The American Association for Laboratory Accreditation (A2LA) is proud to announce the addition of the laboratory accreditation requirements of the newly enacted Consumer Product Safety Improvement Act of 2008 (CP-SIA) to its already broad range of accreditation activities. A2LA is currently accepting new applications for accreditation of laboratories who intend to test to the newly enacted requirements for lead in paint, crib, and pacifier testing. A2LA is also working with existing accredited laboratories to modify their current scopes of accreditation in order to come into compliance with these new requirements. There are resources devoted to ensure prompt attention to all interested parties’ needs.

“The CPSC was very adamant about adhering to the timeline for accreditation, and A2LA is taking the steps necessary to provide first-class, responsive service to our laboratories that will allow them to meet the CPSC’s time line,” said Peter Unger, President of A2LA. “This new legislation (the CPSIA) is paramount to the safety of our nation’s children, and we are happy to see that the CPSC is relying on internationally recognized accreditation of testing laboratories to ensure accurate testing is being conducted.”

The U.S. Consumer Product Safety Commission (CPSC) recently published notices in the Federal Register regarding accreditation requirements for third party testing laboratories that are testing in conformance with the CPSIA for lead in paint, cribs, and pacifiers. According to these publications and the CPSIA, which phases in similar requirements over the next 10 months, all products currently subject to the lead in paint regulation at 16 CFR Part 1303, all cribs subject either to 16 CFR Part 1508 or Part 1509, and all pacifiers, subject to 16 CFR Part 1511, must be tested by a laboratory accredited to ISO/IEC 17025 by an accreditation body that is a signatory to the ILAC Mutual Recognition Arrangement (ILAC MRA). The Commission will vote on accreditation requirements for other children’s products regulations in the coming months.

A2LA became a Full Member Signatory to the ILAC MRA in November 2000, and currently meets this requirement for accrediting bodies. Due to the new legislation, there will likely be a large demand for testing from the toy and children’s products industries in the coming months, and A2LA is gearing up for the potential influx of applications for laboratory accreditation. Lead in paint, crib, and pacifier testing are just

Continued on page 2
General Updates, Notices & Press Releases

A2LA Implements New Veterinary Laboratory Accreditation Program Requirements

The American Association for Laboratory Accreditation (A2LA) is proud to announce the re-introduction of the Veterinary Laboratory Accreditation Program to its broad range of accreditation activities. This program has been completely revised, and applications for accreditation are now being accepted. Roxanne M. Robinson, A2LA Vice President and COO says, “This veterinary accreditation program demonstrates A2LA’s willingness to meet the needs of the veterinary community with a robust accreditation program developed in cooperation with leading, international veterinary authorities.”

The World Organization for Animal Health (OIE) formed in 1924 as the Office International des Epizooties and is still known by the initials of the original organization’s name. Today, it is one of the oldest intergovernmental organizations with 172 member countries on five continents. This organization works closely with, and is recognized by, international bodies such as the World Trade Organization (WTO), World Health Organization (WHO), World Bank, and Food and Agriculture Organization (FAO).

Veterinary laboratories world-wide may choose to meet the ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories as a stand-alone requirement for accreditation or the combined criteria of ISO/IEC 17025:2005 and the OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases, 2008. These OIE requirements are introduced in A2LA R216 – Specific Requirements: Veterinary Laboratory Accreditation Program now available at www.A2LA.org. This document includes instructions on how to obtain a copy of the aforementioned OIE Standard. Upon evidence of original OIE and ISO/IEC 17025:2005 standard ownership, A2LA promptly will send the combined criteria checklist to the applicant facility.

These OIE requirements supplement ISO/IEC 17025:2005 to evaluate diagnostic and clinical veterinary laboratories that conduct commercial, government, academic, and international veterinary testing in the following areas: infectious disease diagnostics, disease surveillance, virology, pathology, microbiology, immunology, screening for growth promoters and drug/chemical residue that includes antibiotics, anthelmethetics, pesticides, metals, organics, DNA/RNA, and GMO.

Dr. Peter Wright, an Expert Participant on the OIE Biological Standards Commission since 1991, says, “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.” A2LA is pleased that our new Veterinary Laboratory Accreditation Program builds upon the ISO/IEC 17025:2005 method validation requirements with the additional OIE-specific requirements applicable to leading veterinary institutions. The addition of A2LA’s Veterinary Laboratory Accreditation Program will provide veterinary laboratories with global recognition for the excellent service provided to their customers.

For more information about this program, please contact Matthew Torres, A2LA Accreditation Officer, at 301 644 3225 or mtorres@A2LA.org.
Remembering Bob Foncannon

It is with great sadness that we announce that A2LA assessor, Robert (Bob) A. Foncannon, age 58, passed away suddenly on Sunday, September 7, 2008 at his residence.

He was born October 11, 1949, in Detroit, MI, the son of L. Gordon and Ruth E. (Gillard) Foncannon. On October 1, 1977, in East Lansing, MI, he married Nancy A. Sutake who survives him. He had lived most of his life in Marcellus and graduated from Marcellus High School in 1967 and from Michigan State University in 1971. He was formerly employed by General Motors and Hager Lumber and was self-employed as an engineering consultant. He was a member of Mensa and a member of the Marcellus Township Planning Commission and the Zoning Board of Appeals. Surviving in addition to his wife, Nancy, are a daughter, Michelle Foncannon of Washington, D.C.; his father, L. Gordon Foncannon of Marcellus and several cousins. Bob will be greatly missed.

Memorials may be directed to the Marcellus Fire and Ambulance Service, P.O. Box 367, Marcellus, MI 49067.

A2LA Welcomes New Staff

In September 2008, A2LA welcomed Jason Poore to our staff as an Accreditation Officer.

Prior to joining A2LA, Jason served as an intern for a U.S. Congressman and as a liability determination adjuster for an insurance company, where he earned a “Distinguished Performance Award”. In addition, Jason has received a Bachelor of Science degree in Political Science from Shippensburg State University in Shippensburg, PA.

We welcome Jason to our growing A2LA family!

ANSI/NCSL Z540.3 Update

Work continues on the *Handbook for the Application of ANSI/NCSL Z540.3 Requirements for the Calibration of Measuring and Test Equipment*. Ultimately, this handbook will provide guidance regarding the requirements found in the Z540.3 standard.

The handbook has been submitted to the NCSLI Board of Directors for comment. Provided no major concerns are identified during the comment period, the handbook is expected to be presented for voting and publication in January 2009.

Spring 2009 Training Schedule Preview

**Title:** Introduction to Measurement Uncertainty
- March 2-3, 2009 - San Antonio, TX ($795.00 non-members, $745.00 members)

**Title:** ISO/IEC 17025 and Accreditation
- March 4-6, 2009 - San Antonio, TX ($995.00 non-members, $945.00 members)

**Venues:**
March 1-6, 2009
The Westin Riverwalk
420 West Market Street
San Antonio, TX 78205
(888) 627-8396
Rate: $199.00 Per Night

More venues and courses will be added over the coming weeks! Please check our website periodically for updates. Also, for additional course information or registration, contact Julie Stevens, A2LA Training Coordinator, at 301 644 3235 or jstevens@a2la.org.

SPRING 2009 Training Schedule Preview
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.

- **I102 – Instructions for Responding to the Assessor Deficiency Report** has been updated to an August 22, 2008 version. ("Document Finder" category: “Information & Instructional Documents”)

- **F106 – Request for Exception to the Policy on Measurement Traceability** has been updated to an August 22, 2008 version. ("Document Finder" category: “General Forms”)

- **R216 – Specific Requirements: Veterinary Laboratory Accreditation Program** has been updated to a September 4, 2008 version. ("Document Finder" category: “Specific Requirements”)

- **C211 – Specific Checklist: Combined ISO/IEC 17025 and Veterinary Laboratory Accreditation Program** has been updated to a September 4, 2008 version. As the title change implies, in addition to including the updated veterinary laboratory program requirements from R216, the checklist also contains the full text of the ISO/IEC 17025 standard. As such, it is available by request only.


- **P104 – Policy for Claims of Measurement Uncertainty for Field Calibrations on Scopes of Accreditation** has been updated to a September 24, 2008 version. ("Document Finder” category: “Policies”)

- **G106 – Guidance on Scopes of Accreditation for PCBs Under the TCB Accreditation Program** has been updated to an October 2, 2008 version. ("Document Finder” category: “A2LA Guidance Documents”)

- **R307 – General Requirements: Accreditation of ISO/IEC Guide 65 Product Certification Bodies** has been updated to an October 2, 2008 version. ("Document Finder” category: “General Requirements”)

- **R308 – Specific Requirements: Telecommunication Certification Body Accreditation Program** has been updated to an October 2, 2008 version. ("Document Finder” category: “Specific Requirements”)

- **F210b – Scope of Accreditation Selection List: Wyoming Storage Tank Remediation Testing Laboratories** has been updated to an October 22, 2008 version. ("Document Finder” category: “General Forms”)

- **G107 – Laboratory Uncertainties Smaller than a National Metrology Institute** has been made obsolete.

- **P102 – A2LA Policy on Measurement Traceability** has been updated to an October 22, 2008 version. ("Document Finder” category: “Policies”)

The corresponding **C105 – General Checklist: A2LA Policy on Measurement Traceability** has also been updated to an October 22, 2008 version. ("Document Finder” category: “General Checklists”)

- **R101 – General Requirements: Accreditation of ISO/IEC 17025 Laboratories** has been updated to an October 22, 2008 version. ("Document Finder” category: “General Requirements”)

- **C213 – Specific Checklist: Information Technology Testing Laboratory Accreditation Program** has been updated to an October 29, 2008 version. ("Document Finder” category: “Specific Checklists”)

If you have any questions about these updates, please contact A2LA at 301 644 3248 or your Accreditation Officer directly. ◆
Does the requirement in Section 5.5.9 of ISO/IEC 17025 apply to equipment that has been sent out for calibration?

**ANSWER:** Yes. When equipment is returned from being calibrated, the lab is responsible for performing a check per a defined procedure and recording the results of that check. The check itself could take a number of different forms, but Section 5.5.9 requires that both the function and calibration status of the equipment be checked and shown to be satisfactory.

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**NEW APPLICATIONS OF ISO/IEC 17025 REQUIREMENTS**

Since the August 2008 issue of *A2LA Today*, the A2LA Criteria Council voted to approve one new application of the ISO/IEC 17025:2005 requirements. This and other explanations may be found on the A2LA website section, “Understanding ISO/IEC 17025”.

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**Meeting Summaries**

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**2008 IEEE Electromagnetic Compatibility (EMC) Symposium**

Once again A2LA attended the IEEE Electromagnetic Compatibility (EMC) Symposium held in “The Motor City”, Detroit, MI. The show ran from August 18-22, 2008 at Detroit’s Cobo Center with Beth Hackett and Rob Miller representing A2LA. This year’s symposium provided a platform for a large number of manufacturers and industries to showcase their newest technologies within the world of EMC and the automotive industry. The symposium also provided the opportunity for A2LA to update the EMC community regarding the new programs available, such as the joint ISO/IEC 17025 Laboratory Accreditation / ISO/IEC Guide 65 Product Certification program for Telecommunication Certification Bodies (TCBs).

Thanks to all who took the time to stop by the A2LA exhibit and inquire about our accreditation programs, specifically attaining information on how to use accreditation to highlight a laboratory’s standard of excellence.

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/.

Stop by and visit our exhibit next year at the 2009 IEEE EMC Symposium, August 17-21, 2008, at the Austin Convention Center in Austin, TX. We look forward to seeing you there.
From October 23-27, 2008, A2LA Accreditation Officer, Matthew Torres, attended the 112th Annual Meeting of the United States Animal Health Association (USAHA) and the 51st Annual Conference of the American Association of Veterinary Laboratory Diagnosticians (AAVLD) in Greensboro, NC. A2LA sincerely and unconditionally thanks all people met at these conferences for sharing their needs and views with us.

AAVLD President, Dr. Grant Maxie, addressed many broad themes shaping the dynamically-changing global veterinary community, including the concepts of “one health” and use of recognized, international standards for quality such as ISO/IEC 17025 and those published by the World Organization for Animal Health (OIE). A2LA also spoke with USAHA President, Dr. James Leafstedt, and Dr. John Clifford, Chief Veterinary Officer and Deputy Administrator of the United States Department of Agriculture. All three individuals and most attendees embraced the shared vision all veterinary stakeholders bring to the state, federal, academic, industrial, and international needs of this diverse and important community.

A2LA met with many representatives from state and academic laboratories. We learned that costs for A2LA’s internationally-recognized accreditation programs are comparable to, or even more cost-effective than, site-visit expenses for the accreditation programs familiar to these laboratories. A2LA and our internationally-recognized partners throughout the world support cost-effective, third-party accreditation to all users. The future of veterinary accreditation is to use recognized, international standards to which existing, robust veterinary programs in Australia and Europe attest. It appears that Canada is already moving in this direction and the United States should not be far behind.

The dynamic forces of change within the veterinary community require increased prominence for states and other stakeholders partnering with Veterinary Services (VS) in a shared vision for America. With the increasing role of state, academic, and industrial partners, we can address the technological, agricultural, industrial, biosecurity, education, and global trade issues that affect all citizens and bring veterinarians and veterinary stakeholders to the forefront of service to the public we all serve.
Laboratory Quality Confab on 
Quality Management in Diagnostic Medicine

The second annual Laboratory Quality Confab on Quality Management in Diagnostic Medicine, sponsored by the Dark Report, was held September 24-25, 2008 in Atlanta, GA. Ray Minnick A2LA Accreditation Officer, represented A2LA at both the tradeshow and the series of lectures and meetings that were held during the Confab. Many important contacts were made and the exchange of information and expressions of interest and support were extremely encouraging to A2LA’s newly launched ISO 15189 Medical Laboratory Accreditation Program. Particularly encouraging was the attention that was directed to introducing the attendees to the value of ISO 15189 to clinical laboratories in their continuing effort to improve the quality of laboratory results and patient safety.

The Confab is designed to provide individuals involved in the Quality Management aspect of a medical laboratory with advanced tools to implement process improvement, problem resolution and reduction in waste of both time and materials. Section 4, the Quality Management Section, of ISO 15189 provides an excellent matrix or foundation to apply these tools.

One of the techniques presented was the practice of “Lean” manufacturing processes to aid laboratories in reducing waste. Lean is the practice of a theory of production that considers the expenditure of resources for any means other than the creation of value for the presumed customer to be wasteful, and thus a target for elimination. In more basic terms, Lean manufacturing is a generic process management philosophy derived mostly from the Toyota Production System.

For many, Lean is the set of “tools” that assist in the identification and steady elimination of waste. As waste is eliminated quality improves while production time and cost are reduced. Examples of such “tools” are Value Stream Mapping, Five S, Kanban (pull systems), and error-proofing.

The Confab also focused on the application of Six Sigma to identify and eliminate defects and errors in a process. This technique may be applied to both production and business processes. A Six Sigma program is formed around a core of employees that have received special training in error reduction.

The central idea behind Six Sigma is that, if you can measure how many “defects” you have in a process, you can systematically figure out how to eliminate them and get as close to “zero defects” as possible. To achieve Six Sigma Quality, a process must produce no more than 3.4 defects per million opportunities. An “opportunity” is defined as a chance for nonconformance, or not meeting the required specifications. This means that one must be nearly flawless in executing key processes.

Both Lean and Six-Sigma are powerful tools in optimizing the Quality Management system reflected in ISO 15189.

One of many very interesting presentations was offered by Mr. Glen Fine from the Clinical and Laboratory Standards Institute (CLSI). Mr. Fine presented a very succinct overview to the attendees discussing the global application of the ISO 15189 and CLSI Quality Management Systems and provided insight on future adaptations both in the United States and abroad.

A2LA looks forward to increased involvement in this field, as we promote the importance of ISO 15189 accreditation and move forward in developing our Medical Testing Laboratory Accreditation Program as a public service to veterinary laboratories worldwide.
The Inter American Accreditation Cooperation (IAAC) annual general assembly meeting and associated committee meetings were held in Asuncion, Paraguay, September 6-12, 2008. This was the thirteenth meeting of IAAC since its founding in 1996. Eighteen resolutions were approved.

One of the more significant resolutions involved the Memorandum of Understanding (MOU) with the National Cooperation on Laboratory Accreditation (NACLA). The General Assembly approved the proposal to amend the IAAC-NACLA MOU with the understanding that, if an agreement is not reached by March 1, 2009, the MOU shall be terminated. Six preconditions for both parties to enter into the revised MOU are:

1. Follow the requirements of the peer evaluation process of accreditation bodies as defined by ILAC documents and ISO/IEC standards.
2. Abide by the ILAC Rules-S2 and support the aims and objectives of ILAC, including the recognition and promotion of the IAAC Multi-lateral Recognition Arrangement and ILAC Mutual Recognition Arrangement to all interested parties including the regulators and specifiers which currently accept NACLA-recognized accreditation bodies.
3. Ensure all accreditation bodies use equivalent procedures in the accreditation of laboratories under the current version of ISO/IEC 17011, any related ILAC and IAAC guidance documents and ISO/IEC 17025 (or ISO 15189 for medical laboratories), use equivalent procedures in the accreditation of inspection bodies under the current version of ISO/IEC 17011, any related ILAC and IAAC guidance documents and ISO/IEC 17020, and use equivalent procedures in the accreditation of reference material producers under the current version of ISO/IEC 17011, any related ILAC and IAAC guidance documents and ISO Guide 34 in combination with ISO/IEC 17025;
4. Enforce all relevant requirements of ISO/IEC 17011, including the requirements for impartiality, for their respective recognized accreditation bodies.
5. Recommend and promote the acceptance by users in its economies of endorsed test reports, calibration certificates, inspection reports, and reference material certificates and statements issued by organizations accredited by ILAC and IAAC signatories;
6. Abide by and use international-consensus standards (e.g., ISO/IEC, ASTM) or ILAC documents for supplemental technical requirements.

IAAC endorsed the formation of a task group to address the current functioning of the international accreditation system (future of ILAC and IAF), its strengths, weaknesses, threats and opportunities, particularly focusing on the development of proposals that strengthen, give credibility, efficiency and capacity to respond to the expectations of stakeholders, lessening the emphasis on the structure that it should or could have.

Other highlights of the IAAC General Assembly include:

- Adoption of the Strategic Plan for 2009-2011.
- Adoption of a new membership fee schedule.
- The Centre d’expertise en analyse environnementale du Quebec (CEAEQ), Canada andDireccion General de Normas y Sistemas de Calidad (DIGENOR), Dominican Republic were approved as associate members.

The following people were elected for two-year terms as chairs of the IAAC committees:

Chair: Beatriz Garcia, OAA, Argentina
Vice Chair: Ileana Martinez, NVLAP, USA
MLA Committee: Mauricio Soares, CGCRE, Brazil
Management Committee: Elizabeth Tejeda, ema, Mexico
Documentation Subcommittee: Maria Miranda, ONARC, Cuba
Promotions Subcommittee: JoAnn Given, ASCLD-LAB, USA
Technical Committee: Johanna Acuna, ECA, Costa Rica
Inspection Bodies Subcommittee: Eduardo Ceballos, INN, Chile
Certification Bodies Subcommittee: Ignacio Guerreiro, Laboratories Subcommittee: Bertha Munguia, A2LA, USA

The meetings involved over 80 people from about two dozen countries. Peter Unger and Bertha Munguia represented A2LA at the various meetings over the seven-day period.

Future meetings of IAAC are scheduled for:

- 2009 – Costa Rica
- 2010 – Brazil
- 2011 – Mexico

Further information on the IAAC meeting can be found at the IAAC web site: www.iaac-accreditation.org.
The International Laboratory Accreditation Cooperation (ILAC) annual general meeting and associated committee meetings were held in Stockholm, Sweden, October 10-22, 2008. This was the eighth occasion where ILAC met jointly with the International Accreditation Forum (IAF), the international organization for accreditation of certification bodies.

A very significant joint resolution of ILAC and IAF was reaffirmed. When a conformity assessment body (CAB), accredited by an accreditation body (AB), is providing certification to any standard used as a basis for accrediting CABs (e.g., ISO/IEC 17025), the AB shall initiate its process for suspension of accreditation of the CAB. It is accepted that a CAB may have to assess subcontractors to confirm that they meet the CAB’s requirements, which may include accreditation standards, e.g., ISO/IEC 17025. Documentation issued to subcontractors as a result of a successful assessment should clearly state that this is only for the purposes of the subcontract and is not certification or accreditation in accordance with ISO/IEC 17011. The intent of this resolution is to eliminate market confusion between certification and accreditation and the respective standards used for each activity and prevent CABs from offering services perceived as the same as those offered by ABs which, in turn, are prohibited from offering conformity assessment services in accordance with ISO/IEC 17011.

Jacques MacMillan of DG Enterprise of the European Commission spoke on the recent EU legislation on accreditation. The legislation defines accreditation as a non-profit, non-commercial, no competition enterprise under the supervision of national authorities. EA has proposed a bilateral MRA policy which would require accreditation bodies outside of Europe to meet the same requirements as European accreditation bodies, including no competition. A2LA has competitors so its bilateral MRA with the European cooperation for Accreditation (EA) may cease in the near future. Nevertheless, the EA, being a recognized regional body of ILAC, is obliged to promote the acceptance of results from laboratories accredited by non-European accreditation bodies which are signatories to the ILAC MRA. Whether these results will be accepted in the mandatory and voluntary sectors remains an open question in light of the chilling effect of the new legislation.

A joint task force of IAF and ILAC Chairs, Vice Chairs, regional and unaffiliated representatives and stakeholders was formed to explore the future of the two organizations. Work has already begun and will involve meetings starting in January. We will include analyses of the activities which are carried out at the global level and could be carried out at the regional level (or vice versa), of how to cooperate with stakeholders at the global level, and of the cost and benefit in terms of efficiency of current and proposed processes and structures.

Other highlights of the ILAC General Assembly include:

- Four new signatories were added to the ILAC Agreement: Laboratory Accreditation Bureau, USA (testing and calibration); Perry Johnson Laboratory Accreditation, Inc, USA (testing only); Oficina Guatemalteca de Acreditacion (OGA), Guatemala (testing only); and Tunisian Accreditation Council (TUNAC), Tunisia (for testing and calibration).

- Acceptance of new Associates: Kyrgyz Accreditation Center (KAC), Kyrgyzstan; and National Institute for the Defense of Competition and for the Protection of Intellectual Property (INDECOPI), Peru.

- Acceptance of new Affiliates: College of American Pathologists (CAP), USA.; and Organismo Uruguayo de Acreditacion (OAU), Uruguay.

- A membership fee increase of 15% across the board.

Continued on page 10
International Activities & Updates

Continued from page 9

Report on ILAC

- Endorsement of the MOU between ILAC and the World Anti-Doping Agency (WADA).
- Transition to ISO 15189:2007 for medical testing laboratory accreditation to be completed by 30 April 2009.
- Agreement that Calibration Measurement Capability (CMC) as used by CIPM is equivalent to Best Measurement Capability (BMC) used by accreditation bodies in accordance with ISO/IEC 17011.

The following people were elected for two-year terms as officers of the ILAC Executive Committee:

Chair: Daniel Pierre, COFRAC, France
Vice Chair: Peter Unger, A2LA, USA
Arrangement Committee: Merih Malmqvist-Nilsson, SWEDAC, Sweden
Accreditation Committee: Regina Robertson, NATA, Australia
Marketing & Communications Committee: Graham Talbot, UKAS, UK
Joint Development Support Committee: Maribel Lopez, ema, Mexico
Arrangement Management Committee: Llew Richards, IANZ, New Zealand
Unaffiliated Representative: Dorsaf Zangar
Laboratory Committee: Maire Walsh, EURACHEM, Ireland
Proficiency Testing Consultative Group: Rick Wilson, CALA, Canada

The meetings involved over 400 people from more than 70 economies. Peter Unger, Roxanne Robinson, Bertha Munguia and Dan Tholen represented A2LA at the various meetings totaling more than 150 hours.

Future meetings of ILAC are scheduled for:
- 2009 – Vancouver
- 2010 – Beijing
- 2011 – Bangkok
- 2012 – Rio de Janeiro

Further information on the ILAC meeting can be found at the ILAC website: www.ilac.org.