A History of Laboratory Accreditation in the United States

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This article is a compilation of the reminiscences of two of the pioneers in the industry: Joseph O'Neil, who was the Executive Director of the American Council of Independent Laboratories (ACIL), and John Locke, the first President of the American Association for Laboratory Accreditation (A2LA) and one of the first employees of the National Institute of Standards and Technology's (NIST) National Voluntary Laboratory Accreditation Program (NVLAP). They start back in the 1960's when the United States' laboratory industry became interested in the subject. Mr. O'Neil has worked with the leaders in the laboratory industry who were instrumental in establishing the laboratory accreditation programs at both NIST and A2LA. Mr. Locke has played a very active and high-level role in laboratory accreditation from its very beginning.

Introduction

Laboratory Accreditation is defined as "Formal recognition that a laboratory is competent to carry out specific tests or calibrations or types of tests or calibrations," but what does it really mean in terms of improved products or services? Accreditation indicates to the user, that at a point in time, the laboratory was able to demonstrate to a competent assessor that they are competent to perform specified tests or calibrations or types of tests or calibrations. Laboratories that have demonstrated their competence may use the accreditation body's logo to attest to their competence. Competence is the main ingredient when granting a laboratory accreditation. This is the reason that accreditation is so important to industry in terms of improved products and services and why accreditation got started in the first place.

The Laboratory's Role

According to Joseph O'Neil, "The lab community was the most influential body to advocate the establishment of a broad-based laboratory accreditation program, and appreciated the value it has for the laboratories and the product manufacturers." Mr. O'Neil recalls two individuals, George Nelson and Roger Amorosi, as being the catalysts for the movement toward establishment of laboratory accreditation in the USA. However, he says many others contributed energetically to the efforts of this activity.

In the 1960's George Nelson, President of Law Engineering was the President of the Association for Testing and Materials (ASTM) & ACIL. He established the ASTM E36 committee for laboratory accreditation while serving on the board of ASTM. The E36 committee developed ASTM E 548 - Requirements for Laboratory Accreditation, which is the root document for ISO/IEC Guide 25-General Requirements for the Competence of Laboratories. ISO/IEC Guide 25 has served as the basis for laboratory accreditation worldwide.

In the 1970's Roger Amorosi, whom I remember fondly from working for him at Detroit Testing Laboratory, was a Vice-President with ETL. Mr. Amorosi was, in the mid-70's, the head of an ACIL working group that dealt with laboratory accreditation. He was instrumental in putting together proposals on the establishment of a broad-based accreditation body by the National Bureau of Standards (NBS), which is now the National Institute of Standards and Technology (NIST).

When Mr. O'Neil was asked why he believed the laboratory industry was interested in accreditation, he saw these as the common themes:

- Other Product Certification — Laboratories found it difficult to compete with a long-standing and most recognized product certifier, Underwriters Laboratories (UL). Accreditation was viewed as a way to raise the prestige and establish credibility for other laboratories.
- The industry felt that accreditation would distinguish the laboratories that were competent from others whose quality was not up to standard.
- It would eliminate multiple second-party audits and give new clients confidence without having to look at the laboratory directly.
- It would give them independent, third-party credentials to assure that they had demonstrated competence.

John Locke recalls the situation as an in insider with the accreditation bodies:

Laboratory Accreditation has a long history of use in the United States for specific markets. Charles Hyer claims that

the earliest system started in the 1920's by the Association of American Railroads. One of the early systems still going strong is for milk testing laboratories by the Food and Drug Administration started in the early 1940's. There were various other formal accreditation systems started in the 1960s and 1970s, but none were large or considered significant.

The thing that really propelled the development of laboratory accreditation was the assessment of individual laboratories by laboratory customers. Many laboratories liked the chance to meet one-on-one with their customers and saw this as marketing. Many would promote the fact that they were "accredited" by some large contractor. Typically, these were large defense contractors. Some contractors would recognize another's assessment of laboratories, but most would not. This practice was also important to many large industrial enterprises, such as those in the auto industry. The result of these second party laboratory assessments was that the laboratories spent man-years of time with assessors, most of whom were looking at the same things. It became expensive, particularly for the large laboratories and they sought relief.

The Roles of NVLAP and A2LA

ASTM was urged to do something about this problem and it convened an industry wide symposium in 1969. From this came ASTM Committee E36 with a mandate to create standards for the assessment of laboratories. In the early 1970's the independent laboratory community began to lobby the Department of Commerce to provide a system in which they could be assessed one time and be recognized so that others would not have to assess them. A number of meetings were held at NBS in the early 1970's, but no specific proposal came about until Betsy Anchor Johnson was named Assistant Secretary of Commerce for Science and Technology. She made this a goal of her administration.

In 1975 a very complex proposal was developed at NBS and published for comment. The independent laboratory community, which had strongly supported the effort, was concerned that the proposal provided little input from the testing community. Changes were made, and in 1976 the National Voluntary Laboratory Accreditation Program was announced, with administration at the Undersecretary's Office and technical support at NBS. This proposal did provide much more involvement of industry, with advisory committees structured to assist in the development programs in each area of development.

But, in order to resolve issues identified by others who had commented on the proposal, NVLAP required that laboratory accreditation programs (LAPs) would be developed only for testing and only on the basis of a request that identified specific tests in a product area that were to be included in the assessment. A need for such a program also had to be shown. The first two LAPs, for example, were for insulation and freshly mixed concrete.

The independent laboratory community found this program unworkable, since they worked for many industries and did a wide variety of testing. To be accredited by NVLAP, they would have to participate in each LAP for the areas in which they were working, an expensive proposition. If there were no LAPs in the area of their testing, NVLAP provided no opportunity for recognition. In 1978 they opted to develop their own laboratory accreditation system, known as the American Association for Laboratory Accreditation (AALA, later changed to A2LA).

A2LA was structured on the Australian model, where recognition was granted in broad fields of testing for those test methods specified on the laboratory's application. This was much more like the evolving laboratory accreditation systems being implemented around the world. NVLAP leads the way in actual accreditations issued, but A2LA gradually caught up and is today accrediting over twice as many laboratories as NVLAP.

Establishment of the Laboratory Accreditation Bureau (L-A-B)

The author recalls the problems of implementing the third edition of QS9000 — it became clear to the automotive industry that the two existing laboratory accreditation bodies in the United States were not going to be able to handle the large number of laboratories seeking accreditation. They sought a solution to their dilemma. The solution has spawned a new accreditation body, Laboratory Accreditation Bureau (L-A-B). L-A-B was established and provides accreditation in broad fields of testing and calibration. While the initial focus was on aiding the automotive community and other laboratory interests in providing compliance with QS9000, L-A-B provides accreditation in other areas where they maintain technical competence. The requirement to compete in a field populated with long established, reputable organizations was going to be challenging.

The establishment of a new, reputable accreditation body was the primary goal of the founders of L-A-B. The need to establish credibility was of the utmost importance. The founders went about this in several ways. The first was to determine who would use the accreditations once they were granted, next was establishing a team that could assure the credibility of the process, and finally there was the challenge of international recognition and mutual recognition by other accreditation bodies.

The automotive industry is one of the largest users of accredited laboratory data, so this area was critical to the establishment of a viable accreditation body. The automotive industry is an area familiar to all the people

involved in establishing L-A-B. Contacting the US automotive base and finding out what it would take to get recognized by them, as a viable provider of laboratory accreditation, met the first challenge. In the end the true authority of an accreditation body is granted by those organizations willing to accept the data of laboratories accredited by it. This challenge was frankly the most critical to the success of L-A-B, and this challenge could only be met by having credible staff.

The building of L-A-B credibility was with the expertise of people who had been involved for many years with hands-on laboratory work and management of such businesses. They have also have been active in the accreditation world for many years, and are familiar with the challenges facing the accreditation community. The Technical Manager was one of the team members drafting the new ISO/IEC Standard 17025, is currently on the Working Group 18 combining the accreditation body standards, and has been active in ILAC for many years. The Program Manager for Calibration was one of the founders of the National Association for Proficiency Testing (NAPT), a veteran lead assessor, trainer and calibration laboratory manager. The Managing Director has thirty-five years experience in conformity assessment culminating with a senior management position with the U.S. leader in product certification. This team has put together a cadre of assessors that collectively provide the expertise to assess all types of laboratories that are considered under the scope of L-A-B. This team of experts has set the stage to meet the final challenge of mutual recognition.

International recognition and mutual recognition by other accreditation bodies has been the most time-consuming challenge. The process is multileveled. The first step was to become active in many organizations that provide mutual recognition. L-A-B has a staff person on the Operations Council and Recognition Committee for NACLA. They have also just been accepted as full members of APLAC. The initial assessment has been performed by NACLA, and the full assessment is being scheduled. The next step will be to become recognized by APLAC, and it is hoped that the NACLA process may provide some groundwork for the APLAC process. All of the pieces for mutual recognition are headed in the correct direction. However, the fact still remains that the largest client base for L-A-B accreditation, the automotive industry, does, and always has, recognized the data from L-A-B accredited laboratories. As part of the recognition process, L-A-B has developed a program in compliance with international standards.

Operating in strict accord with Guide 58, the guidance document for operation of laboratory accreditation bodies, accrediting laboratories to ISO/IEC Guide 25 or 17025, and with expertise all aspects of laboratory accreditation, L-A-B has become one of the leaders in laboratory accreditation activities.

International Recognition through APLAC

According to John Locke, the Asia Pacific Laboratory Accreditation Conference (APLAC) came about as an attempt to duplicate, in the Far East, the European Laboratory Accreditation Conference (ELAC) that had developed in the late 1980s. Both had their genesis in the meetings of the International Laboratory Accreditation Conference (ILAC), first held in 1977, that was designed to harmonize the standards used to assess laboratories and to conduct assessment activities. ILAC had been successful in convincing the International Standards Organization (ISO) to publish laboratory accreditation standards as early as 1982 in the form of ISO Guide 25, so there was a harmonized international procedure available to assess laboratories. But there was no organization to implement a procedure by which laboratory accreditation systems could recognize each other's assessments.

ELAC (now known as EA) was the first to begin the formal assessment of laboratory accreditation systems interested in recognizing the competence of each other's accredited laboratories. A Mutual Recognition Agreement was reached among five European bodies in the late 1980s. ELAC had the advantage of the existence of a Mutual Recognition Arrangement (MRA) among calibration laboratories that had been assessed using a common procedure.

Laboratories in the Asia Pacific region met in the early 1990s to form the Asia Pacific Laboratory Accreditation Cooperation (APLAC) to try to establish a similar process for recognizing each other's accredited laboratories. APLAC moved rapidly to arrive at an MRA that would be equivalent to the EA MRA. Based on assessments performed by EA of APLAC members (EA was assessing APLAC systems for inclusion into the EA MRA as associate members) and by various members who had developed bilateral agreements.

APLAC did its first full assessment using A2LA as the starting point. Five systems were included in the APLAC MRA initially, based on the vote of members of the APLAC MRA Committee chaired by Peter Unger. Later, all members of APLAC were invited to name a representative to the MRA Committee, regardless of whether they had a system ready for evaluation; a procedure previously followed by EA.

The MRA does not guarantee acceptance of test data from an accredited laboratory in one country by all users in another country. It does, however, help to assure the users in one country that laboratories accredited in another country have been assessed to the same rigorous standards. These MRA's are based on assessment of the systems to an ISO standard and an overview of the assessment of a number of laboratories by these systems. There is also proficiency testing results across systems that help to increase confidence in the systems even more. What better

way for a user to have confidence in test results from a laboratory in another country than to rely on these MRA's? The user would otherwise have to evaluate, in some way, laboratories it uses around the world; a costly and tedious enterprise and not necessarily with consistent results.

Current Status of International Laboratory Accreditation

The idea of determining the competence of testing laboratories, wherever they are located, to support industry and government is clearly here to stay. Users cannot go all over the world to assess the laboratories they use to verify that requirements are met. Laboratories cannot continue to have assessors from many different organizations visiting their facilities, disrupting the testing, using staff time, and possibly giving away trade secrets.

In the United States, the private sector system can compete effectively with a government system and can receive international recognition from both private and government systems throughout the world. The mutual recognition of each others accredited laboratories is absolutely essential as well. The alternative is to have laboratories revert back to where they have to be assessed by many organizations because the users recognize only a small selection of accrediting organizations. We would be back where we started, with perhaps fewer assessors.

The Europeans chose to have one laboratory accreditation organization in each country. Mutual recognition was easy, since each system declined to accredit laboratories in another country, except in unusual circumstances. In APLAC, there arose the question as to whether laboratory accreditation systems in competition would be willing to recognize each other's accredited laboratories. This arose because both A2LA and NVLAP sought to become members of the APLAC Arrangement. Management of both of these systems agreed to assessments by each other and the Arrangement included both NVLAP and A2LA. ICBO (International Building Code Officials) have since become a third partner from the United States. Not only can it be done, it must be done if we are to use laboratory accreditation effectively.

In the United States, the National Cooperation for Laboratory Accreditation (NACLA) was formed to provide a regional organization similar to EA and APLAC to evaluate laboratory accreditation systems and create an MRA recognizing each other's accreditations. Joseph O'Neil recalls the laboratory's role in the establishment of NACLA: "In the 70's the laboratory's pushed for accreditation, and got it." This was a case of be careful what you wish for, you may get it. In the '90's the laboratories were pushing for some way to make sense of the accreditation situation in the US, which often required them to obtain multiple and duplicative accreditations.

ACIL and NIST along with the American National Standards Institute (ANSI), were pushing for a system that would minimize this duplication. Some proposed accreditation of the accreditation bodies, but many professionals did not like this idea. The involved organizations decided to put together a system of organized accreditation bodies. George Willingmeyer (ANSI), Joseph O'Neil, and John Locke got together with ANSI to encourage NIST to meet with laboratories to work on a solution. The Laboratory Accreditation Working Group LAWG was formed, and through their meetings, NACLA was established. It was at a later meeting of NACLA that they decided to try to establish a regional cooperation. A NACLA Arrangement is currently in existence that includes the three accreditation systems that were in APLAC.

NACLA has other accreditation bodies in the process of being evaluated for entrance into the Arrangement, and this includes L-A-B. Strong support is developing for an Inter-American recognition body, IAAC, to establish cooperation with EA and APLAC.

ILAC has not sat idly by while these regional bodies created MRA's. At its last meeting in November 2000, an MRA among ILAC members was signed with some 34 participants. ILAC used the recognitions of the regional bodies as the basis for mutual recognition, but reserved the right to include in the MRA any system that was not represented in the regional bodies, but could demonstrate that its system was equivalent to those worldwide. Hence, the Brazilian system and the South African system were included in the ILAC MRA.

The groundwork has been laid. Laboratory accreditation systems around the world are prepared to show that they meet the requirements of the international standard for accreditation bodies, that they fully implement ISO 17025 in assessing their laboratories, and that they accurately reflect the scope of accreditation for laboratories in their system. Thus, users can be confident in the results coming from accredited laboratories that are recognized through these MRA procedures.

What is lacking is acceptance by the users. Many users simply are not familiar enough with the rigor of the process to assure themselves that their interests can be admirably served by an MRA. To overcome this, many of the accreditation systems are trying to use assessors from the laboratory user community. This has the advantage of providing competent assessment skill while providing the users with hands-on experience of the accreditation systems. I look for this trend to continue and for greater acceptance of laboratories recognized by the ILAC MRA.

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