A2LAtoday

The Newsletter of the American Association for Laboratory Accreditation



A2LA is proud to launch our newly designed website! The new design takes into consideration comments, suggestions and criticisms from all of the site's users over the past several years. The changes made are intended to make the site more user-friendly, such that information is more readily at hand and easily retrievable. All of the same information, documents, publications and announcements are contained on the new website but in a more intuitive layout that should make your search and retrieval processes more streamlined.

If you have any comments or questions concerning our new website design, please contact us at info@A2LA.org or 301 644 3248. ◆

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 A2LA Well Represented in Producing the New International Standard for Proficiency Testing

newsletter staff

- Editor: Teresa Barnett
- Layout Design: Gina McInturff



"World Class Accreditation"

A2LA Adopts New Scope & Certificate Format

As of July 20, 2009, A2LA has been publishing a new format for our Certificates and Scopes of Accreditation. These Certificates and Scopes will be crafted in color with the newly refreshed A2LA logo, tag line and color scheme and will contain the signature of A2LA President and CEO, Mr. Peter Unger. The Certificates and Scopes will be uploaded to the A2LA website in print-ready quality and all Certificates and Scopes that are updated, issued or re-issued on or after July 20, 2009 will appear in the new format.



Please be sure to alert your customers and end users of the new look to your accreditation documents so there is no confusion in the marketplace.

If you have any questions, please contact your Accreditation Services staff person directly or A2LA at 301 644 3248. 🔶



Course:

Title: Introduction to Measurement Uncertainty

- October 1-2, 2009-Indianapolis, IN (\$795.00 non-members, \$745.00 members)
- November 16-17, 2009-Charleston, SC (\$795.00 non-members, \$745.00 members)

Title: ISO/IEC 17025 and Accreditation

- September 28-30, 2009-Indianapolis, IN (\$995.00 non-members, \$945.00 members)
- November 18-20, 2009-Charleston, SC (\$995.00 non-members, \$945.00 members)

Title: Assessment of Laboratory Competence

 October 19-23, 2009-San Francisco, CA (\$1595.00 non-members, \$1545.00 members)

Venues:

September 27-October 2, 2009

The Westin Indianapolis

50 South Capitol Avenue Indianapolis, IN 46204 (800) 228 3000 Rate: \$159.00 Per Night

October 18-23, 2009

Sheraton Fisherman's Wharf

2500 Mason Street San Francisco, CA 94133 (888) 627 7024 Rate: \$165.00 Per Night

November 15-20, 2009

The Mills House Hotel

II5 Meeting Street Charleston, SC 29401 (843) 577 2400

For additional course information, please contact Julie Stevens, A2LA Training Coordinator, at 301 644 3235 or **jstevens@A2LA.org**.

Recent Promotions of A2LA Staff

So far in 2009, several reorganizations have occurred within A2LA's Accreditation Services department both to recognize advanced levels of achievement and to maintain an efficiently managed system.

Please join us in congratulating the following staff members who have been promoted within Accreditation Services:

- Pam Wright has been appointed an Accreditation Manager in the Calibration area.
- **Rob Miller** has been appointed an Accreditation Manager in the ElectroMechanical area.
- **Roger Brauninger** has been promoted to the level of Program Manager in the area of Biosafety testing.
- Adam Gouker has been promoted to the level of Program Manager in the area of EMC testing.
- Mike Hart has been promoted to the level of Program Manager in the area of Construction Materials testing.
- **Beth Carbonella** has achieved the level of Senior Accreditation Officer within the Materials/Physical testing group.

The organizational structure of A2LA's Accreditation Services department can be viewed below or via A115a – Accreditation Services Structure Chart which is available on the A2LA website. \diamond



Change in Terminology of the Best Measurement Capability (BMC) for Accredited Calibration Laboratories

Metrological traceability is being disseminated to the market by A2LA (an International Laboratory Accreditation Cooperation (ILAC) MRA signatory) accredited calibration laboratories and by National Metrology Institutes (NMIs) under the CIPM MRA. This traceability provides reliability in measurements around the world.

Currently, the services provided by accredited calibration laboratories are described by the term "Best Measurement Capability" (BMC) which expresses the lowest uncertainty that can be achieved during a calibration. This terminology is widespread in accreditation around the world.

NMIs have a similar description of the services provided to their customers; however, the term is "Calibration and Measurement Capability" (CMC).

The Bureau International des Poids et Mesures (BIPM) and the Regional Metrology Organisations (RMOs) have, in cooperation with the ILAC and Regional Accreditation Bodies (RABs), investigated the difference in terminology and have arrived at the following conclusion: will be changed to CMC (see ILAC 2009-08-20 BMC to CMC Circular). The intention is to achieve world-wide harmonization of terminology in the dissemination of metrological traceability.

A2LA has always required its accredited laboratories to publish its CMC on their Calibration Scope of Accreditation; however, it was termed "Best Uncertainty". In an effort to remain consistent with ILAC and its arrangement signatories, effective immediately, A2LA will begin transitioning our laboratories to the CMC terminology through our regular annual review and renewal of accreditation process; with the expectation that we will complete this transition by September 2010. During this transition period, references on A2LA scopes of accreditation may specify the BMC as well as the CMC terminology. As a consequence of the CIPM-ILAC Common Statement and the ILAC Circular (dated August 20, 2009) the BMC and the CMC shall be considered equal by laboratories, their customers, the market and regulators.

If you have any questions or concerns, please contact your accreditation officer. \blacklozenge

"In the context of the CIPM MRA and ILAC Arrangement, and in relation to the CIPM-ILAC Common Statement, the following shared definition is agreed upon:

CMC is a calibration and measurement capability available to customers under normal conditions:

(a) as published in the BIPM key comparison database (KCDB) of the CIPM MRA; or

(b) as described in the laboratory's scope of accreditation granted by a signatory to the ILAC Arrangement."

ILAC has decided to make a shift of terminology and in the future all references to BMC

CIRCULAR TO ALL ILAC MEMBERS

ACTION REQUIRED BY ILAC MEMBERS ON ILAC GENERAL ASSEMBLY RESOLUTIONS

- **TOPIC:** Change in Terminology Relating to Best Measurement Capability (BMC) and Calibration Measurement Capability (CMC)
- **DATE:** 20 August 2009

The ILAC General Assembly in Sydney 2007 and in Stockholm 2008, made the following resolutions:

ILAC Resolution GA 12.23

ILAC reaffirms its commitment to the agreement (ILAC resolution GA 11.20) between ILAC and BIPM by implementing a terminology change from BMC to CMC as soon as practicable. The General Assembly notes that other issues have been identified during the development of this agreement and these will be addressed in the new measurement uncertainty document currently under preparation.

It is important that action on the above resolution is taken as soon as possible. This will be addressed under the section of this agenda associated with Working Group 2.

ILAC Resolution GA 11.20

The ILAC General Assembly accepts the ILAC/BIPM joint paper on Calibration & Measurement Capabilities (CMC) as a significant step forward in the coordination of this concept between ILAC and BIPM.

ILAC will take this joint paper into account when preparing future documents on measurement uncertainty, in collaboration with the BIPM.

These resolutions were the result of extensive liaison and agreement by ILAC and BIPM, that a change in terminology from BMC (Best Measurement Capability) to CMC (Calibration Measurement Capability) was appropriate and desirable.

The background to these discussions may be found on the ILAC website under Publications and Resources, by scrolling down to Calibration and Measurement Capabilities (CMC) and clicking on CMC in the last sentence. The paper is entitled "Calibration and Measurement Capabilities – A Paper by the Joint BIPM/ILAC working group".

The following points are to be noted.

- 1. References to "BMC" in scopes of accreditation for calibration facilities should be amended to read "CMC". This change is considered to be a terminology change only, as BMC and CMC have been agreed to be equivalent.
- 2. The timeframe for the terminology change has been set at two years from the date of this circular.

The means whereby this change should be made has not been defined but ILAC Members are invited to review the scopes of accreditation of calibration facilities during the next relevant scheduled visit and make the relevant change in terminology from BMC to CMC. This should be undertaken in line with a review of the CMCs of the NMI which provides the calibration laboratory with its metrological traceability. (The CMCs of NMIs can be found on the CIPM-database.)

- 3. Progress by ABs in implementing this terminology change will be reviewed at the next evaluation of the AB that occurs two years from the date of this circular.
- 4. It is recognised that further work is required by ILAC and BIPM to clarify and harmonise matters around CMC. This work is ongoing and further relevant information will be provided at an appropriate time.
- 5. The intention of this terminology harmonisation is to improve the dissemination of metrological traceability. The adoption of the same terminology in relation to accredited calibration facilities and NMIs will greatly assist in this process and provide clarity in the market place.

The ILAC Marketing and Communications Committee has also been asked to prepare suitable material for ABs to distribute that defines the benefits of this terminology change for end users.

New & Updated Documents

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.

P106 – Branch System Policy was updated on June 11,2009. (Document Finder category: "Policies")

R212 – Specific Requirements: Nondestructive Testing Laboratory Accreditation Program was updated on June 11, 2009. (Document Finder category: "Specific Requirements")

R307 – General Requirements: Accreditation of ISO/IEC Guide 65 Product Certification Bodies was updated on August 7, 2009. (Document Finder category: "General Requirements")

R301 – General Requirements: Accreditation of ISO/IEC 17020 Inspection Bodies was updated on August 7, 2009. (Document Finder category: "General Requirements")

P101 – Reference to A2LA Accredited Status-A2LA Advertising Policy was updated on August 7, 2009 (Document Finder category: "Policies"), as was the associated assessor checklist, C104 - General Checklist: Reference to A2LA Accredited Status-A2LA Advertising Policy (Document Finder category: "General Checklists").

R104 – General Requirements: Accreditation of Field Testing and Field Calibration Laboratories was updated on August 6, 2009 (Document Finder category: "General Requirements") and the associated checklist, C103 – General Checklist: Accreditation of Field Testing and Field Calibration Laboratories (Document Finder category: "General Checklists"), was similarly updated on August 7, 2009.

F117 – Technical Staff Matrix for Accreditation: ISO/IEC 17025 was updated on August 12, 2009 (Document Finder category: "Application Forms").

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

Traceability and Use of the NIST Website for Timer & Stopwatch Calibrations

By Rob Knake, A2LA Accreditation Officer

If your organization offers calibrations for timers & stopwatches and uses the "Official U.S. Time Clock" reference standard (available through the National Institute for Standards and Technologies (NIST) website at http://nist.time.gov) to conduct a "Direct Comparison" for calibration, problems arise when it comes to establishing traceability.

More than likely your organization is using a personal computer with a web browser to utilize this resource. However, there is a serious flaw in this approach as your computer's clock will actually supersede the time displayed on the website when your web browser is left open. In essence, once you have opened the website on your internet browser the time being displayed is actually the time being kept by your computer's own internal clock. It is true that many web browsers will automatically refresh at pre-set time intervals, 5, 10, or 15 minutes for example, but during the time in between refreshes, the time displayed is not actually coming directly from NIST but rather from your own personal computer. As such, you no longer have an established traceability chain.

Please note that NIST does provide traceable reference standards for timer & stopwatch calibrations in other formats (telephone & radio signal) that are available to the public and maintain the traceability chain. For more information regarding acceptable methods and acceptable traceable reference standards please refer to NIST Recommended Practice Guide 960-12 Stopwatch and Timer Calibrations, which is available at http://tf.nist.gov/general/pdf/2281.pdf.

As tempting as it may be, the time clock provided by the NIST website should not be used as your laborareference stantory's traceabildard as ity is not established and your laboratory would not be meeting the requirements of ISO/IEC 17025:2005 or P102 - A2LA Policy on Measurement Traceability.

NEW APPLICATIONS OF ISO/IEC 17025 REQUIREMENTS

In August 2009, the A2LA Criteria Council voted to approve four new applications of the ISO/IEC 17025:2005 requirements. These and other explanations may be found on the A2LA website section, "Understanding ISO/ IEC 17025".

Is the master list my lab created to meet Section 4.3.2.1 of the Standard considered a record or is it considered a document that would be subject to document control requirements?

RESPONSE: A2LA considers a laboratory's "master list" to be a record and not a document that is subject to document control requirements. Section 4.3.2.1 of ISO/IEC 17025 indicates that the clause can be met by use of either a master list (subject to requirements associated with record management) OR an equivalent document control procedure (subject to document control requirements).

Per Section 5.9.1 of the Standard, what sort of quality control practices can my laboratory implement for destructive and/or pass/fail types of tests in which no equipment is used?

RESPONSE: Section 5.9.1 requires each laboratory to have quality control procedures for monitoring the validity of tests or calibrations undertaken. This clause also lists possible ways in which this monitoring may occur, but it is clearly stated that the items in the list are not mandatory ("This monitoring... may include...") and that the list is not intended to be comprehensive ("...may include, but not be limited to..."). As such, for tests or calibrations for which the items listed in 5.9.1 are not practical or possible, other means for monitoring quality control may be employed - such as observation of technicians and technique during routine training, performance evaluations, internal audits, etc. The laboratory is not required to have a single procedure to meet the requirements of Section 5.9.1 and so if other forms of monitoring quality control are employed, these may certainly be described in other procedures within the management system, such as training procedures, internal audit procedures, etc. The outcome of all monitoring activities, however, must be recorded and reviewed in compliance with Section 5.9.1.

3 My laboratory is part of a multi-laboratory organization. All laboratories within my organization are A2LA accredited and fall under the classification of a "branch system" as defined by A2LA. If my laboratory receives work from a client but sends the work to another of our accredited branch laboratories (with the final report being issued by my laboratory), is this considered sub-contracting per Section 4.5 of the Standard?

RESPONSE: As stated in Part C, Section I of R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories, A2LA accreditation is "site specific", meaning that each discrete location is considered to be its own entity – whether or not it is part of a larger, accredited, multi-laboratory organization. As such, transfer of work among accredited locations within such a "branch system" is considered to be sub-contracting and is subject to all requirements related to sub-contracting in ISO/ IEC 17025 and related A2LA requirements documents.

Do Sections 4.1.5 (b) and (d) of the Standard require our laboratory to have a Code of Ethics in place?

RESPONSE: ISO/IEC 17025 does not explicitly require that a laboratory have a Code of Conduct or Code of Ethics in place as part of its management system. That said, however, each accredited organization is strongly encouraged to have such measures in place to aid in fully complying with these sections of the Standard and to aid in substantiating the ethical grounds upon which an organization operates if their actions are ever called into question.

A helpful tool to assist any organization in developing and maintaining a Code of Conduct or Code of Ethics is an ethics selfassessment. Such a self-assessment can help an organization identify those areas where they are on strong ethical ground as well as areas that they may wish to examine further as an opportunity to enhance or further define their ethical and leadership practices. Some points to consider in an ethics selfassessment might include:

Updates on A2LA Operations & Policies

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- Do you strive to be a role model for ethical behavior?
- Are your statements and actions consistent with professional ethical standards?
- Are your statements and actions honest even when circumstances would allow you to confuse the issues?
- Do you advocate ethical decision making by your organization's Board, management team and staff?
- Do you use an ethical approach to conflict resolution?
- Do you initiate and encourage discussion on the ethical aspects of your organization's management issues?
- Do you use your authority solely to fulfill your responsibilities and not for self-interest or to further the interests of family, friends or associates?
- When an ethical conflict confronts you or your organization, are you successful in finding an effective resolution and ensuring it is followed?
- Do you demonstrate your organization's vision, mission and value statements in your actions?
- Do you have a routine system in place for members of your organization to make full disclosure and reveal potential conflicts of interest?

- Do you maintain confidences entrusted to you?
- Do you demonstrate through personal action and organizational policies zero tolerance for any form of staff harassment?
- Do you expect and hold staff accountable for adherence to your organization's ethical standards (for example, through periodic performance reviews)?
- Do you hold all staff and business partners accountable for compliance with professional standards, including ethical behavior?
- Are you mindful of the importance of avoiding even the appearance of wrongdoing, conflict of interest or interference with free competition?
- Do your organization's structure and processes ensure the integrity of its activities?
- Does your organization present itself accurately and honestly to the public?
- Do you understand and abide by local, state and federal laws and regulations applicable to you?

(Information drawn from The Joint Commission on Accreditation of Healthcare Organizations, The American College of Healthcare Executives and the Higher Learning Commission.) **♦**

What is an Acceptable Standard Method for Surface Plate Flatness Calibration?

By Robert Knake, A2LA Accreditation Officer

A very important part of the calibration process is determining which method your laboratory will use to perform the calibration. For many calibrations the choice is usually fairly simple and straightforward. The reason for this is that there is often a standard method available that is widely accepted throughout the industry. These methods are often published in international, regional, or national standards and are easy to access for use. However, there are times when determining a standard method for a specific calibration is not clear or straightforward.

Concern was raised in the A2LA Measurement Advisory Committee (MAC) about the confusion that exists among A2LA accredited organizations regarding an acceptable standard method for the calibration of Surface Plate Flatness. It was determined at the MAC meeting held during the A2LA 2009 Conclave that the method described in the article titled "How to Calibrate Surface Plates in the Plant" published in the October 1955 edition of The Tool Engineer is considered an acceptable standard method for the calibration of Surface Plate Flatness. This method is also commonly referred to as the "Moody Method" as it was written by Mr. J. C. Moody.

For those laboratories performing calibrations for Surface Plate Flatness as described in the "Moody Method", A2LA considers you to be using a standard method that does not require validation. If your laboratory chooses to use another method for the calibration of Surface Plate Flatness, your method may be subject to validation per ISO/IEC Section 5.4.5.

For further information please contact Robert Knake at 301 644 3218 or rknake@A2LA.org. ◆

Meeting Summaries

Veterinary Program Update

By Matthew Torres, A2LA Accreditation Officer

In February 2009, the first internationally-recognized accreditation to the revised A2LA Veterinary Laboratory Accreditation Program requirements was granted to the National Veterinary Services Laboratories in Ames, IA and the National Veterinary Services Foreign Animal Disease Diagnostic Laboratory in Plum Island, NY. The Veterinary Laboratory Accreditation Program requirements were revised to include the *OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Disease, 2008*, which differ from ISO/IEC 17025. Dr. Peter Wright, an Expert Participant on the OIE Biological Standards Commission since 1991, states, "We are hearing more and more credit being given to quality management systems like ISO 17025, and veterinary laboratories around the world are picking up on that. Both the quality management system and method validation principles must be present together."

The National Veterinary Services Laboratories (NVSL) provides a wide variety of services and information for both domestic and international purposes centered on diagnosis of domestic and foreign animal diseases, support of disease control and eradication programs, reagents for diagnostic testing, and training. This accreditation program incorporates specific requirements with respect to unique aspects of veterinary laboratories while maintaining standard requirements of ISO/IEC 17025 accreditation. Dr. Elizabeth Lautner, NVSL Director, says, "The NVSL is pleased to achieve accreditation to the new requirements. This is a significant milestone in our continued enhancements of our quality management system to better meet the needs of our customers, stakeholders, and the public."

The NVSL has recently added a new, major facility to their expansive Iowa campus: The new National Centers for Animal Health laboratory facility, which opened in July



2009. Functions of the National Veterinary Services Laboratories are located in this new facility along with the National Animal Disease Center and the Center for Veterinary Biologics.

In March 2009, A2LA initiated a new veterinary training course for those laboratories seeking to understand ISO/IEC 17025:2005 and the new Veterinary Laboratory Accreditation Program requirements. Daren Valentine, A2LA Communications Manager, and Matthew Torres, A2LA Accreditation Officer, conducted the pilot veterinary training course for several state, university, and industry veterinary laboratories at the Maryland De-

American Association for Clinical Chemistry/ Clinical Laboratory Expo (AACC) Annual Meeting

Trace McInturff, Operations Manager, and Randy Querry, Accreditation Manager-Life Sciences, represented A2LA at the 2009 AACC Annual Meeting in Chicago, IL from July 19 – 23. AACC is an international medical society of clinical laboratory professionals, physicians, research scientists and other individuals involved with clinical chemistry and related disciplines.

A2LA attended the US Technical Advisory Group for ISO/TC 212 meeting held in conjunction with the AACC annual meeting. Topics of discussion included the ongoing revisions to ISO 15189 and the current progress on revising several other ISO technical standards. The next US TAG ISO/ TC212 meeting will be held during the CLSI Leadership Conference scheduled for March 22 – 26, 2010 in Baltimore, Maryland.

A2LA exhibited at the AACC Clinical Lab Expo to promote A2LA accreditation and the ILAC Arrangement. The Clinical Lab Expo is said to be the largest clinical laboratory tradeshow in the world, hosting some 600 exhibiting organizations. A2LA fielded many questions from attendees regarding A2LA's history and background, the A2LA assessment and accreditation processes and costs, ISO I5189:2007 standard applications, the ILAC Arrangement, and other accreditation services offered by A2LA, such as reference material producer and proficiency testing provider accreditation.

We were pleased with the interest in our programs and look forward to attending future clinical conferences. ◆

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partment of Agriculture College Park Animal Health Diagnostic Laboratory in College Park, MD. Peter Unger, A2LA President & CEO states, "These new training classes show A2LA's commitment to teaching veterinary laboratories about ISO/IEC17025 - by far the most popular standard for accrediting veterinary laboratories throughout the world. The standard is so valuable because of its flexibility to give power back to the laboratories where it belongs. This makes ISO/IEC 17025 what the most cutting-edge labs are using today." This class is ideal for those seeking to understand 17025 and the role of quality managers in a veterinary testing setting. Essentially, ISO/IEC 17025 explains the duties of the quality manager and an understanding of the interpretation of ISO/IEC 17025 will provide veterinary quality managers with the confidence they need to fulfill their duties. Dr. Thomas Jacobs, Assistant State Veterinarian of Maryland says, "The ISO 17025/OIE Standards were clearly explained by experienced instructors. The handouts, power-point and blackboard presentations were clear and precise. Overall the training allowed us to begin the accreditation process with confidence." In addition to training on ISO/IEC 17025 and A2LA's R216 (Veterinary Laboratory Accreditation Program Requirements), select state participants also shared interest in A2LA's ISO 15189 Medical Accreditation Program. Interested parties may refer to the completely refreshed A2LA webpage which has prominent tabs dedicated to Veterinary Medical Testing and (Human) Medical Testing.

A2LA Accreditation Officer, Matthew Torres, also attended the ACVIM (American College of Veterinary Internal Medicine) conference in Montréal, Québec, Canada from June 2, 2009 to June 6, 2009. This venue was an international educational venture hosted by an American veterinary specialty group. The CVMA (Canadian Veterinary Medical Association) also had a large presence and role in organizing this meeting which was beneficial to all attendees. The overall focus of the meeting, similar to the NAVC (North American Veterinary Conference) and WVC (Western Veterinary Conference) was continuing education for veterinarians with a clinical, practice-oriented theme. The meeting differed, however, in that the ACVIM, like the American Society of Veterinary Clinical Pathologists (ASVCP), also has a focus on board certification in addition to continuing education. Many attendees expressed interest in ISO/ IEC 17025 accreditation in general and veterinary laboratory accreditation specifically.

The high quality of the talks presented at the ACVIM conference made this one of the best venues for broad veterinary continuing education because it is a meeting of internists with diverse specialty groups represented. Many talks were offered on the subjects of ACVIM consensus statements, infectious diseases, neurology, gastroenterology, and food animal health. The outcome of this year's ACVIM consensus statements was communicated effectively by the United States Animal Health Association (USAHA) newsletter published daily. \blacklozenge

2009 NCSL International Conference

This year's NCSLI conference was held at the San Antonio Convention Center in San Antonio, Texas during the last week of July. The theme for this year's convention was "Metrology's Impact on Global Trade". A2LA was represented by Roxanne Robinson, A2LA Vice President/COO, Pamela Wright, A2LA Accreditation Manager, and Rob Knake, A2LA Accreditation Officer. In keeping with this year's theme, Ms. Robinson presented "Metrology & Accreditation – Their Role in the Global Market" at one of many informative technical sessions that were offered during the course of the conference.



A2LA was one of approximately 100 exhibitors that attended the conference, many of which were our accredited laboratories. The conference allowed us to meet with professionals and experts in the calibration arena and explain the benefits that accreditation has to offer. It was also a valuable opportunity for our accredited laboratories and other interested parties to meet with A2LA staff in person and have any of their questions regarding accreditation answered. We look forward to next year's conference which is scheduled for July 25 – July 29, 2010 in Providence, Rhode Island. The theme for 2010 will be "21st Century Innovations in Metrology".

We at A2LA wish to express our sincere 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/. ◆

A2LA Well Represented in Producing the New International Standard for Proficiency Testing

By Dan Tholen, A2LA Assessor

ISO/IEC 17043 (*Conformity assessment - General requirements for proficiency testing*) will soon be an approved International Standard, and A2LA's influence will run throughout the document. ISO CASCO Working Group (WG) 28 held their 5th and possibly final meeting on June 29-July 1 in Milwaukee and recommended that FDIS 17043 be advanced to ballot as an approved International Standard. If the ISO and IEC ballots are successful the Standard will be published in early 2010.

WG28 consisted of 57 experts from 33 different countries and 5 liaison organizations. While the WG is representative of the entire ISO CASCO membership, including all areas of conformity assessment and countries, 7 of the members of WG28 have direct ties to A2LA - by far the most of any accrediting body. Several A2LA assessors and experts from A2LA-accredited organizations participated extensively on WG28. Assessor and A2LA Member, Dan Tholen, served as Convener of WG28 and was supported by assessors, Jeff Gust (Measure PT), Arlene Fox (AOAC International), and Werner Schaefer (Cisco Systems). Also on the Working Group were Henrik Nielsen (HN PT - representing Denmark), Tony Russell (formerly of NATA, Australia), and Tom Coyner (formerly of APG, Inc.) - all from organizations accredited by A2LA as PT providers (as are Measure PT and AOAC International). Dan, Jeff, Arlene, Henrik, Tom, and Tony all attended the meeting in Milwaukee.

ISO/IEC 17043 is a revision of ISO Guide 43-1 and 43-2 (1997). It used ILAC G13:2007 as a base document, and, like ILAC G13, it shares a lot of requirements with ISO/IEC 17025. The revision resulted from an "urgent" request from ILAC in a Work Item Proposal filed in June 2006. The work item was approved by CASCO members and the first meeting of WG28 occurred in December 2006. The rapid progression of the project reflects the urgency felt by ILAC members - it is very unusual to have a Standard approved in less than 3 years from the start of work (4-5 years is typical; 7 years is not unusual). While it is not clear how many ILAC members offer accreditation of PT providers, the number is growing, as are the number of PT



providers seeking accreditation. Many accrediting bodies, particularly in Europe, have delayed offering accreditation of PT providers until there was an ISO standard. Currently A2LA accredits 16 PT providers, which also places A2LA among the global leaders, along with NATA (Australia) and UKAS (United Kingdom).

If, as expected, ISO/IEC 17043 is approved by the ISO and IEC memberships in late 2009, a cascade of events will occur quickly - many accrediting bodies (including A2LA) will use it, rather than ILAC G13, as the general requirements for accreditation; ILAC will withdraw G13 as a current document; APLAC and ILAC (and possibly other regions) will begin negotiations to extend the Mutual Recognition Agreement to include PT providers; and 17043 will become an EN standard - giving it the force of law in Europe (according to the Vienna Agreement). Several accrediting bodies, APLAC, and IAAC are all planning training for PT providers and assessors to prepare for the transition.

The new standard retains most of the management system requirements of 17025 (and ILAC G13), with a few changes to reflect changes in ISO 9001 made since 2005 as well as some wording changes for clarity. The technical requirements are very similar to ILAC G13, but contain a few major changes; most significantly, PT providers in the calibration area will be required to use assigned values with metrological traceability and PT providers in other areas will need to at least consider the traceability and uncertainty necessary to assure that the assigned values are fit for their intended use. Consensus values are allowed in non-

International Activities

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calibration areas, but providers will be required to demonstrate the suitability of the values. The other significant change is that PT providers will not be allowed to subcontract the design of the PT scheme, the evaluation of performance, or the authorization to issue the final reports. Less significant changes include the need to report the uncertainty of the assigned values and to include more information in the final report, including summary statistics for different methods used by participants and general technical comments on performance. These changes are based on the experience of the members of WG28 and their feeling that the most important benefit of PT is as a tool for quality improvement. PT providers see results from all methods in use, they see how mistakes can occur, and they know what participants do to best agree with the assigned value - knowledge that should be shared with all participants.

The members of the writing group brought to WG28 the values that are shared throughout A2LA - external verification of competence, traceability of measurements, and continual quality improvement for all laboratories. The new standard reflects that commitment. \blacklozenge



The American Association for Laboratory Accreditation

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