



**A2LA News:** The Newsletter of the American Association for Laboratory Accreditation\_\_Feb 2007 , Number95

Editors: [Teresa Barnett](#)

Assistant Editors: [Elizabeth Smith](#) and [Tiffany White](#)

Web Layout: [Daren Valentine](#)

[Adobe PDF Version](#)

## In This Issue.....

### General Updates, Notices & Press Releases

- Metric Resources Available
- A2LA and NVLAP sign MOU with VCCI
- MQD-NCSLI Collaborations Continue
- Spring 2007 Training Schedule
- 2007 A2LA Conclave
- New & Departed Staff
- Sam Tyson Honored by ASTM
- Carroll Davis Honored by ASTM
- Joe Greenslade to Serve as IFI Director of Technology

### Meeting Summaries

- R&TTE International MRA Workshop
- 2007 Measurement Science Conference

### Updates on A2LA Operations & Policies

- New & Updated Documents
- New Application of ISO/IEC 17025 Requirements
- Changes to the A2LA Advertising Policy
- New Process for Extensions to the Accreditation Anniversary Date
- Root Cause Analysis
- Deficiencies Against The A2LA Policy on Measurement Traceability
- A2LA to Orient Medical Experts to ISO 15189

### International Activities and Updates

- Report on ILAC 2006

A2LA News February 2007

## Metric Resources Available

### Elizabeth J. Gentry (NIST)

Have you been searching for the appropriate unit symbol to use in a report (e.g., gm or g)? Updating your management system references? Looking for the conversion factor to convert between gallons and liters? If so, look no further. Available metric system reference publications include:

- NIST SP 330, The International System of Units (SI)
- NIST SP 811, Guide for the Use of the International System of Units (SI)
- NIST SP 1038, The International System of Units (SI) - Conversion Factors for General Use
- NIST LC 1136, United States and the Metric System
- NIST SP 304A, A Brief History of Measurement Systems with Metric System (SI) Chart

- NIST SP 365, Metric Conversion Card
- NIST SP 1020 Series, Consumer Package Labeling Guides- Selling by Weight, Volume, Count, and Area

Electronic versions of these and other metric resources are accessible online at [www.nist.gov](http://www.nist.gov). Bulk quantities are also available for on-the-job-training, lab tours, education outreach, metric system training, and management system references. Please contact Elizabeth Gentry at [TheSI@nist.gov](mailto:TheSI@nist.gov) or 301-975-3690 for more information.

[return to top](#)

## A2LA and NVLAP sign MOU with VCCI

A2LA and NVLAP entered into an MOU signed on December 13, 2006 in Tokyo, Japan with [Voluntary Control Council for Interference \(VCCI\)](#). VCCI is a Japanese organization which was started in the mid 1980s by four Japanese industry companies seeking to control electromagnetic interference (EMI) with the backing of the Japanese government.

By signing this memorandum, A2LA and NVLAP intend to provide ISO/IEC 17025 accreditation of any electromagnetic compatibility testing laboratory to the Normative Annex 1 Technical Requirements of Regulations (VCCI V-3) for voluntary control measures of VCCI. Additionally, A2LA and NVLAP will be responsible for notifying VCCI directly of all pertinent information for those laboratories that are accredited to perform testing to VCCI V-3. A form has been developed to capture the necessary information requested by VCCI and will be completed during the course of a laboratory's on-site assessment. For questions or comments on this agreement, please contact A2LA at (301) 644 3248.

To learn more about VCCI, we invite you to visit the VCCI web site at:  
[http://www.vcci.or.jp/vcci\\_e/index.html](http://www.vcci.or.jp/vcci_e/index.html)



*Brad Moore of A2LA and Kurt Fischer of NVLAP meet with representatives of VLAC and VCCI at the MOU signing dinner in Tokyo.*

[return to top](#)

## MQD – NCSLI Collaborations Continue

### Christopher L. Grachanen (Hewlett Packard)

Ask any person who has been a Metrology practitioner for any appreciable length of time about new practitioners entering into the Metrology field and you would likely get a response similar to "what new practitioners?" This sentiment echoes the alarm of many technical professionals at the lack of young people entering into engineering disciplines - and Metrology is certainly not immune. There have been

hundreds of articles written over the years about the mounting crisis America is facing due to the lack of new talent entering into technical professions. The allure of engineering is not striking a chord with young people, as the profession is often perceived as being dull, a lot of hard work and, in this day and age, overly susceptible to layoffs.

So what can be done to help improve the perception of engineering in general and Metrology in particular so that young talent will consider entering the profession? Folks from the [American Society for Quality's Measurement Quality Division \(ASQ MQD\)](#) and [NCSLI](#) have again joined forces to help improve this dire situation. From a grass root meeting of a few concerned Metrology practitioners, a new sub-committee has been created under the auspices of the NCSLI Education and Training committee. The sub-committee (designated 164.1) is called **Metrology Education & Training Outreach** and is chaired by Phil Smith of A2LA. The charter of the 164.1 sub-committee simply stated is:

*Develop and support initiatives and programs enabling Metrology Education & Training in the U.S.*

The sub-committee has had several meetings (the last one held during the 2007 [Measurement Science Conference](#)) to decide on a few specific projects they felt could be accomplished in the 2007-08 time frame while providing the 'biggest bang for the buck' in terms of impact. These projects are as follows, in no particular order:

- Test Equipment Clearing House – Provide guidance and help facilitate the donation of test equipment to metrology education & training programs in terms of tax related documentation and database of donations.
- Multimedia Outreach Project – Create a multimedia CD focusing on Metrology as a career to include videos (one short intro - e.g. 'elevator speech' - and one longer more comprehensive), hyperlinks and reference information about Metrology programs, Metrology resources, suggested reading, etc. In addition, a brochure will also be created with the same 'Metrology as a career' focus.
- Graduating Student Outreach Program – Provide new graduates of Metrology programs a congratulation letter and NCSLI welcome package (the possibility of a free 1 year student membership will be discussed with NCSLI Board of Directors).
- Establish an ANSI/ASTM Outreach Liaison – Leverage existing outreach programs to help promote Metrology careers and enhance NCSLI education & training outreach programs.
- NCSLI Section Coordinator Outreach Training – Provide guidance for section coordinators on ways to get students & professors to attend section meetings.
- Web-based Internship Posting Opportunity – Provide web-based means for posting Metrology Internship opportunities.

Current 164.1 sub-committee members include:

Philip Smith (Chair)	A2LA
Tony Abel	Central Georgia Technical College
Helga Alexander	Keithley Instruments, Inc.
Keith Bennett	Transcat
Keith W. Cable	Davis Inotek
Graham Cameron	Standards Council of Canada
Michelle Foncannon	CalSource, Inc.
Elizabeth J. Gentry	National Institute of Standards and Technology (NIST)
Christopher L. Grachanen	Hewlett-Packard
Paul Hannsen	Workplace Training
Georgia Harris	National Institute of Standards and Technology (NIST)
Shawn Mason	Boston Scientific
Edward Morse	UNC Charlotte
Dan Neal	DDN Laboratory Solutions, Inc.
Herbert O'Neil	Ridgewater College
Christopher J. Pelchat	Nebraska Public Power District
Mark S. Sanders	Lockheed Martin
Dave Schiebel	Butler Community College
Dilip Shah	E=mc <sup>3</sup> Solutions

Dr. Saiyld Fazal Wahid South	Texas College
Larry Yates	Consultant
Howard Zion	Transcat

To find out more information about this wonderful opportunity to get involved and help ensure that young folks are aware of the challenges and rewards of a Metrology career, please contact Phil Smith at [psmith@a2la.org](mailto:psmith@a2la.org) or 301 644 3204.

[return to top](#)

## Spring 2007 Training Schedule

Title: [Introduction to Measurement Uncertainty](#)

- April 23-24, 2007-Boston, MA (\$795.00 for non-members, \$745.00 for members)

Title: [ISO/IEC 17025 and Accreditation](#)

- April 25-27, 2007-Boston, MA (\$995.00 for non-members, \$945.00 for members)
- June 4-6, 2007-Livonia, MI (\$995.00 for non-members, \$945.00 for members)

Title: [Assessment of Laboratory Competence](#)

- May 7-11, 2007-San Francisco, CA (\$1595.00 for non-members, \$1545.00 for members)

Title: [Quality Assurance Analysis Tools for Calibration and Testing Laboratories](#)

- June 7-8, 2007-Livonia, MI (\$795.00 for non-members, \$745.00 for members)

### Venues:

#### **April 23-27, 2007**

Radisson Hotel Boston  
200 Stuart Street  
Boston, MA 02116  
617 482 1800  
Rate: \$169.00

#### **May 7-11, 2007**

Hilton San Francisco Fisherman's Wharf  
2620 Jones Street  
San Francisco, CA 94014  
415 885 4700  
Rate: \$169.00

#### **June 4-8, 2007**

Embassy Suites Hotel Detroit-Livonia/Novi  
19525 Victor Parkway  
Livonia, MI 48152  
734 462 6000  
Rate: \$149.00

[return to top](#)

## 2007 A2LA Conclave

A2LA will be holding its 2007 Conclave on March 19 – 26, 2007 at the Sheraton Columbia in Columbia, MD. Invitations were sent out in early January of 2007. Meetings on March 24th and 25th are open to interested parties and A2LA encourages laboratory representatives to attend. If you would like to attend the Conclave, participate in one of the technical advisory committees or if you should have received an invitation but have not, please contact A2LA (301 644 3248) or your Laboratory Services Officer.

[return to top](#)

## New & Departed Staff



Gina McInturff, Public Affairs Officer

A2LA has recently welcomed into its family [Gina McInturff](#) as our new Public Affairs Officer. Gina has extensive experience in graphic design and production art and as such will be serving not only as A2LA's receptionist, but also as an assistant to our Public Affairs Manager. She has an associate degree in Specialized Technology from the Bradley Academy for Visual Arts in York, PA and an associate degree in Specialized Business from Central Penn Business School in Summerdale, PA.

A2LA has also bid farewell to several of its long-time staff members. Berta Hakes, formerly A2LA's Executive Assistant, is now enjoying semi-retirement. Robert Saylor, formerly A2LA's Accountant, has accepted a position with an accounting firm in Gaithersburg, MD and Brad Moore, formerly an A2LA Senior Laboratory Services Officer, has accepted a position at NIST-NVLAP.

We wish each of them the best of luck in their new ventures. They will be missed at A2LA.

[return to top](#)

## Samuel Tyson Honored by ASTM

In December 2006, Samuel E. Tyson was honored with the [ASTM International](#) Founding Committee Award, the most prestigious award presented by ASTM International [Committee A01 on Steel, Stainless Steel and Related Alloys](#). Committee A01 recognized Tyson for his leadership and exemplary contributions to A01 in the development and promotion of voluntary consensus standards.

During the 1990s Tyson Chaired the ASTM activity within A01 that represented the United States in the [International Organization for Standardization \(ISO\)](#) Technical Committee 17, dealing with all steel products. Tyson is an ASTM fellow and recipient of the Award of Merit, the organization's highest honor for individual contributions to standards activities. He has also received the Committee F04 Robert E. Fairer Award (formerly called the M.O.S.E.S. award) in 1977 and in 1979, and a 2004 Award of Appreciation from A01.

Tyson started his career with Carpenter Technology Corp. in Reading, PA after he earned his B.S. in metallurgy from Pennsylvania State University. He began in the metallurgy department and rose to be general manager of quality assurance before retiring from the firm. During his tenure he focused on

manufacturing and technology of stainless steel products, the quality control of long-steel products made by his corporation, and standards for steel.

*(Details drawn from ASTM Press Release #7563.)*

[return to top](#)

## Carroll Davis Honored by ASTM

In January 2007, Carroll Davis was honored with the [ASTM International H.V. Churchill Award](#). Mr. Davis is the section head of analytical chemistry for the Alcoa Technical Center in Alcoa Center, PA and received the 2006 H.V. Churchill Award from ASTM [Committee E01 on Analytical Chemistry for Metals, Ores and Related Materials](#). The award, named for E01's first chairman and given for meritorious service, recognizes Davis' leadership as chairman of the main E01 committee and chair of three E01 subcommittees.

Davis' career has focused on analytical chemistry for aluminum and aluminum ores, quality system implementation and technical management. Before joining the staff of Alcoa Technical Center, he was section head, analytical chemistry, for the Reynolds Corporate Technology Center in Richmond, VA and he held positions at the Reynolds Metallurgy Laboratory and Reynolds Alumina Research. He holds a B.S. in engineering physics from the University of Arkansas and a master's in material science from the University of Virginia.

Mr. Davis is a member of A2LA and also serves on the A2LA Board of Directors. We offer our sincerest congratulations to him on this well-deserved recognition.

*(Details drawn from ASTM Press Release #7573.)*

[return to top](#)

## Joe Greenslade to Serve as IFI Director of Technology

Charles Wilson, the [Industrial Fasteners Institute's](#) director of engineering, will retire after 43 years with the manufacturers' organization. Joe Greenslade will succeed Wilson as the new IFI director of technology. In his capacity as technology director, Greenslade will serve as the official IFI representative to all standards organizations.

Greenslade has written on technical subjects during his career, which has included positions at Camcar-Textron and Rockford Headed Products in addition to serving as head of Greenslade & Co. (his dimensional calibration services business) for 29 years. He has served on ASME B1 and B18, ASTM F16 and SAE. Greenslade helped with efforts for the U.S. Fastener Quality Act and the Aerospace Screw Thread Conformity Task Forces. He has also served on the A2LA Board of Directors.

We wish him much success in this new venture!

*(Details drawn from Volume 29, Issue 1 of The Newsletter for Fastener Industry Management.)*

[return to top](#)

## R&TTE International MRA Workshop, 2006

The International Workshop on the Mutual Recognition Agreement for R&TTE (Radio & Telephone Terminal Equipment) was held in Tokyo, Japan on December 14 -15, 2006. Brad Moore represented A2LA at this year's workshop. Speakers representing [Japan Voluntary Laboratory Association for Telecommunications Equipment \(JVLATE\)](#), [Communication Information Network Association of Japan \(CIAJ\)](#), [TCB Council](#), [EU-Commission](#), [ANSI](#) and the [FCC](#) provided background information on their respective organizations. In addition each one also presented their current telecom and radio activities, schemes, directives, projects,

etc. An agenda , along with all other available information for the MRA Workshop, can be viewed by visiting the CIAJ website.

For inquiries or questions regarding the specific accreditation programs offered by A2LA, please contact A2LA headquarters at 301 664 3248 or visit our website.

Thank you to CIAJ for hosting this year's workshop.

[return to top](#)

## 2007 Measurement Science Conference

The [Measurement Science Conference](#) (MSC) was held in Long Beach, CA from January 22-26, 2007. A2LA was represented by Roxanne Robinson, Phil Smith, and Dana Leaman. A2LA presented a tutorial on the requirements of ISO/IEC 17025. A similar tutorial is slated for presentation again at next year's conference at Disneyland in Anaheim, CA, which is scheduled from March 10-14, 2008.



Phil Smith (A2LA) & Michelle Foncannon (CalSource) in A2LA booth at MSC 2007

Thanks to those who stopped by the A2LA booth with questions regarding our accreditation programs. For inquiries or questions regarding the accreditation programs offered by A2LA, please contact A2LA headquarters at 301 664 3248 or visit us on the web at: <http://www.a2la.org/>.

We hope to see you in Anaheim!

[return to top](#)

## New & Updated Documents

- The [Annex to the A2LA Policy on Measurement Uncertainty for Automotive and Materials Testing Laboratories](#) has been updated to a November 21, 2006 version. It is available on the A2LA website.
- The [Reference to A2LA Accredited Status – A2LA Advertising Policy](#) has been updated to a December 14, 2006 version. Please refer to the article in this newsletter which specifically addresses the changes made to this policy.

The following checklists have been updated to reflect the December 14, 2006 version of the Advertising Policy:

- *Assessor Checklist: General Criteria (ISO/IEC 17025 – 2005 - Full Text)* – dated December 15, 2006.
- *Combined Assessor Checklist: A2LA Animal Drug Testing Program and ISO/IEC 17025 General Criteria – Full Text* – dated December 15, 2006.
- *Assessor Checklist: General Criteria (ISO/IEC 17025 Full Text) Incorporated With A2LA's Environmental Program Requirements* – dated December 15, 2006.

Since each of these checklists contains the full text of the ISO/IEC 17025 standard, their distribution to outside organizations will be controlled. If you require a copy of any of these documents, please contact A2LA at 301 644 3248.

- The [General Requirements for Accreditation of ISO/IEC 17025 Laboratories](#) document has been updated to a February 6, 2007 version. Since the changes made do not significantly impact a laboratory's operations, it is in effect immediately. Please pay particular attention to the following two changes to this document:

(a) The *General Requirements for Accreditation of ISO/IEC 17025 Laboratories* now explicitly states that laboratories are expected to implement the standard in accordance with A2LA's applications, "[Understanding ISO/IEC 17025](#)", as they appear on the A2LA website. That has always been the understanding, but now it is stated explicitly within the General Requirements and also on the A2LA website.

(b) A2LA staff is in the process of starting a new system for proactively reviewing all expiring Scopes of Accreditation within a given month and automatically granting extensions to those that are considered to be "in good standing". Please refer to the article in this newsletter which specifically addresses this new process.

- A new guidance document, [Quality Control and Proficiency Testing Plan for ISO/IEC 17025-2005 Accredited Electrical, Product Safety, EMC, Environmental Exposure, General Mechanical, and Similar Test Laboratories](#), has been approved and controlled. Please note that this document is for guidance purposes only and may be found under the listing for "Guidance Documents" on the A2LA website document finder.
- The *ISO/IEC Guide 65 Assessor Checklist* has been updated to a January 26, 2007 version for product certification bodies. Since it contains the full text of the ISO/IEC Guide 65 standard, distribution to outside organizations will be controlled. If you require a copy of this checklist, please contact Trace McInturff at 301 644 3223.
- The [AOAC Food & Pharmaceutical Testing Program Requirements](#) have been updated to a January 18, 2007 version and the document is located on the A2LA website. The two corresponding checklists, *A2LA Food Testing Program Assessor Checklist* and *Combined A2LA Food Testing Program and ISO/IEC 17025 Assessor Checklist*, have also been updated to reflect the new requirements. Each is dated January 25, 2007. The latter checklist also incorporates the latest Advertising Policy revision as mentioned above. Since these checklists contain the full text of the AOAC food testing requirements and, in one case, the full text of ISO/IEC 17025, distribution to outside organizations will be controlled. All three of these documents will remain in transition with the prior versions until May 31, 2007. At that time, the three prior versions will be made obsolete. A [transition plan](#) explaining this appears on the website under "Notices" within the document finder. If you have questions about this specific change and transition or if you require a copy of either of these checklists, please contact Roger Brauninger at [rbrauninger@a2la.org](mailto:rbrauninger@a2la.org) or 301 644 3233.

[return to top](#)

## New Application of ISO/IEC 17025 Requirements

In January 2007, the A2LA Criteria Council voted to approve one new application of the ISO/IEC 17025:2005 requirements. This and other explanations may be found on the A2LA website, [Understanding ISO/IEC 17025](#).

~~~~~  
If a laboratory uses non-standard methods, but they are specified/required directly by the client during contract review, must the laboratory validate these methods per ISO/IEC 17025, Section 5.4.5?

If the non-standard method is actually listed on the lab's Scope of Accreditation (e.g., due to frequent or repeat requests for the method by their client) or if the non-standard method is a modification of a standard method listed on the lab's Scope, then the laboratory is responsible for validating that non-standard method per Section 5.4.5 of the standard if they wish the work to be considered accredited.

If the client specifies exactly which non-standard method the laboratory must use but that method is not listed in any form on the lab's Scope of Accreditation, then the client is essentially taking responsibility for the validity of the method itself. In this case, the laboratory need not validate the non-standard method required by their client. However, for the work to be considered accredited, the laboratory's Scope of Accreditation must clearly indicate that the laboratory is accredited to perform client-provided methods and the method required by the client must be within the stated ranges and/or parameters listed on the lab's Scope. Scopes of this nature are "technology-" or "parameter-based" and are the exception rather than the rule. In addition, the laboratory's contract review documentation must clearly indicate that the method used was chosen and required by the client.

For those Scopes of Accreditation that do list specific methods (i.e., Scopes that are **not** technology- or parameter-based) but also include a footnote conferring accreditation for other "similar types of methods", the laboratory is required to validate those "similar methods" in the same manner in which the A2LA assessor confirmed that they validated the specific methods that are actually listed on their Scope of Accreditation.

-----

If you have questions about this or any other application of the ISO/IEC 17025 requirements, please contact A2LA.

[return to top](#)

## Changes to the A2LA Advertising Policy

On December 14, 2006, the [Reference to A2LA Accredited Status - A2LA Advertising Policy](#) was revised. The change was necessitated following A2LA's peer evaluation by our Mutual Recognition Arrangement partners earlier in 2006 in order to bring our requirements for use of the "A2LA Accredited" symbol in harmony with international interpretation of relevant ISO/IEC 17011 criteria.

Section 3.1 of the advertising policy was revised (with a corresponding update to Section 10.2) to address the requirements of ISO/IEC 17011 which A2LA must remain compliant with as an internationally recognized accreditation body. ISO/IEC 17011 requires that when an accreditation body symbol is used on certificates or reports, it must also include an indication of the type of organization that is accredited (e.g., a testing lab, a calibration lab, a reference material producer, a proficiency testing provider, an inspection body, a product certification body, etc.). A2LA has always required that the "A2LA Accredited" symbol be accompanied by the organization's A2LA Certificate Number whenever used on reports or certificates. Now accredited organizations will also be required to include an indication of what type of organization they are with the "A2LA Accredited" symbol and certificate number whenever it is used on reports or certificates. Examples of how this should be displayed are included in the Advertising Policy itself. Implementation timeframes for organizations that are currently accredited, currently enrolled or yet to apply are also spelled out in the revision to Section 3.1.

Additionally, Section 10.5 was added to the advertising policy to require accredited laboratories to sign a sub-license agreement with A2LA prior to using the combined "ILAC MRA - A2LA Accredited" symbol. This practice has been in place for some time so this change to the advertising policy is in effect immediately.

Finally, a new Section 11 was added to the policy to address the issue of "accredited" vs. "non-accredited" work. Please review this section carefully as it now stipulates that, in essence, whenever a report/certificate presents results from tests/calibrations listed on a laboratory's Scope of Accreditation, the work must be done in accordance with all relevant ISO/IEC 17025 requirements (including those for the content of the report/certificate itself) whether or not the "A2LA Accredited" symbol is included on the report/certificate. This must be done in all cases, **unless** the laboratory's contract review documentation clearly indicates that their client does not want or need work done in compliance with ISO/IEC 17025. This change is effective as of January 1, 2007.

If you have any questions about these changes to the advertising policy, please contact your A2LA

Laboratory Services representative.

[return to top](#)

## New Process for Extensions to the Accreditation Anniversary Date

With the release of the February 2007 edition of the A2LA [General Requirements for Accreditation of ISO/IEC 17025 Laboratories](#), A2LA introduces a new process for obtaining an extension to an accredited laboratory's anniversary date. The result of this new process is twofold – A2LA is taking a proactive stance on scope extensions rather than a reactive stance; and A2LA will eliminate the confusion of having both accredited and expired Scopes of Accreditation listed together on the A2LA website.

Previously, if accredited laboratories were in the process of completing their renewal of accreditation and were approaching their accreditation anniversary date, they were required to submit a formal request to A2LA for an extension of their accreditation. If the laboratory was in good standing (e.g., provided the requisite material to A2LA before the imposed due dates, cooperated on the assessor assignment process, etc.) A2LA would extend the laboratory's accreditation for an additional sixty days in order to complete the accreditation process. The accredited scope(s) and certificate(s) were then updated and also posted to the A2LA website. The problem, however, came when extension requests were denied – the scope(s) and certificate(s) stayed on the A2LA website, but with expired anniversary dates.

With the new process for extensions, the A2LA Laboratory Services Officers (LSOs) will receive monthly reports containing information on which scope(s)/certificate(s): (1) are currently expired, (2) will be expiring at the end of the month, or (3) are currently extended and will be expiring at the end-of-the-month. The applicable LSO will review each laboratory's progress through their renewal process and, if the laboratory is in the aforementioned "good standing" with A2LA, will extend their accreditation for up to an additional ninety days in order for them to complete the renewal of accreditation process. If fundamental nonconformances are identified during the on-site assessment, extensions of accreditation will not be considered until the laboratory submits objective evidence demonstrating that the nonconformances have been appropriately resolved. When a laboratory is granted an extension, the revised Certificate(s) and Scope(s) of Accreditation are posted to the A2LA website, reflecting the extended anniversary date. Hard copies of the revised Certificate(s) and Scope(s) of Accreditation will be made available to the laboratory only upon request. As always, however, upon completion of the renewal process a hardcopy of the new Certificate(s) and Scope(s) of Accreditation is reissued, reflecting the renewed anniversary date.

The major change in this process comes when an extension of accreditation is not granted. Upon expiration, these Certificates and Scopes of Accreditation will be removed from the "A2LA Accredited" list on the A2LA website and placed on a separate list called "Laboratories in the Renewal Process". Laboratories that are placed on this list are currently considered **not** accredited but are acknowledged as being somewhere in the renewal process.

If you have any questions regarding this new process for extending a laboratory's accreditation anniversary date, please contact your Laboratory Services Officer.

[return to top](#)

## Root Cause Analysis

Root cause analysis is arguably the most challenging aspect of completing the corrective action response process following an on-site assessment. It is typically viewed as an involved process that takes away from other duties and in some cases, the personnel responsible for the completion of root cause analysis do not fully grasp the process involved.

Once the "how" and the "why" of root cause analysis is understood, the potential benefits become clear and the paradigm shifts from being viewed as a misuse of time to being viewed as an extremely useful tool in the management system.

The most important aspect of a root cause analysis is understanding that it is a methodology and not a recipe. The wide variety of situations that may require evaluation precludes a simple step-by-step procedure. Instead an approach should be developed that will guide us to the underlying causes, while maintaining the flexibility to accommodate the vast array of potential deficiencies.

Let's examine the 'how' of root cause analysis by considering an example:

\*\*\*

*Deficiency #11: Hourly temperature readings were not recorded for the oven, as required by SOP #123.*

*Root Cause: Technician was not aware of the requirement*

*Corrective Action: Retrain affected employee*

\*\*\*

While often submitted to A2LA as the final resolution of the deficiency, the root cause identified by the laboratory is actually only a starting point. The issue must be pursued further in order to get to the root of the problem:

Why wasn't the technician aware of the requirement?

*Because the technician received insufficient training.*

Why wasn't the training sufficient?

*Because this technician was not trained in accordance with our usual training program.*

Why wasn't the established procedure/program followed?

*The training coordinator was on extended medical leave at the time of this technician's training and as such the training was not conducted in accordance with our usual program.*

Although getting closer to the true root of the problem, this still does not explain why the established training program was not followed.

*The technician was not trained in accordance with the established program because the training coordinator was on extended medical leave and no one else was familiar with the program*

But why wasn't someone else familiar with the training program?

*The technician was not trained in accordance with the established program because the training coordinator was on extended medical leave and the quality system did not make provisions for a deputy.*

Bingo! The underlying root cause of this nonconformity is that the established training program had a significant hole in it. As such, the complete corrective action response that the laboratory should submit to A2LA should be along the lines of the following:

\*\*\*

*Deficiency #11: Hourly temperature readings were not recorded for the oven, as required by SOP #123.*

*Root Cause: The technician was not trained in accordance with the established program because the training coordinator was on extended medical leave and the quality system did not make provisions for a deputy.*

*Corrective Actions: 1) retrain employee and 2) review and revise training program to better address absences of key training personnel.*

\*\*\*

After undergoing the progression seen in our example, the inclination would be to take the next logical step and examine why a deputy was not provided for when the quality system was being developed. In many cases, proceeding as such would be prudent. However, in this instance, no new information is likely to result. The past cannot be changed and it isn't likely that any new corrective actions are going to arise from an examination of a decision made years ago.

As we see from this example, a proper root cause analysis not only addresses the immediate issue but also prompts further questioning into the bigger picture. In this example, a review of this root cause analysis will probably prompt further questions, such as "What other employees may have been trained under

similar circumstances?" and "For what other job functions/positions do we need to have fully trained and practiced deputies?"

This leads us to a better understanding of "why" root cause analysis is required by ISO/IEC 17025, particularly since solving the immediate problem is almost always simpler and easier. The purpose of root cause analysis is the orderly identification and correction of systemic errors. In our example, the immediate issue was that a particular technician had not received adequate training – a problem that is easy to rectify. But by performing a proper root cause analysis, a significant hole in the training program – which was a potential source for many future deficiencies – was closed.

All of this being said, in real world applications you may find that your investigation does in fact lead to a simple, singular mistake (e.g., *The technician forgot to record the temperatures*), and so perhaps your first instincts about a simplistic root cause are correct. In these cases, the only true test of the adequacy of the root cause investigation and the resulting corrective action is the presence or absence of subsequent failures.

[return to top](#)

## Deficiencies Against The A2LA Policy on Measurement Traceability

It seems inevitable that during every assessment a deficiency is cited regarding the A2LA Traceability Policy. The most likely issue is lack of an accredited calibration for a facility's standard or equipment. During investigation of the root cause of the deficiency, the first reaction is often one of frustration with the calibration provider for the omission. However, the root cause is, in reality, multifaceted and also involves contract review, purchasing and quality assurance of services received.

*The A2LA Policy on Measurement Traceability* (T1) states, "A2LA requires that all calibrations and verifications of measuring and test equipment, reference standards, and reference materials be conducted by a calibration laboratory accredited to ISO/IEC 17025 by a mutually recognized Accreditation Body; or a reference material producer accredited to ISO/IEC Guide 34 by a mutually recognized Accreditation Body; or a recognized National Metrology Institute (NMI) (i.e. one which supports the measurement comparison activities of the CIPM, Comité International des Poids et Mesures); or a mechanical testing laboratory accredited by A2LA to ISO/IEC 17025 and found to meet the A2LA Calibration Program Requirements (as indicated on their Scope of Accreditation); or a laboratory accredited by A2LA to ISO/IEC 17025 and found to meet the T9 requirements for their in-house calibrations".

What does it all mean? It means that a facility accredited by A2LA must obtain accredited calibrations and verifications of their standards and equipment by an entity that is recognized by A2LA. This would seem to be a straightforward process that involves finding a "recognized" provider and placing an order for service. However, there is a great deal more involved to ensure that the Traceability Policy is met and to avoid that T1 deficiency.

The process begins in a place most Quality Managers don't expect: with the purchase order. It is vitally important that the calibration laboratory's client include detailed information in the purchase order regarding exact specifications, technical information and most importantly a request for an *accredited* calibration or verification. If the equipment must be calibrated to within a certain range, this should be specified as such on the purchase order. Likewise if an accredited calibration is needed it should also be specified on the purchase order.

Let us examine section 4.6 of ISO/IEC 17025:2005, which states: "The laboratory shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations." But how are such a policy and procedure to be applied for the purchase of calibrations or verifications? Does the purchasing process ensure that accredited calibrations are requested? If it does not then the actual root cause of a cited deficiency lies in the laboratory's purchasing process, not necessarily with the calibration provider.

An additional facet of the root cause of a T1 deficiency lies with quality assurance of services received. Assume that a facility properly requests an accredited calibration, but the deficiency was still cited. Why?

Section 4.6 of ISO/IEC 17025:2005 continues to state, "The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or

requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. These purchasing documents shall be reviewed and approved for technical content prior to release."

This means that, when equipment or standards are received back from the calibration supplier, an inspection should be made not only of the equipment itself but also of the calibration or testing certificate to ensure that what was requested in the purchase order was received from the supplier. When this inspection is not made and an accredited certificate is, for whatever reason, not provided by the supplier, a deficiency will be cited by an A2LA assessor if no action is taken to remedy the situation with the calibration provider. In this case the root cause is two-fold: (1) the laboratory did not receive what they requested from their supplier, and (2) the laboratory did not inspect the certificate to ensure that they received what they requested.

To summarize, a laboratory cited with a deficiency for calibrations that do not meet the A2LA Traceability Policy should consider the following during their root cause analysis:

1. Does the purchasing procedure instruct staff to verify the accredited status of the calibration laboratory for the services needed and, if it does, are they directed to specifically request an accredited calibration report?

If the answer is yes then:

2. Does the process involved with inspection of incoming supplies direct staff to review the calibration reports for the proper accreditation body symbol requirements or an indication of accredited status in addition to required technical information?

The answers to these two questions should point to the true root cause of any problem cited by an A2LA assessor regarding T1 of the Traceability Policy. All of this being said, there are certainly requirements and obligations on the part of a calibration provider to ensure that their contract review procedures are adequate. As such, the processes and procedures of both the calibration provider and their client should work in harmony to ensure that the appropriate service is ultimately rendered.

If you have any questions regarding the A2LA Traceability Policy or the content of this article, please contact your A2LA Laboratory Services representative.

[return to top](#)

## A2LA to Orient Medical Experts to ISO 15189: *Medical Laboratories - Particular Requirements for Quality and Competence*

For some time it has been recognized that ISO/IEC 17025: *General Requirements for the Competence of Testing and Calibration Laboratories* did not adapt well to the environment of a medical laboratory. In 2003 a separate standard (ISO 15189: *Medical Laboratories - Particular Requirements for Quality and Competence*) was published to address this situation.

Since its release, ISO 15189 has become the international benchmark for medical laboratories throughout the world. ISO 15189 is being used for the accreditation of medical laboratories throughout Europe (with the exception of Switzerland), in Australia, New Zealand, Canada, Hong Kong, China, Thailand, and South Africa. Other regions are in various stages of adopting the standard. Those areas include Malaysia, The Peoples Republic of China and Japan.

By incorporating the quality precepts of ISO/IEC 17025 and ISO 9000, the standard describes a comprehensive quality system that allows medical laboratories to increase productivity, provide exceptional customer service and dramatically reduce errors. This translates to a laboratory's technical competence being recognized globally as well as regionally or nationally, since the standard has been recognized by [The International Laboratory Accreditation Cooperation \(ILAC\)](#) as the standard upon which to grant accreditation for medical laboratories.

A2LA has been investigating the addition of ISO 15189 accreditation to its service menu. We have taken steps to recruit and train experts in many medical disciplines to serve as potential assessors and to develop the necessary infrastructure to support the project. At the annual Conclave in March 2007, approximately 20 of these experts will undergo a medical orientation course to become familiar with the

provisions of ISO 15189, the [Clinical Laboratory Improvement Amendments of 1988](#) (CLIA88) and the A2LA assessment process.

On Saturday March 24th, the group will take up another challenge; that challenge is to form a standing A2LA Medical Technical Advisory Committee (MedTAC). This committee will consist of not only those that have undergone the orientation course, but also those parties (individuals and companies) that have an interest in the promotion of ISO accreditation of medical laboratories within the United States. The committee will develop answers to accreditation challenges encountered in the assessment process, define common language, and provide direction and expert opinion to A2LA, its Board of Directors and staff.

If you have an interest in attending the inaugural MedTAC meeting, please contact Ray Minnick at 301 644 3215.

[return to top](#)

## Report on ILAC-2006

### Peter Unger, A2LA President

The [International Laboratory Accreditation Cooperation \(ILAC\)](#) annual general meeting and associated committee meetings were held in Cancun, Mexico, 4-16 November 2006. This was the sixth occasion where ILAC met jointly with the [International Accreditation Forum \(IAF\)](#), the international organization for accreditation of certification bodies.

Highlights of the meetings include:

- Seven new signatory accreditation bodies for testing and calibration were added to the MRA: Canadian Association for Environmental Analytical Laboratories (CAEAL), Canada; Philippine Accreditation Office (PAO), Philippines; entidad mexicana de acreditacion (ema), Mexico; Turkish Accreditation Agency (TURKAK), Turkey; Bureau of Laboratory Accreditation, Department of Science Service, Ministry of Science and Technology (BLA-DSS), Thailand; and Assured Calibration and Laboratory Accreditation Select Services (ACLASS), USA. More recently, Ente Costarricense de Acreditacion (ECA), Costa Rica and Voluntary EMC Laboratory Accreditation Inc (VLAC), Japan signed the ILAC MRA for testing. This brings the total to 57 signatories from 46 economies. The ILAC MRA commits signatories to accept each other's accreditation and promote the acceptance of accredited data to users. The ultimate aim is to reduce duplication and facilitate trade.
- Emirates National Accreditation System (ENAS) was accepted as an ILAC Associate.
- Accreditation bodies from Libya and Algeria were accepted as ILAC Affiliates.
- The regional body, Inter-American Accreditation Cooperation (IAAC), was accepted as a signatory to the ILAC MRA.
- Four new stakeholders were accepted: CEOC International, Belgium; European Network of Forensic Science Institutes (ENFSI), the Netherlands; Croatian Laboratories (CROLAB) Croatia; and Association of Forensic Quality Assurance Managers (AFQAM), USA. Annette Dever of NATA Australia was appointed as the ILAC Secretary.
- The Accreditation Committee was assigned new work items to harmonize accreditation of remote calibration, implement ILAC policy on traceability of measurement results (ILAC P10), and develop guidance for accreditation of medical laboratories in accordance with ISO 15189 (the medical laboratory equivalent of ISO/IEC 17025).
- The Proficiency Testing Consultative Group has been asked to revise ILAC P9, *Policy on Participation in National and International PT Activities*, to provide more consistent application of PT participation policies by accreditation bodies.
- The General Assembly endorsed the election of the following officers to the ILAC Executive Committee for 2007-08:

|                                      |                                 |
|--------------------------------------|---------------------------------|
| Chair                                | Daniel Pierre, COFRAC, France   |
| Vice Chair                           | Peter Unger, A2LA, USA          |
| Arrangement Committee                | Orna Dreazen, ISRAC, Israel     |
| Accreditation Committee              | Merih Malmqvist, SWEDAC, Sweden |
| Marketing & Communications Committee | Graham Talbot, UKAS, UK         |

|                                        |                                  |
|----------------------------------------|----------------------------------|
| Joint Development Support Committee    | Maribel Lopez, ema, Mexico       |
| Arrangement Management Committee       | Llew Richards, IANZ, New Zealand |
| Unaffiliated Representative            | Orna Dreazen, ISRAC, Israel      |
| Laboratory Committee                   | Maire Walsh, Ireland             |
| Proficiency Testing Consultative Group | Tony Russell                     |



- The Terms of Reference for the joint meetings of the MRA management and decision-making bodies of ILAC and IAF were endorsed.
- A joint multi-lateral mutual recognition arrangement (MLMRA) for inspection body accreditation will be implemented after the guidance on ISO/IEC 17011 has been approved by ILAC and IAF.

The meetings involved over 200 people from more than 70 economies. In addition to myself as ILAC Vice Chair, A2LA staff was ably represented by Roxanne Robinson, A2LA Vice President, Trace McInturff, Operations Manager, Phil Smith, Public Affairs Manager, and Steve Medellin, Program Manager for Inspection Bodies. Ms. Robinson serves as convener of the working group on maintenance of the peer evaluation process documentation, and co-convenor of ILAC/IAF evaluation process documents. Mr. McInturff is an active member of the ILAC Accreditation Committee and the Proficiency Testing Consultative Group (along with Dan Tholen, A2LA assessor and proficiency testing consultant). Mr. Smith attended the Marketing and Communications Committee meetings. Mr. Medellin attended the Joint Working Group on Inspection Body Accreditation.

Further information on the ILAC meeting can be found at the ILAC web site (i.e. [www.ilac.org](http://www.ilac.org)).

[return to top](#)

A2LA Now Accepts



Please call Teresa McCarthy  
at 301-644-3229  
if you would like to pay by credit card.