By Teresa C. Barnett, A2LA Director of Quality

ISO and the International Organization for Standardization

Q. What does “ISO” stand for?

A. ISO is not an acronym; it is a word chosen by the International Organization for Standardization. “ISO” is taken from the Greek word “isos,” meaning equal. The three official languages of ISO are English, French and Russian; thus the organization’s name would have different acronyms in different languages. For this reason, it adopted the short name ISO (a registered trademark of the organization) which is the same in every country.

Q. What is the International Organization for Standardization?

A. The organization today known as ISO began in 1926 as the International Federation of the National Standardizing Associations (ISA) and became known as the International Organization for Standardization in 1947. The International Organization for Standardization is a worldwide federation of national standards bodies from more than 160 countries, one from each country. The national standards bodies make up the ISO membership and they represent ISO within their country.

The organization’s mission is to promote the development of standardization to facilitate the international exchange of goods and services, and to develop cooperation in the spheres of intellectual, scientific, technological, and economic activity. Its work results in international agreements, which are published as international standards.

A list of ISO membership bodies may be found at [http://www.iso.org/iso/home/about/iso_members.htm](http://www.iso.org/iso/home/about/iso_members.htm)

Q. What are the member categories to ISO and what is A2LA’s status?

A. There are three membership categories for national standards bodies (see description below).

- Full members (or member bodies) influence ISO standards development and strategy by participating and voting in ISO technical and policy meetings. Full members sell and adopt ISO International Standards nationally.

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- Correspondent members observe the development of ISO standards and strategy by attending ISO technical and policy meetings as observers. Correspondent members can sell and adopt ISO International Standards nationally.

- Subscriber members keep up to date on ISO’s work but cannot participate in it. They do not sell or adopt ISO International Standards nationally.

The American National Standards Institute (ANSI) is the U.S. member body to ISO. ANSI coordinates the development of voluntary consensus standards in the United States and represents the needs and views of U.S. stakeholders in standardization forums around the globe. ANSI’s membership is comprised of a broad range of businesses and industrial organizations, standards setting and conformity assessment bodies, trade associations, labor unions, professional societies, consumer groups, academia and government organizations for the purpose of enhancing global business competitiveness and improving the quality of life for the world’s citizens. A2LA has been an active member on several ANSI committees for decades and, through this involvement, has been instrumental in the development of ISO standards, including ISO 15189.

Q. What is a “standard”?
A. A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and services are fit for their purpose. ISO International Standards ensure that products and services are safe, reliable and of good quality. They are strategic tools that reduce costs by minimizing waste and errors and increasing productivity. They help companies to access new markets and facilitate free and fair global trade.

Government and industries around the world have been using international standards for more than half a century to facilitate trade, establish a technical base for regulation and safeguard consumers.

Q. Are ISO and ILAC synonymous or related in any way?
A. ISO and ILAC are two separate entities (see below for more information about ILAC). ISO focuses on the development of standards worldwide and ILAC focuses on the deployment of those standards worldwide to promote trade and acceptance amongst member organizations. ISO and ILAC have a Memorandum of Understanding (MOU) that addresses matters of conformity assessment policy, standards development and practice as they relate to accreditation. The MOU consolidates practices and provides an ongoing mechanism for technical cooperation between ISO and international accreditors (such as A2LA) in order to contribute to the development and subsequent implementation of ISO standards.

ISO 15189

Q. What is ISO 15189 and what is its basis?
A. ISO 15189:2012 is a standard that provides the specific requirements for quality and competence that are particular to medical laboratories. The standard promotes global harmonization of medical practices. It protects the health and safety of patients and healthcare providers, supports efficient exchange of information and protection of data and improves the overall quality of care. ISO 15189 is used by laboratory customers, regulatory authorities and accreditation bodies to ensure competence.

In 2012, ISO published a revised and updated version of the standard, ISO 15189:2012 (Medical Laboratories – Requirements for Quality and Competence), which contains quality management system requirements as well as technical requirements. It also contains an increased focus on technical competence and now requires mandatory assessment against measurement uncertainty and traceability.

Q. What is a “quality management system”?
A. A quality management system (QMS), as required by ISO 15189:2012, is a compilation of organizational documents that establishes the policies and procedures needed to direct and control an organization with regard to quality. It relates to general management activities, the provision and management of resources, the pre-examination, examination and post-examination processes and evaluation and continual improvement. A QMS captures the requirements of an organization and structurally provides a roadmap that explains who, what, when, where and how sustainable and repeatable outcomes will be achieved.

Q. What makes up a quality management system?
A. A quality management system consists of policies, procedures, SOPs and records, all of which provide proof of goals, assign responsibility, describe how those responsibilities are be performed and provide evidence of past accounts or occurrences of compliance.

Q. How widespread is ISO 15189? Is this accreditation program widely accepted?
A. ISO 15189 is an internationally-recognized standard, with over 40 ILAC-recognized accreditation bodies offering ISO 15189 accreditation programs. In some countries it is the standard by which laboratories are reimbursed. Although ISO 15189 is not mandatory in the U.S., an increasing number of medical labs have recognized the benefit of being accredited by an internationally-recognized accreditation body (such as A2LA) along with their CLIA accreditation.

Q. How is ISO 15189 accreditation different from ISO 9001:2008 certification?
A. ISO 9001 is a registration of a quality management system and serves as the basis for many of the other ISO standards because of its intentional generality. ISO 15189 incorporates the essential elements of ISO 9001 and adds technical competency factors relevant to medical laboratories. Its primary application is to improve the management and technical structure of medical laboratories. ISO 15189 accreditation (as opposed to ISO 9001 registration) includes both an assessment of the QMS and an evaluation of the technical competency of the

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A2LA President/CEO
Peter Unger awarded ANSI Gerald H. Ritterbusch Conformity Assessment Medal

By Kelsey Roberts, A2LA Marketing Coordinator

At the ANSI World Standards Week award ceremony, A2LA President/CEO, Peter Unger, was awarded the Gerald H. Ritterbusch Conformity Assessment Medal which honors distinguished service in promoting the understanding and application of conformity assessment methods as a means of providing confidence in standards compliance for the marketplace. The award is named after Gerald H. Ritterbusch, retired director of standards and regulations at Caterpillar.

Mr. Unger was cited for playing a key role in building a strong set of principles and practices in the U.S. conformity assessment community. Through his work at A2LA, in a number of ANSI committees, and with other major laboratory accreditation organizations, he has made a tremendous impact on the efficacy of testing and calibration laboratories in the United States and abroad.

Among Mr. Unger’s most important contributions are his long-term efforts in the development and implementation of the ISO/IEC standards for accreditation. He has significantly enhanced the ability of laboratories to facilitate the volume and speed of trade at the national, regional and international levels.

We at A2LA extend sincere congratulations to our deserving leader! *

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Q. What sorts of requirements are contained within ISO 15189?
A. The standard is divided into five sections:
   - Scope
   - Normative references
   - Terms and conditions
   - Management requirements
   - Technical requirements

Sections 4 and 5 of the document make up the bulk of the standard and are the sections used to assess medical laboratories. They contain all of the requirements for a medical laboratory’s quality management system, as well as the technical requirements used as the basis for confirming a medical laboratory’s competence to perform specific medical tests.

ILAC and Its Significance
Q. What is ILAC?
A. ILAC (the International Laboratory Accreditation Cooperation) is an international cooperation of accreditation bodies (or accreditors) formed more than 30 years ago to help remove technical barriers to trade. When first started in 1977, the aim was to develop international cooperation for facilitating trade by promoting the acceptance of accredited test and calibration results. In 1996, ILAC became a formal cooperation with a charter to establish a network of mutual recognition agreements (MRAs) among accreditors that would fulfill this aim. The ILAC Arrangement (first signed in November 2000) provides significant technical unpinning to international trade. The key to the Arrangement is the global network of accredited laboratories and inspection bodies that are assessed and recognized as being competent by ILAC Arrangement signatory accreditation bodies. The Arrangement’s accreditation body signatories have, in turn, been rigorously peer-reviewed and shown to meet ILAC’s criteria for competence.

Q. Is an accreditor’s participation within ILAC mandatory?
A. Participation within ILAC is not mandatory for all accreditors. Indeed, not every accreditor would be found to meet the stringent requirements for signatory status within the ILAC MRA and so they make the “business decision” not to seek this important recognition.

Q. What is an ILAC “peer evaluation” and what are the benefits of undergoing one?
A. A peer evaluation is the means by which an accreditation body (or accreditor) is found competent and acceptable for consideration as an ILAC MRA signatory. All ILAC MRA signatories have been rigorously evaluated by their fellow signatories to ensure their compliance with ISO/IEC 17011 (“General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies”) and to ensure that they are implementing ISO standards within the accreditation programs they offer in a manner that is consistent world-wide. Ask yourself: “Who has accredited my accreditor?” Signatory status within an international MRA, such as ILAC, is the only answer you should accept. Otherwise, what assurance do you have that your accreditor is competently operating a program for assessment of and accreditation to ISO standards?

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The A2LA ISO 15189 Medical Program

Q. Who is A2LA?
A. A2LA is the largest, multi-discipline accreditation body in the U.S., having accredited over 3500 labs to various ISO standards over its 35-year history. A2LA is also a non-profit, membership organization based in Frederick, Maryland and its accreditations to ISO standards are recognized and accepted not only domestically within the U.S., but also world-wide.

Q. Why did A2LA launch a medical program?
A. A2LA launched a medical program in an effort to continue fulfilling its vision of “being the premier provider of accreditations accepted everywhere and by everyone”.

Q. Is A2LA an ILAC Arrangement Signatory? What is the significance of this?
A. Yes, A2LA was one of the original 28 signatories to the ILAC MRA in November 2000 in Washington D.C. Our Scope of Recognition within ILAC includes the accreditation of medical testing laboratories to ISO 15189. This means that your A2LA ISO 15189 accreditation is accepted by our partners in over 70 countries around the world as being equivalent to the accreditations issued within their own countries. ISO 15189 accreditation by an organization that is not an ILAC MRA signatory can make no such statements and there is no basis for its recognition or acceptance in other countries, or even within the United States, by other accreditors.

Q. What is the difference between A2LA and other accreditors that offer an ISO 15189 program?
A. Our International Recognition:
A2LA is the largest, multi-discipline accreditor in the United States. We are a full signatory to the ILAC Mutual Recognition Arrangement (MRA), which is crucial for several different reasons:

As an ILAC MRA signatory, A2LA undergoes periodic and rigorous peer evaluations by fellow MRA signatories to ensure that it remains in compliance with ISO/IEC 17011, “General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies”. This is the ISO standard that sets out the rules and requirements for the operation of an accreditor. Without a system of peer evaluation and mutual recognition, there is no guarantee that an accreditor is operating to the highest possible standard and there is no guarantee that an accreditor is assessing and accrediting laboratories in a competent manner.

Included in A2LA’s Scope of Recognition through ILAC is the accreditation of medical laboratories to ISO 15189. This provides an independent attestation of A2LA’s competence to offer these accreditations and A2LA is the only accreditation body in the U.S. that is internationally-recognized for ISO 15189 accreditation.

A2LA’s ILAC recognition for the accreditation of medical testing laboratories to ISO 15189 means that your laboratory’s ISO 15189 accreditation through A2LA will be accepted internationally, breaking down restrictive barriers to trade and offering greater opportunities than accreditation through an organization that is not recognized beyond its own customer base.

Our Experience and Access to Expertise:
A2LA has gained tremendous experience in accrediting laboratories to ISO standards over the past 35 years. A2LA launched its ISO 15189 medical accreditation program in November 2000. We have been instrumental in the revision of the standard and we currently accredit against the 2012 version. We are not new to this business and we are certainly not new to the use of ISO standards. ISO standards can be challenging to interpret and implement and so you should partner with an accreditor that knows them and has been working with them for 35 years. Our experience also spans all possible levels of expertise needed by a full service clinical laboratory, not just a single area such as pathology.

An A2LA medical assessment is no “coffee cup audit”. Only so much can be expected of a volunteer assessor corps because they are, after all, volunteers. A2LA’s assessors, on the other hand, are paid, contracted clinical experts and they are required to undergo intensive training (including a week-long orientation course and written exam) and periodic oversight to ensure they are conducting our medical assessments in accordance with A2LA’s procedures and strict expectations for thoroughness and professionalism. Once A2LA accreditation is achieved, you and your customers can be assured that you have demonstrated competence at the highest level, as confirmed by one of the recognized world leaders in accreditation.

A2LA has an established Medical Testing Advisory Committee (MedTAC), which is active in the development of accreditation and assessment guidelines for medical testing laboratories in accordance with ISO 15189. The MedTAC is composed of experts in the medical field and also affords your laboratory a chance to be heard and to be instrumental in the furtherance of the A2LA medical laboratory accreditation program.

Our Services:
Because we are a multi-discipline accreditor, A2LA can serve as a “one stop shop” for all of an organization’s accreditation needs. We understand and accommodate the fact that many organizations do not offer just one type of testing or one type of service. A2LA can accredit for any type of testing in addition to services offered by proficiency testing providers, reference material producers, product certifiers and more. All of this can be done by one accreditor, A2LA, during one on-site visit, saving you time and money.

Do not mistake our multi-discipline nature as being a “watered down” approach to determining competence in each area for which we offer accreditation. Each of our accreditation programs is given the same attention to detail, is held to the same expectations for thoroughness and top-level expertise, and is operated with the same customer service which sets us apart from our competitors.

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Q. I have heard that A2LA and ILAC are “product-focused”, meaning that their emphasis is on and their only expertise is in the accreditation of product testing laboratories. Is this true?
A. No, this is not true. The ILAC MRA includes and A2LA accredits all types of testing laboratories, not just product testing laboratories. This includes, for example, environmental testing, biological testing, forensic examination, pharmaceutical testing and medical testing. A2LA has established accreditation programs in each of these areas, all of which are included in our Scope of Recognition under the ILAC MRA.

Q. Does the ILAC peer evaluation of A2LA include an examination of A2LA’s ability to accredit medical laboratories, specifically?
A. Absolutely. A peer evaluation team is selected to cover all areas for which an accreditor is seeking recognition under the ILAC MRA. Therefore, each team selected to evaluate A2LA includes at least one member with internationally-recognized expertise in the medical field. This individual then systematically examines all aspects of the A2LA medical laboratory accreditation program, including observation of one or more actual A2LA on-site assessments of a medical laboratory to ISO 15189.

Q. Is A2LA as competent to accredit medical testing laboratories as they are to accredit other types of labs?
A. Absolutely. Rest assured that no accreditor is accepted into the ILAC MRA and recognized to accredit medical labs to ISO 15189 unless they have been rigorously evaluated and found competent to do so. The fact that A2LA’s Scope of Recognition under the ILAC MRA includes accreditation of medical laboratories to ISO 15189 provides you with an independent attestation of our competence in this area.

Q. What aspects are there to an A2LA ISO 15189 assessment?
A. An A2LA medical laboratory assessment is a three-tiered approach. First, it includes a thorough examination of the medical laboratory’s compliance with the requirements of ISO 15189. Second, it includes an in-depth review of the medical laboratory’s own policies and procedures and their adherence with them. Finally, for each applicant to the A2LA medical program, a Scope of Accreditation is drafted. This document outlines all of the specialties and sub-specialties (along with the specific tests performed within each) for which the medical laboratory is seeking accreditation. A2LA assessors then perform a technical assessment against the Scope to ensure that the medical laboratory is technically competent to perform every test listed.

Q. How does A2LA ensure accurate evaluation of both QMS and technical issues in its ISO 15189 assessments?
A. A2LA assigns assessors with the education and expertise to complement a laboratory’s desired Scope of Accreditation. All of our medical assessors have extensive experience in assessing CLIA laboratories and have been found to meet A2LA’s stringent requirements for being contracted members of our assessor corps. A lead assessor is assigned as are additional assessors depending on the extensiveness of the laboratory’s desired Scope of Accreditation. The time spent on-site by our assessors is not only commensurate with the desired Scope but also takes into account the time necessary for a thorough review of the laboratory’s management system. All of our assessors, while undeniably technical experts, also undergo extensive training on the assessment of all QMS elements. A2LA approaches this training as an ongoing investment to ensure the high caliber of our assessor corps. All assessors are observed and evaluated performing actual assessments and this evaluation process occurs at regular intervals throughout the term of their contract with A2LA, ensuring a continual level of consistency and expertise.

Q. What are the steps in the A2LA accreditation process and how long does the process typically take from start to finish?
A. To begin the process, the laboratory completes and returns the application for accreditation, including all supporting documentation specified within the application form. A2LA staff reviews the submitted application to ensure that it is complete and then proposes an assessor (team) based upon the laboratory’s desired Scope of Accreditation. The laboratory is informed of the proposed assessor (team) and is provided with bios to ensure that there is no actual or potential conflict of interest in having the assessor (team) visit the laboratory. Once the assessor (team) has been agreed to, the application package is provided to the assessor (team).

The (lead) assessor contacts the applicant to discuss the scheduling of the on-site assessment and, at that time, requests additional management system documentation to aid in the assessor’s document review, which is done in advance of the assessment. (Laboratory’s do have the option of undergoing a pre-assessment, during which the assessor will point out any areas that are not currently in compliance with ISO 15189 and the A2LA accreditation requirements prior to the full assessment.) A full on-site assessment is performed which includes, among other things, an entry briefing, review of management system documentation and records, examination of sample handling processes, interviews of technicians, observation of tests being performed, review of technical records and reporting processes. A written assessment report, including a report of any areas of non-conformance, is provided to the laboratory at the closing meeting of the assessment.

The laboratory then responds to any non-conformities cited by providing A2LA with a detailed corrective action response. A2LA staff reviews the corrective action response to ensure completeness and corresponds with the laboratory directly if any additional information is required. Once the laboratory’s response is complete, all information related to the assessment is forwarded to a panel of the
A2LA Accreditation Council for a vote. Accreditation is granted upon receipt of affirmative votes from the Accreditation Council and once any concerns raised by the Council have been addressed.

On average, new applicants complete the accreditation process within 5 months, from start to finish. Keep in mind that this is greatly dependent upon the laboratory's readiness, preparation and responsiveness.

Please refer to the diagram below for an overview of this process:

The A2LA ISO 15189 Accreditation Process

**Applicant Responsibilities**

1. Lab submits application and supporting documents.
2. Lab submits additional documentation as requested by A2LA.
3. Lab submits additional documents to assessor(s).

**A2LA Responsibilities**

1. Staff reviews application. Is it complete?
   - Yes: Assessor(s) proposed and assigned.
   - No: Lab submits additional documentation requested by A2LA.

**A2LA Assessor Responsibilities**

1. Assessor(s) reviews application and requests additional documentation from the lab to prepare for visit.
2. Document review satisfactory?
   - Yes: On-site assessment scheduled.
   - No: Lab submits additional documentation.

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**Lab Hosts Assessor(s) On-Site**

**Lab Responds to Any Non-Conformances Cited**

Staff reviews response. Is it complete?

- No: Assessment package submitted to accreditation council panel.
- Yes: Accreditation council panel vote.

- Negative vote: Affirmative vote.
- Affirmative vote: Accreditation!

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Q. Can A2LA help me to better understand the requirements of ISO 15189 and how to implement them in my laboratory?

A. A2LA is a 501(c)(3) non-profit educational institution. As such we offer a variety of public training courses with the purpose of helping organizations prepare for, achieve and maintain accreditation to ISO standards. One course currently offered by A2LA is “ISO 15189 and Medical Laboratory Accreditation”, which assists attendees in understanding the benefit of the newly revised ISO 15189 standard and assists them in implementing “best in class” laboratory functions as well as pre-examination, examination and post-examination processes that address the principles of quality medical laboratory services essential to patient care.

In addition, A2LA offers training courses on specific principles contained within all of the ISO standards used by A2LA as the basis for our accreditation programs. Principles include “root cause”, “corrective action”, “measurement uncertainty”, “internal audits” and “proficiency testing”.

More information may be found on our website (http://www.A2LA.org/training/index.cfm) or by contacting our Training Manager, Julie Collins, at jcollins@A2LA.org.

Q. Do all A2LA medical laboratory assessments include a pathologist on the assessor team?

A. Assessor teams are selected based upon a laboratory’s desired Scope of Accreditation. If a laboratory requests the specialty of pathology on their Scope, then a pathologist must be assigned as part of the assessment team. If pathology is not part of the desired Scope, then A2LA does not waste resources or your money in assigning an assessor with expertise in an area that is not relevant to your Scope of Accreditation.

Q. How should I go about choosing an ISO 15189 accredits?

A. Similar to how you expect your customers to select a laboratory based upon their qualifications and credentials, so should you when choosing an ISO 15189 accredits. Anyone can self-declare competence in offering ISO 15189 accredits, but you need to ask yourself: “What are their credentials and who has accredited them?” When it comes to A2LA, the answer is easy. A2LA’s 35 years of experience in accrediting specifically to ISO standards and our signatory status within the ILAC MRA for the accreditation of medical laboratories to ISO 15189 speak for themselves. Our technical expertise is second-to-none as is our experience with management systems and ISO standards. We not only accredit laboratories to these standards, but we are expert enough in their development and implementation to train others in how to utilize them to better their laboratory’s performance. A2LA is also the only accredits in the United States that is recognized internationally, by virtue of our signatory status within the ILAC MRA, for the accreditation of medical laboratories to ISO 15189.

Q. I am already ISO 15189 accredited by another accredits. Can I transfer this accreditation to A2LA?

A. Although accreditation to ISO 15189 by an accredits that is not a signatory to the ILAC MRA cannot be accepted as equivalent to A2LA accreditation, we strive to make the transfer process as little of a burden financially and otherwise as possible. Often, review of the on-site assessment report from another accredits can be used as a starting-point in the A2LA assessment process, which may save you time and on-site assessor expenses. Every situation is different and so we encourage you to contact us directly (info@A2LA.org or 301 644 3248) and we will be happy to walk you through the transfer process.

Q. Is A2LA accreditation affordable?

A. A2LA is one of the most transparent organizations in the business when it comes to our fee structure. There are no hidden fees; no “document fees” or other extraneous costs. When you contact A2LA for an estimate on the cost of our accreditation, you can be confident that you are receiving a complete picture and that you will not be hit with additional fees as you progress through the program. Because the cost is determined by your desired Scope of Accreditation, we invite you to contact A2LA today (301 644 3248) to learn exactly how affordable our accreditation programs are.

For more information about A2LA, please visit our website at http://www.A2LA.org/medical/medical.cfm or call us directly at 301 644 3248 to discuss how A2LA can meet your needs.
The Importance of Endorsing TEST REPORTS

By Teresa C. Barnett, A2LA Director of Quality

A2LA has long-supported the importance of endorsing calibration certificates issued by accredited calibration laboratories as a means of demonstrating traceability. By “endorsing”, we are referring to use of the accreditation body’s symbol on the calibration certificate or inclusion of some narrative mention of who has accredited the calibration laboratory. But the issue of endorsing test reports often takes a back seat in level of importance.

To illustrate how equally important it is for testing laboratories to endorse their reports with an identification of their accredited status by a specific accreditation body, IANZ (New Zealand) has issued a letter “To Whom It May Concern”:

IANZ has signed recognition arrangements with accreditation authorities overseas. This means we (IANZ) fully recognize test reports from overseas countries, provided the test report is endorsed with the symbol of the national accreditation authority. As these arrangements are between accreditation bodies, without such endorsement (with the symbol of the accreditation body), IANZ has no basis for recognizing a test report, even if it is from an accredited laboratory. There are many reasons why a lab may undertake testing for a customer (at their request) that is outside the provisions of accreditation. For example, an accredited test report may require compliance with all aspects of a specific standard. The customer may request only some aspects be covered. Without the accreditation body’s endorsement of a test report, IANZ has no basis for recognizing such a report.

IANZ promotes the use of accredited test reports to all regulators and other specifiers in New Zealand. For many products, there is a mandatory requirement that they be tested in an accredited laboratory. Clearly there is a consequential requirement that the laboratory has the appropriate test included in their scope of accreditation, and that the product passed the test. Under the terms of the recognition arrangements that IANZ has signed, IANZ is obliged to recognize such overseas test reports on the same basis as if they were from a laboratory accredited by IANZ in New Zealand. Where regulators or other specifiers mandate accreditation, and ask if IANZ would recognize such reports, IANZ always implements the recognition obligations we have signed, provided the test reports are properly endorsed.

For many products, market access in New Zealand requires a formal statement from IANZ recognizing test reports on the product. Without the test report being endorsed, IANZ has no basis for such recognition.

A2LA encourages every accredited organization to endorse their reports and certificates for the very reasons outlined by our MRA Partner, IANZ. Our staff are available to discuss options and to help every organization navigate through the requirements associated with use of the “A2LA Accredited” symbol. For more information or assistance, please contact Teresa C. Barnett, A2LA Director of Quality, at tbarnett@A2LA.org or your Accreditation Officer directly.
The 2014 A2LA Technical Forum and Annual Meeting of the Members will be held from Monday, March 31st through Sunday, April 6th at the Baltimore Marriott Inner Harbor at Camden Yards in Baltimore, MD.

The Forum will consist of:
- New assessor orientation.
- Training for contracted assessors.
- A2LA Technical Advisory Committee meetings. (If you are not a committee member but would like to join one of our Technical Advisory Committees, please contact A2LA (301-644-3248) or your Accreditation Officer to learn more about joining.)
- Educational meetings and open forum discussions for all A2LA stakeholders.
- Key note speech on Cultural Intelligence.
- Annual Meeting of the Members.
- Friday welcoming social and Saturday night dinner and entertainment.

In addition to the Forum events, Baltimore has a lot to offer visitors, including dining, nightlife, shopping, The National Aquarium, historic tours and other attractions. Please visit [http://baltimore.org/](http://baltimore.org/) to learn more about everything this area has to offer.

Invitations and on-line registration information were sent out in November 2013. If you did not receive an invitation or know of someone who would like to attend that didn’t receive an invitation, please contact forum@A2LA.org (please include your full name, company (if applicable), full address and phone number in the email) and we will promptly issue a customized invitation. More details on the Forum, including information about accommodations, location, transportation, and an agenda may be found within the invitation.

Registration for the Forum is $250 for each attendee; $200 if you are an A2LA member. Significant others are also welcome to attend for $75. If you are not currently a member and would like to become one to save $50 on registration for the 2014 Technical Forum, please visit our website at: [http://www.A2LA.org/membership/member.cfm](http://www.A2LA.org/membership/member.cfm). In addition to the savings on Forum registration, membership also entitles you to the following benefits:
- Education and training courses on laboratory quality control, quality assurance, internal audit, and assessor procedures at reduced rates.
- Summaries of international developments in laboratory accreditation as related to foreign trade.
- Discounts on accreditation fees for organizational members.
- The right to elect members of the A2LA Board of Directors.

We look forward to seeing you at the 2014 A2LA Technical Forum and Annual Meeting of the Members!
Spring 2014 Training Schedule

**Title:** Assessment of Laboratory Competence
This course presents key critical assessment issues, including the evaluation of analyst/technician competency, method validation, measurement traceability and measurement uncertainty. Attendees learn how to evaluate quality manuals and review and evaluate sample management system documents. A quality manual is also examined as to its impact on operations and the purpose it serves.

- March 31-April 4, 2014-Baltimore, MD ($1595.00 non-members, $1545.00 A2LA members) (In-conjunction with the A2LA Annual Technical Forum)

**Title:** Internal Auditing
This course practices the internationally-recognized approaches to conducting effective internal audits. The techniques learned promote the involvement of an organization’s personnel. This course includes easy-to-implement methods for continual improvement and preparing for external assessments.

- March 10-11, 2014-Savannah, GA ($795.00 non-members, $745.00 A2LA members)
- May 12-13, 2014-Columbus, OH ($795.00 non-members, $745.00 A2LA members)

**Title:** Introduction to Measurement Uncertainty
Every effort is made to eliminate unnecessary complications and to apply The Guide to the Expression of Uncertainty in Measurement (GUM) at its simplest level, removing the mystery associated with measurement uncertainty. Measurement uncertainty problems are solved by brainstorming methods so as to generate interaction by all participants.

*This course is suitable for all personnel of both calibration and testing laboratories.*

- February 24-25, 2014-Phoenix, AZ ($795.00 non-members, $745.00 A2LA members)
- June 16-17, 2014-Chicago, IL ($795.00 non-members, $745.00 A2LA members)

**Title:** ISO/IEC 17025:2005 and Laboratory Accreditation
This course is a comprehensive look at ISO/IEC 17025 and its documentation and internal auditing requirements. In this course, attendees gain critical insight into the interpretation of the requirements of this laboratory standard and also receive a detailed review of the accreditation process.

- February 26-28, 2014-Phoenix, AZ ($995.00 non-members, $945.00 A2LA members)
- April 14-15, 2014-Livonia, MI ($795.00 non-members, $745.00 A2LA members)  
  (Please note that this is a 2-day course)
- June 18-20, 2014-Chicago, IL ($995.00 non-members, $945.00 A2LA members)

**Title:** ISO/IEC 17025:2005 for Accredited Laboratories
This course provides a brief overview of the requirements and provides an understanding of how to apply specific sections of the standard in the laboratory. This course is intended for individuals with a working knowledge of the standard.

- March 12, 2014-Savannah, GA ($495.00 non-members, $445.00 A2LA members)

**Title:** Root Cause Analysis and Corrective Action
This course consists of presentations, discussions and exercises that provide participants with an in-depth understanding of how to analyze a system in order to identify the root causes of problems and to prevent them from recurring.

- April 16, 2014-Livonia, MI ($495.00 non-members, $445.00 A2LA members)

**Venues:**

- **February 23-28, 2014**
  Phoenix, AZ (Introduction to Measurement Uncertainty, ISO/IEC 17025:2005 and Laboratory Accreditation)
  The Westin Phoenix Downtown
  333 N. Central Avenue
  Phoenix, AZ 85004
  (602) 429-3500
  Rate: $209.00 per night (room rate cut-off: January 24, 2014)

- **March 9-12, 2014**
  Savannah, GA (Internal Auditing, ISO/IEC 17025:2005 for Accredited Laboratories)
  Marriott Savannah Riverfront
  100 General McIntosh Blvd.
  Savannah, GA 31401
  (912) 233 7722
  Rate: $155.00 per night (room rate cut-off: February 9, 2014)

- **March 30-April 4, 2014**
  Baltimore, MD (Assessment of Laboratory Competence)
  Baltimore Marriott Inner Harbor at Camden Yards
  110 South Eutaw Street
  Baltimore, MD 21201
  (800) 228-9290
  Rate: $129.00 per night (room rate cut-off: February 15, 2014)

- **April 13-16, 201**
  Detroit Livonia, MI (ISO/IEC 17025:2005 and Laboratory Accreditation, Root Cause Analysis and Corrective Action)
  Marriott Detroit Livonia
  17100 Laurel Park Drive North
  Livonia, MI 48152
  (734) 462-3100
  Rate: $129.00 per night (room rate cut-off: March 24, 2014)

- **May 11-13, 2014**
  Columbus, OH (Internal Auditing)
  Hilton Columbus at Easton
  3900 Chagrin Drive
  Columbus, OH 43219
  (614) 414 5000
  Rate: $189.00 per night (room rate cut-off: April 11, 2014)

- **June 15-20, 2014**
  Chicago, IL (Introduction to Measurement Uncertainty, ISO/IEC 17025:2005 and Laboratory Accreditation)
  Chicago Marriott O’Hare
  8535 West Higgins Road
  Chicago, IL 60631
  (773) 693-4444
  Rate: $164.00 per night (room rate cut-off: May 25, 2014)

For additional information, please contact Julie Collins, A2LA Training Manager, at 301 644 3235 or jcollins@A2LA.org.
Upcoming Webinar Training Events
Offered by A2LA in Partnership with WorkPlace Training

TITLE: Introduction to Measurement Uncertainty
January 14, 2014; February 11, 2014
This 2 Hour Web Event will cover:
- Measurement uncertainty definitions
- Why measurement uncertainty is required
- Measurement uncertainty and ISO 17025/ANSI Z540.3
- Minimum measurement uncertainty contributors
- Simplified process for determining measurement uncertainty
- Measurement uncertainty references
Registration URL: https://student.gototraining.com/r/4650452954213616640
$299.00 per attendee. A2LA Member rate: $279.00 per attendee. Volume discount for attendees available. Contact: info@wptraining.com for more information.

January 21, 2014
This 2 Hour Web Event will cover:
- Understanding ILAC P14 requirements
- Metrological traceability
- Measurement uncertainty contributors
- Reporting customer’s measurement uncertainty
- Test Uncertainty Ratio (TUR) and compliance statements
- Helpful spreadsheet techniques
Registration URL: https://student.gototraining.com/r/4362159905899171840
$299.00 per attendee. A2LA Member rate: $279.00 per attendee. Volume discount for attendees available. Contact: info@wptraining.com for more information.

TITLE: Measurement Uncertainty for Testing Laboratories
January 28, 2014
This 2 Hour Web Event will cover:
- Determining sample size
- Determining repeatability and reproducibility
- Type A and B uncertainty classification
- Combining uncertainties
- Assigning k-factor and t-distribution
- Reporting in an uncertainty budget
Registration URL: https://student.gototraining.com/r/5917873201690502144
$299.00 per attendee. A2LA Member rate: $279.00 per attendee. Volume discount for attendees available. Contact: info@wptraining.com for more information.

A2LA Discount Code is: A2LAWIN2014

Become a Subscriber to ILAC News
ILAC regularly publishes a newsletter, ILAC News, with important updates from the ILAC Secretariat, updates on regional and international cooperations, updates from ILAC MRA signatory accreditation bodies and updates from ILAC stakeholders. Subscriptions to ILAC News are free and we encourage you to subscribe today at the following link: http://accreditation.newsweaver.co.uk/ilac/krpjhsbtl7c? a=6&p=41688165&t=24566955
Since the September issue of A2LA Today, the A2LA Criteria Council voted to approve 12 new explanations of the ISO/IEC 17065:2012 requirements. These and other explanations may be found on the A2LA website under “Accreditation Programs”, “Explanations for the Requirements”.

ISO/IEC 17065:2012, Section 4.1.2.1
QUESTION: What is a “Legally Enforceable Agreement”, and will my assessor be responsible for determining its legality?
RESPONSE: For the purposes of this clause, A2LA determines a “legally enforceable agreement” to be any signed or sign-able record between the Certification Body and its client/customer which meets the requirements of clause 4.1.2.2, and which (as stated in 4.1.2.1) takes into account the responsibilities of the two parties in that agreement. This record can be known by any name, but is typically referred to as a “Contract” for ease of reference.

A2LA assessors will not be determining, nor can they be held responsible for determining its legality.

ISO/IEC 17065:2012, Section 4.6 (a)
QUESTION: Does my organization’s “Publicly Available Information” need to explicitly address each of the procedures called out in this clause if one or more are not applicable to our certification activities?
RESPONSE: Yes, the Certification Body must address each required procedure under this clause, even if the certification activities being performed do not include those actions. For example, an organization operating a certification scheme which does not allow for extensions or reductions to the scope of certification must have documented some statement to the effect of, “We do not offer any extensions or reductions to our certifications.”

ISO/IEC 17065:2012, Section 5.2.2 (a)
QUESTION: My organization has invited numerous possible stakeholders to be part of our “Mechanism for Safeguarding Impartiality,” but all of those stakeholders have declined to participate. How can my organization show that we are maintaining the required balanced representation in light of this?
RESPONSE: Note 2 to clause 5.2.1 and Note 1 to clause 5.2.4 of ISO/IEC 17065 both identify examples of mechanisms and potential invitees that the Certification Body may have overlooked during its invitation process, and should be examined prior to determining that all possible avenues have been exhausted.

The certification body must be able to demonstrate (e.g. by providing records) that they have ensured a balanced interest in their mechanism by identifying and inviting potentially interested parties, and that they have ensured that the composition of their Mechanism is such that no single interest predominates. In all cases, the Certification Body cannot hold more than 50% stake in this Mechanism – it is up to the Certification Body to take additional suitable actions to ensure that these balanced interest requirements are met.

ISO/IEC 17065:2012, Section 6.2.2.4
QUESTION: My Certification Body operates under a larger corporate umbrella, and we send portions of our Evaluation work to another department in the corporation. Is this considered “outsourcing” the work to an outside body?
RESPONSE: Note 2 of clause 6.2.2.1 states “Use of external personnel under contract is not outsourcing.” If there exists a properly executed agreement (e.g. contract) between the department/personnel in question and the Certification Body which meets the requirements of clause 6.1.3, then, no, the example given does not constitute “Outsourcing” of activities by the Certification Body. (This documentation also answers the question, “Is the resource under the direct control of the Certification Body?” for the purposes of judging whether or not the entity in question is an Internal Resource of the Certification Body – see clause 6.2.1)

If the documentation linking the other department or its personnel to the Certification Body does not meet the requirements called out under clause 6.1.3, or if the Certification Body cannot provide evidence that the additional requirements stated under clause 6.1.2 are met for the personnel in question, then the actions taken by the Certification Body are considered “Outsourcing,” and the Certification Body must demonstrate that it complies with the requirements related to outsourced activities.

ISO/IEC 17065:2012, Section 7.3.3
QUESTION: What types of records are required to justify our organization’s competence and capability to perform a
The NOTE under this clause gives excellent guidance for the Certification Body to consider when comparing the new product they are being asked to certify against products they have certified in the past. Similar comparisons should also be made when a new certification scheme or new normative document (such as a different evaluation specification) is introduced to the Certification Body by their client.

If the Certification Body determines that the new product is of the same type as ones with which it has previous experience, no records are needed, but the Certification Body may be asked to explain its rationale in determining that the new product is of the same type as ones that were previously certified.

If the Certification Body cannot explain this rationale to an assessor’s satisfaction, a deficiency may be cited if the assessor can justify that a certification was not “of the same type” as certifications previously granted by the Certification Body (for example, by showing that the new product has substantial differences in technical underpinnings from those the Certification Body used in its comparison).

**A2LA NOTE** – Performing certifications against schemes and underlying technical standards not shown on the Certification Body’s Scope of Accreditation cannot be claimed as Accredited work in accordance with A2LA P101 – Rules for Making Reference to A2LA Accredited Status. A2LA does offer a “F330 - Request for Expansion of Scope of Accreditation - Product Certification” form for Certification Bodies wishing to expand their Scope of Accreditation for situations such as these. The Certification Body must fill out and have the Scope expansion request approved by A2LA and their most recent assessor before offering these certifications as Accredited.

**ISO/IEC 17065:2012, Section 7.3.2**

**QUESTION:** A client has asked us to certify a new product which we have not certified before, but this new product is somewhat similar to ones we have been certifying in the past. How do we determine whether or not we have “prior experience” with the new product we are being asked to certify?

**RESPONSE:** The Certification Body should compare the new product to be certified against those with which it has similar experience by examining the schemes (if different) used for performing the certifications, the technologies inherent in the products, the evaluation techniques which must be implemented to characterize the product to determine its compliance with the requirements in the certification scheme(s), and the technical knowledge of its own personnel in order to ensure that a knowledgeable review and decision on certification can ultimately be made.

The NOTE under this clause gives excellent guidance for the Certification Body to consider when comparing the new product they are being asked to certify against products they have certified in the past. Similar comparisons should also be made when a new certification scheme or new normative document (such as a different evaluation specification) is introduced to the Certification Body by their client.

If the Certification Body determines that the new product is of the same type as ones with which it has previous experience, no records are needed, but the Certification Body may be asked to explain its rationale in determining that the new product is of the same type as ones that were previously certified.

If the Certification Body cannot explain this rationale to an assessor’s satisfaction, a deficiency may be cited if the assessor can justify that a certification was not “of the same type” as certifications previously granted by the Certification Body (for example, by showing that the new product has substantial differences in technical underpinnings from those the Certification Body used in its comparison).

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**ISO/IEC 17065:2012, Section 7.12.3**

**QUESTION:** The certification scheme operated by my organization requires that we re-evaluate products on a four month cycle. Does the language in this clause mean that we only have to keep records for 8 months total, in order to meet the “current and previous” cycle requirement?

**RESPONSE:** Clause 8.4.2 of the standard indicates that the Certification Body’s procedures for record retention must be consistent with any contractual and legal obligations. Those legal and contractual obligations would take precedence over the shorter retention cycle given in the example above.

Above and beyond any legal or scheme obligations for record retention, A2LA requires, as one of the Conditions and Criteria for Accreditation (A2LA R102 - Conditions for Accreditation, clause 4), that the accredited (or applicant) organization must keep copies of records for the entire time period between on-site assessments. Legal and scheme obligations may require longer retention periods, but under no circumstances may the Certification Body dispose of records in any shorter time period.
ISO/IEC 17065:2012, Section 7.13.7

**QUESTION:** How should my organization demonstrate compliance to this clause if we receive an anonymous complaint?

**RESPONSE:** In many instances, it may not be possible for a Certification Body to give a formal notice of complaint resolution to the complainant; one such example is if a complaint is received anonymously. Other examples where it may not be possible to formally notify a complainant could include the complainant not leaving any contact information for receiving feedback, or the complainant changing contact information either voluntarily (i.e. relocation) or involuntarily, (i.e. being dismissed from an employment position).

Possible evidence which would show that the Certification Body has performed their due diligence when the complainant is unreachable could include records of attempted emails with read receipts, phone logs, voicemails, certified postal mailings, or generalized resolution notices to alternate persons that are known to be related to the original complainant.

These examples, are not intended to be all-inclusive, nor are they mandatory actions that must be undertaken by the Certification Body.

Ultimately, the Certification Body must show evidence that they have done reasonable due diligence in attempting to contact or locate the original complainant, and these examples may be useful when considering what actions to undertake to notify the complainant of the outcome. In all cases, these attempts to contact the complainant must be part of the records associated with complaint resolution as required by clause 7.13.1.

ISO/IEC 17065:2012, Section 8.3.1

**QUESTION:** What does A2LA consider to be “External documents” that my organization must control under our document control procedures?

**RESPONSE:** For the purposes of A2LA accreditation, accredited Certification Bodies are required to own or have direct access to, and have under their document control system, current versions of the normative documents that are vital to maintaining their accreditation and to perform their certification activities.

These documents include (in addition to relevant regulations, standards and/or technical methods, etc.) ISO/IEC 17065:2012, general A2LA policy documents, and the specific A2LA program requirement documents relating directly to their field of accreditation. A2LA does not consider “terminology documents”, such as ISO/IEC 17000 and the VIM, to be normative documents that an organization must control within their system.

For example, a Telecommunications Certification Body (TCB) would be expected to possess (or have direct access to) and have under its document control system current versions of the following A2LA documents:

- R307 - General Requirements - Accreditation of ISO-IEC 17065 Product Certification Bodies
- P101 - Rules for Making Reference to A2LA Accredited Status
- R102 - Conditions for Accreditation
- R308 - Specific Requirements - 17065 - Telecommunication Certification Body Accreditation Program

Furthermore, such a TCB would be expected to control copies of all test methods called out in the certification schemes being operated, as well as copies of the schemes themselves.

ISO/IEC 17065:2012, Section 8.6.1

**QUESTION:** My Scope of Accreditation includes multiple product types under a larger scheme. Does my internal audit have to include every product type on my Scope?

**RESPONSE:** A2LA does require a review of records related to each Product Type on the organization’s Scope of Accreditation to be included in their internal audit in order to ensure that the management system is being properly implemented across all certifications.

The internal audit is considered incomplete if the organization fails to include each Product Type during its internal audit.

ISO/IEC 17065:2012, Section 8.6.3

**QUESTION:** What does the standard mean when it says that my internal audit shall “normally” be performed at least once every 12 months?

**RESPONSE:** A Certification Body’s initial internal audit schedule should show that internal audits will be performed once in a 12 month period (or show that one full audit will be performed over a rolling 12 month period).

As the language of the standard states that the Certification Body may choose to “Reduce or Restore” the frequency of their internal audits, A2LA currently does not permit an internal audit schedule which extends beyond the 12 month period specified by the standard (e.g. 8 month audit schedules are permitted, but not 16 months).

If the Certification Body feels that they need to initially schedule more frequent audits, or if the results of any audit show the need to schedule a subsequent audit sooner than 12 months, the Certification Body should not hesitate to adjust their schedule accordingly.

Regardless of the period or frequency defined, any changes to the schedule of the audits (including restoring a schedule to the maximum 12 month time frame), as well as the rationale behind the decisions to change, must be documented and kept...
under record control by the Certification Body. These changes must be supported by records that demonstrate ongoing stability and effectiveness of the management system.

**ISO/IEC 17065:2012, Section 8.6.4 (d)**

**QUESTION:** What does the standard mean when it states that my organization must ensure that any actions resulting from our internal audits are taken in a timely and appropriate manner?

**RESPONSE:** A2LA cannot define what “timely and appropriate” means for its Certification Bodies. The intent of this clause is for the organization to take action as soon as they are able, in order to ensure that the organization’s quality system is running smoothly, and that the certifications being offered are not negatively impacted. An assessor may cite a deficiency if there is evidence that the quality system or offered certifications are being affected by lack of action on an internal audit finding. The Certification Body is still responsible for meeting all requirements related to corrective actions (section 8.7) and preventive actions (section 8.8) when acting upon their internal audit findings.

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### New & Updated Documents

By Teresa C. Barnett, A2LA Director of Quality

The following documents have been updated within the controlled A2LA management system. All of these documents are available on the A2LA website (www.A2LA.org) through the “Search A2LA Site” tool unless otherwise indicated.

- **C210 – Specific Checklist: Construction Materials Testing Laboratory Accreditation Program** was updated on September 10, 2013.
- **A244 – CMT Proficiency Testing Spreadsheet** was updated on September 10, 2013.
- **P115 – Technical Consensus Decisions from the Forensic Examination Advisory Committee** is a new document published on September 6, 2013.
- **C215 – Specific Checklist: World Anti-Doping Agency (WADA) Testing Laboratory Accreditation Program** was updated on September 19, 2013.
- **I602 – Instructions for Responding to the Medical Deficiency Report** was updated on October 11, 2013.
- **1106 – Available Proficiency Testing Programs** was updated on November 6, 2013.
- **R103a – Annex: Proficiency Testing for ISO/IEC 17025 Laboratories** was updated on October 18, 2013.
- **F237 – Food Program Proficiency Testing Spreadsheet** is a new document published on November 7, 2013.

If you have any questions about these updates, please contact A2LA at 301 644 3248 or your Accreditation Officer directly.

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**A2LA Staff Changes**

By Teresa C. Barnett, A2LA Director of Quality

Since the last issue of *A2LA Today*, Adam Gouker has been promoted to A2LA Accreditation Manager, managing a team of Accreditation Services staff in the electrical area. Adam has been with A2LA since February 2006 and has been invaluable in his support of A2LA’s electrical laboratory and product certification body accreditation programs.

All of us at A2LA extend our congratulations to Adam on this well-deserved promotion!

In addition, A2LA has welcomed Ashley Morton to our staff as an Accreditation Officer. Ashley has a B.S. degree in criminal justice from the University of Baltimore. Before joining A2LA, he gained significant experience in the service industry and as owner and manager of his own business.

We welcome Ashley to the growing A2LA family!
Spotlights

A2LA Staff Spotlight: Samantha Dizor-Carter

By Teresa C. Barnett, A2LA Director of Quality

Life at A2LA...

Samantha was an Accreditation Officer for A2LA from February 2006 to July 2008 and she returned to A2LA in this capacity again in August 2010. At that time, she assumed responsibility for A2LA’s Information Technology (IT) accreditation program and, in July 2013, secured recognition for A2LA under the Federal Risk and Authorization Management Program (FedRAMP) as an Accreditation Body accrediting Third Party Assessment Organizations (3PAO). Since then, Samantha has been working with FedRAMP to develop program requirements for the accreditation of 3PAOs. She has also represented A2LA during meetings for FedRAMP and, most recently, she was a panelist at the SINET Showcase for a panel on FedRAMP on December 4. She also spoke at the November 5th Potomac Forum Lt. and Software and Information Industry Association (SIIA) Executive Breakfast series “Achieving Success with the Federal Risk and Authorization Management Program”.

“Sam attacks everything we have asked her to do at A2LA with tireless energy and enthusiasm,” says Trace McInturff, A2LA Director of Accreditation Services. “FedRAMP recognition is yet another testament to her hard work, determination and value here at A2LA.”

On behalf of A2LA, Samantha manages the day-to-day operations of the IT accreditation program, which includes assisting applicants through the accreditation process, developing requirements for specific programs, meeting with government officials, as necessary, for the development of the program and continually monitoring the constantly changing IT industry for new areas of growth.

Samantha has also developed an ISO/IEC 17020 training class for FedRAMP 3PAOs seeking accreditation with A2LA, and she serves as the instructor for the class. In addition to working on the FedRAMP program for A2LA, Samantha also sits on the ASTM E31 committee on Healthcare Informatics. Samantha is a lead quality system assessor for A2LA for ISO/IEC 17025 and ISO/IEC 17020 and is trained on the ISO/IEC 17065 requirements. As part of her Senior Accreditation Officer duties, she also performs oversights of A2LA assessors.

Early Career and Education...

During her time away from A2LA, Samantha was the Internal Auditor for Tektronix. She performed internal audits for the Calibration, Product Test and Component Screening Laboratories, pursuant to the requirements of ISO/IEC 17025:2005 and ISO 9001:2008, and she was responsible for issuing corrective actions for any findings that resulted from the internal audits and reviewing the responses to those corrective actions. She also assisted the laboratories in maintaining accreditations to ISO 17025:2005 and ISO 9001:2008 by reviewing responses to corrective actions from external audits. She addressed quality-related questions when the Quality Manager was absent and completed training with SRI as an AS 9100 Internal Auditor.

Samantha received her B.S. in Physics, with a minor in Mathematics and Computer Science, from Jacksonville University in May 2005.

On a Personal Note...

Samantha lives in Columbia, MD, just outside of Baltimore, with her husband, Robert, and one year old daughter, Victoria. She attends Johns Hopkins University where she is pursuing a Masters in Cyber Security, which she hopes will be of benefit to A2LA with the growth of the IT accreditation program. She enjoys hiking, rock climbing, and reading. When not working for A2LA, Samantha spends time with her family (she is the oldest of eight children, the youngest of whom still live at home with her parents). She also enjoys traveling abroad, and is taking advantage of her sister living in Germany to spend time there.

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An Accredited Organization’s Perspective: Vehicle Systems & Safety Program (University Park, PA)

This column presents the unique perspective of one of our accredited organizations and how accreditation and implementation of ISO standards have benefitted them. All accredited organizations are invited to submit their responses to the five standard questions posed below to our newsletter editor for consideration (submissions should be sent to: Teresa Barnett, A2LA Director of Quality, at tbarnett@A2LA.org.) In each issue of A2LA Today, we will present the responses submitted by one organization. This issue presents those submitted by the Vehicle Systems & Safety Program of The Larson Institute, Penn State University, in University Park, PA.

Why did your organization seek accreditation from A2LA?

When the Vehicle Systems & Safety Program of The Larson Institute at Penn State was first considering ISO/IEC 17025 accreditation, I attended the Automotive Testing Expo in Novi, MI, and was introduced to several of the accreditation bodies. After reviewing information I received at the Expo, I made personal contact with two of the organizations. I was impressed by the quick response from A2LA. But more importantly, from our discussions I was confident that the people were knowledgeable and helpful and would be good guides through the process of our first accreditation.

How did the process of implementing an ISO standard bring to light areas for improvement that have made you a better organization?

I think that the process of implementing ISO/IEC 17025 brought to the forefront the fact that, although the VS&S personnel use quality management procedures to address customer complaints and problems that are encountered with test procedures, the steps of the processes used for resolution were not well recorded. During our initial A2LA audit, the assessor provided suggestions that were used to develop a new system for recording this information.

What benefits has your organization seen as a result of your A2LA accreditation?

Regular internal audits of our test procedures, as required by the ISO/IEC 17025 standard, have improved the clarity of our test procedures and have further emphasized to our personnel the importance of performing tests in accordance with the written procedures, resulting in a more efficient operation.

The A2LA review of our standard practices resulted in the establishment of a web-based site for all quality and test procedure documentation. The site uses MS SharePoint to provide a working interface for personnel at different locations to access and update documentation, to collaborate on issues, to add events to the calendar, and to track progress on certain activities. The benefits of this web-based site are that it provides easy access for all personnel, allows interaction between personnel at different locations, provides one central location for all documentation that eliminated multiple copies, automatically maintains a record of actions taken on quality issues, and is regularly backed up by the IT personnel.

How has A2LA accreditation improved your marketability? How has your business changed for the better since gaining accreditation?

I believe that having the A2LA accreditation demonstrates a commitment to quality, independent research and testing to those who might be interested in contracting with Penn State’s Vehicle Systems & Safety Program. Since the ISO/IEC 17025 accreditation is required by some of the international standard methods of test that we perform, having the A2LA accreditation allows us to pursue activities that we would not otherwise be able to pursue and assures our sponsor that we meet the necessary requirements of the Standard. Also included in the VS&S Program’s Scope of Accreditation are research and testing activities that do not require the ISO/IEC 17025 accreditation. The purpose of this was to ensure the quality and timeliness of research and testing, to enhance the reputation of the VS&S Program, and to demonstrate a high level of professionalism to potential sponsors.

About Vehicle Systems & Safety Program:

The Thomas D. Larson Pennsylvania Transportation Institute at Penn State was founded in 1968. It is an inter-disciplinary research unit under the College of Engineering. The Vehicle Systems and Safety (VS&S) Program is one of three transportation-focused research programs at The Larson Institute. A one-mile oval test track, including full-scale facilities for vehicle durability, friction measurements, and crash testing, is available on-site. Faculty, staff, and students work together in the VS&S Program on funded research and testing projects dealing with the interaction between vehicles and their surroundings, interaction between operators and their vehicles, and vehicle handling, maintenance, reliability, and safety. The accredited activities include the standard tests performed as part of the Federal Transit Administration’s Bus Test Program (Altoona Bus Testing) and crash testing in accordance with ASTM F2656, MASH, and APTA. The VS&S Program plans to expand its accreditation to include friction measuring equipment conformity and calibration in 2014. ✻
The ILAC Seventeenth General Assembly met in Seoul from 16 – 25 October 2013. The excellent arrangements and support services for the General Assembly were provided by the Korean Agency for Technology and Standards (KATS), Korea Laboratory Accreditation Scheme (KOLAS), Korea Accreditation System (KAS) and Korea Accreditation Board (KAB).

The General Assembly accepted the Arab Accreditation Cooperation as a Regional Cooperation Body.

The following new signatories to the ILAC Arrangement were approved for the scopes or scope expansions indicated below:

- Joint Accreditation System of Australia and New Zealand (JAS-ANZ), Australia/New Zealand, for inspection.
- Belgian Accreditation Structure (BELAC), Belgium, for extension of scope to include inspection.
- Institute for Accreditation of Bosnia and Herzegovina (BATA), Bosnia and Herzegovina, for calibration, testing (ISO/IEC 17025), and inspection.
- General Coordination for Accreditation (CGCRE), Brazil, for extension of scope to include inspection.
- Quality Management Program – Laboratory Services (QMP-LS), Canada, for medical testing (ISO 15189).
- Cyprus Organisation for the Promotion of Quality (CYS) Cyprus Accreditation Body (CYSAB), Cyprus, for extension of scope to include inspection.
- Hellenic Accreditation System S.A (ESYD), Greece, for extension of scope to include inspection.
- Oficina Guatemalteca de Acreditación (OGA), Guatemala, for extension of scope to include inspection.
- National Accreditation Board for Certification Bodies (NABCB), India, for inspection.
- National Accreditation Body of Indonesia (KAN), Indonesia, for extension of scope to include testing (ISO 15189).
- L’Ente Italiano di Accreditamento (ACCREDIA), Italy, for extension of scope to include inspection.
- Jamaica National Agency for Accreditation (JANAAC), Jamaica, for testing (ISO/IEC 17025).
- The Kyrgyz Center of Accreditation (KCA), The Kyrgyz Republic, for testing (ISO/IEC 17025).

For a list of all signatories, please visit www.ilac.org.

Ms. Etty Feller from ISRAC was appointed as Chair of the Arrangement Management Committee (AMC) to complete the current term vacated by Andreas Steinhorst, DAkkS, until the 2014 General Assembly.

The ILAC Laboratory Committee recommended that ILAC, in its capacity as an A Liaison organization to ISO, request that ISO/CASCO establish a new work item to comprehensively revise ISO/IEC 17025:2005 as soon as practicable. A letter ballot, based on one vote per member, on whether to proceed with the request to submit a new work item to ISO/CASCO will be commenced on 1 February 2014.

The Arrangement Management Committee considered the need to establish a policy addressing the involvement of Stakeholders in the MRA process and agreed that this was needed. This item was also then discussed during the ILAC Arrangement Committee. It was agreed that ILAC needs to develop a better mechanism to work with and involve the regulators and other stakeholders with whom they are not currently engaging, including looking for opportunities to establish a two-way interaction.

The General Assembly received reports from the Bureau International des Poids et Mesures (BIPM) and the World Anti-Doping Agency (WADA).

Next year’s General Assembly will be held in Bangkok, Thailand, 8-17 October 2014.