

ILAC News

Issue 37, April 2010



- ILAC, IAF and IEC CAB Commence a New Phase of Cooperation
- New Proficiency Testing Standard
- Marketing Workshop for SADC



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From the Chair

The past year has been a very important one for ILAC during which we have registered several important achievements.

First of all, I wish to mention the ever increasing international recognition of the ILAC Arrangement. In this respect, more US regulators (the Consumer Product Safety Commission (CPSC) for toy testing and the Nuclear Regulatory Commission (NRC) in the nuclear area) have clearly expressed their wish to rely on laboratories accredited by ILAC Full Members. In the same vein, ILAC is now also mentioned as a key player by the United Nations.

The relationship with IEC is another success story. In 2010, we are commencing a new concept of cooperation, replacing the onsite joint ILAC/IEC or IAF/IEC assessments of conformity assessment bodies by a unique assessment led by the ILAC Full Member accreditation body in the case of a laboratory and by the IAF MLA signatory in the case of a certification body and using technical experts, chosen by the accreditation body, from a list of experts qualified by the IEC. This new concept will be of great benefit for laboratories and product certification bodies, diminishing the overall cost of achieving both accreditation and recognition by IEC.

The continued excellent cooperation with WADA must also be highlighted. The training of accreditation technical experts by WADA is conducted on an annual basis and WADA relies on accreditation by ILAC members to ensure the competence of their recognised laboratories.

All these examples are very good signs.

Certainly, there is a lot of progress still to be made in many other fields but we are on the right track.

However, I wish to underline again that making the accreditation concept more well-known and the benefits of international recognition through MLAs at the worldwide level more visible, requires a robust cooperation with IAF, our sister organisation.

In this respect, the negative results of the ballots conducted at the end of 2009, about the future of the two organisations, should not be considered as an end to this cooperation.

Nearly two thirds of the members of each organisation expressed their wish to have a unique worldwide cooperation of accreditation bodies. According to our voting rules this was not sufficient (seventy five percent majority required) to achieve such a change.

However, this result definitely does not prevent ILAC and IAF from strengthening their cooperation for the benefit of all accreditation body members, stakeholders and beyond them to the global economy.

Let us improve our efficiency!

Daniel Pierre
Chair





ILAC Secretariat: Alan Squirrell, Annette Dever, Sharon Kelly, Rose Bevins, Alison Hay.

News from the ILAC Secretariat

ILAC Secretariat

The ILAC Secretariat staff is as follows:
Annette Dever – ILAC Secretary; Alan Squirrell – ILAC Executive Liaison Officer; Sharon Kelly – Senior ILAC Coordinator; Alison Hay – ILAC Administrator and Rose Bevins – ILAC Administrator.

ILAC Meetings

The annual meetings for 2009 were hosted by CALA in Vancouver, Canada in October. The Secretariat would like to extend a very big thank you to the CALA staff for the excellent logistical arrangements and support provided throughout the annual conference. The quality of the meeting rooms and conference facilities in general was appreciated by all those in attendance.

The first ILAC Executive meeting for 2010 will be hosted by Cofrac on 9 March, in Paris. This series of meetings will also include the first Joint meeting of the ILAC and IAF Executives (JEC – apologies for creating yet another acronym for everyone to learn) to be held on Monday 8 March and the IAF Executive meeting on Sunday 7 March.

The agenda for the JEC meeting includes those topics of common interest to ILAC and IAF, such as the activities of the joint working groups and committees, joint liaison activities, joint work items undertaken by the Executives and all matters associated with the planning and general logistics for the joint annual meetings. Many of these issues were previously addressed by each Executive Committee separately and then in some instances they were covered again during the meetings of the JCCC. It is anticipated that the three day series of meetings (ie IAF Executive, Joint Executive and ILAC Executive) will provide the opportunity to cover the issues in the most appropriate

forum and with a minimum of duplication.

Also scheduled for Paris in March are the annual series of meetings with BIPM, OIML, ISO and ISO CASCO as well, on this occasion.

The ILAC Secretariat will be represented this year at the ILAC Marketing and Communications Committee meeting scheduled for mid March. The Secretariat works closely with the MCC in a number of areas including the publication of documents and the maintenance and presentation of the ILAC Website.

The mid year meetings in 2010 are being hosted by ema in Mexico City during the week of 21 June 2010. The same format as the March meetings will be followed, with meetings of the IAF Executive, the JEC and the ILAC Executive being held on three consecutive days.

The final Executive meetings for the year will be held in Shanghai, in October, as part of the ILAC and IAF Annual meetings.

ILAC Arrangement

The ILAC Secretariat in its role of providing support for the ILAC Arrangement Management Committee (AMC), the ILAC Arrangement Council and alternating with the IAF MLA MC Secretariat in supporting the Joint Management Committee sessions, is involved in the on-going management activities in relation to the ILAC Arrangement through out the year. In addition, work has begun on the evaluation activities related to the establishment of the ILAC and IAF MLMRA for Inspection.

ILAC-MRA Mark

The ILAC-MRA Mark registration process continues and, as at 23 December

2009, 45 ILAC Full Members had signed Licensing Agreements with ILAC, for the use of the Combined MRA Mark (the Combined MRA Mark is the ILAC-MRA Mark used in combination with the accreditation body's own mark).

Website

The Secretariat, in-conjunction with the ILAC MCC continues to develop the ILAC website. The day to day administration of the website is carried out by the ILAC Administrators, Alison Hay and Rose Bevins. An audit of the ILAC website, by the Secretariat, was carried out during March 2009, with another being scheduled for April 2010.

As always feedback on the website, both positive and negative, is welcome from all users. All feedback is reviewed and acted upon when appropriate.

Ballots

A complete list of all documents that have been (or are being) circulated to members for either comments or voting can be obtained from the ILAC website in the Members Section under Ballots. Members are again reminded of their obligation to vote during both document and membership ballots.

ILAC News

The aim of ILAC News is to provide information on accreditation for ILAC members and their clients, liaison organisations and any organisation that has an interest in the activities and benefits of accreditation. The Secretariat, as always, welcomes feedback on the presentation and content of ILAC News as this is a valuable mechanism for facilitating the on-going development of the newsletter. A huge

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thank you to those members and colleagues that regularly submit articles and photos.

ILAC Liaisons

The review of liaison activities continues to be a major focus of the ILAC Executive Committee, who seeks to ensure that ILAC interests are represented in areas which have an impact on the activities of ILAC and its members. Action items arising out of ILAC's liaison activities are addressed during each Executive meeting as well as on a continuous basis throughout the year.

The Liaison Database, located in the members area of the ILAC website, continues to serve as the main repository for the ever increasing number of reports and documents that are produced as part of ILAC's liaison activity. It can be accessed via the members area of the ILAC website. (ILAC members who have not as yet sought access to the Members Area of the website, can do so on-line, via the 'Home' page of the website).

Since the October 2009 annual meetings, ILAC has participated in a number of liaison activities including, CASCO CPC (Chairman's Policy Committee), WG 29 (Revision of ISO Guide 65 – Product Certification), CASCO Plenary, ISO TC212 (Technical Committee - Clinical laboratory testing and in vitro diagnostic test systems), and the IAF, ILAC and ISO Joint Working Group.

ILAC and IAF were represented at the 44th Meeting of the International Legal Metrology Committee (CIML), held in October in Mombasa, Kenya. ILAC also participated in the WADA Laboratory Committee meeting in Montreal in December 09 as well as meetings of the BIPM Joint Committee for Guides in Metrology (JCGM) and the Joint Committee for Traceability in Laboratory Medicine (JCTLM), that were also held in December 2009.

Several liaison activities, in addition to those mentioned earlier, are also scheduled for the first half of 2010. These include meetings with WADA, ISO technical committees, ISO REMCO and CASCO working groups, OIML, CITAC, CCQM and the DCMAS Network

(Network on Metrology, Accreditation and Standardisation for Developing Countries – formerly JCDMAS).

Joint ILAC/IAF Activities

As many of you would be aware the final discussions regarding the future development of ILAC and IAF were held during the first half day of the Joint General Assembly (JGA) in Vancouver and it was agreed to conduct two ballots addressing various options for the future operation of ILAC and IAF.

The outcome of these ballots resulted in Option One being approved, ie maintain the current structures of ILAC and IAF, while continuing to seek more effective cooperation between the two organisations.

Contact

Information on ILAC can be obtained from the ILAC website at www.ilac.org, or by emailing the Secretariat on ilac@nata.com.au.

Annette Dever
ILAC Secretary



ILAC weblink available for downloading

The ILAC Marketing and Communications Committee has developed a weblink graphic that can be used to link to the ILAC website.

The link can be used by accreditation bodies, accredited laboratories, liaison partners and other interested organisations.

People interested in using the link should visit the ILAC website Publications and Resources page at www.ilac.org/resources where they can download a web-ready graphic in either black and white or colour. Instructions are also provided for the use of the weblink.

CHANGES TO ILAC MEMBERSHIP

The following ILAC membership changes have occurred since the last issue of ILAC News.

Full Members

- Dubai Municipality – Accreditation Department (DAC) for testing and calibration
- Egyptian Accreditation Council (EGAC), Egypt for testing and calibration
- Sri Lanka Accreditation Board for Conformity Assessment (SLAB), Sri Lanka for testing

Associates

- Papua New Guinea Laboratory Accreditation Scheme (PNGLAS)

Stakeholders

- National Laboratories Association of Zimbabwe (NLAZ), Zimbabwe

Withdrawn

- National Cooperation for Laboratory Accreditation (NACLA), USA – Stakeholder member
- Association of Forensic Quality Assurance Managers (AFQAM), USA – Stakeholder member
- British Measurement & Testing Association (BMTA), UK – Stakeholder member

Terminated

- IAR Accreditation Services, LLC (IAR), USA
- Russian Testing Organization (RTO), Russia

ILAC Membership

ILAC membership as at 16 February 2010 is as follows:

- 65 Full Members (Signatories to the ILAC Arrangement) representing 52 economies
- 22 Associates representing 22 economies
- 19 Affiliates representing 18 economies
- 4 Regional Cooperation Bodies
- 1 National Coordination Body
- 25 Stakeholders

The ILAC membership (total 136 bodies) now covers a total of 88 different economies worldwide and over 34,000 laboratories and 6,000 inspection bodies are accredited by the 87 ILAC Full Members and Associates.

ILAC, IAF and IEC CAB Commence a New Phase of Cooperation

By Annette Dever, ILAC Secretary

The cooperation between the International Electrotechnical Commission Conformity Assessment Board (IEC CAB), the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC) took a step forward during the ILAC and IAF Annual Meetings held in Vancouver, Canada on 11 – 20 October 2009.

A delegation from IEC CAB attended part of the Vancouver meetings to meet with delegations from ILAC and IAF, which included the Chairs and senior representatives from the Executive Committees of both organisations. As a result of this meeting a number of new developments in the cooperation between the three organisations were confirmed and these are reflected in the resolutions adopted during the Vancouver Joint ILAC and IAF General Assembly on 19 October 2009, as follows:

- **JGA Vancouver Resolution 2 - IEC**
The Joint General Assembly notes with appreciation the presentation detailing the process and mechanisms of the new model of assessment collaboration between ILAC, IEC and IAF and agrees to commence implementation in 2010 as appropriate. The Joint General Assembly supports the preparation of a joint communiqué by ILAC, IAF and IEC, describing the proposed processes associated with the new model for distribution to the members.
- **JGA Vancouver Resolution 3 - IEC**
The Joint General Assembly agrees with the formation of a single IAF/ILAC/IEC CAB steering committee in support of improved cooperation and agrees to disband the current IAF/ILAC/IEC Technical Panels.
- **JGA Vancouver Resolution 4 - IEC**
The Joint General Assembly supports the development of a tripartite Memorandum of Understanding (MoU) between IAF, ILAC and IEC, which will replace the existing MoUs between ILAC and IEC and between IAF and IEC. The Joint General Assembly gives a mandate to the ILAC and IAF

Executive Committees to develop the text of the MoU with IEC.

JGA Vancouver Resolution 2 – IEC relates to the new model of assessment collaboration between ILAC, IEC and IAF and the agreement to commence implementation of this process in 2010 where possible. A circular and supporting documentation, outlining the implementation process, was sent to all ILAC Full Members on 23 December 2009.

Future development and cooperation between the three organisations will be managed via the IAF/ILAC/IEC CAB Steering Committee...

Under the new model of assessment collaboration, known also as the “common pool model”, when the IEC CA Systems reassessment of a Testing Laboratory (TL) or a Certification Body (CB) coincides with the reassessment schedule of an Accreditation Body (that is a signatory to the ILAC and/or the IAF mutual recognition arrangements (MRA and MLA)), a single reassessment can be undertaken.

The Accreditation Body (AB) will manage the reassessment process, appointing the team and providing the Lead Assessor, while the IEC CA Systems will provide the AB with a list of suitably qualified IEC CA Systems Technical Experts from which to choose the remainder of the reassessment team. IEC CA Systems will accept the outcome of this reassessment process without also

conducting their own on-site reassessment.


The reporting process will be administered by the AB utilising a single report where possible. The use of a single report form will be monitored closely and on-going development of this part of the process will be undertaken on the basis of the experience gained by the reassessment teams in the field. All feedback received on the single assessment process will be provided to the newly formed IAF/ILAC/IEC CAB Steering Committee, the formation of which is the subject of JGA Vancouver Resolution 3 – IEC.

Future development and cooperation between the three organisations will be managed via the IAF/ILAC/IEC CAB Steering Committee referred to above, with ad-hoc task forces being appointed to address specific technical or administrative issues as required.

Pierre de Ruvo, Executive Secretary of the IECEE, has been appointed as Chair of this committee for a three year period and ILAC and IAF will provide the secretariat support for this group. The ILAC and IAF representation on this committee will be finalised during the Joint Session of the ILAC and IAF Executive Committees in March 2010.

The Steering Committee is scheduled to meet annually, in conjunction with the ILAC and IAF Annual Meetings, the next meeting being in Shanghai in October 2010.

JGA Vancouver Resolution 4 – IEC supports the future development of a tripartite MoU between ILAC, IAF and IEC CAB, which will replace the existing bipartite MoUs that ILAC and IAF have signed with IEC CAB. This task will be undertaken by the Steering Committee and it comes at a time when the existing MoU between IEC CAB and ILAC is due for revision.

ILAC is looking forward to working closely with both IAF and IEC CAB to implement these new initiatives that will provide tangible benefits, both for our members and for their accredited laboratories. 

ILAC committee news

SADC Marketing Workshop




By Jon Murthy (UKAS), Member of the ILAC MCC

The ILAC Marketing and Communications Committee (MCC) delivered the latest in its series of Marketing Workshops at the SADC (Southern African Development Community) Trade, Conformity Assessment Bodies and Accreditation Requirements workshop in Pretoria, South Africa. Attended by over 30 delegates representing SADCAS (Southern African Development Community Accreditation Service) staff, National Accreditation Focal Points and SADCA Committee members, the objective of the workshop was to provide general marketing guidance for accreditation bodies and to highlight the resources that have been developed by the MCC for use by the accreditation community.



Following the success of workshops given at the General Assembly meetings in Cancun and Sydney, the MCC has looked to deliver these sessions at Regional meetings to reach a wider audience with more relevant guidance. In this way, Jon Murthy of UKAS and Martine Blum from the EA Secretariat were able to focus on low cost examples of promoting accreditation that will most benefit the region. Attendees were also directed to the ready-made

promotional tools that are downloadable from the ILAC website, which include a series of brochures, powerpoint presentations, and a promotional banner.

The workshop was highly interactive and generated several ideas to promote the awareness of accreditation in the Region. The ILAC MCC will maintain close links with the region to ensure that it provides assistance and support in the achievement of regional accreditation goals. 

World Accreditation Day 2010 – “Global Acceptance”

This year marks the 10th anniversary of the ILAC Mutual Recognition Arrangement (MRA) and the 12th anniversary of the IAF Multilateral Recognition Arrangement (MLA).

The principle aim of these arrangements is as relevant today as it was when they were first established, and that is to support the freedom of world trade by eliminating technical barriers to trade. The creation of an international network among accreditation bodies removes the need for suppliers to have their products or services re-evaluated in each country they enter on a commercial basis. The key to the arrangements is that the results of accredited organisations are recognised as equivalent by signatory accreditation bodies. In this way, certificates




issued by accredited organisations can therefore be accepted throughout the world.

‘Global Acceptance’ is therefore an apt theme for World Accreditation Day 2010, a worldwide initiative jointly established by the International Accreditation Forum (IAF) and the International Laboratory Accreditation Cooperation (ILAC) to raise awareness of the importance of accreditation-related activities. June 9th 2010 will mark the day, which will see major national events and press campaigns carried out in more than 60 countries.

Internationally-agreed standards and accreditation play an important role in the support of competitive markets and cross-border trade. This is increasingly important as supply chains are ever-extending to new overseas markets as businesses seek

to lower costs or satisfy contract terms, whilst maintaining a level of confidence that products are technically compatible, to specification, and safe.

In such complex markets, reassurance in the measurements, tests, inspections, and certification performed in another jurisdiction is essential. Without these standards, the free exchange of goods and services would be hampered by technical barriers, thereby increasing costs for importers and consumers.

Global acceptance of accredited certificates is a central pillar of accreditation as the harmonization of assessment requirements and processes at a worldwide level, provides businesses and regulators with confidence that products entering the market conform to specification, meet national legal and regulatory requirements, and will therefore serve to protect public interests in general. 

International update



ILAC Work proposal in 2006 leads to a new International Standard for PT in 2010

By Dan Tholen, Convenor Wg 28

ISO/IEC 17043 *Conformity assessment - General requirements for proficiency testing* is now an approved International Standard (February 2010), due largely to ILAC's initiative. Four years ago (February 2006) ILAC submitted an "urgent" work proposal to ISO, for the revision of ISO Guide 43-1 and 43-2 as an International Standard. Now the standard is approved and published, and ILAC members are already starting to use it.

The initiative for this proposal came through the work of the ILAC Proficiency Testing Consultative Group (PTCG), and a Resolution from the 2005 ILAC General Assembly. The sense of urgency was widespread in ILAC. All accrediting bodies want competent proficiency testing (PT) for their accredited laboratories and a growing number of PT providers are seeking accreditation as PT providers. Many ILAC members offer accreditation of PT providers, and others have delayed offering accreditation for PT until there was an approved ISO standard. Several different standards were being used, and different ISO and professional sectors were developing PT standards.

The work proposal was accepted by ISO CASCO in May 2006. The work proposal was to revise ISO Guide 43-1



Members of WG 28.

and 43-2 and use ILAC G13 as a base document, along with ISO/IEC 17025. A Working Group (WG) was formed by CASCO (WG 28) with Daniel Tholen (ANSI, USA) as the Convenor. (Mr Tholen is an independent consultant and Lead Assessor for the American Association for Laboratory Accreditation (A2LA), and his participation was supported entirely by A2LA.) Members for WG28 were nominated by CASCO P members (National Standards Bodies) or by CASCO Liaison Organisations. By the end of the process, WG28 consisted of 57 experts from 33 countries and 6 liaison organisations.

Organisations in liaison to CASCO and WG28 included IEC, BIPM, UILI, Eurolab, and Codex Alimentarius.

WG28 included a large number of technical PT experts from all areas of testing and calibration. ILAC nominated seven experts to the WG and three of those experts were able to attend all of the meetings and served on the Convenor's Drafting Committee: Tony Russell (Australia), Jeff Gust (USA), and Brian Brookman (UK). In addition, Michael Koch (Germany), and Piotr Robuch (Belgium) attended the meetings as nominees by ILAC and made enormous contributions to the discussions. Alan Squirrell was also appointed to WG28 by the Convenor, for correspondence and as a guide through the labyrinth of ISO, CASCO, IEC and BIPM.

There were a lot of other ILAC "regulars" on WG28 that participated actively –

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including Regina Robertson (Australia), Ian Mann (Switzerland), Lorraine Turner (UK), Monika Wloka (Germany), Zhang Mingxia (China) and Steve Sidney (South Africa). Peter van de Leemput (Netherlands) provided essential guidance based on his experience as Convener of the CASCO Working Group for ISO/IEC 17025.

Producing an International Standard

The first meeting of WG28 occurred in December 2006, and subsequent meetings occurred in May 2007, in January and September 2008, and in June 2009. Four meetings were at ISO Central Secretariat in Geneva and the final meeting was at ANSI/ANAB Headquarters in Milwaukee (USA). Each meeting lasted 3 days, and 25-35 delegates attended each meeting.

The WG produced 4 Working Drafts, followed by a Committee Draft (approved by ISO CASCO (100%) in June 2008, 580 comments), a Draft International Standard (approved by ISO (94%) and IEC (92%) in February 2009, 400 comments) and a Final Draft International Standard (approved by ISO (98%) and IEC (94%) January 2010, 70 comments).

At the end there was only one country opposed to the standard, out of 60 casting ballots – and the two countries that voted “No” on the work item participated actively on WG28 and voted to approve, and one other country that had voted “No” on the DIS, approved the

FDIS. The standards development went smoothly because the WG28 members were committed to the values that are shared throughout ILAC – external verification of competence, traceability of measurements, and continual quality improvement for all laboratories. The new standard reflects that commitment.

What's New in the New Standard?


The technical requirements in the new standard are very similar to ILAC G13:2007, but contain a few major changes – most significantly – PT providers in the calibration area will be required to use assigned values with metrological traceability, and PT providers in other areas will need to at least consider the traceability and uncertainty necessary to assure that the assigned values are fit for their intended use. Consensus values are allowed, but providers will be required to demonstrate the suitability of the values.

Another significant change is that PT providers will not be allowed to subcontract the design of the PT scheme, the evaluation of performance, or the authorisation to issue the final reports. This is to assure a core competence in the PT provider. Other changes include the need to report the uncertainty of the assigned values and to include more information in the final report, including summary statistics for different methods used by participants and general technical comments on performance. These changes are based on the experience of the members of WG28 that the most important benefit of PT is as a

tool for quality improvement. PT providers see results from all test methods and equipment in use, they see how mistakes can occur, and they know what participants need to do to best agree with the assigned value – the PT providers are expected to share that knowledge with all participants.

The new standard retains most of the management system requirements of ISO/IEC 17025 (and ILAC G13), with a few changes to reflect recent changes in ISO 9001, as well as some wording changes for clarity regarding proficiency testing. The management requirements conform to ISO 17005, and therefore include all of the principle requirements of ISO 9001.

What's Next?

Now that ISO/IEC 17043 is an approved International Standard, a cascade of events will occur quickly – some accrediting bodies have already started the process to use it rather than ILAC G13 as the general requirements for accreditation. In 2 years all PT provider accreditations will be to ISO/IEC 17043 and ILAC will withdraw ILAC G13 as a current document. ILAC and APLAC (and possibly other regions) will start the process to extend the Mutual Recognition Agreement to include accreditation of PT providers; and ISO/IEC 17043 will become an EN standard (according to the Vienna Agreement). Several ILAC member bodies have already conducted training in the new standard, as have the APLAC and IAAC regions. APLAC has approved a training workshop for their members, to be offered later in 2010. 

ISO publishes new standard for Reference Material Producers (RMPs)

The revision of ISO Guide 34 – *General Requirements for the Competence of Reference Material Producers* – was completed in late 2009.

The new guide was produced by ISO REMCO which is the ISO Committee with responsibility for documents relating to reference materials – the values carried by these materials are essential for establishing metrological traceability in the laboratory,

which is a prerequisite for reliable and accurate measurement results.

This is an important guide for RMPs and ILAC members, particularly those accreditation bodies that already offer an accreditation program for RMPs.

The new guide will go a long way to finalising the necessary criteria for the accreditation of RMPs, hopefully leading to an extension of the ILAC Arrangement to

include this activity.

It was pleasing to receive a lot of input from ILAC members (via the Regional Cooperation Bodies) during the drafting of this new guide. The table in Annex C (informative) which cross references clauses in Guide 34 with ISO/IEC 17025 will be particularly useful for the assessment of the competence of RMPs by accreditation bodies.

Alan Squirrell ILAC/REMCO Liaison 

Regional cooperations

From the APLAC Secretariat



By Helen Liddy, Michael Fraser and Janet Clark,
APLAC Secretariat

A most successful week of APLAC 2009 meetings was held in Bali, Indonesia (5-11 December). Congratulations and thank you to Kukuh Achmed and the hardworking and friendly KAN staff for organising the program of meetings and very enjoyable social events. Our special thanks and best wishes for the future go to Dr Sunarya, who has recently retired as Secretary-General of KAN and who, unfortunately, was prevented from attending because of a death in his immediate family.

We were pleased to have the EA Chair, Graham Talbot and the PAC Secretary, Belinda Mort, attend for the week. Ralf Egner of DakS (Germany) attended the MRA Council and General Assembly meetings in his role as team leader for the ILAC evaluation of APLAC.

APLAC Mutual Recognition Arrangement

Congratulations go to the following members:

- SLAB (Sri Lanka) on being accepted into the APLAC MRA for testing and ISO 15189
- NSC-ONAC (Thailand) on the extension of its APLAC MRA signatory status to include inspection and the continuation of its signatory status for testing and calibration
- TAF (Chinese Taipei) on the continuation of its signatory status in the APLAC MRA for testing, calibration, inspection and ISO 15189
- ema (Mexico) on the continuation of its signatory status in the APLAC MRA for testing, calibration, inspection and ISO

15189

- CALA (Canada) on the continuation of its signatory status in the APLAC MRA for testing
- JAS-ANZ (Australasia) on the continuation of its signatory status in the APLAC MRA for inspection

APLAC General Assembly

The series of meetings that formed APLAC 2009 were most successful. Our thanks especially to the 4 new committee Chairs, Zhang Mingxia, Trace McInturff, Dan Tholen and Alan Patterson, who successfully met the challenge of chairing their meetings and all the tasks associated with that.

New Office Bearers

Nigel Jou (TAF) and Chang Kwei Fern (SAC) were elected to the 2 vacant positions on the APLAC Board of Management for a 2 year term, starting on 1 January 2010.

We thank very much Dr Katuo Seta (IAJapan) for his excellent contributions during his term on the APLAC BoM that ended on 31 December 2009.

APLAC Workshops/Training Courses 2010

The APLAC General Assembly endorsed the APLAC budget 2010 that includes funding for 3 training courses in 2010 and USD 70,000.00 funding for the conduct of APLAC PT programs in 2010.

A 2 day training course on ISO/IEC 17011 will be held in Seoul, Korea on 10 and 11 May 2010. This course is aimed at staff of new member bodies and new staff from more established member bodies who wish to become more familiar with the key Standard that governs the operation of accreditation bodies.

A 3 day training course on the recently issued ISO/IEC 17043 will be held in Chinese Taipei sometime in the period September to November 2010, hosted by TAF.

As an updated version of ISO Guide 34 has just been published, a 3 day training course on the new version will be held in Beijing sometime in the period June to August 2010, hosted by CNAS.

APLAC meetings in 2010

Immediately following the ISO/IEC 17011 training course in Seoul, the mid-year APLAC MRA Council meeting will be held on 12 and 13 May, followed by the mid-year meeting of the APLAC Board of Management on 14 and 15 May.


The 2010 General Assembly and associated meetings will be held in Osaka, Japan in the week 4-10 December. The meetings will be jointly hosted by IAJapan, JAB, JCLA and VLAC.

APLAC Workshop 2009

A successful workshop on ISO 15189, covering new directions around POCT and developments in measurement traceability in medical laboratories was held in Auckland, New Zealand from 30 June to 2 July 2009.

We thank Mr Katsuji Shimoda (JAB, Japan), Ms Mponeng Poo (SANAS, South Africa), Mrs Shelli Turner (IANZ, New Zealand), Mr Kevin Taylor (Canterbury Health Laboratories, New Zealand), Dr Graham White (Flinders Medical Centre, SA Pathology, Australia), Dr Wenxiang Chen (Beijing Hospital Institute of Geriatrics, PR China) and Mr Liao Chih-Heng (TAF, Chinese Taipei) for their excellent presentations and moderation of the discussions. We also thank Mr Barry Ashcroft (IANZ) who acted as Workshop Coordinator. Thanks are also due to IANZ and their staff for hosting the event and whose organisation of the workshop made it successful and enjoyable.

New Members

APLAC welcomes the Radio Research Agency of Korea Communications Commission as a new Associate Member. 

A Great Leap forward for EA



EA has been appointed by the European Commission as the official European accreditation infrastructure. The appointment became effective on 1 April 2009 in Brussels when the Guidelines for Cooperation between the European Commission (EC), the EFTA, EA and the competent national authorities were signed¹. The Guidelines set out the common policy objectives and principles of cooperation agreed by the parties.

The appointment of EA as the official European accreditation infrastructure follows the adoption of Regulation (EC) no 765/2008 of the European Parliament and the Council of 9 July 2008 establishing a legal framework for accreditation in the EU/EFTA member states. This regulation came into effect as of 1 January 2010.

A consequence of the appointment requires that EA revises its Articles of Association and Rules of Procedure to reflect EA's new role and responsibilities.

To fulfil this enhanced role to harmonise the accreditation criteria applied to CABs, EA has defined horizontal criteria for conformity assessment bodies (CABs) seeking accreditation for notification purposes, to be applied with relevant harmonised standards, guidance documents and Community or national requirements¹¹.

To achieve consistency throughout Europe, in addition to greater transparency and acceptability to all, including national authorities, the peer-evaluation

process will need to be tailored to fully accommodate the specific needs of regulatory sectors to strengthen the reassurance of sectoral stakeholders and regulators that the accreditation bodies' technical competence is thoroughly assessed.

To meet such ambitions, 13 directive networks covering 21 New Approach Directives have been established to collect, structure and make accessible all technical knowledge required for CABs' assessment. Progress of this wide-ranging task, which reflects the high expectations set by the competent national authorities, will be reported to and monitored by the new EA Horizontal Harmonization Committee.


Communication is a pivotal function for the consistent implementation of the new regulation. The latter formalises EA members' obligations to satisfy the expectations of national authorities and stakeholders, which entrust greater responsibility from their national accreditation body (NAB). A Best Practice Guide on Communications with the Regulators has been published to assist EA and its members to develop and strengthen cooperation with both national and European regulators¹¹¹.

Similarly EA itself shall enhance its communications with the EC: EA shall attend every SOGS¹¹¹¹ meeting dealing with accreditation, as well as meetings of the EC Inter-Service Steering Group for Accreditation in order to discuss the benefits of accreditation with the various EC services; projects are already underway with DGs Environment, Transport, Health & Consumer and Agriculture.

EA is also required to consult and interact in a more efficient and transparent way with its stakeholders. The EA Advisory Board (EAAB) shall be the "appropriate structure to ensure the effective and balanced involvement of all interested parties", particularly to manage the increasing number of bodies wishing to become EA stakeholders. The EAAB Terms of Reference have been revised accordingly.

Moreover, the EA Policy for Relations with Stakeholders (as defined in EA-1/15) has been adopted in order to formally grant a distinct status with associated rights and obligations to those "recognised" stakeholders who wish to become more directly involved in EA's associative life and have a particular institutional interest in contributing to EA's technical activities without, however, meeting the criteria for becoming EA full members.

Remaining issues to be resolved by EA in 2010 include cross-border accreditation and transitional measures for accreditation certificates according to article 39 in the Regulation.

A Framework Partnership Agreement (FPA) with the EC is still under discussion. The FPA will specify the tasks EA will be obliged to perform according to Regulation 765 and the Guidelines signed. The activities EA shall complete following the FPA will be specified in an EA Work Programme, which shall also be approved by the Commission. The Commission will provide funding to EA enabling EA to deliver the services agreed in the work programme and related budget." 

¹ A link to the Guidelines is available on the Homepage of the EA website.

¹¹ See EA-2/17: EA Guidance on the horizontal requirements for the accreditation of conformity assessment bodies for notification purposes.

¹¹¹ A link to the Best Practice Guide is available on the EA website, section Communication Materials / Communication with Regulators.

¹¹¹¹ The SOGS (Senior Officials Group on Standards and Conformity Assessment Policy) is an advisory committee to the European Commission dedicated to conformity assessment and standardisation issues.

EA Membership and Cooperation: State of play in early 2010

German and Italian regulatory adjustments

In accordance with European Regulation no 765/2008 which states that each national authority in the EU Member States shall establish one single national accreditation body in charge of all accreditations, some adjustments have been carried out within the EA membership.

The restructuring process of the German accreditation system has been successfully completed. The merger of DACH, DAP and TGA to form DGA has been accepted by EA as a full member. EA MLA signatory status has also been transferred to DGA. The joint transfer of full EA membership from DKD and DGA to a new legal entity named DAkkS (Deutsche Akkreditierungsstelle GmbH) was also agreed at the 24th EA General Assembly held in November 2009. DAkkS has been formally entrusted with public tasks of the German national accreditation body by the Federal Republic of Germany.

The restructuring process is also underway to the Italian accreditation system. The EA full membership and signatory status have been jointly transferred from SINCERT and SINAL to ACCREDIA (responsible for the accreditation of testing, product and quality system certification, personnel certification, EMS certification and inspection). Similarly, the EA full membership and signatory status of SIT has been transferred to COPA, responsible for the accreditation of calibration. On 8 January 2010, EA was informed that ACCREDIA has been appointed as the Italian national accreditation body for all scopes, including calibration.

To date, the EA family numbers 33 full members representing 33 European countries. Among these, there are 29



The whole EA community attending the 24th EA General Assembly held on 25 and 26 November 2009 in Bruges, Belgium.



A break in the meeting room for the 24th EA General Assembly held on 25 and 26 November 2009 in Bruges, Belgium.


signatories to the EA MLA, of which 20 have signed for all accreditation activities presently covered by the EA MLA.

Extended EA cooperation with non-European countries

Twenty non-European accreditation bodies have signed a contract of cooperation with EA. The last four signatories include the accreditation bodies of Montenegro, Kazakhstan, Kosovo under the UNSC Resolution 1244/1999 and Georgia.

Eleven of these contracts of cooperation have developed into bilateral agreements with EA.

A2LA bilateral agreement with EA

The contract of cooperation between EA and A2LA and the related bilateral agreement has been terminated by A2LA in 2009 because of A2LA's difficulties in fulfilling the future requirements set by EA pursuant to Regulation (EC) no 765/2008. 

EA is standing on its own two feet

To effectively carry out its new role, as defined in Regulation (EC) no 765/2008 which comes into effect from 2010, EA has gained full independence from COFRAC, the French national accreditation body. Taking the appropriate legal advice, EA has formally declared that the Paris offices will accommodate the EA Secretariat and that EA will become the direct employer of its current three members of staff.

In 2006, the EA Secretariat was established as a permanent structure in France. Following a 4-year pilot phase from 2006 to 2009, the EA General Assembly agreed on the transfer of staff from COFRAC to EA in May 2009. The signing of the agreement with COFRAC and the three individual employment contracts took place on 17 December 2009, which will remain a red-letter day in EA's story. All agreements became effective on 1 January 2010.

The EA accounts, which have previously been included in the COFRAC reporting system during the pilot phase, have subsequently been transferred to an independent accounting company in Paris.

The employment of the EA Secretariat proves a significant milestone for the Association, which has now clearly entered into a new phase of its existence as Europe's accreditation structure in order to meet both the challenges of its new role and the expectations of its numerous stakeholders.



Signing of the EA-COFRAC transfer agreement between Graham Talbot, EA Chairman (left), and Daniel Pierre, COFRAC Managing Director (right), on 17 December 2009 in Paris.



Signing of the employment contracts with EA by the 3 staff members of the Paris Secretariat on 17 December 2009. From left to right: Frédérique Laudinet, Martine Blum and Bénédicte Ziemann.

IAAC Report

This report includes IAAC activities from September 2009 to December 2009.

IAAC MLA scope extension

The Inter American Accreditation Cooperation (IAAC) has submitted an application to extend its IAF MLA for the scopes of accreditation of Product and Environmental Management Systems Certification Bodies, and for Inspection Bodies. Currently, IAAC is a Regional

Cooperation Body signatory of the ILAC MRA with a scope in Testing and Calibration Laboratories, and also a signatory of the IAF MLA with a scope in QMS.

IAAC has started operating MLAs for the scopes of EMS Certification Bodies, Product Certification Bodies and

Inspection Bodies.

The ILAC-IAF evaluation team leader performed an evaluation of the IAAC MLA Group, and the MLA Committee, on 29-30 August 2009 and also evaluated the IAAC Secretariat on 1-2 September 2009, in Costa Rica.

New Signatories to the IAAC MLA

NVLAP of the USA was accepted as a signatory to the IAAC MLA for calibration and testing laboratories (ISO/IEC 17025), on 30 August 2009.

Signatories to the IAAC MLA

For Testing and Calibration Laboratories (11)

Argentina – OAA
 Brazil – CGCRE/Inmetro
 Canada – SCC
 Costa Rica – ECA (Testing only)
 Cuba – ONARC
 Guatemala – OGA (Testing only)
 Mexico – ema
 USA - A2LA
 USA – ANSI-ASQ National Accreditation Board, *Doing business as ACLASS*
 USA – ASCLD-LAB (Testing only)
 USA – NVLAP

For Quality Management Systems Certification Bodies (6)

Argentina - OAA
 Brazil - CGCRE/Inmetro
 Canada - SCC
 Mexico - ema
 Peru - INDECOPI/SNA
 USA – ANSI-ASQ National Accreditation Board, *Doing business as ANAB*

For Environmental Management Systems Certification Bodies (5)

Argentina – OAA
 Brazil – CGCRE/Inmetro
 Canada – SCC
 Mexico – ema
 USA – ANSI-ASQ National Accreditation Board, *Doing business as ANAB*

For Product Certification Bodies (4)

Argentina – OAA
 Brazil – Cgcre/Inmetro
 Canada – SCC
 Mexico – ema

The IAAC MLA signatories for the scope of Testing Laboratories based on ISO/IEC 17025 which also include the scope of ISO 15189 for clinical/medical laboratories are the following: OAA of Argentina, SCC

of Canada, OGA of Guatemala, ema of Mexico, and A2LA of USA.

IAAC Membership

IAAC currently has a total of 41 members from 23 countries in the Americas. Twenty-one are full members, 9 are associate members and 11 are stakeholders.

CERTINTEX of Peru joined IAAC as a new Stakeholder member on 4 September 2009.

The following IAAC members changed their names and signed the IAAC MOU once again:

- American Industrial Hygiene Association (AIHA) to American Industrial Hygiene Association - Laboratory Accreditation Program, LLC., (AIHA-LAP).
- Forensic Quality Services International (FQSI) to Forensic Quality Services (FQS).
- INDECOPI-CRT, of Peru, to INDECOPI-SNA, of Peru.

IAAC Officers

During the annual meeting held in September 2009 in Costa Rica, the IAAC General Assembly elected new officers for the Training Sub-committee. The current list of IAAC officers is as follows:

IAAC Chair, Beatriz Garcia of OAA (Argentina)

IAAC Vice-Chair, Ileana Martinez of NVLAP-NIST (USA)

Interim Treasurer, Keith Greenway of ANSI-ASQ Nat. Acc. Board DbA ACLASS (USA)

MLA Committee Chair, Mauricio Soares of Cgcre/Inmetro (Brazil)

MLA Committee Vice-Chair, Alexander Pineda of OGA (Guatemala)

Technical Committee Chair, Johanna Acuña of ECA (Costa Rica)

Technical Committee Vice Chair, Peter Unger of A2LA (USA)

Laboratories Sub-committee Chair, Bertha Munguia of A2LA (USA)

Laboratories Sub-committee Vice Chair, Barbara J Belzer of NVLAP (USA)

Certification Bodies Sub-committee Chair, Ignacio Guerreiro of OAA (Argentina)

Certification Bodies Sub-committee Vice-Chair, Steve Cross of SCC (Canada)

Inspection Bodies Sub-committee Chair, Eduardo Ceballos of INN (Chile)

Inspection Bodies Sub-committee Vice-Chair, Sergio Hurtado of ema (Mexico)

Management Committee Chair, Elizabeth Tejeda of ema (Mexico)

Management Committee Vice-Chair, Cynthia Jimenez of ECA (Costa Rica)

Training Sub-committee Chair, Andrea Jimenez of ema (Mexico)

Training Sub-committee Vice-Chair, Nicolas Molina of DTA-IBMETRO (Bolivia)

Promotions Subcommittee Chair, Jo Ann Given of ASCLD LAB (USA)

Promotions Sub-committee Vice-Chair, Sandra Saraiva of CGCRE/Inmetro (Brazil)

Documentation Sub-committee Chair, Maria Miranda of ONARC (Cuba)

Documentation Sub-committee Vice-Chair, Liliane Somma of OUA (Uruguay)

Training

IAAC has an extensive training program. The following is a list of training activities held in 2009 and planned for 2010:

- Workshop on ISO/IEC 17021 Part 2 to be held in the United States, between October and November 2010
- Peer evaluator training workshop to be held in Rio de Janeiro, Brazil on 20 August 2010
- Workshop on Accreditation Good Practices to be held in Asuncion, Paraguay in June 2010.
- Workshop on ISO/IEC 17024 to be held in Guatemala City, Guatemala, in

Continued next page

March 2010

- Workshop on clinical/medical laboratory accreditation based on ISO 15189 in Santo Domingo, Dominican Republic held on 11-13 November 2009
- Workshop on Food Certification was held in Buenos Aires, Argentina on 28-30 September 2009
- A peer evaluator training workshop was held in San Jose, Costa Rica, on 4 September 2009
- Seminar "Market surveillance through accredited Conformity Assessment Bodies" was held in San Jose, Costa Rica, on 3 September 2009.

IAAC Proficiency Testing programs

IAAC T005 Proficiency Test for preservatives in non-alcoholic beverages. An IAAC regional proficiency testing program on preservative analysis in non alcoholic beverages is being organised by OAA/INTI of Argentina and will be starting soon. Invitations will be sent to IAAC, APLAC and SADCA members.

IAAC T004 Proficiency Test for Wine. An IAAC regional proficiency testing program on wine analysis is being carried out by DTA-IBMETRO of Bolivia. Registration began in April 2009 and the distribution of samples is currently underway. This program includes laboratories from the IAAC and APLAC regions.

IAAC T003 Proficiency Test for Fatty Acids. An IAAC regional proficiency testing program on Fatty Acid composition in Vegetable Oil is being carried out by OAA/INTI of Argentina. This program began in November 2008 and the preliminary report is being finalised. Laboratories from the IAAC region as well as laboratories from 8 APLAC members and 2 SADCA members participated.

IAAC T002 Proficiency Test for Thermocouples. An IAAC regional

proficiency testing program on Type K Thermocouples organised by ECA, Costa Rica, and NVLAP of USA began in April 2009 and is currently underway. This program includes laboratories from the IAAC, APLAC and SADCA regions.

Cooperation with international and regional organisations

Cooperation with IAF:

Beatriz García, IAAC Chair, became a member of the IAF Executive Committee.

Randy Dougherty, IAF Chair, provided a presentation at the IAAC General Assembly meeting held in San Jose, Costa Rica, on 4 September 2009.

IAF and IAAC carried out the joint peer evaluation of OAA, Argentina, in 2008, and the joint evaluation of INN, Chile, in 2009.

At the request of IAF, IAAC will provide two regional peer evaluators (team members) for the evaluation of PAC in 2009, and IAAC will also provide a regional evaluator for the evaluation of EA in 2010.

Cooperation with ILAC:

Peter Unger, ILAC Vice-Chair, attended the IAAC General Assembly meetings held in San Jose, Costa Rica, in September 2009.

At the request of ILAC, IAAC provided a regional evaluator for the evaluation of APLAC.

Cooperation with PAC:

IAAC and PAC representatives held a meeting in Vancouver, Canada, in October 2009, during the IAF/ILAC meetings, and agreed to carry out joint actions and activities aimed at strengthening ties between the Regions and their members. IAAC and PAC shared files regarding MLA activities, procedures and documents.

Anneke Olvera of SCC represented PAC at the IAAC General Assembly meetings held in San Jose, Costa Rica, in September 2009.

Cooperation with APLAC:

Laboratories from eight APLAC members are participating in the IAAC regional proficiency testing program on "Fatty Oils" which began in 2008 and is organised by INTI and OAA of Argentina.

Laboratories from five APLAC members are participating in the IAAC regional proficiency testing program on "Wine Analysis" organised DTA-IBMETRO of Bolivia in 2009.

APLAC has invited IAAC members to participate in its proficiency testing programs during 2009.

In 2009, APLAC and IAAC carried out the joint peer evaluations of AIHA LAP, USA; NVLAP, USA; and ema, Mexico.

APLAC and IAAC held a joint evaluator training course in Maryland, USA, in March 2009. Thirteen IAAC evaluators attended this course and are now qualified as trainee evaluators and may participate in IAAC evaluations.

Cooperation with EA:

Graham Talbot, EA Chair, attended the IAAC General Assembly meetings in San Jose, Costa Rica, in September 2009, and delivered a presentation on the EU Accreditation system. In May 2009, Ileana Martinez of NIST, USA, represented IAAC at the EA General Assembly.

In 2008, EA, IAF and IAAC carried out the joint peer evaluation of Cgcre/Inmetro, Brazil.

Cooperation with SADCA:

Laboratories from two SADCA members are participating in the IAAC regional proficiency testing program on "Fatty Oils" organised by INTI and OAA of Argentina.

Technical Cooperation Projects:

2009-2010 Organisation of American States (OAS) Project

IAAC is currently implementing a technical cooperation project with the OAS for accreditation bodies in developing countries within the Americas region.

The project includes the following activities:

- Witnessing of IAAC peer evaluations
- 2 peer evaluations of ABs
- Training for 3 peer evaluators
- 3 technical training courses
- 1 e-course or webinar
- 3 consultancies to a developing AB
- 3 internships for staff of developing ABs
- 1 regional seminar on accreditation
- 2 national seminar programs on accreditation
- 2 proficiency testing programs.

2009-2010 Physikalisch Technische Bundesanstalt (PTB) Project

IAAC currently has a technical cooperation project with PTB of Germany.

The project activities for 2009-2010 include:

- Workshops on Good Practices in Accreditation of Food Safety, Development of a Business Plan for Accreditation Bodies, Analysis of Proficiency Testing results, etc.
- Internships for accreditation bodies that are developing the inspection body scheme in accreditation bodies that have developed and established the scheme.
- Training for peer evaluator trainees.
- Support to carry out the international evaluations of IAAC and witnessing of IAAC evaluations.

Improvement of IAAC documents and procedures

The General Assembly recently approved changes to the following documents in order to improve IAAC processes: AD 001 IAAC MOU Text, AD 009 IAAC MLA Text, PR 005 Procedure for handling complaints and appeals, PR 007 Procedure for IAAC Adoption of International Documents and PR 011 Procedure for Internal Audits.

The General Assembly also approved revisions to the following IAAC documents: AD 001 IAAC MOU Text, AD 009 IAAC MLA Text, PR 005 Procedure for handling complaints and appeals, PR 007 Procedure for IAAC Adoption of International Documents, PR 011 Procedure for Internal Audits and a policy regarding the disclosure of IAAC peer evaluation reports.

In addition, for immediate implementation a policy regarding disclosure of IAAC peer evaluation reports was approved, and will be included in the next revision of PR002 Policies And Procedures for a Multi-Lateral Recognition Arrangement among Accreditation Bodies. IAAC will inform ILAC of this decision, in accordance with ILAC P-12.

IAAC meetings

- The IAAC 33rd Executive Committee, MLA Committee and Laboratories Subcommittee meetings will be held in Montevideo, Uruguay, on 22-24 March 2010.
- The 15th General Assembly meetings will be held in Rio de Janeiro, Brazil, from 20-27 August 2009.

IAAC Information and Publications

Information on members and IAAC documents is available at the IAAC website: www.iaac.org.mx.



Success Stories from ILAC Signatories

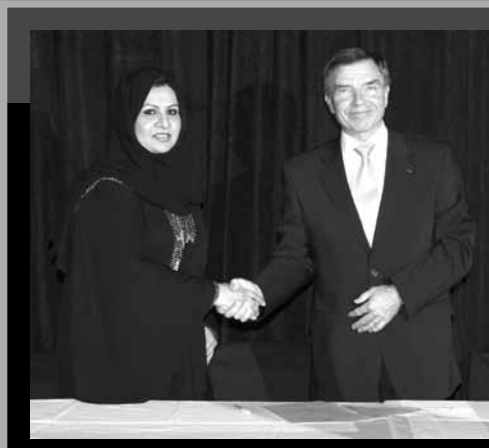
Just a reminder that the ILAC MCC is always interested in receiving 'good news' stories that demonstrate the benefits of accreditation and the ILAC Arrangement.

A collection of good news stories is available on the ILAC website for you to use to promote the benefits of accreditation.

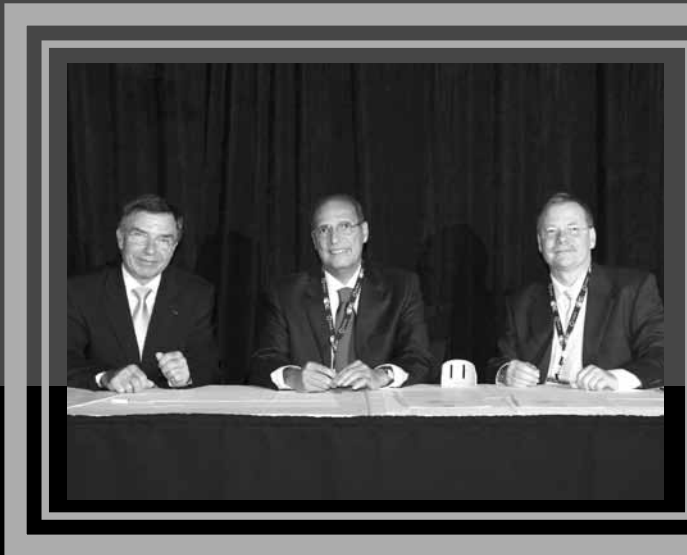
If you have any recent good news stories to share, please do not hesitate to email the Secretariat on ilac@nata.com.au who will arrange for them to be added to the good news stories page on the ILAC website.



ILAC/IAF VANCOUVER



MEETINGS



Accreditation Update

ITALY unifies accreditation system



The long-awaited sanctioning of ACCREDIA as Italy's sole official accreditation body has passed into law.

Two ministerial decrees have been signed to seal ACCREDIA's appointment, allowing Italy to meet the deadline set under Regulation (EC) 765/08.

ACCREDIA was created on 15 July 2009, by the merger of SINAL and SINCERT, as a non-profit-distributing association, to become the sole National Accreditation Body recognised by the Italian state.

The mission, indeed, was the full compliance of the national accreditation system with the regulation of the European Parliament and Commission n° 765, dated 9 July 2008 and applicable from 1 January 2010, for accreditation and market compliance in all EU countries.

The process is therefore complete: it was initiated in 2002 when a memorandum of understanding was signed by all interested categories. The Minister of Economical Development defined the sole accreditation body as a point of qualification for Italian politics in favour of quality.

The choice of ACCREDIA is also approved of and supported by other Ministries which are already members of the body, business



ACCREDIA offices in Rome.

organisations, normative bodies, operators of the conformity assessment system, all other ACCREDIA members, consumers and consultants.


The credibility created by SINAL and SINCERT over time – both nationally and internationally – is a legacy which must not be wasted. It represents the foundation upon which a wider body can be built and in which other competencies which have created the history of Italian accreditation can play a role.

Collaboration and mutual support between the public and private sectors will increasingly be the *modus operandi* of



ACCREDIA President – Federico Grazioli

ACCREDIA. Transparency, independence and impartiality will be confirmed and strengthened. As it has been in the past, Italy's commitment to an international role will be sustained, for the benefit of enterprises and all interested operators.

Within the context of the EU regulations, ACCREDIA can act as the final link in guaranteeing the process of conformity assessment, in both the voluntary and mandatory sectors. ACCREDIA can combine operational efficiency with the guarantee of respect for associated competencies, so that the quality of the Italian economic system is assured, recognised, and given the value it merits. 

Health at the heart of accreditation



Article 69 of the French Hospitals, Patients, Health and Territories Act, passed in summer 2009 (law dated 21 July 2009)

published in the Official Journal on 22 July 2009), renders mandatory and total (for all examination activities) the accreditation of medical biology laboratories (MBL) in order to "provide guarantees on the quality of medical biology examinations, in particular by setting up a procedure for the accreditation of laboratories".

It is for this purpose that the Healthcare

Section was created at Cofrac in October 2009, dedicated essentially, at least initially, to the accreditation of MBLs based on the ISO 15189 standard.

As of 1st January 2010, this new Section is empowered to receive accreditation requests, still on a voluntary basis as before, for all or part of the activity of MBLs. The first mandatory accreditations will come during

the course of 2010. All medical biology laboratories will have to be accredited by the 1 November 2016 to be permitted to operate.

Daniel Pierre, General Director of Cofrac advised "Accreditation leads to better internal organisation of laboratories and the formalisation of the procedures used, in compliance with the ISO 15189 standard."

Though he considers that, for the time being, patients continue to "be under-informed on this subject" and notes a certain heterogeneity in the quality of French biology "particularly regarding the pre-analysis phase", Daniel Pierre insists on a necessary increase in workload caused by a growing demand "as regular as possible, to be able to optimise its management".

The structures particularly concerned are:

- Medical biology laboratories as defined in the Public Health Code;
- All other structures performing examinations on persons or substances of human origin, which aim to provide useful information for the diagnosis, prevention or treatment of illnesses or to assess the state of health of human beings (biological qualification platforms for donations, structures that perform acts of pathological anatomy and cytology, structures that perform biological activities to provide medical assistance with procreation, etc.);
- Forensic biology laboratories.

The Section has undertaken to compile its

own documentary corpus. This activity will be done essentially in accordance with the standard ISO 15189, complemented where applicable by the standard ISO/IEC 22870.

The Section Committee, set up for the Healthcare Section at the end of 2009, met for the first time on 18 November 2009. It has already started to revise available documents in order to adapt them to the specificities of human health and any amendments to regulations. The Committee has also begun to create specific documents to facilitate the implementation of the accreditation process by medical biology laboratories.

Laurent Roullot, Communication Manager 

CALA Honoured to Host ILAC/IAF 2009



Not only can a great deal be learned, but a good degree of satisfaction can be felt, when one looks back into the wake of where they have just been. Assessing the outcomes achieved when an organisation is given the opportunity to host a prestigious international event is both advisable and necessary if the next organisation to host the event is to avoid any pitfalls experienced and continue to make such events even better in the future.

For 10 days in October 2009 (10-20 October 2009), the Canadian Association for Laboratory Accreditation Inc. (CALA) was given the privilege of hosting ILAC/IAF 2009 in Vancouver, Canada. In reality, CALA started its work as host at least eighteen months before the actual event. A dedicated committee comprised of both volunteers and staff met on average once per month to address an extensive list of details in order to



Daniel Pierre, ILAC President (left), Charles Brimley, CALA CEO (Centre) and Thomas Facklam, IAF President (Right) at the "Welcome Reception" to ILAC/IAF 2009.



Caricature artist was a hit with delegates during an evening reception at the Vancouver Club.

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ensure a successful event.

ILAC/IAF 2009 brought together close to 350 of the world's most knowledgeable people from more than 65 countries, on the subject of accreditation of conformity assessment bodies. Based on the positive and supportive feedback we received from many of the delegates, we have concluded that the conference was a tremendous success and we are truly pleased that the international community was so supportive of our initiatives as the event host.

To say that this event surpassed all of our expectations is somewhat of an understatement, since we had some very serious initial concerns based on the severe downturn in the global economy, coupled with the H1N1 Influenza pandemic. Early registrations were in a word "dismal" but in the end, we exceeded our goal for participation.

The success of this event would not have been possible without the expertise and commitment of the secretariats of both ILAC and IAF. Regular input and feedback from secretariat personnel at both ILAC and IAF was instrumental in precisely meeting/ exceeding the needs of all the participants at the event. We thank them for their professionalism and counsel. Our success was in great part due to their diligence and their encouragement throughout.

As you already know, we are very proud to



Magician entertains delegates during dinner cruise on Vancouver Harbour.



Committee meetings were very well attended throughout the event.



"Mostly Marley" band entertained delegates after the "Gala" dinner event.

have hosted such a successful international event while at the same time taking active steps to eliminate the carbon footprint of all delegates travelling to the Vancouver event. Former CALA CEO Rick Wilson spearheaded a tree-planting initiative that saw a total of 310 trees of nine major species plus a variety of ornamentals planted that will as they grow, totally offset this carbon footprint from the event.

In closing let me, on behalf of CALA offer

our ongoing counsel to the new committee planning the ILAC/IAF 2010 event in Shanghai. We are at their service to hopefully answer any questions they may have as they plan out what we know will be another successful event.

Thank you once again for the opportunity to host you all here in Canada.

C Charles Brimley

CALA Chief Executive Officer



Argentine Accreditation Body: Winner of the National Quality Award



The Argentine Accreditation Body (OAA) is a pioneer, being the first accreditation body in the world that has won the National Quality Award.

The purpose of the route towards excellence, that OAA has decided to pursue within the quality culture, is the continuous improvement of the services it provides, both locally and abroad. For this purpose it has adopted the National Quality Award Model in addition to the international requirements through which it has obtained worldwide recognition.

In the course of this route of successes, OAA was granted the Special Mention for Excellence in Integral Management and the National Quality Award in the non-profit organisation category granted by the National Quality Award Foundation in 2009.

The National Quality Award was created in 1992 with the aim of “promoting processes and systems for the continuous improvement of quality in order to support the upgrading and competitiveness of organisations”.

The Award was presented by the Nations President, Dr Cristina Fernández, on 21 October 2009, at the Bicentenary’s Argentinean Women Hall of the Casa Rosada. She was accompanied by the Minister of Industry and Tourism, Ms Débora Giorgi; the Minister of Economy and Public Finances, Mr Amado Boudou; the Minister of Safety, Justice and Human Rights, Dr Julio César Alak; the Minister of Health, Dr Juan Luis Manzur; the Minister of Science, Technology and Productive Innovation, Dr Lino Barañao; the Secretary of Public Management, Dr Juan Manuel Abal Medina; and the head of the National Quality Award Foundation, Mr Norberto Taranto.



OAA staff receiving the National Quality Award.

Why the quality award?

When OAA established its Vision, it strategically decided to follow the route towards excellence using these tools in order to:

- promote the development and communication of its processes and systems aimed at the continuous improvement of quality in the services it provides
- encourage and support the upgrading and competitiveness of organisations and ensure that the needs and expectations of the community are satisfied
- preserve the human work environment, the optimum assignment of tasks and use of resources.

The design of OAA’s Quality System has incorporated the National Quality Award Model to the requirements given in ISO/IEC 17011 used for its peer evaluation, in order to:

- fix goals and deal with improvement plans
- detect the areas in which the opportunities for improvement are more significant
- obtain an evaluation of its integral management system.

Description of the model for the non-profit organisations

The evaluation model defined by the Model for a Management of Excellence in non-profit Organisations (ONG) is divided into three components which in turn are subdivided into several criteria each.

Component Leadership

The component Leadership proposes that leadership must be exercised by Directors who apply a strategic management, with a clear vocation and firm commitment to constantly improve the results, by continually improving the management system, and who promote and apply the values of excellence assuming their social responsibility and contributing to the continuous improvement of their physical, social and economic environment.

Component Management System

The component Management System proposes that an organisation of excellence has to develop action plans that facilitate the fulfillment of the strategic planning focused on the recipients and the community and that it has to manage processes and human

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resources in order to achieve the objectives established by its Management Team, within the framework of its vision, mission and values.

Criterion Strategic Planning: The organisation must have an effective planning system focused on establishing the specific activities needed for the achievement of the objectives and the development of a consistent strategy with the adopted model.

Criterion Focus on the community and recipients: An organisation of excellence must have mechanisms implemented that facilitate their understanding of the requirements and expectations of its present and potential recipients. The relationships with them must ensure that they are adequately assisted and that the commitments assumed are fulfilled. Mechanisms must be in place to determine the satisfaction and loyalty of the recipients.

A system for handling complaints and claims that ensures that these are adequately solved, giving rise to actions that avoid their recurrence, is necessary.

Criterion Process Management: In this criterion it is established how key processes,

such as design, supported, production, services and relationships with providers, should be carried out.

Criterion Human Resources Management:

An organisation of excellence must distinguish itself with respect to the management of its human resources. The planning and conduct of human resources must be aligned with the general planning and strategies of the organisation. Its personnel must be trained in order to carry out their tasks, be fully familiarised with the continuous improvement process and satisfied with their working environment.

Criterion Resources Management: This criterion reviews how the organisation optimises the use of its resources by using them effectively and so that they contribute to provide better results for its interested parties.

The adequate implementation and management of the before-mentioned components must be reflected in the third component Results. The fields considered for the measurement are: satisfaction and loyalty of the recipients, repercussion in the community, economic-financial


results, operative results, human resources management results, results related to providers and actions related to the social transcendence.

New Activities for OAA

Monitoring of Good Laboratory Practice (OECD)

OAA has been appointed the Monitoring Authority of Good Laboratory Practice by the Argentinean Regulatory Authorities, according to OECD requirements. Thus, OAA started the activity of inspection in August 2009.

The first inspection was observed by Dr Francisca Liem, Chief of the Laboratory Data Integrity Branch of the Office of Enforcement and Compliance Assurance from the Environmental Protection Agency of the United States - who congratulated OAA and declared that it was a "historical" moment for Argentina.

The test facility evaluated obtained the statement of compliance with the principles of Good Laboratory Practice for non-clinical studies on agrochemicals. 

Accreditation Week 2009 in Cyprus

Organised by the Cyprus Accreditation Body (16-20 November 2009)



The Cyprus Accreditation Body (CYS-CYSAB) celebrated Accreditation Week 2009 from 16 - 20 November. The goal of the Week was to underline the importance of accreditation in the economic and social life of Cyprus and to inform all interested parties of recent and foreseeable developments, problems and perspectives. Once again the Cyprus Accreditation Body stressed its decisive role in the support of the effective and reliable operation of the quality infrastructure in Cyprus. Particular



Representatives of conformity assessment bodies who were presented with accreditation certificates during the opening ceremony of Accreditation Week 2009, with the Chair and Members of the Board of Governors of CYS-CYSAB and other officials.

emphasis was given to informing its stakeholders of accreditation matters relating to the implementation, by 1 January 2010, of the European Regulation on accreditation and market surveillance. This was an additional reason for the opening ceremony of the Week, being organised in cooperation with the Cyprus Chamber of Commerce and Industry and the Cyprus Employers and Industrialists Federation. During the Week the events received extensive publicity.

Opening Ceremony

On the 16 November the opening ceremony of the Week took place. On behalf of the Board of Governors of CYS-CYSAB, the Chairman Mr S Colocassides welcomed the attendees in-conjunction with Messrs M Tsiakkis and C Christofides representing the Cyprus Chamber of Commerce and Industry and Cyprus Employers and Industrialists Federation respectively. The message from the Minister of Commerce, Industry and Tourism, Mr Paschalides was read by Mr P Koutsoupides, Director of Commerce & Industry (Technology). Dr K Tsimillis, Coordinator of CYS-CYSAB was the main speaker for the event and delivered

The topics covered and speakers for the workshop were as follows:

<ul style="list-style-type: none"> Measurement uncertainty <ul style="list-style-type: none"> Part 1 - Basic rules of measurement uncertainty Part 2 - Other approaches for evaluating uncertainty: Use of precision and bias data and the results from collaborative studies 	Elizabeth Prichard Vicki Barwick
<ul style="list-style-type: none"> Break out session: Establish an uncertainty budget and estimate uncertainty from validation data 	
<ul style="list-style-type: none"> How legislators interpret specifications within the food sector with respect to measurement uncertainty 	Roger Wood
<ul style="list-style-type: none"> Principles of the Eurachem/CITAC Guide "Use of uncertainty for compliance assessment" 	Steve Ellison
<ul style="list-style-type: none"> Break out session: Application of decision rules for the assessment of compliance to specifications and regulations 	
<ul style="list-style-type: none"> Uncertainty, asymmetry and constraints: coverage intervals for large uncertainties 	Steve Ellison
<ul style="list-style-type: none"> Overview of quality management: Introduction to the International Standards used in laboratories 	Kyriacos Tsimillis
<ul style="list-style-type: none"> Different requirements of Standards used in different sectors: Certification, accreditation and compliance - subtle differences 	Kyriacos Tsimillis
<ul style="list-style-type: none"> Vocabulary of terminology in metrology - Eurachem Guide to ISO/IEC Guide 99 	Elizabeth Prichard
<ul style="list-style-type: none"> Frequency of PT participation 	Brian Brookman
<ul style="list-style-type: none"> Update on ISO/IEC 17043 	Brian Brookman

a presentation on "Accreditation and Competitiveness of Products and Services". Accreditation certificates were presented to newly accredited bodies along with a short

presentation on their behalf about their course towards accreditation. The event ended with a reception given by the Board of Governors.

Introduction to Uncertainty and Uncertainty for Compliance assessment

Eurachem Workshop

On the 18 and 19 November, CYS-CYSAB organised a two-day Workshop with invited speakers, including some members of the Executive Committee of EURACHEM, who were visiting Nicosia for their autumn meeting on 20 November. Thirty assessors and technical experts from CYSAB, as well as members of its Technical Committees attended the Workshop, which turned out to be very successful and interactive. The participants had varied backgrounds, with the majority being chemists but there were also representatives from other disciplines such as microbiology, veterinary science and engineering.



The speakers and the participants in the CYS-CYSAB Workshop.

DAC becomes ILAC MRA signatory



Ms Amina Ahmed Mohammed and Mr Daniel Pierre signing the ILAC MRA.



Dubai Accreditation Department (DAC) of Dubai Municipality (DM) has become an ILAC Mutual Recognition Arrangement (MRA) signatory in the field of calibration and testing including medical laboratories.

The ILAC MRA signing ceremony was held on 18 October 2009 in Vancouver, Canada during the ILAC/IAF General Assembly.

Ms Amina Ahmed Mohammed, Director of DAC and Mr Daniel Pierre, Chairman of ILAC signed the MRA.

It is worth noting that the DAC is the only accreditation body in the gulf region who is an ILAC MRA signatory and full member of ILAC.

DAC received appreciation from Dubai Government

Dubai Accreditation Department (DAC) received special appreciation for its achievement of ILAC MRA signatory status. In a special ceremony held in the City Hall, His Excellency the Director General of Dubai Municipality Engineer Hussain Nasser Lootah presented the appreciation certificate to Ms Amina Ahmed, Director of Dubai Accreditation Department. Engineer Lootah on this occasion praised the efforts of DAC staff.



Engineer Hussain Nasser Lootah, Director General of Dubai Municipality presenting the appreciation certificate to the Director of DAC in the presence of senior staff members of DAC.



Speakers at the medical conference held in Dubai.



Delegates at the ISO 15189 internal audit training course.

DAC conducted a training course on ISO 15189

DAC organised a two day training course on internal auditing for ISO 15189 on 2 and 3 November 2009. Dr Thuppil Venkatesh, Adviser of Quality Council of India (QCI) was the resource person. Thirteen participants from various governmental and private medical laboratories attended the training course.

DAC sponsored medical conference in Dubai

DAC sponsored a medical conference on quality health care standards in Dubai. The conference was organised by the Prime Health Care Group, UAE. More than 150 delegates attended the conference. Eng Muhammad Shahid Rasool of Dubai Accreditation Department gave a presentation on "ISO 15189-Global Acceptance of Competence". 


The Egyptian Accreditation Council "EGAC"

Launches Medical Laboratories Accreditation Program

EGAC, a signatory to the ILAC MRA, and is extending its accreditation activities to include medical laboratories EGAC announced on the 4 January 2010 that it is ready to start assessing and accrediting medical laboratories to the requirements of the International Standard ISO 15189:2007.

The launching of the program was announced by Eng Hassan Shaarawi, the Executive Director of EGAC during the Fifth Conference for Quality Assurance held in the Faculty of Medicine, University of Alexandria. The aim of the program is to enhance the credibility of results from medical testing laboratories.

The announcement came after EGAC completed building its capacity to handle the medical laboratory accreditation activities and after becoming a full member of ILAC on 10 October 2009.

EGAC is also planning to expand its accreditation activities on the national and regional levels. 

ema's National Strategy to Strengthen Accreditation and Conformity Assessment



By: Maria Jose Mesen, National & International Coordinator, ema

Regional and international recognition are without doubt a key factor for an accreditation body, and this is why the Mexican Accreditation Body (entidad mexicana de acreditación - ema) has made efforts to become a signatory to the different MRAs and MLAs that the regional and international accreditation forums run and are of interest to Mexico.

However, international recognition must walk hand-in-hand with national recognition, and it is now ema's goal to obtain this by a series of strategies that will allow us to have a greater impact on authorities, clients, academic and interested parties.

Mexico has a territory of 1,964,375 km², made up of 31 States and a Federal District.

Within such a large territory there are many different cultures, climates and topography which deeply mark the different conformity assessment bodies that are developed in

The success of this campaign is such, that we expect 7 more Strategic Regional Groups to be formed in 2010.

a given State. And of course, there is also a difference in the knowledge clients and users have of the Mexican Metrology,


Standardization and Conformity Assessment System in the different States.

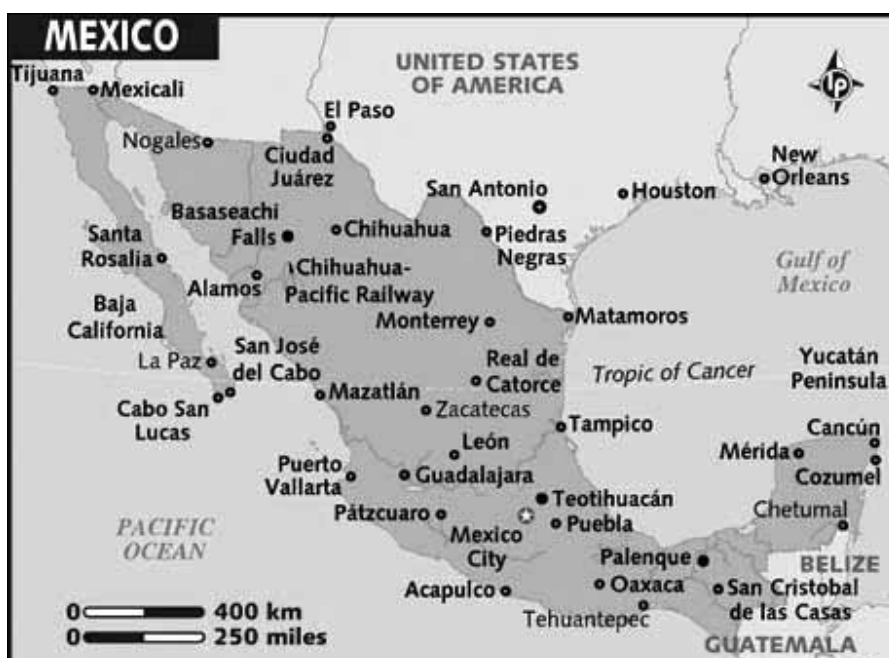
Considering the above, we are convinced that even when there has been a significant increase in the accredited infrastructure of our country (about six times more than in 1995); it is necessary to increase the knowledge of standards and the need to assess them, and in doing so, support our activities. Given our broad territory, this need is especially stronger outside our Capital, Mexico City.

Therefore, ema has reinforced its national campaign named "ema va a su casa" (ema goes to your home town), where we visit different Mexican States, and organise conferences on the importance of complying with standards and the benefits of being accredited and using accredited conformity assessment bodies.

Apart from this, we have organised Strategic Regional Groups in 9 different States. These groups are made up of different interested parties, and they have proven to be a great awareness tool to make society more conscious of topics such as metrology, standardisation, accreditation and conformity assessment. Many seminars took place during 2009 that were organised by these groups, according to the needs and interests of each State.

It is important to point out, that ema's role in the groups is just as a coordinator. The success of this campaign is such, that we expect 7 more Strategic Regional Groups to be formed in 2010.

ema would like to share what we are doing with the accreditation community, hoping that this tool could be useful for other countries that face the same issues as us. 



SADCAS and SANAS sign Twinning partnership arrangement



From left to right: Mrs Maureen P Mutasa – SADCAS CEO, Mr Riundja Kaakunga (Othy) – SADCAS Board of Directors Chairman, Mr Prags Govender – SANAS Board of Directors Chairman, and Mr Ron Josias – Acting CEO SANAS, during the signing ceremony.




The Southern African Development Community Accreditation Service (SADCAS) and the South African Accreditation System (SANAS) have entered into a twinning partnership.

The Twinning Partnership Arrangement was signed at a ceremony held at SANAS Headquarters, Pretoria, South Africa on Thursday 3 December 2009. The ceremony was attended by SADCAS/SANAS Boards of Directors' Chairmen and the respective organisations' Chief Executive Officers, SANAS Senior Managers and Program Managers as well as a representative of the South African Department of Trade and Industry.

The purpose of the Twinning Partnership Arrangement is to help kick start SADCAS' accreditation services with the ultimate goal of ensuring that SADCAS becomes a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) and the International Accreditation Forum (IAF) Multilateral Recognition Arrangement

(MLA). In his welcome and introductory remarks, Mr Prags Govender, the SANAS Board of Directors' Chairman highlighted the important role accreditation plays in regional integration and assured SADCAS of SANAS' commitment to ensuring SADCAS success for the benefit of the region. Speaking at the ceremony, Mr Riundja Ali Kaakunga (Othy), the SADCAS Board of Directors' Chairman outlined the purpose of the Twinning Partnership Arrangement and highlighted the areas of cooperation between SADCAS and SANAS. He also emphasised the need for SADCAS and SANAS to abide by the undertakings in the Arrangement in order to make it a success and to safeguard both organisations' integrity and reputation.

With the signing of the Arrangement SADCAS is now set to kick start its accreditation services. 

Re-regulation of Swedish vehicle inspection



Some of SWEDAC's staff in front of World Trade Center in Stockholm. Photo: Hans Alm

SWEDAC has been working with the Swedish Transport Agency to start the preparations for the re-regulation of Swedish vehicle inspection. At the end of 2009, the Swedish Parliament decided to abolish the current monopoly from the middle of 2010.

It is hoped that an open system will lead to better service and greater availability.

"One possible development is that the Swedish inspection stations will also supplement their activities with other kinds of services, including different kinds of 'condition inspections' i.e. complete assessments of vehicles, when for example

there is a change of owner," says Örjan Ellström, Project Manager at the Swedish Transport Agency.

The Swedish Transport Agency will be the regulatory authority for the re-regulated market and will also be tasked with carrying out surveillance on the market to ensure that activities still retain a high level of quality.

Inspection companies will need to be accredited by SWEDAC according to ISO/IEC 17020, which includes assessing the body's technical competence, equipment standards and quality assurance, as well as their independence.

The Swedish Transport Agency and SWEDAC are currently holding discussions as to what competence requirements should be placed on inspection technicians.

These authorities have expressed a wish to the Ministry of Enterprise, Energy and Communication for requirements for certification of persons to be introduced as part of accreditation.

SWEDAC celebrates 20th anniversary

The accreditation system is becoming even more important for international trade – not

only in the EU internal market, but also globally.

"Collaboration on standardisation and accreditation should not stop at the borders of the EU. 'Tested once – accepted everywhere' is a concept that industry has been demanding for a long time," said the Trade Minister, Mrs Ewa Björling in her speech at SWEDAC's anniversary seminar.

Since SWEDAC was established 20 years ago, the authority has been at the forefront of one of the most extensive de-regulations that has ever taken place in Sweden. The fact that Sweden introduced an open system for testing, inspection and certification based on accreditation, at an early stage, also means that Sweden has less 'homework' to do than many other countries when it comes to implementing the EU Regulation on Accreditation and Market Surveillance which came into force at the beginning of this year.

"The EU countries are facing a major and radical reform. In the future, accreditation will be used in all areas," says Jacques McMillan, the Head of the Regulatory Approach for the Free Movement of Goods Unit at the Enterprise and Industry Directorate-General at the European Commission.

Other speakers at the seminar were SWEDAC's Director General, Hans-Eric Holmqvist, the former Director General, Lars Ettarp and EA Chair, Graham Talbot.

SWEDAC's Stockholm Office in new premises

At the end of 2009 SWEDAC's Stockholm office moved from its premises in Gamla Stan to the World Trade Center in Stockholm city. 'The new premises will be more efficient and reinforce SWEDAC's image as a modern organisation', says Director General, Hans-Eric Holmqvist. The office is easy to get to from Stockholm Central as well as from the airport by bus and the Arlanda Express-train.

New international secretariat at SWEDAC

Recently SWEDAC reorganised its international work by creating an



The Minister for Trade Ewa Björling at SWEDAC's 20th anniversary. Photo: Hans Alm.

international secretariat under the leadership of Merih Malmqvist Nilsson, who is well-known for, among other things, her work for ILAC, IAF and EA. Other employees at the secretariat are Elsbeth Johansson, Annica Poppius, Katarina Wenell and Ingrid

Arremark. The secretariat will be responsible for coordinating SWEDAC's international cooperation with its international development support projects in other countries, as well as its courses in Sweden for international participants. By bringing all the international issues together the work in the international field will be more efficient and better coordinated.

Recently SWEDAC finalised support projects in Sri Lanka and the Ukraine. At present, SWEDAC is engaged in projects in Egypt, Bosnia and Herzegovina and Macedonia aimed at supporting the accreditation systems. Negotiations concerning new projects are also under way. During this year, SWEDAC will welcome about 125 participants to Sweden for the courses 'Quality Infrastructure Development in Support of World Trade', 'Negotiating Trade Agreements' and 'Quality Infrastructure for Food Safety'. 



Merih Malmqvist Nilsson is head of the new international secretariat at SWEDAC.

Croatian Accreditation Agency (HAA)



Ensuring Excellence in the Competence of the Accreditation Body

The mission of the Croatian Accreditation Agency (HAA) is to perform high quality independent assessments of the competence of conformity assessment activities that are recognised internationally for the benefit of the Croatian economy and society.

Major activities of HAA during 2009 related to the preparation of HAA for the peer evaluation by the European co-operation for Accreditation (EA) in order to sign the multilateral agreement (EA MLA) for all accreditation schemes.

The peer evaluation took place in July and November 2009 and the EA evaluation team concluded that HAA has competent and experienced personnel as well as, an organisational structure compliant with the international standard ISO/IEC 17011 for accreditation bodies performing on site assessments of a high quality. But of course, there is always room for improvement. However, it was a great experience. Even before the process has been completed, we can point out a lot of advantages of peer evaluation and the measures that HAA took, in order to respond to the findings of the EA evaluators. The measures relate to changes and amendments to the quality management system documentation, improving the technical competence of personnel and improving the IT system.

HAA has made efforts to improve its quality management system documentation and to decrease the duration of the accreditation process. Apart from rationalising the time period for granting accreditation, it will also enable smoother running of the process and ensure better communication between the accreditation body and the conformity assessment body.

Ensuring excellence in the competence of personnel is the key factor for the credibility of the accreditation process and granted accreditation certificates. Competence should be regularly monitored and kept



HAA Lead Assessors participating in Refresher Training of ISO/IEC 17011 and ISO 19011 requirements.

up to date, either by refreshing knowledge of the standards and regulations, harmonisation amongst the assessors, consistent interpretation of particular requests and similar. Monitoring of personnel involved in the accreditation process should be regularly carried out to ensure the accreditation body provides high quality services.

HAA has upgraded its IT system. The Assessors' data base for retaining details of their activities, as well as acquiring and maintaining their status in a particular area had to be followed up in a proper way. HAA has developed various reports within the existing IT programs, that enable proper follow up and have also ensured that the competence of the assessors can be proven. It also relates to the data base for the participation of laboratories in PT schemes. This demonstrates that IT support is very important as it facilitates easy access to the data base and enables search activities that provide all the relevant data collected in one comprehensive report.


In addition, HAA has benefited from participating in the EU pre-accession projects, such as the regional quality infrastructure projects providing technical assistance to HAA in order to upgrade its institutional capacity to perform its core duties.

There were twelve internal training sessions organised by HAA covering exchange of assessors' experience, improvements to the internal management system documents, etc. HAA employees also participated in 16 technical seminars, such as Setting up a laboratory in compliance with HRN EN ISO/IEC 17025, Traceability and Uncertainty of Measurement for HAA assessors, Assessment of laboratory

performing tests related to the control of food safety, etc organised within EU projects and other organisations, as well as two study visits relating to accreditation of conformity assessment bodies for lifts and pressure equipment.

In 2010 the objective of HAA will be attaining excellence of its activities and strengthening the capacities of employees and HAA external associates (technical assessors and experts). Therefore, HAA will continue organising internal training for employees as well as for the external associates in order to ensure their competence.

HAA, as a national accreditation body in the Republic of Croatia, has continued a very good cooperation with the government institutions responsible for the implementation of the new Croatian technical legislation harmonised with the EU legislation. HAA therefore performs assessments of the technical competence of CABs in various regulated fields such as: construction products, lifts, pressure equipment, personal protection equipment and other industrial products, air quality testing, pollutant air emissions and other environmental protection measures, organic farming, official food control, etc.

Finally, the vision of HAA is to be recognised for the credibility of the Croatian accreditation system, ensuring the acceptance of the Croatian conformity assessment system for products and services internationally and therefore supporting Croatian producers and in particular enabling them to participate in the market. 

Hong Kong to Promote the Development of the Testing and Certification Industry

The Hong Kong Council for Testing and Certification was set up in September 2009 to spearhead the development of the industry in Hong Kong.

The testing and certification industry in Hong Kong has been enjoying a steady growth. Locally, the testing and certification industry plays an important role in the daily life of the Hong Kong community. For example, the medical testing laboratories provide essential support to the medical sector in diagnosis of illness. With heightened public awareness and concern over safety and nutritional content of food, private laboratories have also been playing an increasing role in supporting the food industry on quality assurance.

In support to trading, the industry provides a high volume of testing and inspection services for consumer products manufactured in Hong Kong and the Pearl River Delta Region of the Mainland of China, in particular for toys, electrical and electronic goods, textiles, garments and footwear. The industry also provides certification services for the relevant management systems (eg ISO 9001 on quality management system). Through providing assurance to overseas buyers on the quality and safety of the products, both produced in Hong Kong and the Mainland of China, the industry has played a part in the development of trading and logistics services in Hong Kong as well as the industrialisation of the Pearl River Delta Region.

The local testing and certification industry has already established a good reputation in the region in terms of its professionalism, integrity and knowledge of the international market. Coupled with its proximity to the Mainland of China, which has a rapidly growing market and is a major manufacturing base in the world, Hong Kong has the potential to develop into a major testing and certification centre in the region. Many major international testing and certification



The Hong Kong Council for Testing and Certification held a consultation forum in November 2009 to collect views from the testing and certification industry and other major stakeholders.

companies have already set up branches in Hong Kong.

The government has been providing support to the testing and certification industry, including operating the Hong Kong Accreditation Service (a member of ILAC). The establishment of the Hong Kong Council for Testing and Certification in September 2009, is a further step in promoting the development of the industry and demonstrates the staunch support from the government for the sustained growth of this sector in Hong Kong.

The Council is chaired by Professor CHING

Pak-chung, Pro-Vice-Chancellor of the Chinese University of Hong Kong, with members from the testing and certification industry, business sector, professional bodies as well as relevant public bodies and government departments. The Council is currently working with the testing and certification industry to formulate a three-year market-driven development plan for the industry.

For those interested in the work of Hong Kong Council for Testing and Certification, you are welcomed to visit the Council's website at <http://www.hkctc.gov.hk>.



MAURITAS Accredits The Plant Pathology Laboratory of AREU



The Mauritius Accreditation Service (MAURITAS), which operates under the aegis of the Ministry of Industry, Science and Research, has accredited the Plant Pathology Laboratory of the Agricultural Research and Extension Unit (AREU) to the international standard MS ISO/IEC 17025:2005.

The laboratory successfully went through the various steps of the accreditation process, namely, the document review, pre-assessment and initial assessment, with MAURITAS and its twinning partner, the South African National Accreditation Service (SANAS).

The Accreditation Certificate Award Ceremony for the Plant Pathology Laboratory was held on 5 November 2009 at the Farmers Training School in Wooton, Mauritius. The ceremony was honoured by the Honourable Dharambeer Gokhool, Minister of Industry, Science and Research and the Honourable Satya Veyash Faugoo, Minister of Agro Industry, Food Protection and Security.

"The ceremony being organised today marks an important milestone and a significant achievement of the Plant Pathology Laboratory of AREU with respect to the quality of its testing" claimed the Honourable Dharambeer Gokhool. "It represents one of the most critical steps towards moving for excellence in laboratory testing services in the agro industry sector at national, regional and international level."

The Plant Pathology Laboratory forms part of the Plant Pathology Division of AREU and provides diagnostic services to the planting community of Mauritius and Rodrigues. The scope of accreditation for the laboratory includes detection of plant pathogenic viruses and bacterium *Ralstonia solanacearum*.

MAURITAS provides a national unified




The staff of the Plant Pathology Laboratory during the Accreditation Certificate Award Ceremony.

service for the accreditation of Conformity Assessment Bodies (CABs) such as Calibration and Testing Laboratories, Inspection Bodies and Certification bodies. One of the main objectives of MAURITAS is to provide formal recognition of the technical competence of CABs to operate in accordance to international standards.

MAURITAS has already accredited eight laboratories to the international standard MS

ISO/IEC 17025:2005 and one certification body to MS ISO/IEC 17021:2006 since February 2008. MAURITAS has already embarked on developing an accreditation programme for all inspection bodies against ISO/IEC 17020:1998.

The Minister of Industry, Science and Research seized this opportunity to congratulate MAURITAS for its committed work in the field of accreditation. 

MAURITAS PARTICIPATES IN THE 1ST SADC SET WEEK

The Government of Mauritius organised the first Southern African Development Community (SADC) Science, Engineering and Technology (SET) Week from the 22 to 25 October 2009 at the Swami Vivekananda International Convention Centre, Les Pailles, Mauritius. The theme of this event was: 'Harnessing Science, Engineering and Technology for socio-economic development'.

The Mauritius Accreditation Service (MAURITAS) participated in one of the activities organised to mark the first SADC

SET Week, namely, 'A regional Exhibition on Scientific and Technological development in the region'.

This was a unique opportunity for MAURITAS to sensitise the Mauritian population to the importance of accreditation and its contribution to the daily life of all Mauritian. MAURITAS, therefore, designed a brochure, depicting the various activities of MAURITAS and the accreditation process in Mauritius. A flyer enumerating the various advantages of accreditation was also developed

using information from the International Laboratory Accreditation Cooperation (ILAC) website. Furthermore, MAURITAS designed several posters and presentations that were displayed during the SADC SET week.

The MAURITAS booth attracted a large number of visitors who were mostly unaware of the activities of MAURITAS and knew little about accreditation.

However, after discussions with the staff of MAURITAS, all the visitors were convinced of the importance of accreditation and of the major role being played by MAURITAS in order to increase confidence in Mauritian goods and services both at a national and international level. The brochure and flyer of MAURITAS, as well as those of the Southern African Development Community Accreditation Service (SADCAS) were distributed to visitors of the MAURITAS booth.


In fact, visitors to the MAURITAS booth



The MAURITAS booth receiving visitors during the 1st SADC SET week.

were unanimous that all laboratories in Mauritius should work towards accreditation.

MAURITAS has viewed its participation in the first SADC SET week as being very fruitful, as it has provided an opportunity to bring to light its activities and the importance

of accreditation to the Mauritian public. MAURITAS is therefore aiming to sensitise a larger fraction of the population through the celebration of World Accreditation Day in June 2010 and by also participating in the National SET week in 2010. 

News from TAF

Forum on “Use of TAF Accreditation by Regulatory Authorities”



By Wanji Yang

TAF held a forum on 29 December 2009 and invited representatives from eight regulatory authorities to share their experiences in using TAF accreditation and the benefits they have gained. As the Chair, Dr Jay-San Chen, Director General of BSMI and President of TAF, briefly introduced TAF accreditation status and took two accreditation cooperation programs between BSMI and TAF as examples to demonstrate the benefits of using TAF accreditation.

Mr Kun-Huang Chen, Chief-Secretary of the Children Welfare Bureau Ministry of Interior (CBI), mentioned that TAF had



Presenters at the TAF forum for regulators.

helped to establish two national standards. TAF accreditation is now required for inspection bodies performing playground inspection.

Mr Yu-Ting Lai, Deputy Director from the Public Construction Commission (PCC), shared PCC's strategies and different steps of

blending TAF accreditation into construction related regulations. Better management of civil engineering testing laboratories has helped to reduce risks and build better confidence in public construction work.

Mr Sen Chen, Deputy Director of Council of Labor Affairs (CLA), introduced the

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work that TAF has been involved in the “Workplace Environmental Monitoring System”. CLA and TAF are now working on more cooperation on the accreditation of Taiwan Occupational Safety and Health Management System (TOSHMS) certification.

Mr Wen-Chin Wang, Senior Specialist of the Council of Agriculture (COA), said TAF has been designated for accreditation of “Agriculture Product Resume Traceability” certification bodies. This has enhanced consumers’ confidence in over 130 kinds of agriculture products.

Mr Chien-Chung Liu, Senior Specialist of the Environmental Protection Administration (EPA), explained the role that TAF accredited laboratories and product certification bodies play in the “Green Mark” system.

Ms Sylvia Lin, Director of TAF Laboratory Accreditation Department, reported on behalf of the Bureau of Food and Drug Analysis (BFDA) regarding the joint assessment mechanism for accrediting testing laboratories for drugs and cosmetics. A database of the accredited laboratories has also been established and is open to the public.

TAF has been trying to build more connections with end users, so it invited Mr Cheng-Hsueh Wu, Section Chief of the Consumer Protection Commission (CPC), to speak from the viewpoint of consumer protection. Mr Wu mentioned that TAF accreditation has been used as strong support in making judgements on consumer protection issues. CPC looks forward to seeing more accreditation related promotional activities for public education.

TAF appreciates the support it receives from various regulatory authorities. The discussions in the forum were recorded and later reported by journalists in the newspaper. This kind of activity also provides a good channel for regulatory authorities to learn from each other. TAF will continue carrying out promotional activities for customers, regulatory authorities and end users, and continue moving towards the goal of “Global Acceptance”. 

Stakeholders

EUROLAB workshop on Accreditation with flexible scope

EUROLAB organises twice a year, its General Assembly meeting in different places within the European member states. It also used to be the occasion, to organise a joint workshop open to both the laboratory and stakeholder communities.

On 3 November 2009 the EUROLAB Board and General Assembly meetings were held in Prague, Czech Republic, at the Technical and Test Institute for Construction (TZUS). The day after, on 4 November a workshop was organised by the Technical Committee for Quality Assurance of EUROLAB. It was dedicated to the accreditation with flexible scope as the follow up of the workshop organised three years ago in Borås (Sweden).

Over 50 participants representing 18 European countries, from numerous conformity assessment bodies, various industries and eight accreditation bodies attended the workshop.

The rationale of the workshop was to exchange experience so far, to benchmark and promote good practices and finally to give input to EA, in order:

- to have a common and better understanding of flexible scope;
- to promote and further develop it for the respective benefits of laboratory, client and accreditation communities.

The key issues of flexible scope were presented by different speakers:

- On the accreditation side, two very interesting presentations (from Martina Bednářová - CAI and Hanspeter Ischi - SAS) presented the developments and good practices at the EA level;
- At the EUROLAB level, Manfred Golze - BAM presented the results of a EUROLAB inquiry. The concept of flexible scope accreditation looks promising but there is very limited information available on how it really works;
- Practical experiences of the laboratories were presented in EMC testing by Urs von Känel - Albis Technologies Ltd (in combination with the presentation of Hanspeter Ischi - SAS), in calibration by Pascal Launey - LNE and in physical, chemical or microbiological tests by Katarzyna Rajczakowska - CBJ Polish laboratory;
- Two presentations focused on the issue

of notified bodies and put them into perspective with the new European Regulation 765/2008/EC - requirements for accreditation and market surveillance relating to the marketing of products;

- A fruitful debate on the conclusions to be drawn up was introduced by a presentation made by Magnus Holmgren – SP on the gap analysis between the current situation and future needs.

The outcomes of this workshop were presented to the national accreditation bodies at the EA General Assembly held in Bruges, Belgium on 25–26 November 2009. They have been uploaded onto the EUROLAB website, together with the workshop proceedings. They could be summed up as follows:

- Since the EUROLAB Workshop in Borås there has been considerable progress concerning the implementation of the concept of laboratory accreditation with flexible scope;
- Most of the accreditation bodies grant accreditation with flexible scope to all types of laboratories for all technical fields;
- Harmonisation of the definition and accreditation practices across Europe seems to be making good progress, but still needs to be improved: all EA members should apply the same definitions and rules in order to avoid market distortion;
- Most of the assessors are familiar with the concept of flexible scope but there is still a need for a better understanding and promotion of the concept leading to flexible scope accreditation to customers across Europe and worldwide;
- Flexible scope accreditation is focusing on the competence but there is still strong emphasis on documentation during assessments;
- Develop, together with stakeholders, sectorial guidance documents (e.g. medical and environmental sectors) to facilitate harmonisation and spread good practices for accreditation with flexible scope;
- EUROLAB, in agreement with industry and authorities, should be in a position to set recommendations and rules for flexible scope accreditation which shall be observed by accreditation bodies.

Jean-Marc Aublant – December 15, 2009

ILAC Publications

The following is a listing of titles of all ILAC documents. These can be downloaded from the 'ILAC Documents' section under 'Publications and Resources' on the ILAC website.

Brochures

- The ILAC Mutual Recognition Arrangement
- Signatories to the ILAC Arrangement
- Why Use An Accredited Laboratory?
- Why Become An Accredited Laboratory?
- How Does Using an Accredited Laboratory Benefit Government & Regulators?
- The Advantages of Being An Accredited Laboratory
- Laboratory Accreditation or ISO 9001 Certification
- Benefits for Laboratories Participating in Proficiency Testing Programs
- The route to signing the IAF/ILAC Arrangement

Guidance Documents (G Series)

- ILAC-G3:1994 Guidelines for Training Courses for Assessors
- ILAC-G7:06/2009 Accreditation Requirements and Operating Criteria for Horseracing Laboratories
- ILAC-G8:03/2009 Guidelines on the Reporting of Compliance with Specification
- ILAC-G9:2005 Guidelines for the Selection and Use of Reference Materials
- ILAC-G10:1996 Harmonised Procedures for Surveillance & Reassessment of Accredited Laboratories
- ILAC-G11:07/2006 Guidelines on Assessor Qualification and Competence of Assessors and Technical Experts
- ILAC-G12:2000 Guidelines for the Requirements for the Competence of Reference Material Producers
- ILAC-G13:08/2007 Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes
- ILAC-G17:2002 Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025
- ILAC-G18:2002 The Scope of Accreditation and Consideration of Methods and Criteria for the Assessment of the Scope in Testing
- ILAC-G19:2002 Guidelines for Forensic Science Laboratories
- ILAC-G20:2002 Guidelines on Grading of Non-Conformities
- ILAC-G21:2002 Cross Frontier Accreditation — Principles for Avoiding Duplication
- ILAC-G22:2004 Use of Proficiency Testing as a Tool for Accreditation in Testing
- ILAC-G23:2004 Withdrawn
- ILAC-G24:2007 Guidelines for the determination of calibration intervals of measuring instruments

Procedural Documents (P Series)

- ILAC-P1:07/2007 ILAC Mutual Recognition Arrangement (Arrangement): Requirements for Evaluation of Accreditation Bodies by ILAC-recognised Regional Cooperations
- ILAC-P2:2003 ILAC Mutual Recognition Arrangement (Arrangement): Procedures for the Evaluation of Regional Cooperation Bodies for the Purpose of Recognition
- ILAC-P3:07/2007 ILAC Mutual Recognition Arrangement (Arrangement): Procedures for the Evaluation of Unaffiliated Bodies for the Purpose of Recognition

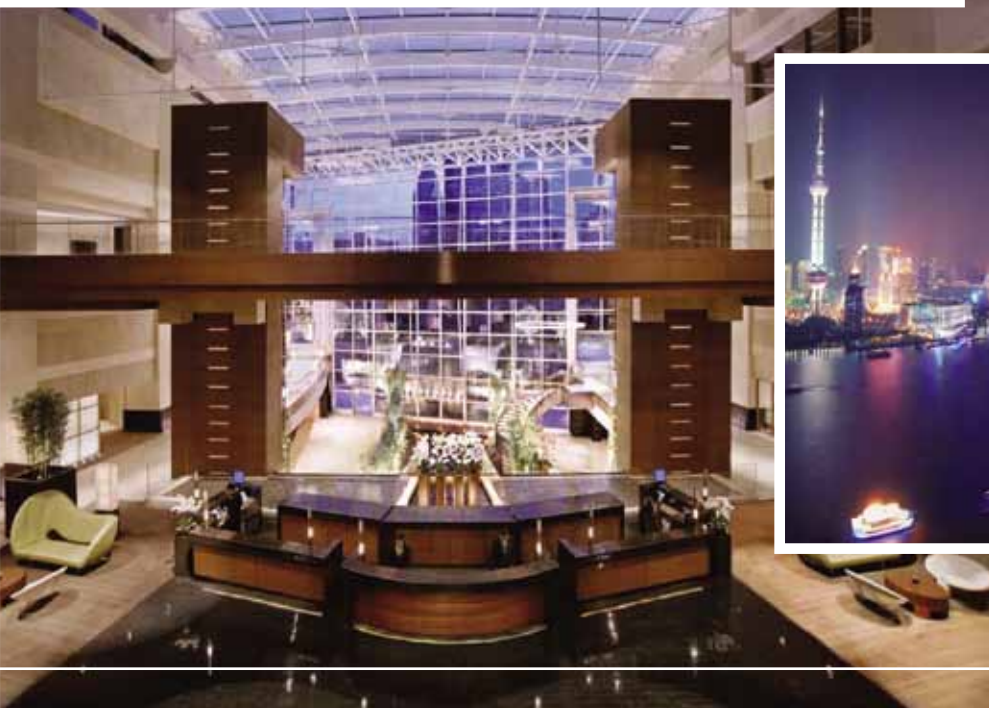
- ILAC-P4:2003 ILAC Mutual Recognition Arrangement (Arrangement): Policy Statement
- ILAC-P5:04/2007 ILAC Mutual Recognition Arrangement (Arrangement)
- ILAC-P6:2003 Application for Full Member Status
- ILAC-P8:07/2006 ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories
- ILAC-P9:2005 ILAC Policy for Participation in National and International Proficiency Testing Activities
- ILAC-P10:2002 ILAC Policy on Traceability of Measurement Results
- ILAC-P11:09/2009 Monitoring Performance of ILAC Evaluators
- ILAC P12:04/2009 Harmonisation of ILAC Work with the Regions

Rules Documents (R Series)

- ILAC-R1:09/2009 Classification and Publication of ILAC Documents
- ILAC-R2:09/2009 ILAC Rules
- ILAC-R3:09/2009 ILAC Strategic Plan
- ILAC-R4:03/2010 Use of the ILAC Logo and Tagline
- ILAC-R5:09/2009 ILAC Procedure for Handling Complaints
- ILAC-R6:09/2009 Procedure for Expansion of the Scope of the ILAC Mutual Recognition Arrangement
- ILAC-R7:09/2009 Rules for the Use of the ILAC MRA Mark

Joint ILAC/IAF Documents (A series)

- IAF/ILAC A1:05/2007 IAF/ILAC MRAs: Requirements for Evaluation of a Regional Group
- IAF/ILAC A2:05/2007 IAF/ILAC MRAs: Requirements for Evaluation of a Single Accreditation Body
- IAF/ILAC A3:05/2007 IAF/ILAC MRAs: Key Performance Indicators - A Tool for the Evaluation Process
- IAF/ILAC A4:2004 Guidance on the Application of ISO/IEC 17020
- IAF/ILAC A5:04/2009 IAF/ILAC MRAs: Application of ISO/IEC 17011:2004



Welcome to

**Shanghai,
China**

**20 – 29
October 2010**

**2010 IAF/ILAC
Joint Annual
Meetings**

China National Accreditation Service for Conformity Assessment (CNAS), is delighted to be hosting the IAF/ILAC 2010 Joint Annual Meetings in Shanghai, China, October 20-29, 2010.

The meetings will be held at HYATT ON THE BUND, Shanghai. The venue is a five-star luxury hotel, uniquely located on the banks of the Huang Pu River at the northern end of the Bund in Shanghai, China. This central Shanghai hotel offers spectacular views of the Bund and Pudong, with convenient access to Shanghai's airports, major areas of the city and the World Expo area.

During the meeting period, we hope that you will enjoy the social program such as the welcome reception, the cocktail dinner, and the Gala dinner with the signing ceremony.

Mark the days now: October 20-29, 2010! For registration, please visit the official website www.iafilac2010.cn.

Email: iafilac2010@cnas.org.cn

