From the President's Desk

Beyond excellence

January 2023—When I was newly elected into my officer role at the CAP in 2019, I had the opportunity to join a meeting of a committee under the umbrella of the Council on Accreditation. This was a committee whose work I knew little about but which I quickly grew to appreciate. In this committee I saw an extreme focus on operational processes and quality management structures. They wanted to prevent errors, not just fix them. This focus on process was different from the focus on blame that we often see in medicine. As I listened to Gaurav Sharma, MD, lead the CAP 15189 Committee, I knew I was among folks dedicated to pushing for ever-better care and quality for our patients and our laboratories. If CAP accreditation helps your laboratory achieve excellence, CAP's ISO 15189 accreditation makes it possible to go beyond excellence.

What makes the ISO 15189 program distinct is the focus on processes and culture in the laboratory. Risk management aspects of the program encourage staff members to flag opportunities without fearing they will get blamed, and quality and other controls help the entire team improve operational efficiency. I have not yet overseen an ISO 15189 program myself, but I have been impressed with the laboratories in which I have seen it implemented.

ISO 15189 is an international quality standard, and any lab with ISO 15189 accreditation is performing as well as any other ISO 15189 lab elsewhere in the world. The benchmark offers laboratories key privileges, such as the ability to participate in pharmaceutical trials and other highly regulated activities. Because it is a voluntary standard, achieving ISO 15189 compliance shows that the organization's leaders have real confidence in their people. They would never make the investment to go for ISO accreditation without the strong belief they could achieve it.

ISO 15189 is relevant to laboratories of any size in any type of practice and anywhere in the world. In a survey of pathologists at ISO 15189-accredited labs performed by the CAP, 95 percent said the program has improved quality and patient safety, while 87 percent said it improved operational efficiency and 74 percent said it made their labs more valuable to the overall organization. Anecdotally, the accreditation improves employee retention by making team members feel more respected and more empowered to make better decisions. It's also important for health care systems with growing laboratory facilities. Achieving an international standard ensures continuous quality and reliability even as labs expand operations.



Dr. Volk

The CAP offers an excellent program and resources to help CAP-accredited laboratories achieve ISO 15189 certification. Developing this program was a major investment for the CAP and it reflects its commitment to quality and excellence in patient care. More than 80 clinical laboratories have already completed it and been accredited, and I expect more will follow. Remarkably, despite the pandemic, we have seen growing interest in the ISO 15189 accreditation program.

The CAP's ISO 15189 program recognizes that each laboratory's situation is unique and provides customized support for achieving quality management standards. Laboratory medical directors or operational leaders should understand that ISO 15189 is a process that may take several years to achieve and it may not be the right fit for all laboratories right now. But should you choose to pursue this lofty goal, professional assessors will help you translate ISO 15189 criteria into practical, useful steps for your lab and staff. The CAP also provides the education and tools needed to implement program requirements, measure progress in quality management, and ensure that your culture and operation can grow into and sustain ISO 15189 accreditation.

I'd like to thank Dr. Sharma, pathologist and laboratory medical director at Henry Ford Health System and past chair of the CAP 15189 Committee, and Caroline Maurer, CAP 15189 program director, for sharing their insights about CAP's ISO 15189 efforts for this column.

Dr. Volk welcomes communication from CAP members. Write to her at president@cap.org.