



**American
Association
for Laboratory
Accreditation**



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A2LA News: The Newsletter of the American Association for Laboratory Accreditation__November 2005, Number 90

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Philip Smith, Business Development Manager, and Dana Leaman, Calibration Program Manager, at the 2005 NCLSI Conference

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First Lab A2LA-Accredited to ISO/IEC 17025:2005

Our congratulations go out to [Battelle Columbus Operations, Instrumentation Services Laboratory](#) located in Columbus, OH, for being the first laboratory accredited by A2LA to the new ISO/IEC 17025:2005 standard. The ISO/IEC 17025:2005 standard was released on May 15, 2005, and Battelle achieved accreditation to the new version of the standard on October 13, 2005. The management at Battelle has provided support to the ISL staff to get initial accreditation and maintain it through training efforts and acquisition of modern standards.

[Battelle](#) is a global science and technology enterprise that develops and commercializes technology and

manages laboratories for customers. Battelle also teams with more than 800 federal, state, and local government agencies, providing science and technology in the areas of national security, homeland defense, health and life sciences, energy, transportation, and environment and is also one of the founding members of the National Conference of Standards Laboratories International (NCSLI).

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Press Release: Involvement in NACLA Terminated

The American Association for Laboratory Accreditation (A2LA) announced that on October 28, 2005, the A2LA Board of Directors voted to terminate membership and discontinue involvement with the [National Cooperation for Laboratory Accreditation \(NACLA\)](#) effective December 31, 2005.

The initial goal of NACLA was to reduce the redundant accreditations of laboratories in the United States in accordance with the Congressional policy of the [National Technology Transfer and Advancement Act \(NTTAA\)](#). This goal is consistent with the A2LA vision of "one accreditation accepted everywhere." A2LA was one of the founding members and advocates of the NACLA organization. In December 2004, A2LA had withdrawn its signatory status to the NACLA *Mutual Recognition Agreement* (MRA). After a prolonged series of attempts to implement reduction of duplicative accreditations, it was determined that the current direction of NACLA is contrary to achieving the original goal.

"We need to concentrate our energies on participation in effective international MRAs (i.e.: ILAC, APLAC, EA, IAAC) to reduce the redundant accreditation burden on our accredited laboratories," said Dr. William G. Kavanagh, Chairman of the A2LA Board of Directors.

A2LA will continue to support and assist efforts to reduce or eliminate the need for redundant, duplicative accreditations. A2LA is committed to working toward a viable system of MRAs among domestic accreditation bodies by relying on international MRAs.

The American Association for Laboratory Accreditation (A2LA) is a nonprofit, non-governmental, public service, membership society. The mission of A2LA is to provide comprehensive accreditation services for laboratories, inspection bodies, proficiency testing providers, and reference material producers. Services are available to any type of laboratory or inspection body, be it private or government. A2LA is the largest multi-discipline accreditation body in the United States and the second largest in the world.

If you would like additional information please contact Philip Smith by phone at 301 644 3204 or by email at psmith@a2la.org.

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New & Updated Documents:

- On August 29, 2005, A2LA issued a revision to the [General Requirements for Accreditation of Laboratories](#). The revision addresses issues such as: updating references to ISO/IEC 17025:2005 and ISO/IEC 17011; requirements for root cause analysis when laboratories respond to deficiencies; the option to have observations documented within the assessor report package; updates to the [A2LA Advertising Policy](#); a new section addressing extraordinary assessments; and further discussion of the process by which extensions of accreditation are granted. This document is available on the A2LA website or as a hardcopy upon request.
- The A2LA [Conditions for Accreditation](#) form was updated to a September 2, 2005, version. The change incorporates a requirement of ISO/IEC 17011 whereby laboratories must make accessible to A2LA any documents that provide insight into their level of independence from any other related activities undertaken by their organization wherever this is relevant. Laboratories are asked to sign this form upon applying for initial or renewal accreditation and whenever there is a change to the official laboratory authorized representative.
- The A2LA proficiency testing provider (PTP) application and assessment materials have been updated to include information relevant to the accreditation of PTPs under the NELAC program. The updated materials include (all available on the A2LA website unless otherwise noted):

The Accreditation Program for Providers of Proficiency Testing (PT) Programs Application Form (dated 9/2/05);

An *A2LA Program for the Accreditation of NELAC Proficiency Testing Providers Procedures Manual* (dated 8/30/05);

Several checklists for the NELAC program, including: an ISO/IEC 17025 – NELAC Chapter 5 combined checklist (dated 8/30/05) – available by request only; a checklist for the *National Standards for Water Proficiency Testing Studies Criteria* (dated 8/30/05); the *NELAC Chapter 2 Proficiency Testing (PT) Providers Requirements* checklist (dated 8/29/05); and a NELAC PTP and Reference Materials Producer (RMP) checklist (dated 8/30/05) – available by request only.

- The *Annex to the A2LA Policy on Measurement Uncertainty For Automotive and Materials Testing Laboratories* has been updated to a September 8, 2005, version to correct an error in the flow chart.
- The *A2LA Advertising Policy* was updated to a September 14, 2005, version. The policy is now more generic in that it applies not only to accredited laboratories, but also to accredited PTPs, RMPs, inspection bodies (IBs), etc. A new section was added relevant to IBs only, and the section regarding the combined ILAC MRA -A2LA Accredited symbol has been clarified as applicable only to A2LA's ILAC Scope of Recognition.
- As related to A2LA's inspection body accreditation program, several new and revised documents have been issued. These include the *General Requirements for Accreditation of Inspection Bodies* (9/15/05) and the ISO 17020 full text checklist - available by request only (9/15/05).
- The *A2LA Animal Drug Testing Program and ISO/IEC 17025 General Criteria - Full Text* assessor checklist has been updated to a September 15, 2005, version to reflect the requirements of ISO/IEC 17025:2005 and also to reflect the revision to the *Advertising Policy* - available by request only.
- The *A2LA Food Testing Program and ISO/IEC 17025 General Criteria - Full Text* assessor checklist has been updated to a September 15, 2005 version to reflect the requirements of ISO/IEC 17025:2005 and also to reflect the revision to the *Advertising Policy*. It is available upon request only and is not available on the A2LA website.
- The *General Criteria (ISO/IEC 17025 - Full Text Incorporated with A2LA's Environmental Program Requirements)* assessor checklist has been updated to a September 14, 2005, version to reflect the requirements of ISO/IEC 17025:2005 and also to reflect the revision to the *Advertising Policy* -available by request only.
- The *A2LA Food Testing Program Requirements* checklist (not combined with ISO/IEC 17025) has been updated to a September 9, 2005, version - available by request only.
- The *General Criteria (ISO/IEC 17025 - 2005 - Full Text)* checklist has been updated to a September 15, 2005, version to reflect the revision to the *Advertising Policy* - available by request only.
- With the conversion to ISO/IEC 17025:2005, several documents have been updated to reflect the new version of the standard. The following checklists were revised simply to update references to and sections from ISO/IEC 17025:2005:

- *Assessor Checklist: Environmental Lead (Pb) Program Requirements* (9/13/05)
- *Assessor Checklist: A2LA Wyoming Storage Tank Remediation (STR) Laboratory Accreditation Program Requirements Checklist* (9/13/05)
- *Assessor Checklist: A2LA Kentucky UST Laboratory Accreditation Program Requirements* (9/13/05)
- *Assessor Checklist: A2LA Calibration Program Requirements* (9/13/05)
- *Assessor Checklist: A2LA Requirements for the Accreditation of Site Testing and Site Calibration Laboratories* (9/13/05)

The following requirements documents were revised simply to update references to and sections from ISO/IEC 17025:2005:

- *Annex to the A2LA Policy on Measurement Uncertainty for Construction Materials and Geotechnical Laboratories* (9/13/05)
- *Animal Drug Testing Program Requirements* (9/13/05)
- *A2LA Proficiency Testing Requirements for Accredited Testing and Calibration Laboratories* (9/13/05)
- *Putting Green Materials Testing Program* (9/15/05)
- *Automotive EMC Laboratory Accreditation Program* (9/13/05)
- *Construction Materials Testing Program Requirements* (9/13/05)
- *Geotechnical Engineering Testing Program Requirements* (9/13/05)
- *Nondestructive Program Requirements* (9/13/05)

- [A2LA Specific Criteria for the Accreditation of Site Testing and Site Calibration Laboratories](#) (9/13/05)
- [Calibration Program Requirements](#) (9/13/05)
- [Kentucky Underground Storage Tank Laboratory Accreditation Program Requirements](#) (9/13/05)
- [Wyoming Storage Tank Remediation \(STR\) Laboratory Accreditation Program Requirements](#) (9/13/05)
- [A2LA Food Testing Program Requirements](#) (9/15/05)
- [Environmental Lead Program Requirements](#) (9/13/05)
- The [Instructions: Responding to the Assessor Deficiency Report](#) document was revised to a September 30, 2005, version to incorporate clause references from ISO/IEC 17025:2005 and also to reflect recent changes to the [General Requirements for the Accreditation of Laboratories](#).
- The [Aerospace Materials Testing Laboratory Requirements](#) document is available on the A2LA website as of September 30, 2005. It is intended for use by laboratories seeking accreditation to SAE AS7101

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Acceptance of Accredited Calibration Providers Approved by NRC

In a letter and attached safety evaluation report (SER) issued to the Arizona Public Service Company dated September 28, 2005, the [Office of Nuclear Reactor Regulation](#) approved a requested change to the quality assurance (QA) program of the Palo Verde Nuclear Generating Station Units 1, 2 and 3. The change provides for acceptance of accreditation to ISO/IEC 17025, [General Requirements for the Competence of Testing and Calibration Laboratories](#), as a means of qualifying calibration laboratories to provide commercial-grade calibration services to the Palo Verde Nuclear Generating Station. The accreditation process will be accepted in lieu of a supplier audit, commercial-grade survey, or in-process surveillance. This method for qualifying the calibration supplier and accepting its calibration services will be applied only to commercial-grade calibration services as defined by [10 CFR Part 21](#). Almost all calibration services provided to nuclear power plants are considered commercial grade.

The SER includes the following stipulation:

The NRC staff recognizes the Mutual Recognition Arrangement (MRA) conferred by signatory status with ILAC. However the NRC staff's evaluation and approval are limited to NVLAP and to A2LA accreditations, which are recognized by NVLAP through the ILAC MRA.

With the issuance of the SER, other nuclear generating stations can take advantage of the approved changes by updating their licensing documents and procedures. No additional approvals are required. This decision helps eliminate the need for laboratory audits performed by the nuclear industry.

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A2LA Recognized as NELAC Proficiency Testing Provider Accreditor / Proficiency Testing Oversight Body (PTPA/PTOB)

A2LA is now a [National Environmental Laboratory Accreditation Conference \(NELAC\)](#)-recognized Proficiency Testing Provider Accreditor / Proficiency Testing Oversight Body (PTPA/PTOB). The announcement was made on August 8, 2005, by Ms. Lara Autry (EPA, NELAP Director) during The Forum on Laboratory Accreditation – NELAC 11 Conference held in Raleigh, NC. NELAC is a voluntary association of state and federal agencies with the purpose of establishing and promoting mutually acceptable performance standards for the operation of environmental laboratories. EPA's [National Environmental Laboratory Accreditation Program \(NELAP\)](#) office provides support to NELAC and evaluation of the accrediting authority's programs.

The purpose of the PTPA/PTOB program is to identify proficiency testing providers that have the capabilities to competently operate proficiency testing schemes to the NELAC requirements. Successful providers will then be granted an A2LA Scope of Accreditation that identifies the proficiency testing samples (analytes)

that they can produce under this program.

By recognizing A2LA, the EPA and NELAP accrediting authorities are gaining a PTPA/PTOB that has assessors with the technical expertise to competently conduct assessments to the stringent NELAC requirements, a mature and efficient system to review and process the accreditations, and the statistical experience needed to effectively implement the ongoing monitoring and oversight roles.

The proficiency testing (PT) providers in turn will receive one accreditation that covers all of the NELAC fields of proficiency testing. The A2LA program also has the capabilities to provide the PT providers an option to become accredited for PT schemes outside the NELAC scope. Finally, the PT providers' accreditation by A2LA will help facilitate the acceptance of their products globally.

A2LA has been accrediting proficiency testing providers since 2000 and currently has nine providers accredited that offer PT schemes for various fields of testing and calibration.

Inquiries may be directed to Randall Querry, Program Manager, A2LA at (301) 644-3221 or via email at rquerry@A2LA.org.

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USDA Accepts ISO/IEC 17025 Accredited Laboratories for Positive Results

The [United States Department of Agriculture \(USDA\) FSIS Notice 54-05](#) was issued on August 29, 2005, stating its policy on the use of results from third party laboratories. FSIS may rely on a third party laboratory's positive result to take action on a product (e.g., request a recall or take regulatory action) and this notice describes the circumstances under which FSIS considers it appropriate to rely on such results.

The policy states that FSIS will consider four questions when deciding to accept third party laboratory results. The questions are:

Question 1: Was the procedure used to collect, handle and transport the sample equivalent to FSIS procedures? FSIS will request documentation of the procedures used and will assess whether the integrity of the sample or specimen could have been compromised during collection and transport.

Question 2: Was the sample or specimen handled using a documented chain of custody establishing that the integrity of the sample or specimen was not compromised during transport from point of collection to the laboratory or within the laboratory? FSIS will assess the documentation of the chain of custody to determine whether the people who handled the sample kept it intact and properly maintained throughout the process.

Question 3: Was there assurance that the results obtained by the third party laboratory are reliable and accurate for the analysis in question? FSIS will assess the available information from the laboratory (e.g. whether the laboratory is accredited under the International Organization for Standardization Standard 17025 (ISO/IEC 17025) and whether the analysis was performed in accordance with that accreditation) to determine whether the Agency can confidently rely on the laboratory's results.

Question 4: Was the sample or specimen analyzed in accordance with documented analytical methodology that has a sensitivity and specificity that are determined by FSIS to be equivalent to the FSIS laboratory methodology in question?

For further information about this policy, please contact Roger Brauning at A2LA (301 644 3233 or rbrauning@a2la.org).

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AEMCLAP News Update

The Automotive EMC Laboratory Recognition Program (AEMCLRP) Committee is preparing to release the

fourth revision of the AEMCLRP document. Expect its release by the end of October 2005. You will notice that a number of test methods in [revision 3](#), such as BCI-Closed Loop, Radiated Immunity Reverberation – Mode Stirring, Radiated Emissions – Reverberation Method, and Radiated Immunity – Tri-plate (test method will no longer be used after 12/31/05), are not available in [revision 4](#). There will be a number of test methods added to revision 4 to replace those removed. Laboratories have the option of being assessed to the draft requirements in the event the assessment occurs prior to the formal release of revision 4. Please indicate to your on-site assessor or to Brad Moore at A2LA **prior to** the assessor arriving on site if you wish to be assessed to the revision 4 requirements.

A new requirement you will be seeing in the revision 4 program document is, “Each test setup shall have a ‘test setup designator’ which shall be published on the laboratory’s Scope of Accreditation.”

For example, the new Scope listings will look similar to the following:

AEMCLAP Tests

<u>Test Technology</u>	<u>Test Method(s)</u>
Bulk Current Injection (BCI)	ISO 11452-4, GMW3097 Section 3.4.1
AEMCLRP Rev. 4 Appendix I	DC-10614, ES-XW7T-1A278-AC

BCI Chamber #1

(DC, GM, Ford)

We are taking a proactive approach to updating laboratory Scopes of Accreditation currently undergoing assessment activities prior to the release of the revision 4 document. Any lab can request that its Scope be updated to reflect the “test setup designator”. Otherwise, Scopes will be updated at the time of the annual review or renewal assessment.

There has been confusion recently between test methods that are listed under AEMCLAP tests and the non-AEMCLAP tests portion on the Scope. Available test methods will only be listed for AEMCLAP tests if laboratories undergo a successful assessment to A2LA requirements and AEMCLRP requirements and if they can provide successful proficiency testing results approved by the AEMCLRP committee. Any test method subjected only to an assessment to A2LA requirements and A2LA proficiency testing requirements will be listed under non-AEMCLAP tests. The AEMCLRP committee will only recognize test methods listed under AEMCLAP tests.

Lastly, AEMCLRP recognition now requires that all AEMCLAP labs submit an applicable performance history (PH) for all recognized test methods along with the annual review and renewal of accreditation documentation. The requirement is stated in Appendix C of the revision 4 AEMCLRP document.

Please direct any questions to Brad Moore at A2LA (301 644 3226 or bmoore@a2la.org).

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Spring 2006 Training Course Schedule

Title: [Introduction to Measurement Uncertainty](#)

- January 30-31, 2006 – Charleston, SC (\$795.00 for non-members, \$745.00 for members)
- March 27-28, 2006 – San Francisco, CA (\$795.00 for non-members, \$745.00 for members)
- June 5-6, 2006 – Chicago, IL (\$795.00 for non-members, \$745.00 for members)

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

- February 1-3 – Charleston, SC (\$995.00 for non-members, \$945.00 for members)
- March 29-31 – San Francisco, CA (\$995.00 for non-members, \$945.00 for members)
- June 7-9, 2006 – Chicago, IL (\$995.00 for non-members, \$945.00 for members)

Title: [Assessment of Laboratory Competence](#)

- May 1-5, 2006 – Atlanta, GA (\$1595.00 for non-members, \$1545.00 for members)

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

- May 22-23, 2006 – Novi, MI (\$795.00 for non-members, \$745.00 for members)

For additional information, please contact Julie Stevens, A2LA Training Coordinator, at 301 644 3235 or jstevens@a2la.org.

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Ideas for Future Newsletter Articles

A2LA always welcomes ideas for articles in future issues of *A2LA News*. We frequently include articles written by our assessors in response to their suggestions for topics of interest, and we would certainly welcome ideas from any of our other readers.

- Is there a particular accreditation requirement that you would like to see further discussed?
- Is there a particular A2LA policy on which you would like to see additional information or background?
- Do you have questions about our national or international involvements and how they impact you?
- Are you aware of clients or industry specifiers that are now accepting your A2LA accreditation in order to contract work with you?

Please feel free to contact the *A2LA News* editors, Teresa Barnett (301 644 3202, tbarnett@a2la.org) or Tim Rasinski (301 644 3232, trasinski@a2la.org) with any ideas or suggestions you may have for consideration in future newsletter issues.

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Report on ILAC-2005

by Peter Unger

The [International Laboratory Accreditation Cooperation \(ILAC\)](#) annual general meeting and associated committee meetings were held in Auckland, New Zealand, September 12-20. This was the fifth occasion where ILAC met jointly with the [International Accreditation Forum \(IAF\)](#), the international organization for accreditation of certification bodies.

Highlights of the meetings include:

- Four new signatory accreditation bodies for testing and calibration were added to the MRA, [Organismo Argentino de Acreditacion \(OAA\)](#), [National Laboratories Accreditation Bureau \(NLAB\)](#), [Polish Centre for Accreditation \(PCA\)](#), and [National Accreditation Body of Republica de Cuba \(ONARC\)](#). This brings the total to 49 signatories from 40 economies. (RENAR Romania was removed as an ILAC MRA signatory.)
- Accreditation bodies from the Russian Federation, Morocco, Luxembourg, United Arab Emirates, and Canada were accepted as ILAC Associates.
- Accreditation bodies from Mongolia, Georgia, and Kenya were accepted as ILAC Affiliates.
- A new regional cooperation body, the Central Asia Cooperation on Metrology, Accreditation, Standardization and Quality (CAC-MAS-Q), representing Kazakhstan, Kyrgyzstan, Tajikistan, and Uzbekistan was accepted.
- The first meeting of the Proficiency Testing Consultative Forum took place.
- Urgent revision of ISO/IEC Guide 43 on proficiency testing was endorsed to include [ILAC G13](#), the widely used document for accreditation criteria for proficiency testing providers.
- Amendment of the rules for the ILAC MRA mark to allow sub-licensees to use the combined mark/accreditation body symbol on calibration certificates and test reports, pre-printed letterhead,

quotations for work, advertisements, websites, and other documents was endorsed. Instructions will be available at a later date.

- A joint statement was endorsed with the [Bureau International de Poids et Mesure \(BIPM\)](#) formalizing closer cooperation and reaffirming the respective roles of each body in assuring traceability of measurements.
- The two-year transition period for the implementation of the amended ISO/IEC 17025:2005 standard (by June 1, 2007) was reaffirmed.
- Joint sessions 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 once a consensus on technical issues under debate is achieved, possibly by the November 2006 annual meeting.
- Inclusion of reference materials producer accreditation to ISO Guide 34 in combination with ISO/IEC 17025 under the current ILAC arrangement when appropriate procedures for this activity are developed and accepted was endorsed.
- The effective date of January 1, 2006, of the ILAC P9, *ILAC Policy for Participation in National and International Proficiency Testing Activities*, was reaffirmed.
- All ILAC members shall now have a cross-frontier accreditation policy in harmony with [ILAC G21](#).
- The location of the ILAC annual meetings for 2006 (Cancun, Mexico) and 2007 (Australia) has been affirmed.

The meetings involved over 200 people from more than 70 economies. A2LA was represented by Peter Unger, A2LA President, Roxanne Robinson, A2LA Vice President, and Trace McInturff, Operations Manager. Mr. Unger serves as ILAC Vice Chair, Ms. Robinson serves as Vice Chair of the Arrangement Committee, convener of the working group on maintenance of the peer evaluation process documentation, and co-convener of ILAC/IAF evaluation process documents, and Mr. McInturff is an active member of the ILAC Accreditation Committee and serves as convener of the working group for providing the Marketing and Communications Committee (MCC) with input and also serves on the reference materials working group.

Further information on the ILAC meeting can be found at the ILAC web site.

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Attention: Laboratories Accredited for Scale and Balance Calibrations

In the past, A2LA has found it acceptable to forego listing the best uncertainty values on Scopes of Accreditation for scale and balance calibration services due to circumstances surrounding these types of measurements. However, included in the guidance outlined by the [International Laboratory Accreditation Cooperation \(ILAC\)](#) in [ILAC G4:1994 Guidelines on Scopes of Accreditation](#), a minimum set of elements should be included on the scope document. Of these elements, it is recommended that the "identification of the best measurement capability" be expressed on the published scope document issued by the accrediting body.

Therefore, as of **January 1, 2006**, A2LA will begin requiring the inclusion of these best uncertainty values on the Scopes of Accreditation for scale and balance calibrations. For all laboratory Scopes currently listing accreditation for these calibrations, the inclusion of this uncertainty information will be addressed during the next on-site assessment to allow for a technical review and approval of these values.

If you have any questions regarding this matter, please do not hesitate to contact someone in our calibration department at 301 644 3248.

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Joint ISO-ILAC-IAF Communiqué

With the wide recognition that ISO 9001 enjoys across all areas of business, laboratories accredited to the more appropriate ISO/IEC 17025 standard are naturally interested in ways to promote ISO/IEC 17025 as being as applicable and relevant to them as ISO 9001 is to a manufacturing plant, for example.

ISO, the [International Laboratory Accreditation Cooperation \(ILAC\)](#), and the [International Accreditation Forum \(IAF\)](#) have issued a joint communiqué on the *Management Systems Requirements of ISO/IEC 17025:2005, General Requirements for the Competence of Testing and Calibration Laboratories* to address this need. The communiqué states the following:

A laboratory's fulfillment of the requirements of ISO/IEC 17025:2005 means the laboratory meets both the technical competence requirements and **management system requirements** that are necessary for it to consistently deliver technically valid test results and calibrations. The **management system requirements** in ISO/IEC 17025 (Section 4) are written in language relevant to laboratory operations and meet the principles of ISO 9001:2000 **Quality Management Systems – Requirements** and are aligned with its pertinent requirements.

A2LA's Certificates of Accreditation have already been revised to capture the language within this communiqué and can be used as a further means of promoting ISO/IEC 17025 as the relevant standard for laboratories while still meeting the principles of ISO 9001:2000. An official version of the ISO-ILAC-IAF communiqué can be obtained from the ILAC website.

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Omitting Measurement Data When Making Statements of Compliance

Many times accredited calibration service providers only provide a statement of "in" or "out" of tolerance on the calibration certificates issued to their customers. Pursuant to the requirements in ISO/IEC 17025 regarding calibration certificates, it is acceptable to issue certificates with these tolerance statements while omitting actual measurement results and uncertainties. However, even though the measurement uncertainty is not provided on the traceable certificate, the calibration service provider must be able to make this measurement data and associated uncertainties available if requested at a later date, as required by ISO/IEC 17025 (both 1999 and 2005), section 5.10.4.2 which states:

When a statement of compliance with a specification is made omitting the measurement results and associated uncertainties, the laboratory shall record those results and maintain them for possible future reference...

As accredited certificates of this nature are more common as a base level of the calibration provider's service, we encourage customers to talk to their calibration service provider so that their measurement needs are clearly communicated and understood. Also, calibration service providers are urged to get a better understanding of the needs of their customers through the contract review process.

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Policies, Procedures, and the Quality Manual

Several sections of ISO/IEC 17025 require a policy and/or procedure. Section 4.2, Quality Systems, has different requirements for how the laboratory handles policies and procedures.

Section 4.2.2 of ISO/IEC 17025:2005 requires that, "The laboratory's management system policies related to quality...shall be defined in a quality manual (however named)." The wording of the 1999 version is similar and includes the same requirement. Therefore, any section of 17025 requiring a policy must have that policy documented in the quality manual.

Section 4.2.5 requires, "The quality manual shall include or make reference to the supporting procedures..." Section 4.2.3 of the 1999 version is similar. Here, 17025 gives the lab the option of having procedures

contained within the quality manual or as separate documents. This is convenient, in that revisions to a procedure will not require a revision and reissue of the entire quality manual if the procedures are separate documents.

Often, a laboratory uses a format for procedures that includes a "purpose" or "goal" statement. This statement is usually sufficient to satisfy the policy requirements of ISO/IEC 17025 (if no separate policy statement exists) in that it contains all of the critical elements of a policy and is acceptable to A2LA. However, if the procedure itself is not part of the quality manual, then the requirement of section 4.2.2 is not met.

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Revisiting Common Practices in Measurement Uncertainty Estimates for Testing Labs

- Article written by Marlene Moore, A2LA Assessor

Testing laboratories continuously re-evaluate all aspects of their testing operations. Many common practices or assumed conditions may need to be updated or revised to incorporate more current practices. Just as there have been many advances in electronics, instrumentation, and other computer assisted operations, many practices learned on the job or at universities may now be out-dated.

For example, the last newsletter identified new definitions by IUPAC for the measurement of pH, including one point calibration and the availability of pH buffers that are recognized around the world as traceable.

Future articles that will report on these changes are expected to include:

- Class A glassware – Has the manufacturing process changed so that the Class A mark on glassware does not guarantee the accuracy of the glassware? If this is the case, then the glassware must be checked prior to use in order to verify that the marking is accurate for the application.
- Chemistry measurement uncertainty estimations using the 95% confidence limits of control samples is being compared to the more rigorous technique defined in the *Guide to the Expression of Uncertainty in Measurement* (GUM) or EUROCHEM/CITAC document. (See [Estimating Uncertainty of Measurement for Testing Laboratories](#) by Thom Adams, July 2004 Section 2). When the testing of control materials is designed properly (e.g. the warning limits used for Shewart control charts), the need to estimate the uncertainty using a more rigorous uncertainty estimate is not necessary.
- Microbiology uncertainty estimates are being proposed and implemented for methods that use counting for the measurements. This requires the use of lognormal transformations and is not calculated in the same manner as in chemical measurements where a normal distribution of the data is developed and applied.
- Skill of chemistry laboratory personnel may require additional performance measures on the job due to the reduction of intense laboratory testing skills in some undergraduate programs. The use of computer modeling rather than bench experimentation is becoming more prevalent.
- Another item starting to surface as we identify the components associated with uncertainty is the purity of standards, reagents, gasses, and other supplied materials as presented on certificates of analysis. In many cases, where accredited (ISO/IEC17025 not 9001) certificates are available, many testing laboratories need to read the certificates and determine if the information is appropriate for the use considered by the laboratory. For example, the concentration used in the testing method is 1000 ppm; however, the certificate indicates the value is actually 1010 ppm. This may result in significant errors if the uncertainty of the certificate is not taken into account.

As laboratories identify the components contributing to the estimation of uncertainty, new topics of discussion have surfaced for the evaluation of many common practices. The new wave in testing laboratories is to ask, "How does this step in the process affect the estimate of uncertainty and is this effect significant?" In many cases, the answers are not just a calculation or taking a number from a certificate. The answer may be to re-evaluate the process to develop more efficient operations or, in other cases, additional training or process steps must be added in order to ensure the estimate is within defined specifications.

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Perspectives on A2LA from an MRA Partner



I am Sylvia Lin, Deputy Director of the Laboratory Accreditation Department, [Taiwan Accreditation Foundation \(TAF\)](#). TAF is one of A2LA's partners under the [ILAC](#) and [APLAC](#) mutual recognition arrangements (MRA).

I came to A2LA on August 9, 2005, and will stay until November 2. The outstanding performance of both Peter Unger and Roxanne Robinson within ILAC and APLAC as well as A2LA's well-known reputation drew me to come here to learn the best practices of accreditation. This trip serves as a benchmarking experience for me.

TAF is a non-governmental and non-profit organization that is overseen by the Ministry of Economics Affairs. When TAF was established in September 2003, the 13-year-old government-funded laboratory accreditation scheme, Chinese National Laboratory Accreditation (CNLA), was transferred to TAF. TAF provides accreditation services in a variety of testing and calibration fields and has about 1050 accredited laboratories. A2LA is a mature organization and CNLA is also mature, but as an accreditation scheme not an organization. TAF is relatively new to the operation of a non-profit organization. (CNLA was formed in 1990 and operated by the Center for Measurement Standards. In 2003, TAF took over operation of CNLA as a non-profit organization by the Taiwanese government.)

During the past 2 months at A2LA, I attended training for new A2LA employees, talked to and worked with A2LA staff, read documents, observed meetings, and hung around. It gave me a lot to think about within a broad range of issues when trying to compare the function and operation of the A2LA Board of Directors, job allocation, strategic plan, finance, business development, information systems, etc. to those of TAF.

At this time, I would like to share a comparison of the number and types of deficiencies cited during assessments by A2LA and CNLA (Figures 1 and 2). The A2LA data was obtained from the A2LA website, [Most Commonly Cited Deficiencies](#) (12/06/02), and the CNLA data was based on that from 2 or 3 years ago as well. The Y axes of the figures are percentage of total management deficiencies cited or total technical deficiencies cited and the X axes are the sections of ISO/IEC17025:1999.

Among the deficiencies in management requirements, there are differences in section 4.6 (Purchasing Services & Supplies) and section 4.12 (Control of Records) but the differences are less than 10%.

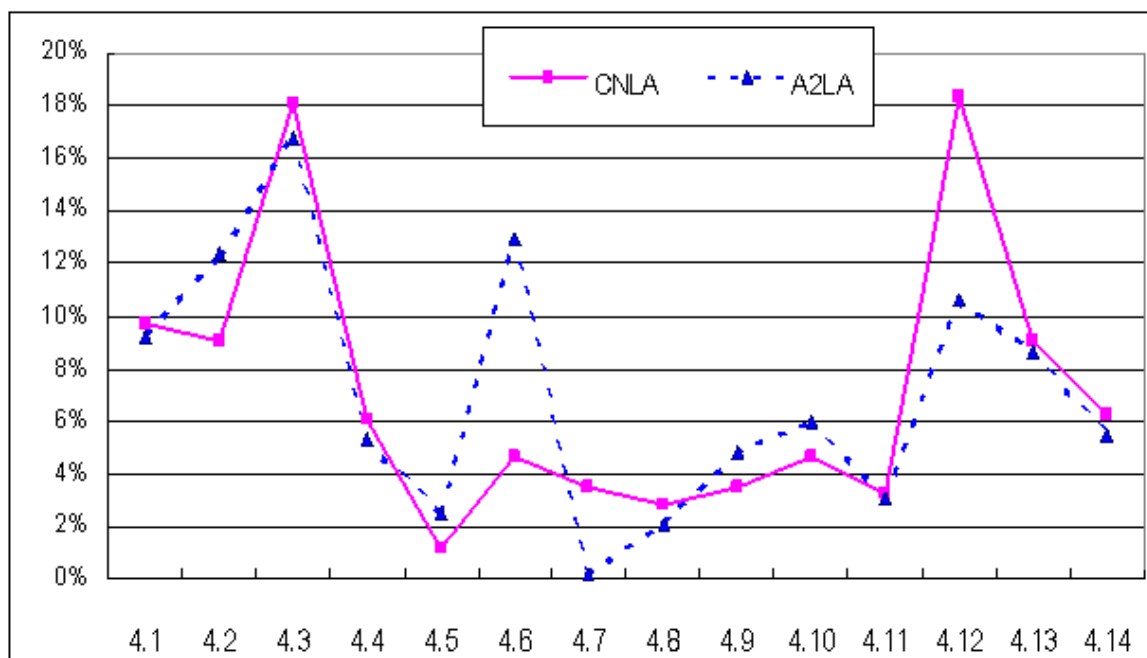


Figure1: Comparison of Deficiencies Cited Against Management Requirements of ISO/IEC 17025:1999

Regarding technical requirements, the pattern looked more similar. However, the differences are about 10% in a few areas, such as section 5.4 (Test and Calibration Methods and Method Validation) and section 5.6 (Measurement Traceability).

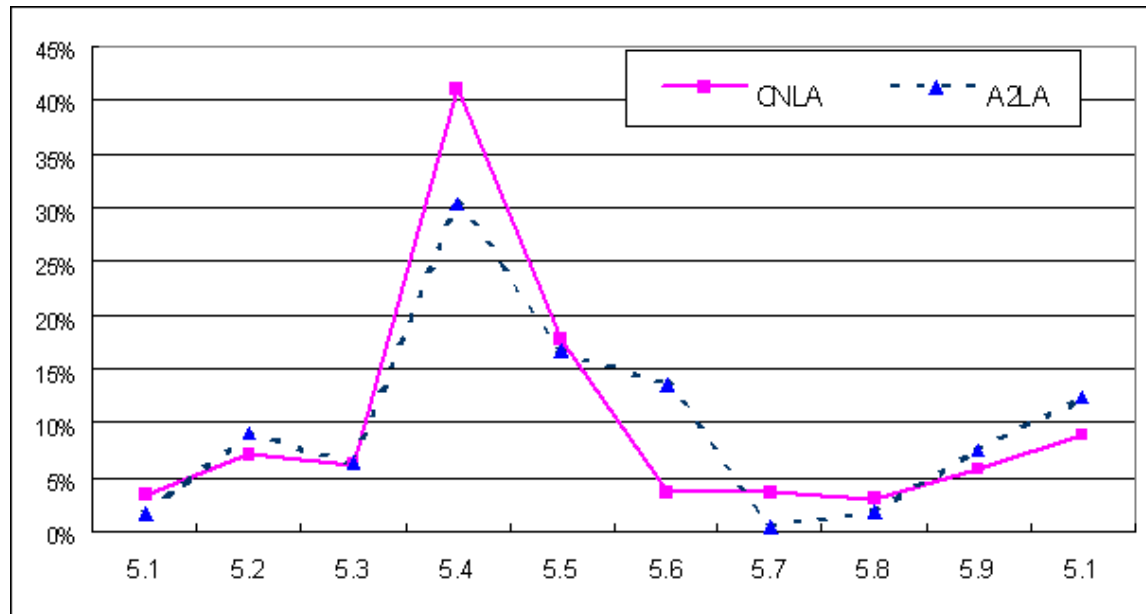


Figure2: Comparison of Deficiencies Cited Against Technical Requirements of ISO/IEC 17025:1999

In general, the deficiencies cited by both accreditation bodies' assessors were allocated consistently with regard to percentage of total management requirements and technical requirements. However it is difficult to determine whether the differences observed are related to trends within the laboratories themselves or trends in the observation and assessment techniques of the assessors. The assessors used by A2LA and CNLA are the same in that they are all technical experts trained in the elements of ISO/IEC 17025. The way in which assessments are arranged and conducted may be slightly different, though. CNLA assigns mostly two-person assessment teams, while A2LA uses many one-person assessment teams. CNLA also has about 200 assessors while A2LA has about 100 assessors. Data collected in the future related to deficiencies cited may allow us to explore the matter further and draw more conclusions.

Allow me to take this opportunity to express my appreciation to A2LA's staff for their arrangements and hospitality, particularly to Peter Unger for accepting my stay here and Berta Hakes for her maternal care.

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Examples of the Effectiveness of A2LA's MRAs

A2LA is always seeking examples of how laboratories are able to utilize the mutual recognition arrangements (MRAs) of which we are signatories in order to expand their customer base, to break into new domestic or international markets, to meet specifier requirements or to reduce the number of accreditations they must maintain. Below is a list of examples that have been brought to our attention throughout 2005:

- The CDMA (Code Division Multiple Access) Certification Forum has published a 2005 version of its *Testing Facility Authorization Process* which relies heavily on having its candidate testing facilities accredited by accreditation bodies recognized under the [International Laboratory Accreditation Cooperation \(ILAC\) MRA](#).
- A2LA was able to accept an assessment by [Deutsche Akkreditierungsstelle Technik e.V. \(DATECH\)](#) of an A2LA-accredited laboratory in Germany in place of an on-site surveillance assessment by A2LA by virtue of the [European cooperation for Accreditation \(EA\) MLA](#).
- General Electric has begun to accept laboratories accredited by A2LA by virtue of A2LA's signatory

status within the ILAC MRA.

- Because of our MRA partner status with [Japan Accreditation Board \(JAB\)](#), A2LA worked with General Motors to facilitate its acceptance of JAB accredited laboratories in Japan, rather than having A2LA conduct separate assessments of these laboratories.
- The State of Minnesota Dental Association and the Metropolitan Council Environmental Services have specified in their document related to hydraulic testing of amalgam separators that all hydraulic testing laboratories must be accredited by an accreditation body which is a signatory to the ILAC MRA.
- A company in Kenya that imports goods from the U.S. contacted us for a list of accredited laboratories that their U.S. supplier could contract with in order to have the imported goods tested. Because of A2LA's status as an ILAC signatory, the tested products will not have to be retested in Kenya.
- A user of accredited lab services submitted a testimonial that A2LA's international recognition by virtue of the MRAs of which we are signatories is key, as it frequently uses A2LA accredited labs for products that must comply with the European Pressure Equipment Directive 97/23/EC.
- Automotive testing laboratories have begun to make use of A2LA's MRA signatory status to market themselves to international automakers, reacting to the shift in market share away from the U.S. "Big Three."
- The U.S. Department of Energy's [National Nuclear Security Administration \(NNSA\)](#) Metrology Program now explicitly recognizes accreditation bodies that are signatories to the ILAC MRA for the purposes of accrediting DOE/NNSA Contractor Standards Laboratories.
- The US [Nuclear Regulatory Commission \(NRC\)](#) has begun to accept A2LA accredited calibration laboratories (by virtue of A2LA's signatory status within international MRAs) without the need for additional audits by the NRC.

If there are other examples of the effectiveness of these MRAs that you are aware of, please feel free to share your experiences with A2LA by contacting Teresa Barnett, A2LA Quality Manager (301 644 3202 or tbarnett@a2la.org).

