture of improvement—but we still had a lot of work to do on our procedural documentation,” he says. “The ISO inspectors took an approach that was very educational, but they didn’t pull any punches. As good as we thought we were, it was a learning experience for us.”

Process improvement specialist Kristy Short puts things a little more bluntly. “I like to say that I was drowning in a sea of nonconformity,” she says. Perhaps the biggest area of nonconformity was document control. Though ProMedica Laboratories already used a document control system (Beckman Coulter’s Quality Link), “we did not control every single document in our laboratory. We had a lot of cheat sheets around the laboratory that didn’t really reference an SOP,” she says. “You could never tell if they were up to date. Those were the hardest things to get rid of. We went into one of our departments and took everything off the walls, and we saw people digging in the trash later, digging them out.”

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## Following the Exact Recipe

In the words of QA specialist Amanda Wright, “Everything in the laboratory follows a recipe, and you need that exact recipe. If your notes are outdated, you’re going to do something wrong. If your reagent changes, you’re gonna need a new procedure, and your notes could change from there.” It took some time for staff to accept that.

It also took some ingenuity and playfulness. For example, Wright and Short held “scavenger hunts” in the document-control system, asking, for example, “Can you find out the title of this document? The revision? Who approved it?” “And if they could find a nonconformity, they could turn it into us for a candy bar, and the candy bar had a sticker on it that said, ‘You helped ISO-tize the lab,’” Short says.



ProMedica offers diagnostic, medical and surgical specialties in areas such as emergency medicine and trauma, heart and vascular, oncology, orthopaedics, neurology, and women’s and children’s services.

## Allowing People to Come Along at Their Own Pace

The good news was that during all of this, staff not only remained engaged, but became even more so as they learned more about the ISO 15189 standard. “When they actually began to see that helping improve the process made their job easier, that helped many more people get on board,” Sattler says. Paradoxically—but, he says, ultimately for the best—this increased staff engagement led to a delayed accreditation schedule.

“As we were going through our ISO prep, we had some staff limitations,” he explains. “Our associates came to us and said, ‘At least in a particular section, we don’t think we can be prepared for the inspection in this amount of time.’ We considered their request, and we told ‘em, ‘We’re going to agree. What do you think is a suitable amount of time to postpone? We agreed on a later date for the inspection, and that really sent a powerful message to the staff, and then they all worked really, really hard in a cheerful manner to deliver on that date.’”

Why not instead put the hammer down and insist that staff do whatever necessary to deliver by the original deadline? That would be counterproductive, Dr. Walsh says. “You set deadlines, but you have to make ‘em soft deadlines,” he argues. “Most labs today, they’re understaffed. You

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tell ‘em, ‘Oh, by the way, we want to have this done in 60 days,’ and people just throw their hands up and give up. You have to allow people to come along at their own pace.”

It may have taken ProMedica a little longer than planned to become ISO 15189 accredited, but accredited they did become, in November 2011. “Yes, an organization could probably go faster, but we did it with existing resources, and we listened to our staff when they said, ‘We need more time,’” says Sattler. “We thought it was more important to get where we needed to go, even if it took us a little bit longer. Their work was really good. And when the inspectors came in, we did really well, and they said, ‘Wow, your level of staff engagement is really wonderful.’”

## Funding the ISO Project through Efficiency Improvement

What was that about “existing resources”? It’s true. ProMedica did not devote any additional monies to the ISO 15189 accreditation project; all related expenses were funded out of the existing laboratory budget. “Hospital administration, corporate administration—they thought accreditation was a great idea, but there was no funding for it,” says Dr. Walsh. “They didn’t go out of their way to help. We eventually got funding for personnel, but we were way down the road before that happened.” So, Sattler says, “to invest more resources in accreditation, we had to generate some efficiency improvements and then take those improvements and re-invest them in the additional resources.”

Fortunately, ProMedica got a break on the item that is often a laboratory’s greatest accreditation-related expense—the electronic document control system. “We were lucky in the relationship we had with Beckman Coulter,” Dr. Walsh explains. “They gave us a wonderful deal on it. If we had to go through standard capital procurement, it probably never would have happened. Document control, I think, would have been harder if we did not have the electronic format.”

## A Drop in Complaints

Though Sattler and Dr. Walsh haven’t formally quantified the gains that have resulted from attaining ISO 15189 accreditation, they say they see its benefits every day. “We perform very well against our budget targets,” Sattler reports, while Dr. Walsh says that as a result of the ISO 15189 process, “the medical staff and the senior executives understand that when the lab identifies a problem that they go through a very

defined process and they permanently correct it. So the number of sporadic complaints has dropped significantly. Now, if there's an issue, you can address it on the root level and come back with solutions."

Not only that, but the laboratory becoming ISO 15189 accredited seems to have sparked ISO fever elsewhere within ProMedica. Dr. Walsh says, "I chair peer review for the health system, and we've putting the ISO process in there, and it's had a huge impact. Now, if there were mistakes made, we're coming to grips with why they happened, rather than saying, 'Let's put your picture up on the wall and say he or she is a bad doctor and we're gonna discipline 'em.'"

*For more CAP 15189 program information, go to [cap.org/cap15189](http://cap.org/cap15189)*

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### **The Right Thing to Do**

That said, he's quick to emphasize, ISO accreditation isn't a "flavor of the month," a trend to be eventually discarded. "People have to understand that this is the right thing to do," he says. "It improves quality, it reduces costs, it improves morale. ISO is a religious conversion. I mean, you've got to believe in it. And you've got to make sure what you've done continues to go forward, rather than fall apart."