

Achieving CLIA, ISO 15189 at Same Time with A2LA

► **Physicians Choice Laboratory Services is seeking ISO 15189 and CLIA from one source**

►► **CEO SUMMARY: An interesting milestone for the clinical lab industry is on the horizon. Physicians Choice Laboratory Services in South Carolina will soon become one of the first lab organizations in the United States to earn joint CLIA and ISO 15189 accreditations with the American Association of Laboratory Accreditation (A2LA). While it was undergoing ISO 15189 accreditation, the organization began to prepare for CLIA accreditation through A2LA, both for a single price.**

FOR THE FIRST TIME, A LAB IN THE UNITED STATES is working toward accreditation to CLIA and ISO 15189 during the same time frame and through the same accrediting body.

This accomplishment is happening at Physicians Choice Laboratory Services (PCLS) of Rock Hill, South Carolina. In December 2014, it was accredited to ISO 15189:2012 and soon, PCLS will receive its additional CLIA accreditation.

PCLS' CLIA accreditation will also be a milestone event for the **American Association for Laboratory Accreditation (A2LA)**. That's because it will be one of the first CLIA accreditations issued by A2LA since CMS granted deeming authority to A2LA last year. (See *TDR*, April 7, 2014.)

"PCLS is now the seventh clinical lab and the first toxicology lab in the United States to be accredited to ISO 15189:2012 by A2LA," stated Dinah Myers, PCLS Chief Compliance and Quality Officer. "Achieving the ISO 15189 accreditation is a visible symbol of the quality foundation of this lab.

"PCLS achieved the accreditation after a review of its quality management system and after demonstrating its competence in clinical laboratory testing," she said. "Accreditation to ISO 15189 through A2LA demonstrates our competence to manage and perform the activities defined by A2LA's Scope of Accreditation (A2LA Certificate 3556.01). These activities include clinical testing in chemistry, cytogenetics, and cytology."

► **ISO Brings Many Benefits**

According to Myers, multiple benefits resulted from undertaking the ISO accreditation and CLIA certification at almost the same time. "As the quality management system (QMS) of ISO 15189 took root in our lab, it improved communication across all areas and functions of our lab," she noted. "Next, we gained a sharper focus on meeting the needs and requirements of our customers, which is a fundamental goal of the ISO 15189 accreditation. Another big win for us was reduced variation in work processes which reduced variation in analytical results."

PCLS is an esoteric laboratory focusing on customized treatment information for clinicians nationwide. The lab's services improve physician awareness of patient conformance with drug therapy, identify and reduce narcotic diversion, minimize adverse drug reactions, improve women's healthcare, and facilitate personalized patient care through innovative molecular diagnostics and analytical services.

When the lab was founded in 2009, Myers joined the staff after working for more than 20 years under ISO quality standards in consumer labs, testing labs, and calibration labs. PCLS is the first clinical laboratory in her career. Recognizing that all labs produce results as an end product of running processes repeatedly, it was not difficult to transfer what she knew from other labs into the clinical laboratory operations of PCLS, she said.

► Standards Compared

"It doesn't matter what field is served by a lab," observed Myers. "What is essential is to identify the processes and the measurable parameters of quality metrics used by the lab team," she explained. "Every lab must meet certain statutory and regulatory requirements, regardless of whether the lab is in the medical industry or other industries. The ISO family of standards requires that the lab meets those compliance and regulatory standards.

"Currently PCLS is CLIA certified by the **College of American Pathologists**," continued Myers. "However, because PCLS was going to be accredited to ISO 15189:2012, it made sense to have A2LA accredit the lab to the CLIA standards as well. Although the requirements are similar, the ISO standard goes much further in terms of its requirements for a quality management system and for the document management system."

In the fall of 2012, the lab began the ISO accreditation process, which took just over one year to complete. "Adopting ISO 15189 introduced its quality management

Earning ISO 15189 while Also Certifying to CLIA

CLINICAL LABORATORIES NOW HAVE a choice when seeking to be accredited to CLIA that includes the ability to simultaneously accredit to ISO 15189:2012.

Last year, the federal Centers for Medicare & Medicaid Services (CMS) approved A2LA to accredit laboratories to the CLIA waived testing requirements. A2LA adopted the guidelines published by the CDC (CS242576-A) related to waived testing. Although A2LA does not accredit laboratories that perform waived testing exclusively, those laboratories that perform non-waived testing in addition to waived testing are eligible for A2LA accreditation, A2LA said.

The decision by CMS meant that A2LA is the only accreditation body in the United States with the following dual recognitions in clinical laboratory testing. It can accredit laboratories under the International Laboratory Accreditation Cooperation (ILAC) accreditation to ISO 15189:2012, and it can accredit labs to the requirements of the Clinical Laboratory Improvement Amendments.

Clinical labs can apply for accreditation to ISO 15189:2012 or CLIA or both. For labs seeking to be accredited to both standards, A2LA offers a service called Platinum Choice, and it has a single price for the dual accreditation and certification to the two standards.

system (QMS) into our lab," she noted. "Also, unlike other accreditations for clinical labs in the United States, only A2LA ISO 15189:2012 is recognized worldwide. PCLS serves physician clients nationwide, but now we can compete internationally because most companies in Europe require ISO accreditation to do business."

PCLS benefited from its adoption of the QMS of ISO 15189 because the QMS allows lab directors and managers to now gain a deeper understanding of their lab's strengths and weaknesses. "For example, the 15189 accreditation process usually uncov-

ers two common weaknesses: communication and documentation,” noted Myers.

“Throughout the process of becoming accredited to ISO 15189:2012, it became clear that—even though the communication throughout the PCLS laboratory was excellent—we still had room for improvement,” she said. “To accomplish this, our lab started at the lowest level of the organization and went right to the top of the organization. At each level, it is important to explain that information must flow both ways. Each individual must understand his or her role in the quality management system and the importance of fully meeting the needs of our lab’s customers.

► Meeting Customers’ Needs

“Understanding your customers’ requirements is another lesson learned from the accreditation process,” she continued. “One key ISO standard specifies that your lab must meet the requirements of its customers. If your lab can’t meet those requirements, then the QMS standard requires you to notify your customers about that inability to meet their needs.

“Most labs have set processes,” she stated. “But if those processes don’t help the lab to meet customers’ requirements, then those processes are inadequate to the job. Many labs, when asked for something by a customer, might typically answer with ‘This is the way we do it, and if your request doesn’t fit into our processes, then we can’t help you.’

“Our lab team learned from this accreditation process that if our processes don’t allow us to meet our customers’ requirements then it was time to adjust the processes until they support us in meeting our customers’ requirements,” she said.

“Another lesson we learned was that we have three shifts running every day and every person who performs the same job should perform that job in the same manner,” she stated. “We brought the people together who work on alternate shifts so that we could develop best practices and spread them across all shifts.

Factors in Lab’s Decision to Accredite to ISO 15189

BASED ON HER EXPERIENCE with testing laboratories in other industries, Dina Myers said that one factor influenced the decision by PCLS to opt for A2LA as its ISO 15189 accrediting body.

“When our team studied the ISO offerings of CAP and A2LA, it believed that there is a significant difference between what A2LA offers and what CAP offers,” explained Myers, who is Chief Compliance and Quality Officer at Physicians Choice Laboratory Services. “CAP certifies to its own version of 15189, called CAP 15189.

“By contrast, A2LA accredits to ISO 15189:2012,” she continued. “Moreover, A2LA is a signatory of the **International Laboratory Accreditation Cooperation** (ILAC) and A2LA is itself accredited to the requirements of ISO/IEC 17011:2004 Conformity assessment—General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies. This means that A2LA itself is itself audited and thus must meet this international standard for accrediting bodies.

“There was another factor that influenced this decision,” said Myers. “The PCLS team studied CAP’s version of 15189 and found that it does not require clients to perform a determination of measurement uncertainty. That is a very important element of ISO 15189:2012, whether you’re testing in a calibration lab or in a clinical lab. ISO 15189 states that clinical labs must perform a determination of measurement uncertainty for every analyte.”

“In so doing, we eliminated variation in processes, and that allowed us to eliminate variation in our results,” added Myers. “This is essential because consistency of work performed is one of the strong points of having a quality management system.” **TDR**

—Joseph Burns

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