A2LA Financial Manager, Lisa Drake, Retires After 25 Years

By John Locke and Peter Unger

A2LA’s first employee and Financial Manager, Lisa Drake, retired on 29 July 2011 after 25+ years of dedicated service to the Association.

Lisa has been a key contributor to laboratory accreditation activities since 1976. In those 35 years she worked first for the National Voluntary Laboratory Accreditation Program (NVLAP) at the National Bureau of Standards (NBS) for 10 years and then with A2LA (at first known as AALA) for 25 years.

AALA was established on 12 July 1978 about two years after NVLAP was formed. When John Locke moved to NBS in 1981 to take over all management of NVLAP, Lisa became his key administrative assistant. John retired from NBS in 1985 after the Deputy Director of NBS, at an ASTM meeting, told the assembled that NBS did not want the responsibility of policing the nation’s laboratories. NVLAP appeared to have a short life.

In the meantime, AALA began with Chair Roger Amorosi under the management of Stigar-Willis, a management firm. Its first five accreditations occurred in 1980. In January 1986, Chair Gladys Berchtold and Vice Chair John Blair interviewed John Locke and offered him the job as Executive Director under the management firm name of CASSI. There was no office space, no furniture, no personnel; just faith that they could get the job done. The first thing John did was contact Lisa to see if she might be willing to join this adventure. He was afraid she would be wedded to a government career but she said “yes” and began working for CASSI and AALA on 1 April 1986. As President of CASSI, John was hired on that date as well but had to postpone his work for one month in order to complete a project already underway.

Office space was found in a high rise building right across the road from NBS. In early March, John noticed an ad for an auction of office furniture. Lisa and Pete Unger, still working for NBS, attended the auction and bought a number of desks and the big oval conference table that served the Association so well. On the weekend before April...
Updates on A2LA

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1, the furniture was moved in and Lisa started work. She was by herself in that space for the first month. AALA had inherited four big boxes of records from John Magnotti, who had been prior manager of AALA, and Lisa busied herself in organizing the files, interacting with the accredited laboratories and assessors, setting up telephones, purchasing supplies and responding to inquiries from laboratories seeking accreditation. There were, at that time, about 80 accredited laboratories.

Lisa was invaluable. She was receptionist, office manager, lab services officer, bookkeeper, word processor, human resources manager and, finally, financial services manager. Her conscientiousness over the years was truly remarkable. As A2LA grew and hired more people to take over some of the work, she became the financial manager and “go to” person for everyone.

A2LA’s financial status was very tight. Thanks to Chair Berchtold, interest-free loans were received from the American Council of Independent Laboratories, from ASTM and from CASSI, which was enough to keep the Association going. As accredited laboratories were added, Lisa became the key to A2LA’s success. She billed all laboratories for their accreditations and assessments, kept track of and paid the assessors, prepared the books and did the long range planning.

By 1989, A2LA had a substantial surplus in funding and was able to pay off all the loans. CASSI staff became employees of A2LA. Lisa had a big hand in setting up the employee benefit packages, insurance and all things financial. She was strong and meticulous and was trusted completely, by the A2LA employees as well as the Board of Directors. Moreover, she was a delight to work with.

As A2LA President and CEO, Pete Unger, observed at her retirement luncheon, Lisa served as the “backbone” of A2LA in the late 1980s with “very little skeleton around her.” She helped shepherd the growth of the Association since 1985 from 70 accreditations and revenues of $100,000 to over 2,300 accreditations and revenues of $11 million today.

Lisa will be missed by the entire A2LA family and we wish her much happiness in her well-deserved retirement!

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New & Updated Documents

By Teresa Barnett, A2LA Quality Manager

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 “Document Finder” option unless otherwise indicated.

- **C651 – Specific Checklist: ISO 15189 Medical Specialty of Chemistry** was updated on 6 June 2011. (Document Finder category: Specific Checklists)
- **R303 – General Requirements: TNI Proficiency Testing and SSAS Provider Accreditation Program** was updated on 14 June 2011. (Document Finder category: General Requirements)
- **R222 – Specific Requirements: EPA ENERGY STAR Accreditation Program** was updated on 10 June 2011. (Document Finder category: Specific Requirements)
- **P101 – Reference to A2LA Accredited Status-A2LA Advertising Policy** and the associated **C104 – General Checklist: Reference to A2LA Accredited Status-A2LA Advertising Policy** were updated on 17 June and 21 June 2011, respectively. (Document Finder categories: Policies and General Checklists)
- The new document, **R223 – Specific Requirements: GE Aviation S400 Accreditation Program**, was created on 20 June 2011. (Document Finder category: Specific Requirements)
- The new form, **F228 – A2LA GEAE S400 Laboratory Consent Agreement**, was created on 22 June 2011. (Document Finder category: General Forms)
- The new document, **P111 – Technical Consensus Decisions from the Electro-Mechanical Advisory Committee (EMAC)**, was created on 8 July 2011. (Document Finder category: Policies)
- **C105 – General Checklist: A2LA Policy on Measurement Traceability** was updated on 20 July 2011. (Document Finder category: General Checklists)
- **G113 – Guidance on Completing the C101 General Checklist for ISO/IEC 17025 Laboratories** was created on 26 July 2011. This document is available by request only and only after demonstrating ownership of the ISO/IEC 17025 standard.

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

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Roxanne Robinson, Peter Unger and Lisa Drake
NEW EXPLANATIONS OF ISO/IEC 17025 REQUIREMENTS

By Teresa Barnett, A2LA Quality Manager

Since the March 2011 issue of A2LA Today, the A2LA Criteria Council voted to approve two new explanations of the ISO/IEC 17025:2005 requirements. These and other explanations may be found on the A2LA website under “Accreditation Programs,” “Explanations for the ISO/IEC 17025 Requirements.”

QUESTION: My internal audit consists of completing only the A2LA ISO/IEC 17025 checklist. Is this sufficient?

RESPONSE: No. Section 4.14.1 of ISO/IEC 17025 states that the internal audit must “verify that [the laboratory’s] operations continue to comply with the requirements of the management system and this International Standard” (i.e., ISO/IEC 17025) and that the audit “shall address all elements of the management system, including the testing and/or calibration activities.” Section 4.1.2 of ISO/IEC 17025 also states that the laboratory must “carry out its testing and calibration activities in such a way as to meet the requirements of organizations providing recognition.” (i.e., A2LA)

As such, your internal audit program (in accordance with your pre-determined schedule) must consist of at least the following:

- Determination of compliance with ISO/IEC 17025;
- Determination of compliance with all laboratory policies, procedures, instructions, etc. that form your management system;
- Determination of compliance within all testing and/or calibration activities;
- Determination of compliance with all relevant A2LA policies and requirements (NOTE: This may be accomplished via an audit against the actual A2LA policy and requirement documents; however, if all required elements of the relevant A2LA policies and requirements have been enveloped within the laboratory’s management system, then an audit of the management system itself will necessarily include an examination of compliance with relevant A2LA policies and requirements.)

QUESTION: Does clause 5.8.4 require continuous monitoring if items are stored or conditioned under specified environmental conditions for long periods of time?

RESPONSE: When environmental conditions are specified for the storage or conditioning of test or calibration items, these conditions must be “maintained, monitored and recorded” per section 5.8.4 of ISO/IEC 17025. This means that the laboratory must have a system in place to monitor & record environmental conditions to ensure that they remain in a specified state for the duration of the storage and/or conditioning period – no matter how long it is.

Appropriate procedures and facilities may include (but are not limited to):

a) Instrumentation programmed with an alarm that will be recorded when conditions fall outside set criteria and a procedure that addresses actions to be taken whenever an alarm is triggered (e.g., stopping & restarting the conditioning process).

b) The use of a chart recorder, data logging system, min/max thermometer or other device used for monitoring environmental conditions for the duration of the storage and/or conditioning process and a procedure that addresses actions to be taken when conditions fall outside set criteria (e.g., stopping & restarting the conditioning process).
Fall 2011 Training Schedule

Course:

**Title:** Introduction to Measurement Uncertainty
- 19-20 September 2011 - Columbus, OH ($795.00 non-members, $745.00 members)
- 14-15 November 2011 - Charleston, SC ($795.00 non-members, $745.00 members)

**Title:** ISO/IEC 17025 and Accreditation
- September 21-23, 2011 - Columbus, OH ($995.00 non-members, $945.00 members)
- November 16-17, 2011 - Charleston, SC ($795.00 non-members, $745.00 members)

**Title:** Root Cause Analysis and Corrective Action
- 18 November 2011 - Charleston, SC ($495.00 non-members, $445.00 members)

**Title:** Assessment of Laboratory Competence
- 17-21 October 2011 - Savannah, GA ($1595.00 non-members, $1545.00 members)

Venues:

**18-23 September 2011**
Hilton Columbus at Easton
3900 Chagrin Drive
Columbus, OH 43219
614 414 5000
Rate: $185.00 per Night

**16-21 October 2011**
Marriott Savannah Riverfront
100 General McIntosh Blvd.
Savannah, GA 31401
800 285 0398
Rate: $155.00 per Night

**13-18 November 2011**
Courtyard by Marriott Charleston Historic District
125 Calhoun Street
Charleston, SC 29401
843 805 7900
Rate: $179.00 per Night

For additional information, please contact Julie Collins, A2LA Training Program Manager, at 301 644 3235 or jcollins@A2LA.org.

Physical Measurement of Thermocouples:

**A Three-Day Course in Thermoelectric Thermometry**
Thermocouples are widely used; unfortunately, they are also widely misunderstood.

A thorough grasp of the fundamental mathematical, physical, and electronic concepts behind thermoelectric thermometry is an absolute requirement for making accurate measurements with thermocouples.

This course is about thermometry -- more specifically, thermoelectric thermometry. It follows a deep technical track starting with Seebeck and Onsager and culminating with practical measurements using thermocouples.

The course is broken into sections covering the mathematical, physical, and electronic considerations necessary in order to obtain reliable data in which you may have confidence.

Measurements and calibrations involving thermocouples raise a never-ending series of questions, which undermine the confidence level whenever measurements are taken – questions such as the following:

- How is MGO cable made? What difference does it make?
- Why are type K thermocouples used more often than type T thermocouples?
- Which type thermocouple is better suited in an oxidizing environment?
- How does a particular failure mode appear in terms of the data – or, better yet, in terms of the physical structure?
- What is “inhomogeneity” and how can it be measured? If you measure it, how can it be practically applied?

This three-day course answers questions such as these and more!
This course is initially being offered at your facility as on-site training.

**Cost:** $7500 ($2500/day) plus expenses and course materials.

For additional information and/or to schedule your on-site course, please contact A2LA’s Training Program Manager, Julie Collins, at 301 644 3235 or jcollins@A2LA.org.
On 16 August 2011, A2LA was honored by the Employer Support of the Guard and Reserve (ESGR) with the “Patriot Award” for employer continuing support of S Sgt Douglas Cowles – an A2LA calibration assessor who joined the Naval Reserve.

The ESGR is a Department of Defense organization within the Office of the Assistant Secretary of Defense for Reserve Affairs. The ESGR believes that, in today’s environment, civilian employers play a critical role in the defense of the nation by complying with existing employment laws protecting the rights of workers who also serve in the Reserve forces. The ESGR was established in 1972 to promote cooperation and understanding between Reserve members and their civilian employers.

The National Committee for Employer Support of the Guard conducts the Patriot Award program, designed to recognize employers who support a strong National Guard and Reserve force. Employers qualify for recognition when they practice leadership and personnel policies that support employee participation in the Guard and Reserve. Pam Wright, A2LA Calibration Accreditation Manager, was named for the award and gratefully accepted it on behalf of A2LA, which is listed on the ESGR website as an outstanding employer.

A2LA would like to thank S Sgt Doug Cowles for his service to our country and for nominating A2LA for this award.

For more information about these upcoming webinars and for instructions on how to register, please visit our website at: http://www.A2LA.org/training/workplace.cfm.
The American Association for Laboratory Accreditation (A2LA) is seeking technically qualified individuals interested in serving as paid, technical assessors in the following areas:

**Assessors for EMC/Telecom/Radio Laboratories (ISO/IEC 17025) & Product Certification Bodies (ISO/IEC Guide 65) -**
Ideal candidates will have the following qualifications:
- 10+ years technical experience in EMC/Telecom/Radio
- Knowledge of FCC equipment authorization processes
- Knowledge of APEC TEL MRA and related economies
- Experience with Quality Management Systems
- Great organizational and communication skills
- Willingness to work with great people!

**Assessors for Food Testing Laboratories (ISO/IEC 17025) -**
Ideal candidates will have the following qualifications:
- 10+ years technical experience in Food Microbiology
- Knowledge of the AOAC Food Guidelines*
- Experience with Quality Management Systems
- Great organizational and communication skills
- Willingness to work with great people!

**Please send resume to:**
**Trace McInturff**
A2LA Operations Manager
at: tmcinturff@A2LA.org

* A2LA Food Program requirements utilize the AOAC International Accreditation Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals.
**AACC Clinical Lab Expo**

By Larnell Simpson, A2LA Program Manager

This year, the American Association for Clinical Chemistry (AACC) Clinical Lab Expo broke pre-existing records with 675 exhibitors and more than 2,000 booths. Vendors from all over the world within every clinical discipline filled the Georgia World Congress Center from 24-28 July 2011.

The AACC Expo provided a forum for the full spectrum of tools that clinical lab scientists are looking for to meet new challenges in existing and emerging markets. Unique niche products were abundant. More revealing than the gadgets was the dense population of foreign exhibitors anxious to enter the American market. In fact, industry experts pointed to growth in foreign markets as the reason for the increase in exhibitor numbers and registration. Many of the exhibitors and visitors appeared to be familiar with laboratory accreditation through APLAC and ILAC signatories. Significant interest appeared to come from the Caribbean, South Africa and U.S. Government entities. Visitors to the A2LA booth had either had a personal experience with A2LA or recognized us as the leading accreditation body in the U.S. and therefore wanted to align themselves strategically with the industry leader.

A2LA Vice President/COO, Roxanne Robinson, served as an industry expert during a workshop discussion focusing primarily on ISO 15189 and the “marriage” between it and CLIA. Also participating in the panel discussion was Linda Crawford of IQMH, our Canadian counterparts. With newer, faster, smaller and cheaper point-of-care (POC) products becoming available, the question of consistency and safety for the end user is raised. The consistent message heard from interested parties was not "if" but "when" ISO 15189 would become a standard recognized equally in the U.S. In a forum built to showcase new and state of the art technology, it was apparent that recognition of ISO 15189 domestically has begun to grow in the U.S. and A2LA is proud to have achieved APLAC recognition for our ISO 15189 accreditation program. While it is certain that ISO 15189 has not yet achieved the recognition and acceptance in the U.S. that it has received abroad, it is reassuring to know that the proverbial seed has been planted.

If you have any questions about or if you are interested in the A2LA medical laboratory accreditation program, please contact Larnell Simpson, A2LA Program Manager, at 301 644 3231 or lsimpson@A2LA.org.

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**2011 IEEE EMC Symposium**

By Adam Gouker, A2LA Program Manager

The 2011 IEEE EMC Society’s International Symposium on Electromagnetic Compatibility was held on 14-19 August 2011 in Long Beach, CA. A2LA was represented by Adam Gouker, EMC Program Manager, and Mike Buzard, Accreditation Officer. This year’s symposium was well attended, with more than 1400 registered attendees and over 100 exhibitors.

Aside from networking on the exhibit floor, the symposium provided a unique opportunity to attend technical sessions, committee meetings, experiments, and demonstrations throughout the convention center. On Monday August 15th, A2LA attended ACIL’s Conformity Assessment Section (CAS) meeting to give a presentation on the status of our accreditation program and participated in a joint meeting with the VCCI Council (Japan) on Tuesday August 16th to discuss details of the MOU between our organizations. Both meetings were highly successful and proved beneficial to all participants.

A2LA appreciated the opportunity to attend this year’s symposium and looks forward to next year’s exhibition in Pittsburgh, PA, which is scheduled for 5-10 August 2012. We genuinely thank all of those who stopped by our booth to make personal introductions and ask questions relating to A2LA’s accreditation programs.

For inquiries or questions regarding the accreditation programs offered by A2LA, please contact A2LA headquarters at 301 644 3248 or visit us on the web at: www.A2LA.org.
The NELAC Institute (TNI) – Environmental Measurement Symposium

By Randy Querry, A2LA Accreditation Manager

TNI held its National Environmental Monitoring Conference and The Forum on Laboratory Accreditation in Bellevue, Washington the week of 14 August 2011.

Randy Querry, A2LA Life Sciences Accreditation Manager, represented A2LA at the meetings.

This was a well-attended event with over 400 participants, including environmental scientists, chemists, biologists, quality managers, laboratory directors, regulatory affairs managers, proficiency testing providers, assessors and regulators. Approximately fifty exhibitors were on hand to promote their services and products.

Numerous expert and executive committees conducted meetings throughout the week that spanned the various TNI programs, including proficiency testing, quality systems, field sampling activities, assessment and accreditation activities and stationary source audit sampling, to name a few.

Highlights from the week in Bellevue include:

SSAS Provider Accreditation Program

The Stationary Source Audit Sample (SSAS) Program was established for the environmental monitoring industry that measures emissions of pollutants from stationary sources such as smoke stacks. The US EPA Office of Air and Radiation administered a program that provided free audit samples to the states and local government agencies. Due to the increasing need for audit samples and the existence of private sector organizations that can provide them, the EPA has opted to discontinue supplying the samples. The US EPA’s Measurement and Technology Group, Office of Air Quality Planning and Standards has approved the TNI Stationary Source Audit Sample Program. A2LA is a TNI recognized SSAS provider accreditation body. Our assessment criteria are based on the TNI General Requirements for Stationary Source Sample Providers, Volume 1, Module 1 (2009-Rev 0.2) which is available on the TNI website at http://nelac-institute.org/ssas/.

A2LA is now accepting applications from SSAS Providers who are interested in being accredited under this program (http://www.A2LA.org/pt/proficiencytesting.cfm). We are also offering scope expansions to existing A2LA Accredited TNI proficiency testing providers that offer stationary source audit samples. For more information on our SSAS provider accreditation program, please contact Robert Knake at (301) 644-3218 or via email at rknake@A2LA.org.

FSMO Accreditation Program

The National Environmental Field Activities Program (NEFAP) has been very active in 2011. This program was established to provide an accreditation program for field sampling and measurement organizations (FSMOs) and to provide oversight of the accreditation bodies providing the FSMO accreditations. A2LA has been preliminarily recognized as a TNI accreditation body for FSMOs as a result of our successful completion of the document review phase of the TNI recognition process. As such, we have been approved to accept applications from FSMOs interested in TNI accreditation. The A2LA assessment and accreditation criteria are based on the TNI FSMO Sector Volume 1: General Requirements for Field Sampling and Measurement Organizations, which follows the format of ISO/IEC 17025:2005. Interested FSMOs may obtain an application for A2LA accreditation at http://www.A2LA.org/appsweb/ApplyTestLab.cfm. Please contact Lauren Hedrick with any questions pertaining to our FSMO accreditation program at (240) 575-7482 or via email at lhedrick@A2LA.org.

The next TNI Conference will be held in Sarasota, FL, 30 January –2 February, 2012.