MAKING THE COMMITMENT TO
ISO/IEC 17025…WITH A LITTLE HELP

Committing to the goal of achieving ISO/IEC 17025 accreditation can be daunting. Understanding the nuances of the standard, the many ways your laboratory can meet the standard’s requirements, and the difference between “shall” and “should,” are keys to success, but it’s always nice to have a helping hand. For the past seven years, APHL has provided assistance to those laboratories not involved in US Food and Drug Administration (FDA) ISO cooperative agreements but who were interested in becoming accredited. APHL Accreditation Process Consultant Yvonne Salfinger has assisted 16 laboratories working toward ISO/IEC 17025 accreditation without any dedicated federal funding; of those, seven have become accredited. As the following laboratorians will attest, having a helping hand on your journey can be crucial to achieving accreditation.

SOUTH DAKOTA STATE UNIVERSITY ANIMAL DISEASE RESEARCH & DIAGNOSTIC LABORATORY

South Dakota State University (SDSU) Animal Disease Research & Diagnostic Laboratory was interested in becoming accredited in part due to the laboratory’s participation in several testing networks with the FDA and the US Department of Agriculture (USDA).

“This accreditation is a demonstration that our laboratory has a robust quality system, performs accurate testing, and has proficient staff,” said Laura Ruesch, Food Safety Section Leader at SDSU. “Also along with the compliance aspect, our Food Safety [section] has always been customer centric and wants to ensure that the results we provide to our clients are reliable and consistent. Having ISO/IEC 17025 accreditation also helps us exceed our customer’s expectations.”

Ruesch recalled Salfinger’s “invaluable” assistance in their accreditation journey, “reviewing documents, helping interpret standard requirements, giving guidance about writing an RFP for accreditation services, and providing examples of great policies/procedures from other labs. She even traveled to South Dakota to perform an informal audit to find key problems before hiring our auditing body.”

HAWAII STATE LABORATORIES DIVISION

Hawaii State Laboratories Division (HSLD) is committed to maintaining a culture of quality and as such, the management and staff accept the responsibility of maintaining established performance standard principles and practices throughout the laboratory. Rebecca Sciulli, former quality manager at HSLD, recalled that after HSLD become a Food Emergency Response Network (FERN)-funded laboratory in 2005 and following the passing of the Food Safety Modernization Act (FSMA), “it became apparent that we needed to work towards ISO/IEC 17025 accreditation, with the goal of not only enhancing HSLD’s quality systems but to be more competitive in securing future FDA/FERN funding.”

Sciulli’s goal was for HSLD to become ISO/IEC 17025 accredited before she retired. She was able to meet her goal with help from Salfinger.

“HLSLD has been a provisional member of the National Animal Health Laboratory Network (NAHLN) for many years and as such, our laboratory has demonstrated that our Quality Management System has met the requirements of ISO standards. In order for us to achieve ISO/IEC 17025 accreditation, we needed someone to perform a gap analysis and help us assess where we are as an organization and where we need to be to become an ISO/IEC 17025 accredited lab. Yvonne started the process by reviewing our Quality Manual and SOPs, did a walk-through of our laboratory and helped us every step of the way. It took us two years to get through the gap assessment process—including modifying,
updating and creating some SOPs—but it paid off in the end when HSLD received its ISO/IEC 17025 accreditation certificate in January 2018. And in January 2019, HLSD also became an ISO/IEC 17025-accredited laboratory for the tests performed as a NAHLN laboratory.”

ADVICE TO LABORATORIES INTERESTED IN ISO/IEC 17025 ACCREDITATION

While many laboratories recognize the value of accreditation, it can be an intimidating journey. Washington State Department of Health needed ISO/IEC 17025 accreditation in order to continue receiving FDA grants. However, it was a lot of work to get accredited. Ailyn Perez-Osorio, manager of the WA Environmental Sciences Laboratory, offered some advice to labs interested in accreditation.

“Be prepared, as this is an expensive endeavor, and the accreditation process adds costs that are not often planned for. Also, the amount of added work due to implementing new standards can be frustrating to employees and customers...if you are already stretched, be sure to allocate resources before you dive in.”

Sculi recommended that labs have the buy in from management, middle managers and staff.

“You need them to ensure that what needs to be implemented is done and maintained. Be patient, have a gap analysis of your QMS done, ask for expert advice and reach out to other Quality Managers outside your jurisdiction, many of whom are generous with their time and will even share their work products, if you ask.”

Ruesch echoed these sentiments and added that starting with a limited scope was a good idea.

“[Starting small] allowed us to focus more intensely on the Quality System behind the technical protocols. Now that the larger system is in place, it is easy to add additional technical methods. Also, if you can afford it, have electronic quality management software in place. It makes your job of doing quality work with all the record trail and data traceability way easier.”

APHL RESOURCES

APHL continues to offer many resources for laboratories who are interested in achieving or expanding their scope of ISO/IEC 17025 accreditation.

- Resource Repository: APHL hosts two restricted-access document repositories which house documents that align with both the 2005 and 2017 versions of the ISO/IEC 17025 standard that can be downloaded and edited to meet individual laboratory needs. These documents include standard operating procedures, templates, work plans, sample worksheets, and more. To request access to these repositories, please email foodsafety@aphl.org.

- ISO/IEC 17025 Training Resources: APHL has compiled various training resources for laboratorians to utilize, including previously-recorded webinars, recorded meeting presentations on ISO/IEC 17025 accreditation, and a curated list of available ISO/IEC 17025 related trainings, which is updated every six months.

- Quality Management Training Series: APHL developed a Quality Management Training Series, which provides quality management training tools for new laboratory hires and refresher training for veteran staff. The materials consist of customizable, online modules and include PowerPoints, instructional documents to support content, and quizzes and answer keys on the target topic. APHL is currently updating these modules to align with the 2017 standard.