

# ILAC News

Issue 34, October 2008



CASCO update

14th International  
Congress of  
Metrology – France

ema celebrates  
accreditation

PNAC organises  
assessors training  
course



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# From the Chair

*We should be happy!* Many, many lights are green in the accreditation world. There has been an increase in the demand for accreditation in all countries, an increase in ILAC membership and an increase in the number of liaison partners to ILAC. This is evidence of the good health of the activity of accreditation.



I have written 'activity' and not 'business' as I want to again remind you and underline that accreditation is definitely not a 'business' and should stay a not-for-profit and non-commercial activity if we want regulators to rely on it.

In the introduction of the standard ISO/IEC 17011, we can read that accreditation bodies 'normally operate in a non profit distributing manner'. To me, this statement is too weak. What does 'normally' mean?

This weakness in the standard consequently also creates a weakness in the ILAC rules for membership and it's a matter of fact that a few of our members are 'business oriented', which is not an element of confidence from the regulators point of view (at least the European ones).

Here is a real dilemma for ILAC. We could certainly establish membership rules going beyond the international standard but then we would be accused of becoming a 'closed shop'.

Moreover, being exclusive would perhaps also make us fail in fulfilling the ILAC vision, as mentioned in our current Strategic and Business Plan: 'To be the accepted global solution for the demonstration of equivalence of testing, calibration, and inspection results'.

Indeed, the ILAC policy has always been to be inclusive and open. The aim of this policy is also to try to educate and assist those bodies, classified as affiliates, which simply declare their intention to operate their accreditation programs in compliance with the requirement of the relevant standards.

We certainly have to be proud of this policy which is very helpful for developing accreditation bodies. But the adverse effect of such a policy could be that it will remain difficult to facilitate the recognition of accreditation through the ILAC Arrangement, by governments in many countries, which is one of our goals in the *ILAC Strategic and Business Plan*.

In my view, a strengthening of the requirements of the ISO/IEC 17011 Standard is probably needed to resolve the problem.

I started this editorial by using the words 'happy' and 'green lights'. I don't want to conclude it with an anxious note. On the basis of the competence, the dedication and the enthusiasm of its members, I am more than confident in the capacity of the accreditation community, in cooperation with its stakeholders, to overcome this situation.

**Daniel Pierre**  
Chair



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

# News from the ILAC Secretariat

While members will recognise this as the regular contribution to *ILAC News* from the Secretariat, you will also notice some differences. We have decided to change the emphasis of the article to focus more on the day-to-day operation and activities of the Secretariat, rather than just providing an overview of ILAC activities in general.

## Secretariat staff

The ILAC Secretariat has experienced some staff changes over recent months, with Amanda Stubbs leaving her role as ILAC Administrator in May of this year, to pursue new challenges. The Secretariat wishes Amanda and her family all the best for the future and thank her for her contribution.

The Secretariat is very pleased to welcome Rose Bevins who has replaced Amanda and is sharing the role of ILAC Administrator with Alison Hay. Rose joined the Secretariat in May and is working three days a week.

As members will already be aware, the staff of the ILAC Secretariat all work on a part-time basis, which ensures maximum efficiency. To support this, tasks are shared where practical and there is a strong emphasis on communication. This approach allows the Secretariat to minimise disruptions to work flow that might otherwise arise as a result of international travel, holiday or sick leave.

ILAC Secretariat staff members are: ILAC Secretary, Annette Dever; ILAC Executive Liaison Officer, Alan Squirrell; Senior ILAC Coordinator, Sharon Kelly; ILAC Administrator, Alison Hay; ILAC Administrator, Rose Bevins.

## Secretariat activities

### Meetings

The mid year meetings of the ILAC Executive and the ILAC Arrangement Management Committee (AMC) were hosted by Cofrac in Paris, in July and were attended by Annette Dever (supporting the ILAC Executive and JCCC) and Sharon Kelly (supporting the ILAC AMC and the JMC meetings). Meetings of the IAF Executive

and the IAF MLA Management Committee (MC), were also held during the same week, as were meetings of the Joint Committee for Closer Cooperation (JCCC) and the joint session of the ILAC AMC and the IAF MLA MC, otherwise known as the JMC.

On what could be described as 'super Wednesday', representatives from ISO travelled to Paris for a meeting of the IAF/ILAC/ISO Joint Working Group, meetings of the IAF MLA MC, ILAC AMC and the JMC were held and UNIDO funded a delegation, consisting of the Co-Chairs of the Joint Development Support Committee (JDSC) and the ILAC Secretary, to travel to Vienna for meetings.

Preparations for the 2008 Annual ILAC/IAF meetings in Stockholm, 10–22 October 2008 are now well advanced.

Please see the ILAC website link for updated information: [www.ilaciaf2008.org](http://www.ilaciaf2008.org). As 2008 is an election year for the ILAC Executive Committee positions, a request for nominations was circulated to all members on 28 July 2008.

## 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 JMC sessions, is currently involved with the follow up activities and the actions arising out of the July 2008 meetings of the AMC and the JMC, held in Paris.

Following the Paris meetings, secretary for the IAF MLA MC, Monika Wloka and Senior ILAC Coordinator, Sharon Kelly, are also busy with preparations for the training workshop being run for evaluators of the Regional Cooperations, on Friday 10 October in Stockholm.

## ILAC-MRA mark

The ILAC-MRA mark registration process continues and, as at 28 May 2008, 43 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).

In conjunction with the ILAC Marketing and Communications Committee (MCC), the Secretariat has recently circulated a survey to all ILAC full members, to establish how many accreditation bodies are actively using the combined MRA mark and how many have signed sub-licensing agreements with their accredited laboratories, for the use of the Laboratory Combined MRA mark. This information will be used to assist ILAC in promoting the use of the ILAC-MRA mark and to also highlight any areas which may be in need of review.

## Website

The Secretariat is continuing to develop the ILAC website with significant updates completed for the ILAC and joint ILAC/IAF committee pages in the members only area. The day-to-day administration of the ILAC website is carried out by the ILAC Administrators, Alison Hay and Rose Bevins. The Secretariat has completed an audit of the ILAC website, resulting in some updates and refinements being made.

The search engine on the ILAC website has also had some further refinements recently. The search now also includes PDFs and other documents within the public area of the website. It does not include the documents in the members' area due to the security requirements of that part of the site.

If members want to change their password for access to the 'members only' area of the website, there is now an option to create your own password. Visit the home page of the members' only area and click on the 'change your password' link on the left hand side of the page. As always feedback on the website is welcome from all users.

## ILAC News

The Secretariat is also closely involved in the preparation of *ILAC News*, with stories, photographs and captions being

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compiled into what is hopefully an interesting and informative newsletter for the ILAC members, their clients and related organisations that have an interest in the activities and benefits of accreditation. Feedback from members on the presentation and content of *ILAC News* is, as always, very welcome.

## Marketing activities

The Secretariat works very closely with the ILAC Marketing and Communications Committee (MCC) and whenever possible attends the MCC committee meetings. As members will be aware the first International Accreditation Day was held on 9 June 2008, with many members reporting on the successful activities undertaken by their organisations to highlight the benefits of accreditation. A survey has been circulated to both the ILAC and IAF memberships to obtain feedback from the members on the inaugural International Accreditation Day.

## Other activities

Following a special half day meeting of the ILAC Executive in Amsterdam earlier this year, to begin the process of reviewing the ILAC Strategic and Business Plan, an Executive Task Force, led by ILAC's Vice-Chair Peter Unger, was formed to manage the revision process. A lot of work has been undertaken by this task force in the intervening months and following a final discussion and review session, during the Paris Executive meeting in July, the ILAC Strategic Plan revision is now out for a 60 day comment period to all ILAC members.

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 were also recently notified of the publication of the revised *ILAC Rules*. It should be noted that the date of notification of publication on the ILAC website, is the date of implementation for the new *ILAC Rules*—28 July 2008.

## 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. This area of activity is coordinated within the Secretariat by Alan Squirrell, who in addition to representing ILAC in a number of major liaison activities, coordinates ILAC's

liaison activities with organisations, other than the International Organization for Standardization (ISO).

The Liaison Database, available from 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 rapidly expanding liaison activity.

As reported previously, the regular annual series of meetings between ILAC and the Bureau International des Poids et Mesures (BIPM), including representatives from the Regional Membership Organisations of both ILAC and BIPM, were held in Paris in March 2008. These meetings included a workshop on the progress made in adopting and implementing the joint statement on calibration and measurement capability (CMC) as well as an update on progress in our endeavours to strengthen the links between accreditation (ILAC Arrangement) and Metrology (CIPM MRA) and disseminate traceability of measurements from NMIs to field laboratories. This work was further reinforced at the April 2008 meeting of the BIPM—Consultative Committee for Amount of Substance (CCQM) with respect to chemical measurements and was discussed again at the June 2008 ISO REMCO (Reference Materials) meeting.

The Co-chairs of the ILAC and IAF Joint Development Support Committee (JDSC) and the ILAC Secretary, met with UNIDO officials in Vienna in July 2008. The discussions focused on identifying areas of mutual interest where the three organisations could work together in 2008–2009. Further consideration was also given to the practical mechanisms by which the three organisations can work together, in the most effective and efficient manner, to achieve shared goals.

ILAC's continuing close cooperation with EURACHEM and CITAC (Cooperation on International Traceability in Analytical Chemistry) supports the important metrological initiatives in chemical and biological measurement also being undertaken in conjunction with BIPM. Liaison activity with EURACHEM and CITAC also includes work on method validation, measurement uncertainty and compliance with limits, the use of 'good quality' reference materials and proficiency testing.

Progress is continuing on the ILAC and OIML (Organisation Internationale de Metrologie Legale) Joint Work Programme, following the ILAC/IAF/OIML meeting in March 2008.

ILAC continues its very active role in many ISO technical committees and CASCO working groups. In 2008 ILAC liaison officers have participated in meetings of the CASCO CPC (Chairman's Policy Committee), WG 27 (*Drafting requirements for use in conformity assessment applications*), WG 29 (*Revision of ISO Guide 65—Product Certification*), CASCO WG28 (*Revision of ISO Guide 43—Proficiency Testing*), CASCO Plenary, ISO TC212 (*Technical Committee—Clinical laboratory testing and in vitro diagnostic test systems*), ISO TC 69 (*Technical Committee—Applications of statistical methods*), ISO TC 176 (*Technical Committee—Quality Management and Quality Assurance*) and the IAF, ILAC and ISO Joint Working Group.

ILAC played an active role in the Seminar on Accreditation of Proficiency Testing Providers and Reference Material Producers, conducted by INMETRO in Rio de Janeiro, on 5 and 6 June 2008, with Alan Squirrell representing ILAC and participating as one of the presenters. This seminar was held immediately prior to the annual ISO REMCO (reference materials) meetings where Alan also represented ILAC.

ILAC and the World Anti Doping Agency (WADA) have continued the cooperation began in 2003. A meeting of the ILAC Accreditation Committee and WADA Working Group was held in May 2008 in Capetown, and another is being planned for Stockholm, where further joint initiatives will be discussed. As previously reported, Alan Squirrell representing ILAC, holds a seat on the WADA Laboratory Committee (LC) and participates, either in person or via teleconference, in four WADA LC meetings per year.

The remainder of the year will see ILAC involved in meetings of the CASCO Plenary, other associated CASCO meetings, the Joint Committee on Traceability in Laboratory Medicine (JCTLM), the EURACHEM sixth PT Workshop and the 13th International Legal Metrology Conference.

The Secretariat would like to take this opportunity to thank all of the liaison officers, and their organisations, who give up their time to assist ILAC in carrying out these activities for the benefit of all ILAC members.

Information on ILAC can be obtained from the ILAC website at [www.ilac.org](http://www.ilac.org), or by emailing the Secretariat on [ilac@nata.asn.au](mailto:ilac@nata.asn.au).

**Annette Dever**  
ILAC Secretary

# ILAC committee news

## Changes to ILAC Membership

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

### Full Members

Perry Johnson Laboratory Accreditation Inc. (PJLA), USA; Tunisian Accreditation Council (TUNAC), Tunisia; Oficina Guatemalteca de Acreditación (OGA), Guatemala

### Associates

National Institute for the Defence of Competition and for the Protection of Intellectual Property—(INDECOPI), Peru; Philippine Accreditation Office (PAO), Philippines (Signatory status for PAO, to the APLAC MRA for calibration and testing was suspended by APLAC on 5 June 2008. As a result of this, ILAC membership status for PAO was changed from Full Member to Associate).

### Stakeholders

Clinical and Laboratory Standards Institute (CLSI), USA; British Measurement and Testing Association (BMTA), UK.

## Regional Cooperation Bodies

The Regional Cooperation Body, Central Asian Cooperation on Metrology Accreditation and Quality (CAC-MAS-Q) has advised it is no longer operational as this organisation and accordingly membership has been terminated.

## ILAC Membership

ILAC membership as at 6 August 2008 is as follows: 61 Full Members (Signatories to the ILAC Arrangement) representing 46 economies; 20 Associates representing 19 economies; 19 Affiliates representing 17 economies; 4 Regional Cooperation Bodies; 1 National Coordination Body; 26 Stakeholders.

The ILAC membership (total 131 bodies) now covers a total of 79 different economies worldwide and approximately 30,000 laboratories and 5,000 inspection bodies are accredited by the 81 ILAC Full Members and Associates.

## Marketing and Communications Committee (MCC)

By Ian Roy, Member MCC—iroy@ianz.govt.nz

An updated version of the popular brochure '*How does using an accredited laboratory benefit Government and Regulators?*' is now available to members. The brochure explains the role and benefits of accreditation in government activities.

While the broad substance of the brochure remains the same, a new section has been added called '*Accreditation in support of regulation*'.

The new section explains the recent historical shift of the use of accreditation from the voluntary sector to also the mandatory (government) sector. The additional text refers to the use of accreditation by pan-regional bodies in their activities such as the Asia Pacific Economic Cooperation (APEC), the Association of Southeast Asian Nations (ASEAN), as well as the Council of the European Union and the European Parliament.

In APEC, for example, accreditation is now used to underpin the conformity assessment component of the APEC agreements. The ASEAN MRA for electrical and electronic equipment has included accreditation as a means of meeting the mandatory requirements of each member, and to facilitate the implementation of the ASEAN Free Trade Area (AFTA). In Europe, the Council of the European Union and the European Parliament have agreed on a regulation that from 2010 will cover the use of accreditation as a means to show compliance with mandatory requirements.

The mainstream acceptance of accreditation by these bodies, and domestic regulators within individual governments, also helps member governments of the World Trade Organisation (WTO) to meet their responsibilities of the Technical Barriers to Trade Agreement (TBT Agreement), and the Sanitary and Phyto-sanitary Agreement (SPS Agreement) too.

Emphasis is also given to the recognition and increased coordinating roles of the Asia Pacific Laboratory Accreditation Cooperation (APLAC), European

cooperation for Accreditation (EA), and the Inter American Accreditation Cooperation (IAAC), by regional and domestic government bodies.

## Report from the Accreditation Committee (AIC) of ILAC

The Accreditation Committee of ILAC is approaching its 8th meeting since it was set up in the new structure of ILAC, during the General Assembly meeting in 2004. According to the *ILAC Rules*, members of all categories are entitled to participate in the work of the Accreditation Committee. The committee welcomes your nominations and looks forward to seeing all nominees in its meetings and to also see you all active in its work in general.

Those who are interested in participating in the working groups of the committee can find the relevant information on the working groups and their terms of reference on the ILAC website in the Members' Area.

The work of the Accreditation Committee is widespread and available to all ILAC members. This report will give a short summary from some of the areas where there are tangible results at the moment.

## Cooperation with WADA

The ILAC AIC/WADA (World Anti-Doping Association) working group provides a means for close cooperation between ILAC and WADA. In addition to considering issues around the application of ISO/IEC 17025, the working group also considers the application of the WADA International Standard for Laboratories (ISL) in the accreditation process. The overall aim is to harmonise the activities of WADA and ILAC in relation to anti-doping laboratories.

In the last few years WADA has provided an annual training course for assessors in the application of the ISL. This course is open to accreditation body assessors, for those bodies that accredit WADA laboratories. Invitations for the courses are sent out by the ILAC secretariat on behalf of WADA whenever a course is due. The courses are free of charge and some funding for travel and accommodation is available. One seat is usually available per accreditation body active in the area.

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## Cooperation with forensic science and crime scene investigation organisations

The AIC has recently started a work item for drafting guidance, which will encompass the assessment of both forensic science laboratories and crime scene investigation (CSI) organisations. The work will be based on guidance drafted by EA (European co-operation for Accreditation) and ENFSI (European Network of Forensic Science Institutes) and will also include in its task the review of ILAC G19 *Guidelines for Forensic Science Laboratories*. This has been set up as a joint activity between ILAC and IAF, due to the fact that some countries accredit CSI organisations to ISO/IEC 17020, which is a standard of interest for both the ILAC and the IAF communities.

## Cooperation with BIPM and the national metrology institutes

ILAC member accreditation bodies are encouraged to promote and to respond without delay to accreditation applications from national metrology institutes (NMIs). However, there is certain reluctance to accreditation from the NMI community under the requirements of ISO/IEC 17011 to ISO/IEC 17025. The AIC has looked into the reasons for the lack of interest from the NMI community. Some of the reasons provided are: (i) some prefer peer evaluation as this is accepted by BIPM as an activity comparable to accreditation; (ii) some believe that accreditation would be costly; (iii) some would like to have less frequent surveillance than what is required normally under accreditation; and (iv) some are concerned with the choice of technical assessors. ILAC liaison persons to the BIPM discuss these issues with the BIPM on a regular basis and we would like to encourage all ILAC member accreditation bodies to have an open dialogue on accreditation with the national metrology institute in their economy. ILAC AIC sees it as a very important building block in the quality of testing and calibration to have the full chain of traceability accredited according to international standards and as part of the ILAC MRA.

The terminology used for expressing the scope of accredited calibration laboratories has also been a point of discussion between BIPM and ILAC for a long time. The common term has now been agreed upon as Calibration and Measurement Capability (CMC). The AIC has identified a number

of points to be discussed as a result of the change of terminology for accredited laboratories. The result of these discussions will be presented to the ILAC community as soon as the committee work is finalised.

## Cooperation with the OIML

The AIC has close cooperation with OIML on accreditation of conformity assessment bodies in legal metrology. The issues which are discussed in this area are very similar to those in our cooperation with BIPM. OIML has implementation documents for different types of conformity assessment in legal metrology. These documents have been submitted to the ILAC and IAF communities for comments at different stages and OIML has kindly considered the comments in its approval process. These documents state the specific issues which OIML would like conformity assessment bodies and accreditation bodies to address.

The AIC is now working on identifying the economies where conformity assessment bodies in legal metrology are required to be accredited. There is also a need to identify assessors with knowledge on the specific needs of legal metrology. The AIC will need the cooperation of ILAC accreditation body members in this area and will respond soon.

## Other work items related to calibration and traceability

ILAC G8, *Guidelines on the Reporting of Compliance with Specification* has been out for ballot and has been passed.

The AIC is working on a revision of ILAC G2 (currently withdrawn) concerning the traceability in measurements. There are suggestions to have two separate guidance documents, one for physical measurements and one for chemical and medical. The working group will start with a draft which concentrates on physical measurements, after which a more informed discussion will hopefully take place during the meeting in Stockholm.

The criteria for the accreditation of reference material producers have been identified and the list has been out for comments. The ILAC community has shown great interest in the work and all the comments have been appropriately considered by the working group. This is the first step in the work to draft a guidance document for the assessment of reference material producers and as such, it only gives a table of contents for the full

document. It will therefore not be sent out for voting. Instead, the working group will now focus on how to take this to the second stage where assessment guidance will be given for each identified key criteria. Once this is drafted, it will be put through the normal ILAC procedure for commenting and approving documents.

## Cooperation with the medical profession

ILAC has very close cooperation with the medical sector in particular through the work of ISO TC 212 which is the ISO committee that drafts conformity assessment standards in the medical area, for example ISO 15189. ISO 15189 underwent a minor amendment in 2007. A recent proposed extensive revision of ISO 15189 has been placed on hold until the views of major stakeholders are surveyed and to allow time for knowledge using the current standard to be gained.

In the meanwhile, the AIC is working hard to facilitate the work of accreditation bodies which are just starting to accredit in the medical area, by collecting the experience gained by ILAC members who have been active in the area for some time. The AIC acknowledges that there are differences between different economies in the approach to the medical sector. These differences may be cultural or socio-economic but need to be considered when implementing ISO 15189 so that the robustness of the ILAC MRA can be guaranteed. The AIC working group, WG6, is working on a document which will provide support for accreditation bodies which are just starting or are planning to start accreditation in the medical area. The AIC believes that this work will also give valuable information to more experienced accreditation bodies.

Traceability in the medical sector is another part of the work that is being performed by the AIC. The ILAC General Assembly has already decided that ILAC member accreditation bodies shall use ISO/IEC 17025 together with ISO 15195 when accrediting reference laboratories in the medical sector. There are very few accredited reference laboratories at the moment and the AIC would like to encourage all ILAC member accreditation bodies to have close cooperation with the reference laboratories in their economies, so that the chain of traceability in the medical sector can also be guaranteed under the robustness of accreditation.

The agenda and minutes of the committee are available through the AIC secretariat in SWEDAC, the ILAC secretariat and the AIC section of the members area of the ILAC website. Also, if you are interested in the committee papers, we would be happy to help you through the archive that we keep.

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### 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 Resources page at [www.ilac.org/resources](http://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.

# International update



## CASCO

*By Conformity Assessment Head, Sean MacCurtain and Conformity Assessment Project Manager, Stefan Marinkovic*

The ISO committee on conformity assessment (ISO/CASCO), was busy throughout 2008 with new projects, workshops, the establishment of a new structure and the review of existing documents.

Market surveillance is a recent global concern. There is growing interest from all sectors—market, governments and civil societies, regarding the safety (and legality) of what is put on the market. Market surveillance is considered to be an important topical issue and ISO/CASCO will be holding a one-day workshop on 29 October 2008 in order to understand if and how ISO might be able to assist in this area.

In November 2007, CASCO changed its structure so as to better address the needs and concerns of the conformity assessment world. The Chairman's Policy and Coordination Group (CPC), which is the general policy designing group, did not change, but two new groups were created: Strategic Alliance and Regulatory Group (STAR) and Technical Interface Group (TIG).

STAR provides a mechanism that allows regulators and industry sectors to interact with ISO/CASCO. Thanks to this forum, it will be easier to identify future trends in conformity assessment. ILAC is represented in this group.

TIG monitors the development of standards in ISO. The purpose of this group is to ensure that ISO standards are written consistently and harmoniously with regard to conformity assessment. The consistent and harmonious

interpretation of conformity assessment requirements in ISO standards is taken care of by a dedicated interpretation panel within CASCO.

The complete collection of ISO/CASCO standards and guides is 27 documents. There are currently four documents under development of which ISO/IEC 17065 (working draft stage) and ISO/IEC 17043 (committee draft stage) are of particular importance for ILAC Members. Three of the documents under development are revisions of ISO/CASCO guides and one will be the second part of an existing International Standard which specifies the requirements for third party certification auditing of management systems (ISO/IEC 17021-2). One part of ISO/IEC Guide 98, which is a revision of the Guide to the expression of uncertainty in measurement—GUM will be published in 2008, and ISO/IEC Guide 99, International vocabulary of metrology—Basic and general concepts and associated terms—VIM, is already available.

ISO/CASCO and ISO/DEVCO (ISO committee on developing country matters) organise joint workshops to exchange views with stakeholders from developing countries and to give training on conformity assessment matters. The latest workshops took place in Kiev in June 2008 (Regional workshop on Conformity Assessment supporting development and trade) and in Tunis in November 2007 (Regional workshop on Conformity Assessment for sustainable development).

ISO/CASCO also attends the WTO TBT (World Trade Organization Agreement on Technical Barriers to Trade) meetings and keeps abreast of the ongoing work of WTO related to conformity assessment.

## Euro-Asian Council for Standardization, Metrology and Certification (EASC)



*Delegates at the 33rd EASC meeting held in Baku, Azerbaijanian Republic.*

### On the 33rd EASC meeting

The 33rd Meeting of the Euro-Asian Council for Standardization, Metrology and Certification (EASC) was held in Baku, (the Azerbaijanian Republic) on June 4–5, 2008. The Meeting summed up the EASC work over the reporting period and directed further ways of cooperation in the area of harmonization of technical regulations, interstate standardization, metrology, conformity approval and accreditation.

**The following delegations took part in the Meeting:** The Azerbaijanian Republic, Republic of Belarus, Georgia, Republic of Kazakhstan, Kyrghyzian Republic, Republic of Moldova Russian Federation, Republic of Tajikistan, Republic of Uzbekistan, Ukraine, CIS Executive Committee.

**Representatives of international and regional organisations of:** ISO, CEN and COOMET.

**National organizations for standardisation, metrology, conformity approval:** BSI; DIN; Lithuanian standards board; Polish committee for standardization; Institute for standardization of Serbia; AFNOR; CSMT.

**As well as representatives of:** The Russian Union of manufacturers and entrepreneurs: Close Corporation 'Sony CIS'.

Fifty five matters concerning further development of work on harmonisation

of technical regulations, interstate standardisation, metrology, conformity approval including accreditation in the CIS member-states were considered at the EASC Meeting.

EASC activity report for the period between the 31st and 33rd EASC meetings was presented by Elkin G.I., EASC Chairman, Director General of the Federal Agency for technical regulation and metrology of the Azerbaijanian Republic.

The participants of the Meeting listened to information of EASC member-states of the works carried out in these countries within technical regulation, standardisation, metrology, conformity approval and accreditation as well as reports of the representatives of the international, regional and national organisations for standardisation and metrology.

At the 33rd EASC meeting, reports of the following were presented: Secretary General of ISO's Alan Bryden, on prospects of ISO development and key tasks for EASC members; Director of CEN's Department for foreign policy and legislation, Hugues Plissart de Brandignies, President of COOMET's, Sidorenko G.S., with information of COOMET activity and directions of interaction with EASC; Vice-President of COOMET, of PTV works, Klaus-Dieter Sommer, including international and regional organisations for metrology.

At the 33rd EASC Meeting the following representatives of the foreign organisations

for standardisation, metrology, certification and accreditation presented their reports and information materials: BSI's Yakubov Vladimir Alexandrovich; DIN's Gerd Slapke; Lithuanian standards board's Brunonas Sickus; Polish committee for standardization's Tomasz Schweitzer; Institute for standardization of Serbia's Ivan Krstic; AFNOR's Roselyne Dussau; CSMT's Vojtech Petrik and Jiri Sobola.

At the 33rd EASC Meeting the results of the first competition for CIS premium for achievements in the field of quality of products and services were summarized and according to the provision (adopted by the Political Executives Council) concerning the competition of 2009 a decision of this competition announcement was adopted.

A decision was taken about direction of the CIS Executive Committee on the appeal to the EC Chairman about consideration of the possibility of extending the terms of preliminary registration of chemical substances in accordance with the EC new technical legislation in registration, evaluation, authorization and restriction of chemicals (REACH). At present most of CIS manufacturers-exporters are not ready to export products into EC according to REACH.

The Participants of the Meeting were informed by the representative of CIS Executive Committee about the decisions of Political Executives Council of 22 November 2007 on the adoption of the prepared by EASC protocols for amendment of the Agreement dated 13 March, 1992 for carrying out consistent policy in the field of standardisation, metrology and certification and 'Agreement dated 10 February, 1995 on relieve of customs duty, taxes and issue of special permissions to transport normative documents, standards, measuring instrument and specimens taken for the purpose of calibration and metrological attestation'.

### On the issues of technical standards regulations and intergovernmental standardisation.

The participants of the 33rd Meeting considered the issue of signing the draft of 'Agreement on the foundations of harmonization of technical regulations of CIS member-states' which is protracted by the position of Russian Federation. The participants of the Meeting requested the Russian Federation to form its position concerning the draft 'Agreement on the

foundations of harmonisation of technical regulations’.

At the 33rd Meeting there was adopted ‘Plan of EASC actions for the period till 2015.’ Decision of the development of ‘Strategy of EASC development’ was taken.

EASC works for intergovernmental standardization were directed to harmonisation of the intergovernmental standards with the international and European standards in order to ensure an access of CIS member-states’ products to the international and European markets, to renew the present fund of intergovernmental standards, for protection of CIS member-states’ markets from low-quality and unsafe products and creation of evidential base for conformity assessment of products to technical regulations meeting international and European standards and requirements.

Seventy three intergovernmental standards and alterations to harmonise these with the international and European standards have been adopted. (Level of harmonisation is 54 per cent).

The issue of updating the database of Information and Search System ‘CIS Standard’ was considered at the Meeting.

An issue of carrying out operation testing of the EASC integrated automated information system (AIS EASC) is part of the draft Program of works for intergovernmental standardisation.

#### **In the field of metrology**

In the field of metrological provision the issues of: updating ‘Program of works for standardisation, metrology and conformity assessment within nondestructive check for the period of 2008–2009’; ‘Program for development and application of intergovernmental standards of composition and properties of substances and materials for the period of 2006–2010’; on the process of realisation and updating of ‘Program of works for development of attested data of physical constants and properties of substances and materials on specific thematic directions’; on realisation of the Program ‘Creation of standards of new generation unit of length within  $10^{-9}$ – $10^{-4}$  for the period of 2007–2009’; updating of the Program for development and review of the fundamental normative documents of Governmental Measurement System; on realization of the ‘Program for decision of issues for metrological ensuring of

measurements of energy of all kinds of fuel combustion’ were considered.

Information of consideration of the new version of Model Law ‘On ensuring of unity of measurement’ of CIS inter-Parliamentary Assembly was heard.

Thirty two standards were adopted as intergovernmental ones. National Bodies of CIS member-states have kept work for updating of information included into Register of intergovernmental standards (MCO).

#### **In the field of conformity assessment**

Work carried out by EASC contributed to elimination of barriers connected with conformity attestation (certification) of products, while going through CIS member-states.

At present CIS member-states introduced the form of conformity attestation in the form of declaration of conformity that requires mutual study of existing in CIS member-states specific norms of legislation for creation of mutual measures assigned for elimination of possible barriers to trade.

Use by CIS member-states of new technical regulation forms adopted by WTO also requires corresponding coordination of the activity at the intergovernmental level.

The national authorities and EASC members’ take a direct and active part in improving the products manufactured in CIS member-states and EASC members.

*“Work carried out by EASC contributed to elimination of barriers connected with conformity attestation (certification) of products, while going through CIS member-states.”*

On 16 April, 2008 the draft developed by EASC of the intergovernmental agreement ‘On the modules of conformity assessment (attestation) and requirements concerning marking by the united sign of access at the national markets of CIS member-states’ was considered by the Economic Commission of the CIS Economic Council. This information was taken into account.

On the basis of the Economic Commission decision No. 4 (126) of 16 April 2008 the updated draft agreement CIS Executive Committee directed to the governments of CIS member-states in order to submit it for endorsement. EASC was recommended to finish the draft of this document taking into account the opinions received from CIS member-states and to submit it for the second time to the Economic Commission of the CIS Economic Council. This document shall be signed by the Heads of the CIS member-states governments.

In view of CIS member-states interaction in the accreditation matters there was adopted the Program of interaction for accreditation of CIS member-states and for development of this program there has been adopted a program for development of intergovernmental standards on accreditation issues on the basis of international normative documents (fundamental documents).

Decision of the development of the draft Agreement for conformity assessment accreditation issues. It is supposed that the document shall be signed by the Heads of CIS member-states governments.

#### **In the field of surveillance of observation of technical regulations, norms and rules requirements**

Experimental exploitation of the automated system ‘Dangerous products’ was completed. The decision of bringing the system into service for prompt allocation of information of the identified dangerous products and undertaking of the necessary measures in CIS member-states was taken. Information of the normative-legal base used by CIS member-states surveillance public authorities within control and surveillance of observation technical regulations, standards and rules were updated. EASC Standards Bureau summarised the given information and sent it to all national authorities of CIS member-states for use in work.

At the 33rd Meeting a set of organizational matters was considered and the following decision was made: to hold a meeting of the national authorities heads (34th EASC Meeting) in December in Ukraine.

The 35th EASC Meeting is planned for May–June 2009 in Minsk (Republic of Belarus). In compliance with EASC Provision on standardization, metrology and certification.

# Regional cooperations



## Update from APLAC

By Helen Liddy and Janet Clark

Since our last report for *ILAC News*, APLAC's mid-year Board of Management and MRA Council meetings have been held in Long Beach, California from 3–6 June 2008. The meetings were successful and APLAC extends appreciation to the USA members who were joint hosts, and especially IAS's, Nancy Libby for all her organising.

The Draft Minutes of both of these meetings are now available in the 'Members Only' section of the APLAC website.

APLAC congratulates PJLA, USA which was accepted as a signatory to the MRA for testing on 6 June 2008.

APLAC welcomes Indecopi, Peru, which has become a full member. Indecopi is the National Institute for the Defense of Competition and for the Protection of Intellectual Property, and is Peru's government-authorized accreditation body.

APLAC is holding a workshop for staff of members involved in the accreditation of inspection bodies in Taipei, Chinese Taipei on 27–29 October 2008. The presenters are Merih Malmqvist Nilsson (SWEDAC), Nigel Jou (TAF) and Geoff Hallam (IANZ). The workshop will include a sharing of experiences among accreditation bodies on issues specific to the accreditation of inspection bodies. The other regions and PAC will be invited to send a participant each.

Another workshop on the accreditation of RMPs is planned for the latter part of 2008 in Hong Kong, China. No further details are available at this time but, again, the other regions and APMP will be invited to send a participant each.

The next APLAC evaluator training course will be held in Singapore on 3–5 December, immediately prior to APLAC 2008. The course will be coordinated

by CALA's Ned Gravel, and the course presenters will be IANZ's Ned, Barry Ashcroft and DMSc's Panadda Silva.

The APLAC General Assembly and Technical Meetings will be hosted by SAC, Singapore from 6–12 December 2008. It is hoped that the website will be available by the second half of July. Members are encouraged to register their attendance and book their accommodation as soon as possible.

APLAC bids farewell to Lilian Luiyf who has been with APLAC for some months assisting in the secretariat. She has accepted a permanent position elsewhere and we wish her all the best in her new endeavours. Joyce Caruana will be assisting the secretariat for the next couple of months.



## A legal framework for accreditation in Europe

By EA Vice Chair, Graham Talbot

Monday 23 June 2008 will be remembered as a noteworthy day in the history of accreditation in Europe. On this date, the Council of the European Union and the European Parliament agreed on a Regulation that will, for the first time, provide a legal framework for the provision of accreditation services across Europe. The Regulation will apply from January 2010 and will cover the operation of accreditation in support of voluntary conformity assessment as well as conformity assessment required by legislation. Under the Regulation, accreditation, when carried out against the recognised harmonised standards, is regarded as a public authority activity and EU Member States will be required to appoint a single national accreditation body for these activities. The national accreditation body can be a public or private organisation but, regardless of its status, it will be regarded as carrying out a public authority activity.

The Regulation has been developed against the background of a growing recognition of the importance of

accreditation to the EU's economic infrastructure. The main aims of the Regulation are to reinforce the status of accreditation, to improve the consistency of the accreditation services offered and, ultimately, to increase confidence in accreditation as a tool for government and business. To this end, the Regulation sets common requirements for national accreditation bodies to be monitored by EU member state governments. In essence, the Regulation will require national accreditation bodies to be independent from the conformity assessment bodies they accredit; to be objective and impartial; to employ competent personnel for the tasks to be carried out; to operate on a not for profit basis; not to offer services offered by conformity assessment bodies; and not to compete with other national accreditation bodies.

The Regulation also recognises the European co-operation for Accreditation (EA) as the co-ordinating organisation for accreditation at the European level. National accreditation bodies in the EU member states will be required to be members of EA and to participate in the peer evaluation programme operated by EA as the preferred means of demonstrating compliance with the requirements.

A related EU Decision, agreed at the same time as the Regulation, will set a common framework for EU Directives relating to the marketing of products. The Decision establishes a model text for future directives and revisions to existing directives covering elements such as the use of standards, CE marking, conformity assessment procedures and the appointment of conformity assessment bodies to operate the conformity assessment procedures 'notified bodies'. The Decision places greater emphasis on the use of accreditation in the assessment of 'notified bodies', again with the intention of improving the consistency of approach across Europe.

EA has worked in close co-operation with the Commission as the Regulation has been developed and regards the outcome as positive for accreditation overall. EA members are excited by the prospect of greater recognition by their national authorities and increased opportunity for accreditation to support EU policy. They also recognise the challenge of

ensuring that accreditation meets the raised expectations of governments across Europe. EA has a number of projects in place to ensure that members can respond to the increasing demands they expect to be placed on them as a result of the Regulation and Decision.

The agreement of these legal texts is the culmination of policy discussions going back almost 20 years. As early as 1989, the European Commission published the Global Approach to Certification and Testing, which set out many of the principles now adopted into European law. When published, these principles were seen as guidelines for member states but it has been clear for some time that a greater degree of formality was required and this has now been achieved by the adoption of the Regulation.

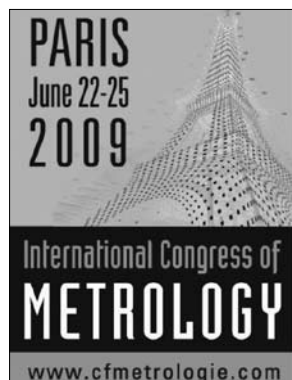
For many EU accreditation bodies, the Regulation will have little practical impact since legal frameworks for accreditation exist in many of the 27 EU member states. Many accreditation bodies are already part of government and are nominated as the sole national accreditation bodies for the countries concerned. This is not the case across all member states, and in some economies accreditation has developed as a private sector activity including an element of competition. In these countries, some rationalisation of the accreditation structure will be required and governments across the EU are now working to put systems in place that will meet the requirements of the Regulation. More changes will be required in some member states than others.

The EU legislative process is a complex one and compromises have had to be made to secure the adoption of the Regulation by the Council and the European Parliament. As a result, the impact of some elements of the new law is still not entirely clear and work is needed to ensure that there is a common understanding of the requirements. In addition, EA recognises that the Regulation will, in some ways, lead to requirements being placed on accreditation bodies in Europe that are not required elsewhere. EA is working with the Commission and its international partners in ILAC and IAF to ensure that the benefits of global mutual recognition of accreditation are not lost as the new requirements for Europe are implemented.

Despite these outstanding questions, EA believes that the new legal framework will ultimately improve the understanding and

acceptance of accreditation as a tool to assist free trade across Europe. Could this be the way forward internationally too?

Further information on the EU Regulation and Decision, including links to the agreed legal texts, is available from the EA website at [www.european-accreditation.org](http://www.european-accreditation.org).



## 14th International Congress of Metrology 22–25 June 2009 Paris – France

### Added value through better measurement

Round tables, conferences, a technical exhibition and visits to firms with a unique objective—the improvement of measurement process. Email: [info@cfmetrologie.com](mailto:info@cfmetrologie.com). Visit [www.cfmetrologie.com](http://www.cfmetrologie.com).

EA is a partner of the 2009 International Congress of Metrology that will take place between 22–25 June 2009 in Paris. The Secretariat is involved in the organising committee and the EA Chair has been appointed as a member of the Scientific committee in charge of reviewing and selecting the keynote papers for the Congress. EA will also arrange and facilitate a roundtable on accreditation and accredited conformity assessment services as means to support the diffusion and consolidation of the metrological culture and practices in modern economies and societies. Visit [www.secretariat@european-accreditation.org](mailto:www.secretariat@european-accreditation.org)

## Interview with Jacques McMillan, Head of Unit, DG Enterprise, European Commission, Tallinn, 28 May 2008

The adoption of the new legislative package is a win-win achievement for all operators on the internal market and will facilitate the development of an open and fair European market.

**How would you best qualify the adoption of the new legislative package in terms of benefits for the European society, business, the European infrastructure for accreditation and EA accreditation bodies?**

“The adoption of the Regulation constitutes a major breakthrough because it gives a legal basis in two areas where it was missing. Market surveillance has been beyond the Commission’s political reach for 25 years and for accreditation, the package is providing the stabilising instrument that we have been looking for, for about 25 years as well.

“It is a win-win achievement for everyone, interested parties, economic operators, conformity assessment community, public authorities, regulators and enforcement parties.

“It marks a new start for the internal market because it is now possible to abandon the distinction between the ‘old’ and ‘new’ approaches which means that modern instruments developed for the new approach can now apply more easily and generally to all sectors irrespective of whether harmonised standards are used or not.”

**What are the Commission’s expectations vis-à-vis EA?**

“EA should now feel and operate in a strong position to ensure equal, comparable quality of accreditation services throughout the Union and, above all, transparency in the accreditation processes.

Transparency is fundamental to the operation of the internal market because it is the one element that turns the word ‘trust’ into a reality with respect to the Member States work; transparency is the key feature for the whole infrastructure to operate as expected.

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“All quality instruments put in place including accreditation have been designed with one objective: to create the level of trust indispensable for an open market and fair trade.”

### What are the next immediate actions to be undertaken in the short term to support implementation of the new legislation with regard to accreditation and EA?

“Our first task is to get an agreement on the guidelines for cooperation that will link EA not only to the Commission and EFTA but also to all EA major stakeholders including the national authorities. This entails the signing of a partnership agreement to translate the political guidelines into concrete terms for the implementation and reinforcement of the peer evaluation process, that must be seen as the major pillar of the whole European infrastructure. Also the agreement will help strengthen answerability of EA to public authorities both at European and national levels.”

### To conclude

“One could see the road of accreditation in Europe over the last 25 to 30 years as a bit 'bumpy'. The fact is that we have developed a policy which we have put in place and which has operated well over the last 10 years or so. Now the Regulation is and should be a new start in that it forms the legal foundation for accreditation in Europe, protecting accreditation against the temptation to go commercial. It also gives accreditation bodies the means to be and act as the last level control in the whole quality chain that should ensure that products marketed in Europe are safe. Moreover it covers accreditation activities not only linked to products but also to services, in this way contributing to the establishment of a single and uniform system of accreditation at Community level.

“We should all see the Regulation as a launching pad to EA which gives EA and its members in relation to major stakeholders and PA the best framework to deliver their services properly and efficiently. We should definitely avoid to see the Regulation as an obligation to put into place protective measures but use it as a dynamic instrument to put EA and European accreditation in a position of authority.

“I would add that the legislative package

will also give Europe accreditation the means to be a leader in the world in ensuring and demonstrating in reality the added value of accreditation. Long life to EA and our cooperation with EA!”



## Pacific Accreditation Cooperation (PAC)

### PAC 15th Plenary a Great Success

The 15th Plenary meetings of PAC were held in Kuala Lumpur, Malaysia from 21 to 27 June 2008. More than 70 representatives from PAC Members, certification bodies, industry, fellow regional accreditation groups and other interested parties attended the meetings. PAC extends its thanks to Standards Malaysia for their hard work, superb arrangements and warm hospitality in hosting the meetings at the Kuala Lumpur Convention Centre.

### Opening ceremony and seminar

This session was hosted by Standards Malaysia and was attended by over 70 delegates representing government, industry, regulators, end users, accreditors and certification bodies. After the official opening of the 15th PAC Plenary meetings by Dato Abdul Hanan, Secretary General, Ministry of Science, Technology and Innovation, five very interesting presentations followed, covering such diverse issues as the benefits of accredited certification to consumers and the possible impact on trade of the new European accreditation policy. PAC thanks Standards Malaysia for hosting the session and to the speakers: SGS's (Malaysia) Sdn.Bhd Amargit Singh; Malaysian Association of Standards Users (MASU) Ratna Devi Nadarajan; Federation of Manufacturers (FMM), S Krishnarajah; European co-operation for Accreditation (EA) Dr Lorenzo Thione, Chair; United Nations Framework Convention on Climate Change (UNFCCC) Bilal Anwar and Malaysian National Accreditation Committee Ir. Mah Lok Abdullah, Chair,

chaired a lively Q&A session at the end of the seminar.

### Open forum and strategic planning session

Convened by SCC Canada's Elva Nilsen, the PAC Chair, the afternoon of 23 June saw vigorous discussion on proposed strategic directions for PAC. Delegates split into six groups to brainstorm and prioritise issues covering membership, funding, promotion, increased regional and international recognition, increased member participation, expanding PAC MLA programs and maintaining PAC's region specific focus. The PAC Executive Committee will discuss a series of recommendations arising from the forum and an implementation plan will be delivered to members.

### Technical Committee

The PAC Technical Committee, chaired by SCC Canada's Joan Brough-Kerrebyn, met during the week, to review progress made with PAC initiatives as well as IAF and CASCO projects. Issues included Implementation of the IAF Cross Frontier Policy, closer cooperation with IAAC, consultancy versus certification in government tenders and client transfer within the CB community.

### Training activities

An experienced peer evaluators workshop held during the meetings was well attended, with PAC peer evaluators discussing issues of harmonisation of understanding, as well as specific items arising from recent PAC peer evaluations. The session was convened by SAC Singapore's Phua Kim Chua.

A course on ISO/IEC 17024 *Conformity Assessment—General Requirements for Bodies Operating Certification of Persons* was also held during the week. This course was hosted by ANSI USA's Dr Roy Swift, and was held over two days. Feedback from more than 50 participants was extremely positive and our thanks go to Roy for conducting such an important and well-received course.

### Developing Programs Committee

This Committee chaired by NABC India's B Venkataraman, also met during the week, and discussed training priorities for PAC over the next three years, as well as possible sources of funding.

PTB's Dr Ulrich Diekmann made a very interesting presentation during the meeting.

Delegates agreed that training priorities for 2009 include Food Safety Management Systems (FSMS), Auditor Competence and Greenhouse Gases (GHG). One of these courses will be conducted during the 2009 Plenary and further information on all courses will be posted on the PAC website, as it becomes available.

## Communications and Marketing Committee

Lane Hallenbeck (ANSI USA) chaired this meeting, which discussed current and future promotional initiatives for PAC. Members noted the new PAC brochure and letter introducing PAC activities to government and regulators and agreed that the PAC promotional DVD should be updated and reissued as soon as possible after the meetings. The second issue of the PAC newsletter will be published electronically in the next quarter and interested parties are welcome to contact the PAC Secretary to be added to the newsletter distribution list.

The revamped PAC website was also launched during the meetings and will go live by the end of July at [www.apec-pac.org](http://www.apec-pac.org).

## PAC Membership

PAC welcomed Dubai Accreditation Center (DAC) (Dubai) as its latest full member during the official dinner. Following the recent transfer of International Accreditation Service, Inc (IAS) (Iran), National Accreditation Board for Certification Bodies (NABCB) (India) and PNAC (Pakistan) from associate to full membership during the meetings, the number of PAC Members is currently 24, with 22 full members and two associate members.

### Full Members of PAC

JAS-ANZ (Australia & New Zealand), SCC (Canada), CNAS (PR China), DAC (Dubai), HKAS (Hong Kong, China), NABCB (India), KAN (Indonesia), IAS (Iran), JAB (Japan), JASC (Japan), JIPDEC (Japan), KAB (Korea), KAS (Korea), Standards Malaysia (Malaysia), ema (Mexico), PNAC (Pakistan), PAO (Philippines), SAC (Singapore), TAF (Chinese Taipei), NAC (Thailand), ANSI (USA), and STAMEQ (Vietnam).

**Associate Members of PAC:** AACBF (Asian Accredited Certification Bodies Federation), IIOC (The Independent International Organisation for Certification).

## PAC Executive Committee

Elections held during the Plenary unanimously returned the following EC members for a further three year term: PAC Chair-SCC Canada's Elva Nilsen; JAB Japan's Vice Chair-Shinichi Iguchi, Full members NABCB India's B Venkataraman and CNAS PR China's Xiao Jianhua. ANSI USA's Lane Hallenbeck was elected to the vacancy created by JAS-ANZ Australia & New Zealand's Tony Craven's resignation in late 2007. Associate Member representative, Asian Accredited Certification Bodies Federation AACBF's Roberto Lorenzoni and Full Member representative, Standards Malaysia's Ridzwan Kasim comprise the other two members of the EC, supported by Secretary, Belinda Mort.

## PAC MLA Activities

The PAC MLA Management Committee (MLAMC) and MLA Group both met during the week to discuss issues related to the PAC Peer Evaluation process. Following a unanimous vote at the MLA Group meeting, CNAS (PR China) joined the PAC MLA for Product at the official dinner.

## Product

Members of the PAC MLA for Product are: JAS-ANZ (Australia and New Zealand), SCC (Canada), CNAS (PR China), KAS (Rep. of Korea), ema (Mexico), SAC (Singapore), TAF (Chinese Taipei), and ANSI (USA), a total number of eight signatories with several others currently being processed.

## Environmental Management Systems (EMS)

There are currently 12 signatories to the PAC MLA for EMS being: JAS-ANZ (Australia and New Zealand), SCC (Canada), CNAS (PR China), NABCB (India), KAN (Indonesia), JAB (Japan), KAB (Korea), Standards Malaysia (Malaysia), ema (Mexico), PAO (Philippines), NAC (Thailand) and TAF (Chinese Taipei).

## Quality Management Systems (QMS)

There are currently 15 signatories to the PAC MLA for QMS, being: JAS-ANZ (Australia & New Zealand), SCC (Canada), CNAS (PR China), HKAS (Hong Kong, China), NABCB (India), KAN (Indonesia), JAB (Japan), KAB (Korea), Standards Malaysia (Malaysia), ema (Mexico), PAO (Philippines), SAC (Singapore), NAC (Thailand), TAF (Chinese Taipei) and BoA (Vietnam).

The PAC MLA Group also recommended to the Plenary that the current MLAs be expanded to include Food Safety Management Systems (FSMS), Information Security Management Systems (ISMS) and Certification of Persons. The PAC Plenary unanimously endorsed the PAC MLAMC and Technical Committee to progress the development of these three new MLAs.

Further information on PAC and PAC activities is available at [www.apec-pac.org](http://www.apec-pac.org) or by contacting the PAC Secretary, Belinda Mort at ph:+612 6345 5828 or email [pacsecr@email.com](mailto:pacsecr@email.com).



## IAAC Report to ILAC

This report includes IAAC activities from January 2008 to July 2008.

## Signatories of the IAAC MLA

### For Testing and Calibration Laboratories (9)

Argentina—OAA, Brazil—Cgre/INMETRO, Canada—SCC, Costa Rica—ECA (Testing only), Cuba—ONARC, Guatemala—OGA (Testing only), Mexico—ema, USA—A2LA, USA—ANAB, Doing Business As: ACLASS

### For Quality Management Systems Certification Bodies (6)

Argentina—OAA, Brazil—Cgre/INMETRO, Canada—SCC, Mexico—ema, Peru—INDECOPI/CRT, USA—ANAB

## IAAC Membership

IAAC currently has a total of 41 members from 22 countries in the Americas. 23 are full members, seven are associate members and 11 are stakeholders.

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## IAAC Officers

IAAC Chair, SCC Canada's Pat Paladino; IAAC Vice-Chair, OAA Argentina's Beatriz Garcia; Treasurer, ACLASS USA's Keith Greenway; MLA Committee Chair, em Mexico's Fabian Hernandez; Technical Committee Chair, OAA (Argentina) Beatriz Garcia; Laboratories Subcommittee Chair, A2LA USA's Bertha Munguia; Certification Bodies Subcommittee Chair, ANAB USA's Randy Dougherty; Inspection Bodies Subcommittee Chair, INN Chile's Eduardo Ceballos; Management Committee Chair, ONARC Cuba's Maria Miranda; Training Subcommittee Chair, CNA Panama's Francisco de la Barrera; Promotions Subcommittee Chair, ASCLD-LAB USA's Jo Ann Given; Documentation Subcommittee Chair, OAA Argentina's Maria Marta Mazzinni.

## Training

Training is a key activity for IAAC. The following is a list of courses held and planned for 2008 and 2009: Training exercise for IAAC peer evaluators was held 13–15 February 2008 in San Jose, Costa Rica; Course on Proficiency Testing Validation Methods was held 2–4 March 2008, in Buenos Aires, Argentina; 3rd Part Workshop: 'Proficiency Testing workshop' was held 22–25 April 2008, in San Jose, Costa Rica; Peer evaluator training course for Spanish speakers to be held in Mexico, in November 2008; Training course on ISO 17024 to be held in Paraguay, in September 2008; Training course on ISO 17020 to be held in Panama, in March 2009; A Peer Evaluator training course in English, with cooperation from APLAC, is planned for 2009 at a location to be determined.

## IAAC Proficiency Testing programs

'Volumetric Glassware'—The program was organised by em Mexico. It began in March 2006 and was finalised in March 2008. Centro Nacional de Metrología, CENAM, was the reference laboratory for the program.

'Meat'—The program is organised by INTI and OAA of Argentina and is ongoing. APLAC and SADCA laboratories are also participating.

'Thermocouples'—This program is currently under development by ECA of Costa Rica with support provided by NVLAP of the USA.

Two new regional Proficiency Testing programs are being planned for 2008. The scope of the programs is currently under discussion.

## Cooperation with PAC

The Pacific Accreditation Cooperation (PAC) and the InterAmerican Accreditation Cooperation (IAAC) signed a Memorandum of Understanding (MoU) on 17 August, 2007, during the IAAC General Assembly in Ottawa. The Arrangement encourages increased cooperation on accreditation to foster the development of related programs in the Americas and Asia-Pacific regions.

## Cooperation with APLAC

Implementation of the IAAC and APLAC MoU has been progressing well with several successes in cooperation and participation in proficiency testing programs and training courses.

## Cooperation with ILAC

The ILAC Marketing and Communications Committee (MCC) meeting and the ILAC Marketing Seminar will be held during the week of IAAC General Assembly meetings in Asunción, Paraguay, in September 2008.

## Technical Cooperation Projects

### 2007–2010 Organisation of American States (OAS) Project

A new four year project was approved by the OAS for technical support and cooperation for accreditation bodies in developing countries within the Americas region. The project includes funding for: witnessing of an IAAC peer evaluation; peer evaluations of ABs; training for peer evaluators; technical training courses; consultancies to a developing AB; internships for staff of developing ABs; a seminar on accreditation; and proficiency testing programs.

The previous project with OAS was a success. It provided funding to support witnessing of an IAAC peer evaluation and permitted IAAC to conduct:

Two peer evaluations of ABs; training for two peer evaluators; three technical training courses; three consultancies to a developing AB; three internships for

staff of developing ABs; a seminar on accreditation; and two proficiency testing programs.

## New PTB Project

The IAAC Executive Committee met with the PTB in January 2008 to review the results of the first project and to discuss a new technical cooperation project based on the 2008–2011 IAAC Strategic Plan. The new three year project is expected to be approved shortly and will include activities such as: technical assistance to IAAC developing economy members; support for peer evaluator training; workshops to harmonise evaluation criteria; joint regional assessments; use of assessors from other regional bodies; development of promotional materials for stakeholder members, national authorities, regulators, industry sectors, and other interested parties; technical training workshops for accreditation bodies and certification bodies on ISO 17021, 22003, 22003, 22004 and 22005; proficiency testing programs and training for accreditation bodies to develop proficiency testing providers.

## International Accreditation Day

IAAC members organised events for 9 June 2008 throughout the Americas, promoting the benefits of accreditation in celebration of the first international accreditation day.

## IAAC meetings

The 29th Executive Committee and MLA Committee meetings were held in Guatemala City, Guatemala, on 12–14 March 2008. Two important accomplishments of the meetings were the development of a succession plan for key positions within IAAC and finalising the draft Strategic Plan for 2008–2011.

The 13th General Assembly meetings will be held in Asunción, Paraguay, from 6–12 September 2008.

## IAAC Information and Publications

IAAC documents and information on members are available at the IAAC website: [www.iaac.org.mx](http://www.iaac.org.mx)

# Accreditation Update



## An unforgettable week: ema celebrates accreditation day

From technical and actual issues of importance to Conformity Assessment Bodies (CABs), to political topics concerning Accreditation, the entidad mexicana de acreditación (ema) celebrated the first International Accreditation Day during a successful week of events.

What resulted from an ILAC Joint Development Support Committee (JDSC) idea, and moved later to an ILAC Marketing and Communications Committee (MCC) proposal to all IAF and ILAC members, is now a reality in which Mexico fulfilled its objective: there is no doubt that our celebration of the first International Accreditation Day proved to be a way to promote and reinforce Accreditation in our economy.

From 9 to 13 June 2008 ema held an 'Accreditation Week' in Mexico City. The Secretary of Economy was in charge of the Opening Ceremony on 9 June. In his speech, he congratulated ema on the 'power of ideas' as a means to transform the national system for accreditation. He spoke of 'accreditation as an issue of great relevance for an economy's performance', and gave examples of how we all consume fresh food and use electrical objects to demonstrate the relevance of accreditation to every day consumables.

The Secretary of Economy said that a way to strengthen an economy is to 'eliminate obsolete regulations' and 'consolidate a system that assures quality and security of products'. He concluded by congratulating ema for organising the event. It is necessary for authorities to understand the need for accreditation, and this was one step forward.

Five conferences were also held. The first one, tackled the importance for Government Authorities to work with accredited CABs, and their experience of working with such bodies. For this conference we had speakers from different State Departments: Economy, Energy, Labour, Environment, Health, and Communications and Transport. For the other conferences, speakers from different Associations and Chambers presented the importance to the industrial sector of working with accredited bodies and the relevance of accreditation to the trading



Left to right: ema's Executive Director Maribel Lopez; UKAS & EA's Paul Stennett; ema's President Francisco Reed; Secretary of Economy Eduardo Sojo; ILAC's Orna Dreazen and Vice President of the Confederation of Industry Chambers' Rosendo Valles .



Panel of local and international speakers at the ema conference for accreditation day.

sector of the country. The importance of accreditation to the academic sector was also addressed.

The event looked at the present and future of accreditation in the world, with the participation of Paul Stennett, Maribel Lopez, and Orna Dreazen. Paul represented EA and presented with UKAS as an example, the importance of government support to Accreditation.

Maribel, as former IAAC President, gave a presentation on the status of accreditation in America and the challenges it faces. Orna, who represented ILAC in our event, gave us a presentation on the Cooperation and spoke of the importance and necessity of accreditation bodies participating in regional and international organisations. ILAC participating in this event was of great importance to ema, since it had the

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desired impact on authorities and ema is very grateful for the international speakers who shared their knowledge.

During the rest of the week, each day was dedicated to a different CAB. On 10 June, the conferences looked into issues concerning Testing Laboratories, and the 11 June was dedicated to Calibration Laboratories. Inspection Bodies had 12 June for their topics and the week ended on 13 June with Certification Bodies.

The topics for these days included Testing Laboratories—Good Laboratory Practices (Many thanks to our friend Orna Dreazen for her speech), PT Providers, Changes in Traceability and Uncertainty Policies, Most frequent Non-Conformities when applying ISO/IEC 17025, Accreditation of Forensic Laboratories (Many thanks to our friend John Neuner from ASCLD/LAB for his speech), Calibration Frequency, Technical Guide on Calibration of Liquid Thermometers; Calibration Laboratories—Calibration Measurement Capacity, Most frequent Non-Conformities in Calibration Laboratories, Reference Materials, Technical Guides on different issues: traceability, uncertainty, mass, volume, temperature, pressure, and dimensional; Inspection Bodies—Approach with government authorities and future vision, Most frequent non-conformities in: measurement instruments, electric installations, gas, environment, commercial information and polluting emissions.

During the entire week, we received over 900 people for the events of Accreditation Week. More than 786 people attended as participants, we had over 80 speakers, plus more than 30 of ema's staff and many special guests. We received participants from Argentina, Ecuador and Perú, and from all around Mexico. And of course our international speakers from Israel, USA and United Kingdom.

The more than satisfactory attendance, together with the topics that were covered, exceeded our expectation for the First International Accreditation Day celebration in Mexico. After lots of hard work by ema's staff over the past six months, we are now looking at the beneficiary result that the event had for accreditation in our country, and we are now working on the development of new ideas for next year. Hope you can join us!

## DAC celebrated first International Accreditation Day



Engineer Salah Amiri is balloting to choose the winners of 'Accreditation Quiz' on 9th June 2008 for International Accreditation Day. Amina Ahmed Mohammed, Director of Dubai Accreditation Department (DAC) and Dr Mohammed Saad, Principal Accreditation Officer of DAC are also present.

In line with the joint declaration by ILAC and IAF regarding the designation of 9 June 2008 as the first International Accreditation Day, The Dubai Accreditation Department (Formerly Dubai Accreditation Center) decided to celebrate the first International Accreditation Day in full swing. A number of activities were conducted. The awareness campaign regarding accreditation started on 1 June. Various posters were distributed, press notes were issued and an accreditation quiz competition was organised during the campaign. The crest of the activities was the ceremony on 9 June 2008.

The ceremony was held in the City Hall of Dubai Municipality. In her inaugural speech Dubai Accreditation Department Director, Amina Ahmed Mohammed highlighted the importance of accreditation of conformity assessment bodies. She asked regulators, interest groups and the general public to play their role in encouraging accreditation which in-turn enhances quality and safety in every day life. She appreciated the commitment of conformity assessment bodies towards accreditation.

Amina Ahmed praised the role of ILAC and IAF in promoting accreditation culture world wide and said that the designation of 9 June 2008 as the first International Accreditation Day is a vital step in this regard. Ms Ahmed also presented the report about DAC activities and future plans.

Dubai Municipality Assistant Director General, Abdul Kareem Julfar was the guest of honour. In his speech he highlighted the Dubai Municipality vision



Award presentation to best accredited inspection body.

'creating an excellent city that provides the essence of success and comfort of living' and appreciated the role of Dubai Accreditation Department in this regard.

To make the first International Accreditation Day memorable and commendable the Dubai Accreditation Department announced special awards in the following categories:

Best Accredited Laboratory—2007 award presentation; Best Accredited Inspection Body—2007 award presentation; Best Technical Assessor—2007 award presentation.

Arab Center for Engineering Studies (ACES) Laboratory, Dubai was declared 'Best Accredited Laboratory for 2007'. Dutest Inspection Services, Dubai was declared 'Best Accredited Inspection Body for 2007' and Huw Woodyatt was declared 'Best Technical Assessor for 2007'.

Prizes were given to the three winners of the Accreditation Quiz Competition and certificates were awarded to the successful participants in the ISO/IEC 17020 Lead Assessor training course held on 11-15 May 2008.

# Cgcre/Inmetro, Brazil

## 31st ISO/REMCO Meeting



*Seminar on Reference Material Producer and Proficiency Testing Provider Accreditation, Rio de Janeiro, Brazil.*

The 31st Meeting of the Reference Materials Committee (ISO/REMCO) was held from 10 to 13 June 2008, in Rio de Janeiro, Brazil. The Committee is responsible for the elaboration and revision of ISO Guides related to reference materials, the key elements in assuring reliability and metrological traceability of measurement results made by laboratories in various technological fields.

The meeting was convened by Dr Adriaan van der Veen, from NMI (the Netherlands), with the support of Stéphane Sauvage, from the ISO Secretariat. Representatives from Belgium, Brazil, United States, Spain, China, France, Germany, South Africa, Mexico, Korea, United Kingdom, Japan and Slovakia attended the meeting. There were representatives from organisations such as BIPM, ILAC, International Association for Geanalysts and European Directorate for the Quality of Medicines.

Besides the Brazilian representative of ABNT (Inmetro), Dr Renata Borges, observers from different areas of Inmetro attended the meeting. This provided an opportunity to improve their knowledge on the production and certification of reference materials.

The meeting reached very good results, with the approval of many resolutions relevant for the development of this field of knowledge. The next committee meeting will take place in Oxford, United Kingdom in 2009.

### Seminar on accreditation of proficiency testing providers and reference materials producers

On 5 and 6 June 2008, Inmetro hosted the Seminar on Accreditation of Proficiency Testing Providers and Reference Materials Producers in Rio de Janeiro, Brazil. Eight of the world's most important specialists in this field made presentations to more than 170 people, from different organisations and economies, including Argentina, Peru, Bolivia and Guatemala.

On the first day, the focus was on the production and certification of reference materials, addressing the experiences of the National Metrology Institutes. The opening lecture was presented by the President of Inmetro, Professor João Alziro Herz da Jornada, who acknowledged the relevance of such a seminar to Brazil and confirmed Inmetro's commitment to these subjects. The first technical lecture was by Dr Adriaan van der Veen from NMI (The Netherlands) and the Chair of ISO Reference Materials Committee (ISO REMCO). He presented the ISO REMCO current and future works. This was followed by Dr Robert Watters, Chief of the Measurement Services Division (MSD) of the National Institute of Standards and Technology (NIST/USA), presenting some Technical and Economic Considerations for the Development of Certified Reference Materials. Dr Thomas Steiger, BAM (Germany) showed the *COMAR Database, a Tool for Finding Reference Materials*, a work

developed together with Rita Pradel. Dr Steve Wood, Head of Reference Materials and Calibration Services of LGC (United Kingdom), presented LGC Experiences in Production and Characterisation of Pure Substances & the Role of NMIs in this Context and in Certification of Reference Materials by Interlaboratory Comparisons. Finally, Chemical Metrology Division of Inmetro representative, Dr Janaina Caixeiro, presented the Brazilian NMI Experience in the Production and Certification of Reference Materials—Ethanol and Biodiesel Examples.

On the second day, the main focus was reference materials producers (RMP) and proficiency testing providers (PTP) accreditation. The General Coordinator for Accreditation, Marcos Aurélio Lima de Oliveira, and those responsible for the implementation of the accreditation programs, Dr Renata Borges and Suzana Moura, opened the event presenting the actions taken so far and perspectives for future works. This was followed by three lectures presented by representatives of accreditation bodies, sharing their experiences in the implementation of PTP and RMP accreditation programs: Hong Kong Accreditation Service (HKAS)—Accreditation Manager, W W Wong, American Association for Laboratory Accreditation (A2LA/USA)—Senior Scientific Officer, Randall Querry; and China National Accreditation Service for Conformity Assessment (CNAS)—Project Manager, He Ping.

As for future Mutual Recognition Agreements (MRA) at the international level, Cgcre/Inmetro plans to be a signatory to these in order to promote the acceptance of testing and measurement results in the global market. In relation to this, the experience of HKAS co-ordinating three workshops promoted by the Asia-Pacific Laboratory Accreditation Cooperation (APLAC), which led to the APLAC MRA for Reference Materials was described. This work was convened within APLAC by W W Wong.

Alan Squirrell, from the ILAC Secretariat, discussed the work within the International Laboratory Accreditation Cooperation, focusing on the future Agreements for PTP and RMP Accreditation.

There was active participation by the

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audience and many questions were posed to the lecturers, showing the level of interest of the laboratory community, regulators, Brazilian proficiency testing providers and reference materials producers in both types of accreditation. The Seminar was successful in reaching its goals by sharing the experiences of some relevant national metrology institutes and accreditation bodies, and highlighting to the interested community the types of accreditation that will be available from Cgcre in the near future.

### Training course on accreditation of proficiency testing providers and reference materials producers

General Coordination for Accreditation hosted the Training Course on Accreditation of Proficiency Testing Providers (PTP) and Reference Materials Producers (RMP), from 2 to 4 June 2008 in Rio de Janeiro, Brazil. Forty-five assessors and accreditation officers from Cgcre/Inmetro (General Coordination for Accreditation) attended the training course.

On the first day, the aspects related to the PTP and RMP accreditation processes were discussed, from the point of view of the experience of American Association for Laboratory Accreditation (A2LA/USA), presented by Randall Querry, Accreditation Manager of A2LA. The relevant points of the document ILAC G:13, the A2LA accreditation policies, the combined use of ISO Guide 34 and ISO/IEC 17025 in the assessment of technical competence of RMP and the interpretation of the APLAC TC008 document were discussed.

On the next two days, Dr Adriaan van der Veen from NMI (The Netherlands) and also the Chair of ISO Reference Materials Committee (ISO REMCO), talked about standards used for the evaluation of interlaboratory comparisons, in particular ISO 13528:2005, and carried out some exercises with the participants.

Afterwards, Dr van der Veen presented the ISO REMCO current and future works, the use of interlaboratory comparisons for the certification of reference materials and explained ISO Guide 35:2006.

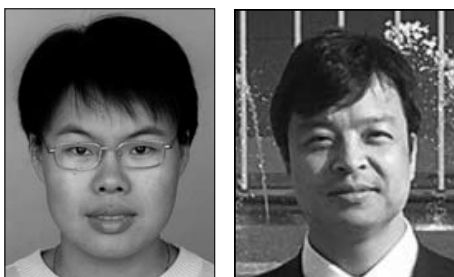
Due to the relevance of the subject and the expertise of the lecturers, the audience participated actively. This training was an important step towards the implementation of the two accreditation programs by Cgcre/Inmetro.



## China National Accreditation Service for Conformity Assessment (CNAS)

### Discussion on Traceability in Laboratory Medicine and ISO 15195 Accreditation

By Zhai Peijun, Hu Dongmei



Authors Hu Dongmei and Zhai Peijun.

With the implementation of ISO 15189, the accreditation for medical laboratories is growing rapidly around the world, and the problem of metrological traceability in medical examinations is being revealed day by day. Various brands of analysis systems are being used in examinations in laboratory medicine, and they have different ways of traceability, which leads to the incomparability of the examination results of the same measurand either among laboratories or within one laboratory. Therefore, the examination results of patient samples are not comparable irrespective of the place and time. For this reason, without a worldwide traceability system, the competent accreditation of medical laboratories and its MRA would be like building a castle in the air. The foundation needed for this 'castle' is the metrological traceability in laboratory medicine. Therefore, the study on metrological traceability is an advanced and basic work in laboratory medicine.

CNAS has been implementing medical laboratory accreditation in accordance with ISO 15189 for more than four years. At the same time, it has made some research

on metrological traceability in laboratory medicine and on accreditation for reference measurement laboratories. Here we share some of our experiences with peer bodies in ILAC, and hope it can be of help to the accreditation of laboratory medicine.

### Importance of metrological traceability in laboratory medicine

Laboratory medicine is playing a more and more important role in the prevention, diagnoses, treatment, screening and monitoring of diseases and also in physical check-ups. It was supposed under investigation that about 70 to 80 per cent of the information for diagnosis and treatment is from the examinations of medical laboratories. Therefore, the accuracy of the examination results is very important for correct diagnosis and treatment, to ensure the health and safety of patients.

On the other hand, there are always some differences among the results for the same measurand in different hospitals, and then repeated examinations are performed for patients to get so called 'correct' results. Besides the consideration of deviations in the patient samples, the non-transferability and incomparability among examination results caused by the differences of the analysis systems and examination procedures has resulted in an increasing financial burden for patients.

The above presents two questions: 'is the result accurate?' (accuracy) and 'are the results consistent?' (comparability and transferability). The accuracy of the examination results can be achieved by comparing the examination results with a reference value; the comparability and transferability of the examination results can be defined by comparing the results of one laboratory with the results from other laboratories. These two ways have the same characteristic of comparing the examination results with an assigned value (reference value or consensus value) of a higher metrological level. This comparison is the method of achieving metrological traceability; therefore, the answer to the above questions is the metrological traceability in laboratory medicine.

When possible, the examination results shall be traceable to a higher level of reference material and reference measurement procedure, and by this way, the transferability and comparability of patient examination results can be

achieved over time and space.

Metrological traceability is the basis to ensure the reliability of examination results. The definition of traceability in VIM is, 'property of a measurement result relating the result to a stated metrological reference through an unbroken chain of calibrations of a measuring system or comparisons, each contributing to the stated measurement uncertainty'. The traceability of most physical properties has been set up by the establishment and development of the SI units and through a series of calibration instruments. This global traceability network has been set up under the leadership of BIPM. However, most of the examinations in laboratory medicine are done on biological materials and the establishment of their traceability depends on the availability of reference materials and reference measurement procedures, therefore, the situation is more complex and difficult. Metrological traceability in laboratory medicine is a newly developed scientific work from the point of view of the international development, but is also a basic work considering the role and significance of the examination results.

## Methods and routes to establish the traceability system in laboratory medicine

### Ideas on the establishment of the frame and structure of the national traceability system in laboratory medicine

Metrological traceability in laboratory medicine cannot be established without a whole traceability system, and the full-scale program on a national level is needed. We can follow the example of the framework of a national traceability system on physical and chemical measurands, to set up such a network for laboratory medicine at two levels. The first level is the primary reference measurement laboratory on a national level; the national metrology institute (NMI) is preferred to be one such kind of laboratory, and together with other qualified reference laboratories that hold some properties with the highest level of metrological traceability in the country, to act as the 'source' of a national traceability system. The main task at this level is to set up the primary reference measurement procedures and primary reference materials. The second level is the

reference measurement laboratory, which is responsible for performing calibrations for routine medical laboratories and determining the target value of ring trials by providing reference measurement services. These laboratories provide calibration services for the routine medical laboratories.

Emphasis is placed on the reference measurement laboratories. What kind of laboratories can be taken as reference measurement laboratories? Considering the function, workload and cost of a reference measurement laboratory, a nation-wide network cannot be on a big scale and may mainly consist of research institutes of laboratory medicine, some manufacturers of in vitro diagnostic devices, and sometimes of calibration laboratories which have experience in traceability work in laboratory medicine and some medical laboratories in hospitals. Considering the cost and interest, transferring from the research institutes of laboratory medicine and medical calibration laboratories of a higher level of traceability to reference measurement laboratories is the most economic and efficient method to set up a traceability network. There is the same requirement both in ISO/IEC 17025 and ISO 15195 that the reference measurement (calibration) instruments cannot be used for other purposes except calibration. Under such requirements, the instruments used for reference measurement (calibration) cannot be used in the routine examination; therefore, it is very difficult for the routine medical laboratories to become reference measurement laboratories.

After this national traceability network has been set up, authoritative or regulatory support will help to request the routine medical laboratories to demonstrate their traceability by tracing to the reference measurement laboratory network.

In China, National Institute of Metrology (NIM), National Center for Clinical Laboratory (NCCL) and CNAS have been working together to establish a China metrological network in laboratory medicine and some progress has been made in this field.

### Participation in the international comparisons and international traceability network in laboratory medicine

When the national traceability network in laboratory medicine has been set up, traceability to the international traceability

network by means of taking part in the international comparisons must be taken into account. These comparisons, including ring trials among reference measurement laboratories as well as the international key comparisons organised by CIPM among NMIs, provide the foundations for taking part in the international network of reference measurement laboratories, and finally entry into the global traceability system for laboratory medicine.

Therefore, the international requirements need to be taken into consideration when establishing a national traceability system, to prearrange the interface and ground for entering into the international system. We can follow the requirements and methods specified by the Joint Committee on Traceability in Laboratory Medicine (JCTLM) to enter the international traceability system.

JCTLM is an international joint committee on traceability in laboratory medicine composed of representatives from BIPM, ILAC and IFCC. The aims are to provide: a global platform for traceability to appropriate measurement standards; to guide and promote internationally recognised equivalent measurement in laboratory medicine; to provide support for comparability, reliability and equivalence of the examination results in laboratory medicine; to promote the public healthcare and the free trade of IVD products.

The JCTLM procedures contain descriptions of the ideas and framework for the international network of medical reference measurement laboratories; the requirements for accreditation for these laboratories using both ISO/IEC 17025 and ISO 15195; the use of reference measurement procedures, and the need to take part in ring trials. Laboratories that have fulfilled the above requirements will be included in the JCTLM list of reference measurement laboratories.

China Joint Committee on Traceability in Laboratory Medicine was set up in March 2007 under the sponsorship and promotion of CNAS, and the approval of the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) of P.R.C. This committee is composed of CNAS, NIM, NCCL and representatives of the IVD medical device manufacturers and medical laboratories.

The aim of this committee is to develop the China metrological traceability system in laboratory medicine.

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## Role of accreditation in establishing a metrological traceability system for laboratory medicine

### Requirements and standards for accreditation

Besides the requirements of JCTLM, there are several international standards published by ISO/TC212 Clinical Laboratory Testing and in vitro Diagnostic Test System that should be used in the accreditation of measurement reference laboratories. These standards provide the requirements and basis for the construction of quality and competence in the measurement reference laboratories and for the development of accreditation, they include *ISO 15193:2002 In vitro diagnostic systems—Measurement of quantities in samples of biological origin—Description of reference procedures*; *ISO 15194:2002 In vitro diagnostic systems—Measurement of quantities in samples of biological origin—Description of reference materials*; *ISO 15195:2003 Laboratory medicine—Requirements for reference measurement laboratories*; *ISO 17511:2003 In vitro diagnostic medical devices—Measurement of quantities in biological samples—Metrological traceability of values assigned to calibrators and control materials*; *ISO 18153:2003 In vitro diagnostic medical devices—Measurement of quantities in biological samples—Metrological traceability of assigned values for catalytic concentration of enzymes in calibrators and control materials*.

In some disciplines of laboratory medicine such as haematology and biochemistry, the calibrators and the trueness control materials are used as the media of the metrological traceability. Under such circumstances, these calibrators and controls are playing the role of the reference materials; their quality and the assigned values can directly affect the final examination results of the patients. The ISO Committee on reference materials (ISO/REMCO) has been considering the coordination with ISO/TC212 in the standardisation work, and was planning to bring the calibrators used for medical examination into the scope of reference materials at their Plenary meeting in 2007. From the results of our research, international guides for reference materials such as *ISO Guide 34* and *ISO Guide 35* have great significance on the production of reference materials in laboratory medicine. The manufacturers

of calibrators and the trueness control materials used for medical examination should be encouraged by the accreditation body to study the appropriateness of conforming to these International Guides; at the same time, the accreditation bodies should apply these requirements to their accreditation activities in accrediting these medical reference material producers.

### Accreditation activities in the traceability system for laboratory medicine

The qualification of the laboratories is an indispensable part of the construction of the traceability system, and the composition of the traceability system should involve this matter. It is stated in ISO 15195 that the medical reference measurement system consists of reference materials, reference measurement procedures and reference measurement laboratories. Correspondingly, the organisations involved in the medical traceability system are, reference measurement laboratories, reference material producers, proficiency testing providers, and the authoritative institute to validate the reference measurement procedures. Among these organisations, all bodies except those that validate the reference measurement procedures have been involved in accreditation activities.

In the activities of accrediting the national primary standard laboratory (usually the national institute of metrology), new requirements in two areas have been suggested to the accreditation body. On one hand, they hope to harmonise the time of assessments of CIPM's peer evaluation with the accreditation body; on the other hand, they hope to share the assessors with CIPM. These two questions have been under consideration by CNAS.

JCTLM has set up the premises for the reference measurement laboratories applying for inclusion in the JCTLM list. It is required that they are accredited according to both ISO 15195 and ISO/IEC 17025 by an accreditation body before they are allowed to be put into the reference measurement laboratory list of JCTLM. Therefore, the accreditation body should develop their accreditation program according to ISO/IEC 17011, ISO 15195 and ISO/IEC 17025, and note that the requirement for participating in ring trials by JCTLM shall be taken as the requirement for proficiency testing in

the medical field, and the ILAC policies for proficiency testing and regional accreditation cooperation organisations can also apply to these kinds of laboratories, provided the frequencies and discipline classifications for the proficiency testing are in the medical field.

One important function of the medical reference measurement laboratories is to provide assigned values for the proficiency testing of routine medical laboratories. These reference laboratories that intend to be the proficiency testing providers for the routine medical laboratories can therefore develop into professional proficiency testing providers. Under such circumstances, these reference measurement laboratories need to set up a proficiency testing provider management system according to *ISO Guide 43*, which is under revision as a new International Standard—ISO/IEC 17043, and *ILAC G13*, and then seek accreditation from an accreditation body.

There are no clear requirements for the production of the calibrators and trueness controls material in the JCTLM's route map or the international requirements and guides, even though these are another important part of the medical reference measurement system. Since the calibrators and trueness controls are important for the examination results for patients, the accreditation bodies should encourage the manufacturers to set up their quality management system according to the relative guides of REMCO, to ensure the reliability of the calibrators and trueness controls.

It should be noted that RMP and PTP accreditation is now under development in ILAC, but it is not mentioned in the framework of the JCTLM. Suggestions from ILAC and JCTLM are recommended in this area.

ISO/REMCO has been paying attention to the development of the standardisation work in the medical field. It has been considering bringing the medical control materials into the scope of reference materials since 2006, and to coordinate with ISO/TC212 on the relevant international standards for reference materials in 2007. It is recommended that ILAC and the accreditation bodies should monitor these developments.

On all accounts, the need for competence recognition derived from the medical traceability will bring new challenges for the accreditation bodies.

## Conclusions

We can make the following conclusions from the above:

The metrological traceability in laboratory medicine is attracting more and more international organisations; It also brings forward a new challenge to accreditation bodies; The construction of the metrological traceability in laboratory medicine is a systematic work at a national level, which cannot be fulfilled only by the accreditation body; The contributions of the national institute of metrology and research institutes of laboratory medicine can promote the whole progress, and in this progress the accreditation body can play an important role; It is not the end target to establish a national traceability system in laboratory medicine, it is the basis for the construction and development of the international traceability system in laboratory medicine; It is an advanced idea and has very important significance to introduce the accreditation of RMP and PTP into the construction of the traceability system in laboratory medicine.

## References

*Outline of the calibration and measurement hierarchy in laboratory medicine (JCTLM); Process for listing reference measurement laboratory services (JCTLM); Process for review of reference measurement services from laboratories preparing for accreditation (JCTLM); Process for review of reference measurement services who are accredited as calibration laboratories (JCTLM); Process for requesting and processing nominations for JCTLM listing of reference measurement laboratory services (JCTLM); ISO/IEC 17025 Requirements for competence of testing and calibration laboratories; ISO15195 Laboratory medicine- requirements for reference measurement laboratories; ISO Guide 34 Guidance of competence of reference material producer; ISO/IEC Guide 43 Proficiency testing by means of interlaboratories comparison; Resolutions of 8th and 10th General Assembly of ILAC; Resolutions of 30th annual meeting of REMCO; International vocabulary of basic and general terms in metrology (VIM).*

## Nineteen Medical Laboratories gain Accreditation to ISO 15189



A ceremony is held to grant accreditation to medical laboratories designated for 2008 Beijing Olympic Games.

Nineteen medical laboratories have obtained accreditation from CNAS at a ceremony in Beijing on 11 July, including laboratories of the Chinese PLA General Hospital, Beijing Tongren Hospital, Beijing Hospital and Beijing Union Hospital.

Medical examination is not aimed for trade, however, with the trend of globalisation and the development of convenient transportation facilities, people travel more frequently nowadays, which leads to the need for consistent and standardised medical service including medical examination.

The Beijing Municipal Health Bureau of China and CNAS initiated the National Accreditation Program for Beijing Medical Laboratories Designated for 2008 Beijing Olympic Games in April 2007 with the aim to improve the quality, competency and safety of the medical laboratories in the Beijing area; to facilitate the mutual recognition of the examination results of various medical laboratories; and to provide the 2008 Beijing Olympic Games with good quality medical services.

The accreditation program for medical laboratories designated for the 2008 Beijing Olympic Games has been successfully achieved. This serves as a

demonstration of the good quality and competence of these medical laboratories to all foreign friends from all over the world, showing that they can get internationally recognised medical examination services in Beijing. Laboratory accreditation will help to establish and deliver trust and could serve as the platform for the already implemented policy of 'one examination report, accepted everywhere' in Beijing.

The cooperation between Beijing Municipal Health Bureau and CNAS is a successful example of establishing a model of administration which uses laboratory accreditation results, and that is highly praised by all societies. Beijing Municipal Health Bureau takes advantage of its leading role to select the organisations which can be relied on to serve the community and by using this model the administration efficiency is increased, the cost is reduced, and the impartiality is ensured. The successful experiences and administration of the model of the National Accreditation Program for Beijing Medical Laboratories Designated for 2008 Beijing Olympic Games has evoked great interest in the Ministry of Health of The People's Republic of China and other health authorities in other provinces and municipals.



## National Association of Testing Authorities, Australia, (NATA) to assist Gulf with technical infrastructure



NATA Chief Executive, Alan Patterson at the official signing of the contract for the Gulf Accreditation Center. The event attracted local media.

Australia is assisting the Gulf States to ensure their laboratory technical procedures meet international standards.

NATA announced it has signed a contract to provide consulting services to help with the establishment of a Gulf Accreditation Center.

The center will ensure member technical facilities meet international standards in their testing procedures. By doing so, the facilities concerned assist the development of trade links and reliable technical infrastructure.

The contract between NATA and Cooperation Council for the Arab States of the Gulf was hailed by NATA Chief Executive Alan Patterson as “an important event in helping promote accreditation globally.”

In his speech to the Cooperation Council for the Arab States of the Gulf, distinguished guests and local media, Mr Patterson emphasised the importance of NATA’s consultative role and the positive effects on removing technical barriers to trade.

“Today presents a great opportunity for all parties concerned with the project and marks another milestone along the path to the successful launch of the Gulf Accreditation Center. NATA is proud to assist in this important process.

“But today is not just about facilitating the removal of external technical trade barriers. There are practical local reasons

why this is an important occasion.

“It means the region—already actively involved in and cognisant of accreditation and its benefits—is determined to not only ensure its technical infrastructure meets the highest possible internationally agreed standards, but facilitates trade between member countries and the GCC aim of regional economic integration.

“It means the citizens of the Gulf Countries can be assured that the tests they require across a very wide range of activities are undertaken with a high degree of quality assurance in mind. It provides greater confidence in and across markets and allows Government, industry and business to better manage risk. It effectively enhances business opportunities for industries and manufacturers in the region.

“Technical accreditation is something that touches all our lives, whether we are aware of it or not. We rely on machines, home goods, measuring devices and instruments to be safe, accurate and reliable. Technical accreditation delivers that reliability. It ensures that our medical tests are accurate, that pipelines won’t burst, that forensic evidence is accurate, that roads won’t crumble, that bridges won’t collapse, planes continue to fly and that racing horses and camels compete fairly, NATA Chief Executive, Alan Patterson said during his presentation to the Gulf States.

According to Mr Patterson, NATA through its 60 plus year history, has been to a large degree responsible for establishing international frameworks by which technical facilities can assure their customers that their results are reliable.

“It’s immensely pleasing to be able to pass on the expertise we have gained in this field to new accreditation bodies such as the Gulf Accreditation Center.”

The center will provide all accreditation services required by a regional conformity assessment scheme to Bahrain, Saudi Arabia, Oman, Kuwait and Qatar, and the United Arab Emirates.

The project will also establish policies and operational documentation such as operating manuals, quality manual, job descriptions and technical, administrative and financial procedures.

The project is expected to take four months to complete, and will involve a team of NATA managers, consultants and technical experts.

## IAJapan signed MoU for Cooperation with JAB



JAB Permanent Executive Director, Shinichi IGUCHI and IAJapan’s CE Katuo SETA, sign the MoU for cooperation in accreditation activities.

On 30 June 2008, International Accreditation Japan (IAJapan) signed a Memorandum of Understanding (MoU) with the Japan Accreditation Board for Conformity Assessment (JAB) to improve efficiency of accreditation activities, to enhance the quality of accreditation, and to contribute further to the international accreditation community.

In Japan, there are some bodies which accredit laboratories, inspection bodies and certification bodies on the basis of Japanese laws and regulations, as well as bodies which accredit laboratories, inspection bodies and certification bodies on a voluntary basis. Under such circumstances, each body may specialise in a specific sector, making use of its own expertise.

On the other hand, this could lead to lower efficiency due to redundancy and lead to inconsistent operation. The Japanese Industrial Standards Committee (JISC), which is a governmental advisory body on industrial standards and conformity assessment, has recommended accreditation bodies strengthen the cooperation for their activities and establish the Japanese Accreditation Council (JAC). As one of the results of the activities of JAC, IAJapan signed the MoU for cooperation with JAB to strengthen cooperation between these two bodies.

The areas of cooperation are:

- 1) Mutual use of technical resources for accreditation including technical documents; proficiency testing; technical experts, instructors for training and laboratory assessors and joint hosting of seminar and training course.
- 2) Information sharing and promotional activities such as; information sharing among executives and persons in charge; promotion for accreditation and international issues.

## Pakistan National Accreditation Council (PNAC) organises 5-day assessor training course on ISO 15189



More than twenty pathologists, laboratory managers and doctors participated in the course organised and held by Pakistan National Accreditation Council (PNAC) in collaboration with Norwegian Accreditation (NA). The course was conducted by Cecilie Laake and Anne Graendsen of NA. In the past PNAC has conducted laboratory management courses on ISO 15189 (the International standard for medical laboratories), but this was the first time that PNAC has organised an assessor course on ISO 15189 in the country. The main objective of the course was to create a pool of assessors for medical laboratories and build indigenous capacity to prepare the pathology laboratories in accordance with the international standard.



Secretary Ministry of Science & Technology Sharif Ahmed congratulating CEO, TUSDEC Suhael Ahmed after signing of MoU between PNAC and TUSDEC. DG, PNAC is also present.



Islamabad: Secretary Ministry of Science & Technology Sharif Ahmed Khan giving away certificate to a participant on completion of 5-day Assessor Training Course on ISO 15189, while DG, PNAC and Cecilie Laake of NA are watching.

### Sectoral committee recommends launch of inspection bodies accreditation scheme

Pakistan National Accreditation Council, PNAC has nearly completed all the formalities to launch the accreditation scheme for Inspection Bodies (IBs) in accordance with ISO 17020—the International standard for IBs. In this regard, the first meeting of the Sectoral

Committee for Inspection Bodies (IBs) was held in the conference room of PNAC. Technical members from public and private sector organisations participated in the meeting and reviewed the technical documents prepared by PNAC for launching the accreditation scheme for Inspection Bodies. The documents including specific criteria for lifting equipment, pressure vessel, electric equipment and non-destructive testing were discussed in detail by the Sectoral

Committee. During the meeting the qualification criteria for inspectors was also reviewed. The committee noted that sufficient preparation work has already been done by PNAC including holding of seminars and training courses in the recent past and after vetting of the technical documents, the scheme may be launched.

The Pakistan National Accreditation Council (PNAC) and the Technology Upgradation and Skill Development Company (TUSDEC) of the Ministry of Industry and Production signed a Memorandum of Understanding (MoU) to jointly collaborate and promote accreditation of testing and calibration laboratories by strengthening, upgrading and if necessary establishing new laboratories in strategic industrial clusters. The MoU was signed by the Director General, PNAC and the Chief Executive Officer, TUSDEC, Suhael Ahmed. The Secretary, Ministry of Science and Technology, Sharif Ahmed witnessed the occasion. Under the MoU, PNAC and TUSDEC will establish a working relationship to coordinate and organize joint seminars and skill development courses under the awareness raising and training program on quality issues. Both organisations will also promote testing and calibration from the accredited laboratories and prepare viable proposals/projects for technology upgrading under National Quality Policy and Plan (NQP&P).



## Croatian Accreditation Agency (HAA)

### Pre peer evaluation of Croatian Accreditation Agency

On 23 and 24 June 2008 an EA team conducted a pre-peer evaluation of the HAA management system. The two days of meetings included interviews and extensive discussions with HAA management and staff and presentation of documents and files.

Consequently, all the HAA staff members were pleased with the final conclusion by the EA evaluation team reporting that HAA has a competent and experienced staff, appropriate organisation structure and performs professional assessments on site.

Hopefully, at the autumn session, the EA MAC will decide that the full evaluation can take place and will assign an entire evaluation team who will thoroughly check all the accreditation scopes and perform an on site evaluation visit.

HAA started working towards an EA Multilateral agreement on 1 March 2007, by submitting an application for the following MLA scopes: calibration laboratories (HRN EN ISO/IEC 17025); testing laboratories (HRN EN ISO/IEC 17025); bodies for the certification of quality management systems (QMS) (HRN EN ISO/IEC 17021); bodies for the certification of environmental management systems (EMS) (HRN EN ISO/IEC 17021); bodies for the certification of products (HRN EN 45011); bodies for the certification of persons (HRN EN ISO/IEC 17024) and inspection bodies (HRN EN ISO/IEC 17020).

The Republic of Croatia commenced negotiations for full membership to the European Union with the European Commission for all *acquis communautaire* chapters. HAA is actively involved in this historical process and supports all the ministries responsible for different fields (industrial products, environmental protection, public health, consumer protection) but is particularly included in negotiations for Chapter 1: Free Movements of Goods.

Besides HAA, other ministries are also looking forward to the final results of the EA evaluation, as well as HAA signing the Multilateral Agreement with the European co-operation for Accreditation.

## Korea Laboratory Accreditation Scheme (KOLAS)

### The First International Accreditation Day seminar in Korea



KOLAS organised and hosted a commemorative seminar on 9 June for the first International Accreditation Day. The event was held under the Korean Agency for Technology and Standards (KATS), organised by Korea Testing & Research Institute (KTR) and sponsored by The Seoul Economic Daily. About 200 national and international experts in accreditation, interested parties, accredited organisations, assessors, and other specialists participated.

Trust, the theme of this year's International Accreditation Day, was chosen to highlight the way in which accreditation practices are harmonised worldwide to underpin global free trade of products and services conforming to customer's requirements and to legal requirements regarding health and safety and protection of public interests in general.

In order to secure the credibility of testing reports issued by KOLAS—accredited laboratories, KOLAS operates an accreditation system based on an organisation structure, experts and processes appropriate to internationally recognised standards.

The commemorative seminar covered a review of the historical background, significance of the accreditation system, effects and need for the Mutual Recognition Arrangement (MRA). A case study of Ottogi Co., Ltd., which is one of Korea's food enterprises that has advanced successfully into the European market

with a KOLAS-accredited internationally recognised testing report was discussed.

Information on KOLAS' basic direction for on-site assessment, status of international harmonisation, as well as policy for operating the accreditation system was also provided at the seminar.

This event contributed to informing relevant stakeholders, including accreditation bodies, accredited organisations and the general public, of the importance of accreditation and international trends relating to accreditation systems.



## Kenya Accreditation Service (KENAS)

### KENAS makes inroads into Accreditation of inspection bodies



*Need for competence in the inspection of motor vehicles, for example, inspection of the Public Service Vehicles (PSV) that include the 'Matatu'.*

### Inspection of motor vehicles and inspection of buildings and structures in the construction industry.

Two stakeholder meetings were held at KENAS on 22 May and 6 June 2008. The topics of discussion included ensuring quality and safety in the building and construction industry and bringing order and sanity in the 'Matatu' industry using measurable indicators and improvement of applicable social aspects respectively.

## Quality and safety in the construction industry

The issues addressed in this discussion included: Use of applicable standards and codes in the construction industry that will ensure quality and safety; The need for the industry to embrace competence in all the conformity assessment activities pertaining to the industry in terms of the personnel and the infrastructure including equipment through the implementation of conformity assessment standards such as ISO/IEC 17020—inspection, ISO/IEC 17024—personnel certification and ISO/IEC 17025—testing and calibration; the need to entrench accreditation in the various technical regulations issued by various regulatory authorities and institutions particularly in the fields of inspection, certification and testing; The need for all stakeholders to work together towards realising these noble objectives that will lead to sustainable economic development.

## Order and sanity in the Matatu industry using measurable indicators and improvement of applicable social aspects.

The issues addressed in this session included: The gains of privatisation of the motor vehicle inspection activities. This will ease conformance through provision of choice and avoidance of time wastage emanating from long queues; The need for the industry to embrace competence in all the conformity assessment activities pertaining to the industry in terms of the personnel and the infrastructure, including equipment, through the implementation of conformity assessment standards such as ISO/IEC 17020, ISO/IEC 17024, ISO/IEC 17025; Certification of personnel through training and examination of inspectors, drivers, welders and conductors etc, including issuance of licenses and certificates of good conduct; Use of certified body builders and fabricators; Use of standards in the inspection and testing regimes including procurement, for example, KS 1515—Code for Motor Vehicle inspection, design of bumps, matatu stages and termini and procurement of equipment; Use of accredited general testing and medical laboratories in carrying out tests on materials for safety belts, fuels, quality of welds, quality of road construction materials, strength of steel tubes and angle irons used in motor vehicle body building/fabrication, pollution levels through emissions such as NO<sub>x</sub>,

CO, CO<sub>2</sub>, SO<sub>2</sub>, etc, noise levels, drunken driving and abuse of drugs; Use of KENAS accredited calibration centres to calibrate speed governors, speed guns, breathalysers, equipment for measuring noise levels, emissions; Need to entrench accreditation in the various technical regulations issued by various regulatory authorities and

institutions particularly in the fields of inspection, certification and testing.

Article by Sammy K. Milgo, Accreditation Manager, Kenya Accreditation Service (KENAS), PO Box 47400-00100, Nairobi, Kenya, ph: +254 020 607380, or email: info@kenyaaccreditation.org.

## SWEDAC receives the Honours Prize in the Users Award contest



*SWEDAC Head of IT, Richard Ericsson, SWEDAC IT expert, Anna Lorentzon, President of the Swedish Trade Union Confederation and chair of the Users' Award jury Wanja Lundby-Wedin and SWEDAC Registrar, Susanne during the award ceremony.*

*English text by: Merih Malmqvist Nilsson, SWEDAC*

*Photo and original text by: Johan Mikaelsson, SWEDAC*

The 'Users' Award' contest is arranged by LO, the Swedish Trade Union Confederation comprising 15 affiliates with a total of more than 1.8 million members. It is also supported by TCO (The Swedish Confederation for Professional Employees) which comprises 16 affiliated trade unions with a total of 1.2 million members; VINNOVA (Research and Innovation for Sustainable Growth) and KTH (The Royal Institute of Technology in Stockholm). The aim of the award is to promote innovative IT-systems which support the development of work routines and systems which transfer the control to the end-users, ultimately promoting better IT support at work.

SWEDAC received the 'Honours' Prize' (second place) for its electronic reporting system MobiDoc and the awarding committee commented on its ease of use.

"The SWEDAC system is easy to use and customised for the purposes of assessment. The accreditation client receives clear reports and the communication over the Internet significantly cuts down handling time,"

an awarding committee spokesperson said.

MobiDoc has been developed for SWEDAC but is now also being used by other accreditation bodies. The needs of the users have steered the development of MobiDoc and the audience and jury were particularly impressed by the fact that SWEDAC has implemented the system in small stages and that the first use was limited to enthusiastic volunteers.

During the finals, MobiDoc and the web based WebiDoc were demonstrated to the audience and the jury by SWEDAC Head of IT, Richard Ericsson and SWEDAC IT expert, Anna Lorentzon.

"Today there is nobody who does not want to use MobiDoc and WebiDoc," Richard Ericsson, said.

The motivation for the 'Honours' Prize' mentions among other things, that the system facilitates the work of the users and has created a harmonised work procedure in all areas of SWEDAC's work. The winners are not only SWEDAC assessors but also SWEDAC's clients who save time and effort and have a transparent handling process.

SWEDAC is planning to have information on MobiDoc and WebiDoc available during the General Assembly meetings in Stockholm.

## Mauritius Accreditation Service (MAURITAS)

### First accreditation certificates granted by MAURITAS

The first accreditation certificates have been granted by the Mauritius Accreditation Service (MAURITAS) during the first half of 2008. Mauritius Turf Club Laboratory (Chemical Testing) and Assay Office Laboratory (Chemical Testing), during the first half of 2008.

The certificates were granted following the document review, pre-assessment and initial assessment in collaboration with the twinning partner, the South African National Accreditation System (SANAS).

MAURITAS now expects to accredit more and more laboratories in the coming months, and will also start the process of accrediting its certification bodies in collaboration with Norwegian Accreditation.



Minister Jeetah awards the MAURITAS accreditation certificate to the first laboratory in Mauritius.

## Norwegian Accreditation (NA)

### Norwegian Accreditation continues its assistance towards developing economies

By Norwegian Accreditation's, Khalid Saeed, PhD  
Technical Director

In its continuing quest for the provision of assistance towards building the capacities of National Accreditation Bodies, Norwegian Accreditation hosted a three day working seminar for assessors representing accreditation bodies of West Balkan during the period 3–5 June 2008. The seminar was partly financed by the European standardisation body CEN through Regional Quality infrastructure project— CARDS 2006.

A delegation of eight assessors representing the Accreditation Directorate, Albania, Croatian Accreditation Agency, Accreditation Board of Serbia, Accreditation Body of Montenegro, Agency for Standardization and Accreditation, Kosovo, Accreditation Institute of the Republic of Macedonia, Macedonia and Institute for Accreditation, Bosnia, participated in the seminar.

During the seminar, the participants received training in the development of quality management systems in compliance with the ISO/IEC 17011 standard by reviewing the Norwegian Accreditation quality system. The participants



Vida Zivkovic (Serbia), Zlatko Grgic (Croatia), Ermira Fyshku (Albania), Khalid Saeed (Norway), Dragan Pusara (Serbia), Adriana Shala (Kosovo), Dejan Stojkovski (Macedonia), Ana Radovic (Montenegro) and Nezheta Vrcic (Bosnia).

also observed assessments (renewal/ re-accreditation) of one testing and one calibration laboratory.

The seminar demonstrated that it is extremely useful for the developing economies to have closer ties with the established accreditation bodies, not only to gain knowledge and experience in the operation of an accreditation body, but it also provides a unique opportunity to share ideas and experience.

At the end of the seminar, the

participants indicated that they have similar quality systems for the handling of applications, conducting on-site assessments and post assessment work leading to final accreditation. The delegates agreed to continue cooperation with each other in the region, in order to make effective use of available resources in terms of technical assessors and experts. The delegates expressed their desire to continue cooperation with Norwegian Accreditation in future.



## Oficina Gutemalteca de Acreditación (OGA)

### OGA's News

By OGA's Technical Officer, Duberly Barillas



*Celebration of International Accreditation Day. Lic. Victor Gandy, Executive Secretary of the Inter-American Accreditation Cooperation (IAAC) and the Vice Minister of Economy, Lic. Erasmo Velásquez during the ceremony to present the OGA's Multilateral Recognition Agreement (MLA) of the IAAC for testing laboratories.*

In the framework to the celebration of the International Accreditation Day, on 9 June, OGA organised a special act to inform about the IAAC MLA. The Ministry of Economy Authorities' (MINECO) and the Executive Secretary of the Inter-American Accreditation Cooperation (IAAC) attended the ceremony. Representatives of the private, public and academic sectors were informed of the importance of the OGA's IAAC Multilateral Recognition Agreement (MLA) for testing laboratories. The presentation of IAAC's representative, emphasised that the reports or certificates issued by accredited laboratories in Guatemala through this agreement, are recognised not only nationally but also internationally, generating trust among users of these services.

OGA was also accepted as a signatory to the Mutual Recognition Agreement—(MRA)—of the International Laboratory Accreditation Cooperation—ILAC for testing laboratories.

OGA as a part of the National Quality System and responsible for managing the Accreditation in Guatemala expressed its commitment to maintain and improve its recognition.

Between 15 and 17 July, a measurement uncertainty workshop was held in the auditorium of the National Metrology Centre of Economy Ministry. The event was

convened by Dr Gustavo Delgado.

The focus of the workshop was to support representatives of laboratories participating in the PTB-AGACE Project to define their own uncertainty budget, according to international guidelines.

OGA's activities are on the road—new applications for medical, testing and calibration laboratories have been received.



## The International Accreditation Day celebrated in Italy

The Italian Accreditation System celebrated the ILAC/IAF Accreditation Day with a remarkable symposium held in Rome at the headquarters of the Union of the Italian Chambers of Commerce on 12 July 2008. The Italian Accreditation System is represented by SINCERT, SINAL and SIT, that accredit, respectively, the certification and inspection bodies, the testing and the calibration laboratories. These three bodies are joined in FIDEA— Italian Federation of Accreditation Bodies.

The meeting was attended by more than 200 people from European and Italian public authorities, the relevant Italian standardisation bodies (UNI and CEI), the main certification bodies and laboratories, as well as the major associations of manufacturing, trade and service industries relying upon accredited conformity assessment services.

Indeed, on this occasion, Italian public authorities and all the national relevant stakeholders agreed with the relevance of accreditation and certification activities, with regard to the guarantees that they offer in providing the high quality services that manufacturers need and in being the last level of control in the chain for the safe marketing of products.

The main issue of the symposium was the new European Regulation setting out the requirements for accreditation and market surveillance, related to the marketing of products, that was approved by the European Council on 23 June 2008, and to become operational by 1 January 2010. This is part of a broad package of measures adopted with



*The audience in the picturesque Sala Adriana, that dates back to ancient Rome.*

the aim to reinforce and facilitate the functioning of the internal market for goods.

The topic of the new Regulation on accreditation was presented by Jacques McMillan, of the Directorate General for Enterprise and Industry—Regulatory approach for the free movement of goods—of the European Commission. Among others, the Regulation establishes a legal base for accreditation, recognises accreditation to be a public authority to be carried out by a single national accreditation body per member State, sets the framework for the formal recognition of the European co-operation for Accreditation (EA) as the official European accreditation infrastructure and strengthens the use of accreditation in the regulatory area.

Indeed, as far as Italy is concerned, the setting up of a single Accreditation Entity is the primary challenge that SINCERT, SINAL and SIT have to face, with the involvement of the national public authorities that, during the meeting, remarked publicly on the role and the value of accreditation and offered their support for this important task.



## PJLA granted International recognition status



Left to right: APLAC MRA's Council Chair Barry Ashcroft, PJLA's Technical Program Manager Katie Barry, PJLA's President/Operations Manager Tracy Szerszen and APLAC's Chair Terence Chan.

We are proud to announce that Perry Johnson Laboratory Accreditation, Inc (PJLA) has now been accepted as an Asia Pacific Laboratory Accreditation Cooperation (APLAC) and an International Laboratory Accreditation Cooperation (ILAC) MRA Signatory for our Testing

Program. This was finalised on 6 June 2008 when PJLA attended the 21st APLAC MRA Council Meeting in Long Beach, California. This is a major step for PJLA and its testing laboratories, it means that the ISO/IEC 17025:2005 accreditation granted by PJLA to testing laboratories is internationally recognised. In addition,

this recognition ensures the results of these testing laboratories are accepted worldwide.

To view PJLA's updated status as an APLAC and ILAC MRA Signatory for Testing Accreditation visit the APLAC website at [www.aplac.org](http://www.aplac.org) and the ILAC website at [www.ilac.org](http://www.ilac.org)

 **Irish National Accreditation Board**

**Irish National Accreditation Board (INAB)**

recently carried out a two phase survey on Knowledge of Accreditation. Phase 1 covered the industry and government perspective, while phase 2 addressed the end users of accreditation i.e our members customers. A summary of both surveys is available from: [www.inab.ie/news/AwarenessofAccreditationandINAB.html](http://www.inab.ie/news/AwarenessofAccreditationandINAB.html)

**Success Stories from ILAC Signatories**

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 at [www.ilac.org](http://www.ilac.org).

If you have any recent 'good news' stories to share, please do not hesitate to email [iroy@ianz.govt.nz](mailto:iroy@ianz.govt.nz) who will arrange for them to be added to the good news stories page on the ILAC website.

The following photos show the exposition stands at the TUNAC forum.



## TUNAC signs Mutual Recognition Agreement with ILAC

On 20 June 2008, Tunisian Accreditation Council (TUNAC) signed a mutual recognition agreement with ILAC. This date will remain engraved in TUNAC's history. It was the result of a long process marked out by moments of reorganisation and redeployment of financial and human resources and especially of a profitable collaboration with several supporting programs and public and private institutes.

Under the patronage of the Minister of Industry, Energy and Small and medium-Enterprises, Afif Chelbi and with the presence of ILAC Chair, Daniel Pierre, TUNAC completed its recognition process on a worldwide scale. Therefore, from now on the accreditations delivered by TUNAC are recognised everywhere in the world and in particular in the countries with which Tunisia develops commercial exchange.

The signature of these agreements was held in conjunction with the forum organised by TUNAC in the Hotel Abou Nawas, Tunis for the celebration of its 14th birthday. The topic was 'TUNAC's Accreditation - Visa to export.' There were more than three hundred representatives of the accredited organisations, the public authorities, the private companies, the industry supporting programs, TUNAC experts and assessors as well as other private guests such as the first secretary of the European delegation in Tunisia and the director of the Swiss Accreditation Service, Hanspeter Ischi.

The forum was an occasion to approach many topics and to carry out a review of the recognition of the Tunisian accreditation and the acceptance of the documents produced by the accredited laboratories. Some of the key points included Accreditation: a universal concept of proof of competence; Place of the accreditation in the agreements related to the free trade of the goods with the European Union; The accreditation: as a public service, and Testimonies of

*continued next page*

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accredited laboratories on the contribution of the accreditation for the laboratory and the enterprises.

During his opening speech, the Minister of Industry, Energy and Small and medium-Enterprises specified that the international recognition of TUNAC accreditation represents a new asset for the Tunisian export businesses and that accreditation remains an essential tool to prove the quality of a product or a service since it is guaranteeing integrity, impartiality and competence of the quality infrastructure.

For his part, the ILAC Chair, Daniel Pierre, affirmed that the admission of Tunisia into the international accreditation family is the dedication of a long process of apprenticeship, competence of the operators of TUNAC and transparency of the national testing and calibration laboratories. He added that the multilateral agreements that TUNAC has achieved should not be an objective in itself, the action must continue to reinforce this international recognition.

Mr. Pierre added that the aim of ILAC is to concrete the emblem 'tested once, accepted everywhere'. He claimed that the cooperation between ILAC and the international organisations such as WTO, UNIDO and ISO demonstrated the worldwide awareness on the role of conformity assessment on the free movement of goods.

Mr Pierre also raised among the other tasks of ILAC, is the important and ongoing joint activities and cooperation with IAF.

A press conference intended for the Tunisian media (TV, radio, daily and weekly newspapers, specialised financial magazines), was attended by ILAC Chair, Daniel Pierre, TUNAC General Director, Aymen Mekki, and SAS Director, Hanspeter Ischi. This press conference provided an opportunity to give full information on the importance of accreditation and the international recognition of TUNAC in the field of testing and calibration to the media.

In addition, exposition stands were organised for the industry supporting programs and the accredited organisations, as well as a ceremony for presenting the certificates of accreditation for some newly accredited bodies.



ILAC MRA signing by Daniel Pierre and Aymen Mekki in the presence of Afif Chelbi, Minister of Industry, Energy and Small and Medium Enterprises.

## Stakeholders

### Oxford to Host 12th Biological and Environment Reference Material Symposium (BERM 12)

The 12th Biological and Environmental Reference Material Symposium (BERM 12) will be held from 7 to 10 July 2009 at Keble College, Oxford, UK.

The scientific programme will consist of six themes: The International Framework; QA/QC for the User; Environment and Energy; Health, Medicine and Forensic; Food; and Challenges and trends.

These themes will be addressed by presentations and posters. The timetable will also allow for poster sessions during the symposium.

The scientific programme is being developed to be of interest to all those

concerned with the production and use of reference materials.

Registrations for BERM 12 can be made for the complete symposium, or for any individual day. Accommodation has been arranged in Keble College, giving the delegates the complete 'college experience' in the historic and world-famous University of Oxford. A social programme is also being developed to take advantage of this excellent location.

More information on the scientific and social programmes, how to submit a presentation or poster, and registration options can be found on the BERM 12 website at [www.berm12.org](http://www.berm12.org).

# ILAC Publications

The following is a listing of titles of all ILAC public documents at 28 July. These can be downloaded from the ILAC Documents section under Resources on the ILAC website

## Brochures

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

## Information Documents (I Series)

ILAC-I1:1994 Legal Liability in Testing  
 ILAC-I2:1994 This document is currently under review  
 ILAC-I3:1996 Withdrawn  
 ILAC-I4:1996 Withdrawn

## Guidance Documents (G Series)

ILAC-G3:1994 Guidelines for Training Courses for Assessors  
 ILAC-G7:1996 Accreditation Requirements and Operating Criteria for Horseracing Laboratories  
 ILAC-G8:1996 Guidelines on Assessment and 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 Qualifications & Competence of Assessors and Technical Experts  
 ILAC-G12:2000 Guidelines for the Requirements for the Competence of Reference Material Producers  
 ILAC-G13:07/2007 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

## Secretariat Documents (S Series)

ILAC-S1:2003 Guidelines for the Proposal, Drafting, Approval and Publication of ILAC Documents  
 ILAC-S2:07/2008 Rules  
 ILAC-S3:2004 ILAC Strategic and Business Plan  
 ILAC-S4:05/2007 Use of the ILAC Logo  
 ILAC-S5:09/2007 ILAC Procedure for Handling Complaints  
 ILAC-S6:10/2007 Procedure for Expansion of the Scope of the ILAC Mutual Recognition Arrangement

## 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-P7:2003 ILAC Mutual Recognition Arrangement (Arrangement): Key performance Indicators (KPIs) (Link to IAF/ILAC A3:2005)  
 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-P11:2004 Monitoring Performance of ILAC Evaluators  
 ILAC P12:2005 Harmonisation of ILAC Work with the Regions  
 ILAC Mutual Recognition Arrangement (Arrangement): Terms of Reference and Composition of the Arrangement Management Committee

## Joint ILAC/IAF Documents (A series)

IAF/ILAC A1:05/2007 IAF/ILAC MRAs: Evaluation of a Regional Group  
 IAF/ILAC A2:05/2007 IAF/ILAC MRAs: Evaluation of a Single Accreditation Body  
 IAF/ILAC A3:05/2007 IAF/ILAC MRAs: Key Performance Indicators  
 IAF/ILAC A4:2004 Guidance on the Application of ISO/IEC 17020

# Welcome

## to Stockholm, Sweden

### 10-22 October 2008

#### **Stockholm will be the venue for the ILAC/IAF Conference 2008**

SWEDAC, the Swedish Board for Accreditation and Conformity Assessment, invites you to the meeting in Sweden's beautiful capital. We will do our best to offer good facilities and surroundings for a successful conference and a memorable stay here.

The Clarion Hotel Stockholm, the venue for the meetings, is centrally situated close to the city centre.

You will find restaurants and shops as well as public transport at walking distance.

Besides successful meetings, we hope that you

will enjoy the social programme like the welcome reception in the City Hall, the Swedish dinner at the Vasa Museum and the Banquet with the signing ceremony at the Clarion Hotel Stockholm. We will also offer some options to join sightseeing tours in Stockholm and surrounding areas.

#### **Contacts**

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[www.ilaciaf2008.org](http://www.ilaciaf2008.org)