



**American  
Association  
for Laboratory  
Accreditation**



**A2LA News:** The Newsletter of the American Association for Laboratory Accreditation\_\_ *December 2002, Number 80*

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**A2LA Signs IAAC Recognition Arrangement**

On October 24, 2002, A2LA joined INMETRO of Brazil and SCC of Canada in signing the newly established Inter-American Accreditation Cooperation (IAAC) Multilateral Recognition Arrangement (MLA).

The Inter-American Accreditation Cooperation is a relatively new regional cooperation of accreditation, certification and inspection bodies, as well as representatives from testing and calibration laboratories and other interested parties from countries in North and South America. Similar to APLAC and EA, IAAC's main objective is to facilitate commercial exchange among the member nations or blocs of nations in the economies it serves through a system of recognition arrangements of various types of conformity assessment bodies.

By signing the arrangement, A2LA, SCC and INMETRO agree to formally recognize and promote the equivalency of each other's laboratory accreditations. Since these three bodies already recognize each other under the ILAC (International Laboratory Accreditation Cooperation) Mutual Recognition Agreement (MRA), this first signing is largely symbolic but forms the foundation for expanding recognition in the Americas. Additional IAAC member accreditation bodies in the Americas are preparing for formal IAAC on-site evaluations and expect to be invited to sign the MLA once all requirements are met. Once this happens, A2LA accreditations will become more widely recognized.



*Photographs of A2LA's President Peter S. Unger at the IAAC 7th Annual Meeting*

To learn more about IAAC, we invite you to visit the IAAC web site at <http://www.ibpinetsp.com.br/iaac/>

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**A2LA Recognized Under Florida Building Code**

The State of Florida has developed a system for product approval under the new Florida building code. This new system is meant to ensure that safe products and technologies are used in building construction and also to encourage new products and technologies that can increase safety or meet safety requirements through less expensive means. Criteria has been established for approval of public and private entities that test, evaluate and certify panel walls, exterior doors, roofing products, skylights, windows, shutters and structural components as well as new and innovative building products. This approval may be obtained through either local jurisdictions for local approvals or the Florida Building Commission for statewide approval. A2LA accreditation has been recognized as meeting the requirements for testing laboratories that conduct tests on these products. Thus, A2LA accredited laboratories may apply to the Building Commission for statewide approval. Further information may be obtained from

[www.floridabuilding.org](http://www.floridabuilding.org) or by contacting Teresa C. Adams, A2LA Operations Manager, at 301 644 3202 or [tcadams@a2la.org](mailto:tcadams@a2la.org).

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## Labs Must Notify A2LA Before Moving

The A2LA *Conditions for Accreditation* have recently been revised to require laboratories to notify A2LA of changes **or pending changes** to their location. In the past laboratories were asked to notify A2LA once the relocation was complete. At that time the Scope of Accreditation was revised and reissued to reflect the new address and information was then collected related to specifics associated with the move (e.g., new floor plan, recalibration records, etc.). With this revision to the *Conditions*, A2LA's process for handling laboratory relocations has also been modified. First, the Scope of Accreditation will not automatically be revised and reissued. Rather, this will be done once sufficient information has been presented to confirm the laboratory's ongoing competence at the new site. During this time the laboratory's accreditation will be classified as 'inactive' until such demonstration of ongoing competence is provided and confirmed by A2LA staff and the prior assessor.

The rationale behind this change is the fact that many laboratory moves require a brief, on-site visit by an assessor to determine ongoing competence. Thus, our policy will be to require such an on-site visit unless there are valid reasons or special circumstances for not doing so. This decision will be made by A2LA in consultation with the last assessor(s) to visit the laboratory. It is important to point out that if A2LA is appropriately informed of **pending changes** to a laboratory's location, the period of inactivation should be minimal as we will have had advance notice of the need to review supporting documentation or schedule a brief visit to the new facility.

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## ISO/IEC 17025 Internal Audit and Management Review Requirements

Now that most laboratories have undergone assessment to ISO/IEC 17025 and have transitioned from ISO/IEC Guide 25, annual review applications and supporting documentation are starting to come into A2LA based on the new standard. Two of the most important pieces of supporting documentation are the records of the internal audit and management review. The requirements of ISO/IEC 17025 regarding these items are more specific than in ISO/IEC Guide 25, and failure to meet the new requirements is the single most common reason for a follow-up letter to a lab and a delay in completing the annual review.

### Internal Audit

Section 4.13.1 requires an internal audit to "verify that its (the laboratory's) operations continue to comply with the requirements of the **quality system and this international standard** (ISO/IEC 17025). The internal audit programme shall address **all** elements of the quality system, **including the testing and/or calibration activities** (emphasis added)." In these two sentences ISO/IEC 17025 defines three items that must be covered by a complete internal audit: compliance with ISO/IEC 17025; compliance with its own quality system (defined in section 4.2.1 as its "policies, systems, programmes, procedures and instructions"); and competence in its testing and/or calibration methods as defined in its Scope of Accreditation.

ISO/IEC Guide 25 only required a record of findings of the audit. ISO/IEC 17025 requires much more. Section 4.13.3 requires, "The area of activity audited, the audit findings and corrective actions that arise from them shall be recorded." As a record of the audit to conformance to ISO/IEC 17025, our assessors use the *Assessor Checklist: General Criteria (ISO/IEC 17025)*. Many labs also use it as guidance and documentation of their own internal audits. However, it only covers one of the three items required for an internal audit. Our assessors also use a *Method Review Matrix* as a record of observations of test methods. In auditing the test methods, it is important that individuals actually be observed performing the testing. Since our assessors only spend a few days in a lab, it may not always be practical for them to observe the entirety of a long-term test or a rarely performed test, but this should not be a problem for an internal audit where time is less of a constraint. A2LA does not require the use of these documents by laboratories and any format that records the same basic information is acceptable.

While a review to ISO/IEC 17025 will audit the conformance of internally generated documents to the format and requirements of the standard, it does not verify that the lab actually follows its own procedures. This is the final item that must be covered by the internal audit. Since quality systems are highly individualized, there is no standard form used by A2LA as a record of a review. One option is a checklist of SOPs with room for a date, sign off, and observations.

Finally, included with records and findings of the audit the lab should include records of corrective actions (as defined in section 4.10 of ISO/IEC 17025) taken as a result of the internal audit.

### Management Review

ISO/IEC 17025 is similar to ISO/IEC Guide 25 in that it only requires the findings of the management review and consequent actions be recorded. However, it is more specific in addressing the items that must be covered in a management review. Section 4.14.1 lists ten specific items that the lab "shall" take into account. The question we will ask is, "How did you take account of these items?" We cannot dictate how this is answered, but one of the easiest ways is to have an agenda or minutes showing that each of the items was covered.

There is one final issue regarding internal audit and management review that will cause a delay in completing the annual review. Many labs that are part of a production facility are also functioning under one of the ISO 9000 standards. With the focus on production it is easy for the lab's internal audit and management review to get swallowed up as part of the company-wide audit/review process. All of the items above must be addressed **as related to the laboratory**. This does not mean that the lab's internal audit and management review cannot be part of a larger, company-wide review, but all requirements of ISO/IEC 17025 must be addressed for the lab.

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### Last Hard Copy of A2LA News

This December 2002 issue is the last hard copy issue of A2LA News. All 2003 issues will be published electronically only and posted to the A2LA web site at [www.a2la.org](http://www.a2la.org).

If you wish to receive notification when the new issues are posted, be sure to subscribe to our free news information service. To subscribe, go to the A2LA web site and select the link "Subscribe to our mailing list" that is located on the home page.

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### Uncertainty Classification for Test Methods Now Available

A2LA published its *Interim Policy on Measurement Uncertainty for Testing Laboratories* in August 2000 as a means to facilitate the transition to compliance with ISO/IEC 17025. The document identified five categories of test methods and corresponding levels of rigor required for analysis of measurement uncertainty.

Following implementation of the *Interim Policy*, A2LA asked assessors to include information on the classification of test methods assessed during on-site assessments. Based on that information and experience, discipline-specific lists of example test methods in each category were developed. These lists were reviewed by the various A2LA Technical Advisory Committees and the approved lists published as the *Annex to A2LA Interim Policy on Measurement Uncertainty for Testing Laboratories*. This document is available electronically at [http://www.a2la.org/policies/Annex\\_uncert\\_policy.pdf](http://www.a2la.org/policies/Annex_uncert_policy.pdf).

As is stated in the introduction to the *Annex*, it is imperative to note that the A2LA *Interim Policy* is subject to change as additional guidance is made available internationally, and the *Annex* is only intended to provide examples of how test methods are typically categorized. The classifications are dependent on the particular circumstances in a laboratory and may not apply in all cases. The fact that a method is listed in Category I or II of the *Annex* does not absolve a laboratory from compliance with 5.4.6.2 of ISO/IEC 17025 or the need to address measurement uncertainty.

The *Annex* will be updated as new examples become available. If you have any questions or input regarding the *Annex*, please contact Warren Merkel at [wmerkel@a2la.org](mailto:wmerkel@a2la.org) or 301 644 3204.

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### Measurement Uncertainty Claims for Site Calibration

Calibration Scopes of Accreditation contain a column titled "Best Uncertainty." Best uncertainty (often called Best Measurement Capability or BMC) is defined as the smallest uncertainty of measurement that a laboratory can achieve within its scope of accreditation when performing more or less routine calibrations of nearly ideal measurement equipment. When performing a calibration, accredited calibration laboratories are required to report the **actual** measurement uncertainty on the calibration certificate of the measurement in question, not the accredited best uncertainty unless that best uncertainty actually applies. This is of particular importance when dealing with calibrations performed at the client's site. Uncertainties for calibrations performed at a customer's site can be expected to be larger than the BMC listed on the A2LA Scope. Allowances must be made for aspects such as environmental conditions at the place of calibration and adverse effects caused by transportation of the calibration equipment. The usual allowance for the uncertainty introduced by the item being calibrated (e.g., resolution) must also be considered and this, on its own, could result in the calibration uncertainty being larger than the BMC.

Under a new policy issued by A2LA, the Scopes of Accreditation for calibration laboratories that are

accredited specifically for performing site calibration will include a disclaimer explaining this in detail. The disclaimer is being added to alleviate some of the misunderstandings that have been expressed about the information contained on the Calibration Scopes of Accreditation. The new policy, explained in the *A2LA Policy for Claims of Measurement Uncertainty for On-site Calibrations on Scopes of Accreditation*, was sent to all accredited and enrolled calibration laboratories in November 2002. The information contained in this policy document has also been included in the revised [A2LA Specific Criteria for the Accreditation of Site Testing and Site Calibration Laboratories - October 2002](#).

For more information on BMCs, please visit the [Frequently Asked Questions](#) section of the A2LA web site.

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## A2LA Program Manager Spotted

If you get the ASTM magazine *Standardization*, turn to page 34 of the November 2002 edition. The handsome technician in the photograph (the one without the stopwatch) is A2LA's own Randy Querry. The picture was taken in about 1992 when he worked for the Cement & Concrete Reference Laboratory with another A2LA employee, Joe Kane. Regardless of what the caption says, Randy is actually trying to use the giant clock to figure out when happy hour starts. The guy with the stop watch is helping.

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## Spring 2003 Training Course Schedule

### Title: ISO 17025 and Accreditation

- February 3-4, 2003-Charleston, SC
- April 7-8, 2003-Dallas, TX
- June 2-3, 2003-Chicago, IL

### Title: Introduction to Measurement Uncertainty For Testing Labs\*

- February 5-6, 2003-Charleston, SC
- April 9-10, 2003-Dallas, TX
- June 4-5, 2003-Chicago, IL

### Title: Introduction to Measurement Uncertainty for Calibration, Mechanical and Dimensional Labs\*

- February 5-7, 2003-Charleston, SC
- April 9-11, 2003-Dallas, TX
- June 4-6, 2003-Chicago, IL

### Title: Advanced Measurement Uncertainty Seminar

- February 10, 2003-Charleston, SC
- April 14, 2003-Dallas, TX
- June 9, 2003-Chicago, IL

For a description of these courses and information on registration costs, please visit our web site, [www.a2la.org](http://www.a2la.org), and click on the "Training Catalog" link. You can also contact Ms. Julie Stevens, A2LA Training Coordinator, at (301) 644 3235 (e-mail: [jstevens@a2la.org](mailto:jstevens@a2la.org)). \*If you are not sure which measurement uncertainty course is applicable, please [contact A2LA](#).

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## Revised Requirements for Food Testing Labs

A2LA has begun the transition that will affect food and pharmaceutical testing laboratories that are currently accredited or are seeking to become accredited under the *A2LA Food Microbiology Program Requirements and/or the A2LA Food Chemistry Program Requirements*. The change involves moving from an A2LA version of AOAC International's Analytical Laboratory Accreditation Criteria Committee's (ALACC) criteria to the use of the requirements as spelled out in the *AOAC International Accreditation Criteria for Laboratories Performing Food Microbiological and Chemical Analyses in Foods, Feeds, and Pharmaceutical Testing*. The requirement's changes involve minor clarifications; however, a number of formerly disparate food chemistry and food microbiological technical requirements have also been unified as well.

The most significant change involves the manner in which A2LA will administer the program. Because this document contains both the full text of the ISO/IEC 17025-1999 standard as well as the specific criterion pertinent to food testing laboratories, it is available only from AOAC International ([www.aoac.org](http://www.aoac.org)). Because it also utilizes the full text of the requirements document, the associated assessor checklist will

not be made available electronically at the A2LA web site. Copies of the checklist will instead be made available only to those laboratories that can provide evidence that they have obtained a legitimate copy of the requirements document.

As of June 1, 2003, all A2LA laboratories pursuing accreditation to the food program requirements shall be assessed against the new requirements. Prior to June 1, 2003, assessment to the new requirements is optional.

Please contact Roger Brauning at 301 644 3233 or via email at [rbrauning@a2la.org](mailto:rbrauning@a2la.org) for further information on this program.

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## News From Financial Services

- With all A2LA assessments beginning January 1, 2003, we will be billing our clients at an hourly rate instead of 'to the nearest ¼ day.' Currently, A2LA's daily assessor services rate is \$800 per an 8-hour day; therefore, we will be billing for assessment services at \$100/hour. Assessment services will no longer be rounded to the nearest ¼ day;
- Effective January 1, 2003, the IRS mileage rate for privately owned vehicles will decrease from \$0.365 to \$0.36;
- A2LA continues to accept MasterCard and Visa payments for membership dues, training invoices, accreditation fees, etc. Please contact Teresa McCarthy at 301 644 3229 or [tmccarthy@a2la.org](mailto:tmccarthy@a2la.org) if you would like to make a credit card payment.

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## Board News

The A2LA Board of Directors (BOD) met October 17-18, 2002 at A2LA Headquarters in Frederick, MD.

Meeting highlights include the following items:

- Operations Manager, Teresa Adams, presented Board members with the results of a recent report on the most common deficiencies cited by assessors during A2LA assessments. The report includes data from 299 assessment reports from 81 different assessors covering all fields of accreditation. The data was collected and analyzed from March through September 2002. The information points to several key areas where problems, misunderstandings and misinterpretations of the accreditation requirements commonly occur and can be used as a training tool to ensure a more thorough understanding of the requirements for accreditation. The report is posted on A2LA's web site at the following URL: [http://www.a2la.org/guidance/Common\\_17025\\_Defs.pdf](http://www.a2la.org/guidance/Common_17025_Defs.pdf);
- Board members discussed the difficulty testing laboratories are having with the ISO/IEC 17025 requirements for measurement uncertainty. This issue was discussed extensively at the International Laboratory Accreditation Cooperation (ILAC) Technical Accreditation Issues Committee (TAIC) meeting held in Berlin in September 2002 (see Uncertainty Major Topic At International Forum);
- Board members approved the addition of another Accreditation Council member, Mr. James Ingram, a calibration expert;
- The A2LA policy on handling relocations of accreditation laboratories was revised (see *Labs Must Notify A2LA Before Moving*);
- The A2LA 2003 budget was approved.

The next meeting of the A2LA BOD will be held on March 10, 2003 in Columbia, MD.

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## ILAC General Assembly and Conference Held in Berlin

The International Laboratory Accreditation Cooperation (ILAC) 2002 General Assembly and Conference were held in Berlin, Germany on September 16-27, 2002 in conjunction with the International Accreditation Forum's 2002 Annual Meeting. A brief summary of some of the issues discussed at the various meetings is provided below:

### ILAC General Assembly News

Highlights of the General Assembly were:

- Two more accreditation bodies formally signed the ILAC Mutual Recognition Arrangement (MLA), IPQ (Portugal) and BmWA (Austria);
- Peter Unger, A2LA President, was re-elected to the ILAC Executive Committee for 2003-2004 and

- will continue to serve as the Chairman of the Arrangement Management Committee;
- Jacqueline Sample, U.S. Navy, was newly elected as Chair of the ILAC Public Affairs Committee. Ms. Sample is also a member of the A2LA Accreditation Council;
- The ILAC Articles of Incorporation and revised Bylaws were approved. Among the most significant changes was the restriction of the term "ILAC full member" to MRA signatories only. Non-signatories become voting "associates" or non-voting "affiliates;"
- The ILAC budget was increased by almost 20% to reduce the subsidies being provided by NATA (Australia) as host of the Secretariat. The A2LA fee will be about \$9,000 for 2003. Further increases are expected in 2004 to pay for some important projects, such as peer evaluator training;
- The design of the ILAC mark to be used by MRA signatories and their accredited labs on test reports was discussed. There was some debate over whether there should be a "common mark" with the IAF or a separate ILAC MRA mark and IAF mark. A formal letter ballot of the ILAC membership will decide the issue.

The 2003 ILAC General Assembly will be held in Bratislava, Slovakia.

### **Technical Accreditation Issues Committee (TAIC) News**

The A2LA Vice President, Roxanne Robinson, attended the ILAC Technical Accreditation Issues Committee (TAIC) meeting. Specific ISO/IEC 17025 interpretation issues were discussed in an effort to increase the uniformity of assessments for all MRA partners. A related article on the TAIC's discussion regarding the application of measurement uncertainty in testing appears in this issue of A2LA News.

### **ILAC 2002 Conference News**

The ILAC Conference was held September 23-25, 2002. Presentations on a number of important accreditation issues were made, including measurement uncertainty, traceability, and assessor competency. Summary slides containing the major points of discussion are available for viewing at <http://www.ilac-iaf-2002.de/pdf/session0.pdf>.

### **ILAC and IAF**

ILAC is the world's principal international forum for the development of laboratory accreditation practices and procedures, the promotion of laboratory accreditation as a trade facilitation tool, the assistance of developing accreditation systems, and the recognition of competent test facilities around the globe. More information on ILAC can be obtained at [www.ilac.org](http://www.ilac.org).

The ILAC Mutual Recognition Arrangement forms a global network of accredited testing and calibration laboratories that are assessed and recognized as being competent by ILAC Arrangement signatory accreditation bodies. The signatories have, in turn, been peer-reviewed and shown to meet ILAC's criteria for competence. A2LA is a signatory to the ILAC MRA along with 41 other accreditation bodies worldwide.

The International Accreditation Forum, Inc. is a world association of Conformity Assessment Accreditation Bodies and other bodies interested in conformity assessment in the fields of management systems, products, services, personnel and other similar programs of conformity assessment. IAF members accredit certification or registration bodies that issue certificates attesting that an organization's management, products or personnel comply with a specified standard (called conformity assessment).

Many accreditation bodies worldwide are full-service accreditation bodies that offer accreditation not only for laboratories but also for certification/registration bodies. Thus, many organizations are members of both ILAC and IAF. A Joint Committee on Closer Cooperation (JCCC) has been working with ILAC and IAF to determine common goals. As a first step, the organizations are holding joint meetings to determine the feasibility of closer cooperation.

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### **Uncertainty Major Topic at International Forum**

Compliance with the ISO/IEC 17025 section 5.4.6.2 requirement specifying that testing laboratories must have and apply procedures for estimating uncertainty continues to be difficult for many testing laboratories worldwide.

Three key reasons for this have been identified:

- Few consensus standards currently address measurement uncertainty for testing;
- There are very few relevant examples of uncertainty budgets available for specific testing disciplines;
- Testing laboratory clients are not always requesting measurement uncertainty information on the testing reports and may not understand the importance or relevance of this information.

Application of measurement uncertainty in testing was one of the key issues recently discussed at the

International Laboratory Accreditation Cooperation (ILAC) Technical Accreditation Issues Committee (TAIC) held in Berlin, Germany on September 19, 2002. ILAC is the world's principal international forum for the development of laboratory accreditation practices and procedures, the promotion of laboratory accreditation as a trade facilitation tool, the assistance of developing accreditation systems, and the recognition of competent test facilities around the globe.

The ILAC TAIC committee members agreed that to meet section 5.4.6.2, laboratories must be able to demonstrate to the accreditation body that measurement uncertainty budgets for their accredited tests can be readily generated **at the time of the on-site assessment**. Presenting the accreditation body assessor with procedures on how to calculate the uncertainty values without providing actual budgets is not sufficient to demonstrate compliance with the clause.

To assist testing laboratories two regional accreditation body cooperations, EA (European Cooperation for Accreditation) and APLAC (Asia Pacific Laboratory Accreditation Cooperation), are developing guidance documents that will include example budgets. EA and APLAC will finalize their guidance documents independently and provide them to the ILAC TAIC for review. It is possible that the two documents will be merged into a single ILAC publication.

Through the development of appropriate examples, the inclusion of more detailed budgets in the consensus standards, and educational efforts to explain the value of measurement uncertainty information, the international accreditation body community believes that testing laboratories will be able to fully meet the ISO/IEC 17025 requirement in the coming years. Meanwhile, accreditation bodies are providing their accredited laboratories with practical implementation guidelines.

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### **Certification Program Recognizes A2LA Accredited Labs**

The Safety Equipment Institute (SEI) is a private, non-profit organization that administers third-party certification programs to test and certify a broad range of safety and protective products.

Safety and protective products certified by SEI must periodically undergo compliance testing to specified standards at independent testing laboratories that have been evaluated and awarded contracts by the SEI Board of Directors. Three SEI contracted labs are also A2LA accredited. In an effort to minimize redundant assessments of these three laboratories, SEI has agreed to rely on the laboratories' A2LA assessments in place of SEI evaluations.

Under the agreement signed on May 7, 2002, A2LA will assess the three laboratories in accordance with A2LA requirements and for the specific test methods agreed upon by the laboratories and SEI and provide the assessment reports to SEI within a specified time frame. A2LA must notify SEI of any changes to the accreditation status of the laboratories that could impact the laboratories' status in the SEI certification program. SEI reserves the right to conduct interim audits of the laboratories if necessary.

SEI is accredited to ISO/IEC Guide 65:1996 by the American National Standards Institute (ANSI) and the Standards Council of Canada (SCC). To find out more about SEI, you can visit its web site at [www.seinet.org](http://www.seinet.org).

A2LA continues to seek opportunities to increase the value of A2LA accreditation by getting users of laboratories to formally recognize A2LA accreditation as an alternative to their own laboratory approval programs where such recognition is mutually beneficial to all parties. Laboratories seeking to gain wider recognition of their A2LA accreditation with specific parties can contact A2LA for guidance and assistance.

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### **Announcements**

#### **2002 Annual Meeting**

All interested parties are welcome to attend A2LA's 2003 Annual Meeting, which will be held on Monday, March 10, at the Sheraton Columbia Hotel, in Columbia, MD from 8:00 to 10:00 am. Additional details will be included in the next issue of *A2LA News* to be published during the first quarter of 2003. Make your plans now to attend.

#### **2001 Annual Report**

A2LA's 2001 annual report is available for viewing and printing at A2LA's web site, [www.a2la.org](http://www.a2la.org). To obtain a hard copy of the Adobe PDF version directly from A2LA, please send an e-mail request containing your complete mailing address to Ms. Karen Rudd at [krudd@a2la.org](mailto:krudd@a2la.org).

#### **Uncertainty Publications Now Available**

Two new uncertainty guidance documents are now available on our web site, [www.a2la.org](http://www.a2la.org). The first

focuses on the estimation of measurement uncertainty for dimensional testing and calibration results ([http://www.a2la.org/guidance/est\\_mu\\_dimen.pdf](http://www.a2la.org/guidance/est_mu_dimen.pdf)). The second document provides guidance specifically for testing labs and includes a brief discussion on obtaining uncertainty estimates from control chart data and an introduction to the ISO *Guide to the Expression of Uncertainty in Measurement* ([http://www.a2la.org/guidance/est\\_mu\\_testing.pdf](http://www.a2la.org/guidance/est_mu_testing.pdf)). We hope that these documents will be useful additions to the available literature on estimation of measurement uncertainty. As always, we welcome your comments and questions (please contact Thom Adams at 301 644 3219, or by email at [tmadams@a2la.org](mailto:tmadams@a2la.org)).

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