



APLAC TECHNICAL COMMITTEE

22nd Meeting – Taipei, TAIWAN

MINUTES

Date and Venue

On: Monday 13 June 2016, 01:30 pm to 5:00 pm

At: Sheraton Grand Taipei Hotel, Taipei, Taiwan

Item	Subject	Information/Discussion/Open Action Items	Action Items
1	Opening of the meeting		
1.1	Introductions	The Chair called the meeting to order at 1:30 pm. The Chair reviewed housekeeping items and rules. The sign-in sheet was circulated. Attendees were reminded that each AB is only allowed one (1) member on the Technical Committee. The Chair announced that this is his last meeting as Chair.	
2	Membership of APLAC Technical Committee		
2.1	Review and confirmation of membership of APLAC Technical Committee	Membership was reconfirmed in Colombo (2015) for three (3) more years, through 2018. The latest issue of SEC 029, Issue 58 05/2016 was circulated. Attendees were reminded that if a change in AB staff is	

		needed, to make the necessary change on the list and the change request will be forwarded to the APLAC Secretariat. As well, members were asked to double-check e-mail addresses on SEC 029, as there are at least four (4) e-mail addresses that appear to be wrong. Members were reminded that TC members must have the following qualifications: • Tertiary qualification in a technical or science discipline; • Direct technical work experience; • Be prepared to attend meetings and to actively contribute to the work of the technical committee.	
2.2	Introduction of Alternates	None received.	
2.3	Apologies	None received.	
3	Adoption of the Agenda	The agenda was adopted as is. There were no additions or changes.	
4	Minutes of Colombo TC Meeting	The Draft Minutes were distributed to members of the TC by email on June 18, 2015. The minutes were approved with one change; specifically, on Page 3, the reference to ISO/IEC 17065 was changed to ISO/IEC 17025.	
5	Terms of Reference	The Terms of Reference were reviewed, and found to be up-to-date and applicable.	
5.1	Terms of Reference for Subcommittees of TC/WG	The Chair noted that terms of reference for SC/WGs will be discussed during the reports from each SC/WG.	
6	Liaison and Cooperation with Other International Organizations		
6.1	ILAC Accreditation Committee (AIC) Report	For Information The Chair noted that the AIC reports from Milan (October 2015) and Frankfurt (April 2016) are attached to the agenda.	

6.2	ISO Standards update	Report on ISO/CASCO WG 44 (Revision of ISO/IEC 17025) Zhang Mingxia, the ILAC representative on ISO/CASCO WG44, reported on the latest activities of the working group. A PowerPoint presentation was attached to the agenda. Rather than go through the whole presentation, the following items were highlighted: • A CD2 was necessary due to the large number of comments received on the CD1. • CD2 was released 24 March, 2016 and the comment period closed 23 May, 2016. A strong majority voted in favour of moving to a DIS. • A Committee Internal Ballot (CIB) was sent out to members to try and gain an understanding of the sampling issue but consensus was not achieved; 42 members voted 'yes' and 38 members voted 'no' • The WG addressed the issue of sampling by adding a definition for "laboratory" (i.e., a body that performs one or more of the following activities: calibration; testing; sampling, associated with subsequent sampling and testing) • Reporting of results (7.9.3) – it was noted that ILAC disagrees with the change in this section, and recommends that the current wording in the 2005 version is maintained • Changes in requirements for calibration certificates The work plan for ISO/CASCO WG44 is for the drafting committee to meet in July and for the full WG to meet in September, to review comments from CD2. It is anticipated that the new standard will be published in the third quarter of 2017.	
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		The transition period was briefly discussed. There is support for a transition period of three (3) years, but this has yet to be decided by ILAC. Mingxia highlighted specific comments that were raised by ILAC, including: -replacing the statement that ISO/IEC 17025 is not intended for product certification purposes -the need for more clarity on what is meant by a “competent” PT provider -some wording suggestions around the Option A and Option B for management requirements There was a question on whether there was any movement to create a new standard on ‘sampling’. Peter Unger reminded attendees that if a CASCO member or liaison organization really wanted to move this way, a New Work Item Proposal (NWIP) would need to be submitted to ISO/CASCO. Bill Hirt indicated that he will forward a document on “Good Sampling Practices” to the Chair, who in turn will forward it to the TC, for your information purposes. (<i>This was completed the next day, Tuesday June 14, 2016</i>). There was another question raised on whether APLAC will be submitting any comments on ISO/IEC 17025 to ISO/CASCO. While APLAC cannot submit comments directly, attendees were reminded that comments can be forwarded: 1) through national standards bodies in their own economy and/or 2) as an AB, comments can be submitted through the Joint ILAC AIC/Lab Committee working group. Report on ISO/CASCO WG42 (Revision of ISO/IEC 17011)	
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7	Report of APLAC Technical Subcommittees		
7.1	Inspection Subcommittee	Geoff Hallam started his report on the Inspection SC by reiterating the importance of checking e-mail contact information, and encouraged anyone with an interest in this SC to double-check e-mail addresses. As a bulk of the work of the SC is done via e-mail, it's important that he has the correct e-mail for anyone who has an interest in contributing to this SC. One of the activities of the SC was to investigate ILAC/IAF A4 and thoroughly review TC006 for the need for revision. Geoff noted that as A4 is gone and has been replaced by P15 (2012), once P15 is finalized the first part of that action will disappear. As for the second part of the action, the plan is to draft TC006 and send for a full Technical Committee review before the next APLAC TC meeting. <u>Raj Nathan of IAS queried if Geoff had any specific strategy on revisions to the TC006 document to avoid any possible misinterpretations from the P15 document.</u> Geoff s responded that his personal view is that a great deal of educational material is in TC006 and is very relevant, especially for developing economies. Therefore, the plan <u>his view</u> is not to radically change TC006, but just to re-reference it to the newer version of ISO/IEC 17020. Another (previously identified) activity of the Inspection SC was to create a guidance document for the assessment of Inspection Bodies to include the AB selection of branch locations (w.r.t. key activities) and the selection of inspectors	

		to witness. Kathryn Lockyer from JAZ-ANZ agreed to take on this work item. As part of the review of TC006, the SC was tasked at including some guidance on scopes. However, Geoff noted that there is on-going work at ILAC on scopes, and there is no need to duplicate this work at APLAC. Therefore, attendees were encouraged to review the current ILAC document, and send any comments to Geoff. Geoff also noted that the report on the 9th meeting of the ILAC Inspection Committee, which took place on April 2, 2016, was attached to the agenda.	
7.2	Reference Material Subcommittee	Mr. Wang Wah Wong reported that a workshop on RMP and a workshop on PTP were both approved, and will be held back-to-back in November 2016 in Hong Kong. It is a 4-day program, and part of the first day will look at common issues. The first two (2) days will be on RMP and will include new issues in ISO 17034. Days 3 and 4 will focus on ISO/IEC 17043 (PTP accreditation). The last day there will be an experience-sharing session. WW thanked members who provided input into the development of the workshops. There have been efforts made to engage all regions of ILAC in the workshops, and ABs from Europe and IAAC have been invited to participate. WW also reported that ISO 17034 is expected to be published in September 2016. Anticipating this step, a request has been forwarded to MRA Council to discuss the transition period at the upcoming MRA Council meeting later this week. A survey of SC members indicated a preference for a three (3)-year transition period. It was noted that IAAC also did a survey, and the preference was a 3-year transition period	Action Item 16-1: TC Chair to write a letter to the ILAC AIC, encouraging use of TC008 as the basis for an ILAC document, with the ultimate goal of expediting a MRA for RMP accreditation.

		Another work item following the publishing of ISO 17034 will be to update TC008. WW also reported on other ISO REMCO Guides published in 2015. Of particular note is ISO Guide 33, which provides guidance on use of RMs by laboratories. This ISO Guide does make TC012 kind of redundant, and the SC is wondering if it should be withdrawn in light of ISO Guide 33. There was some discussion on the fact that there is still not a MRA for RMP accreditation at the global level, and the need for an ILAC document that is similar to TC008.	
7.3	Medical Testing Subcommittee	Dr. (Professor) Katsuo Kubono reported on the activities of the Medical Testing Subcommittee. The draft document “Guidance on the assessment and accreditation of the pre-examination processes (sample treatment) for medical testing laboratories” will be forwarded for full TC member 60-day comment after this TC meeting. He also reported on the major outcomes of the ILAC WG6, noting that it was decided that the ILAC G26 draft will be circulated for 60-day ILAC member comment. After comments are reviewed by the WG, it will be sent for a 30-day ballot. There was a revision made to the SC Terms of Reference and going forward, the SC plans to investigate the accreditation needs of Medical Imaging and Physiological Testing. Dr. Kubono announced that this is his last TC meeting, and asked for a volunteer to take over as convener of the Medical	ACTION 16-2: Medical SC to send Guidance document for full TC member 60-day comment.

		Testing SC. The Chair thanked Dr. Kubono for all his efforts over the years. Zhang Mingxia noted that there are two (2) new standards (ISO 35001 and ISO/TS 20658). The Medical Testing SC will monitor these standards for their impact (if any) on medical testing.	
7.4	Calibration Subcommittee	Mr. Ned Gravel reported that The Terms of Reference of the Calibration Sub Committee have been reviewed and that no changes are recommended at this time. Anyone who has an interest to be on the Calibration SC are to e-mail Ned. There are no APLAC documents currently being reviewed by the Calibration Sub Committee. In general, the SC feels that the concepts of traceability, calibration and uncertainty are much better expressed in the new version of ISO/IEC 17025 than in the 2005 version but it was hoped that some of the concepts currently in the Informative Annex A on Metrological Traceability are moved back into the requirements portion of the clause dealing with Traceability (Clause 6.6). Ned also made attendees aware that his affiliation has changed, and he is now a Senior Adviser to IAS USA. POST MEETING: The PIC has asked the Calibration SC to review APLAC TC010 and to compare it against the ILAC document on Uncertainty of Measurement. If the Calibration SC feels that APLAC TC010 is equivalent to the ILAC document then TC010 will be withdrawn. If the SC feels that it is not equivalent and will be retained, then they will commence reviewing and revising, if applicable.	ACTION 16- 3: Calibration SC to review APLAC TC010 and to compare it against the ILAC document on Uncertainty of Measurement. A decision to be made to either withdraw the document or update it.

7.5	APEC TEL Conformity Assessment & MRA Task Force Subcommittee	The Chair noted that the APLAC Liaison report on the APEC TEL Conformity Assessment & MRA Task Force work was attached to the agenda. Of particular significance, the following was noted: -the FCC rule changes in the USA; the FCC maintains their position that all laboratories performing testing in support of DoC and/or Certification will need to be accredited and designated through a government to government MRA by the July 13, 2016 deadline.	
7.6	Proficiency Testing Subcommittee	Ms. Martha Mejía reported on the Proficiency Testing Subcommittee activities, and encouraged new members to join this SC. She reported that there are two documents being drafted by the SC; specifically: a) A document on the scope of PT Providers; the SC is planning to distribute this document to the TC prior to the next TC meeting; and, b) A document on remote PTP assessments, which will also be sent to TC members for comment.	
7.7	Uncertainty in Testing Working Group	Mr. Yoshi Uematsu provided a status update on TC004 and TC005. Work is on-going, and the documents will be forwarded to the TC. He also noted that work on ILAC G17 has been postponed, as the ILAC WG was awaiting the outcome of ISO/IEC 17025. However, since it appears that the standard is not going to go into detail on reporting MU, Yoshi thinks that the discussion on G17 should probably be resumed.	
7.8	Accreditation of Software	The first draft of the guide on software testing has been	ACTION 16-4: Dr. Choe to send the

	Testing Working Group	developed with several experts and has been circulated to the members of the TC. Dr. Gum Ho-Choe delivered a presentation on the status of the updated draft and the comments received. There were very few comments following the 60-day comment period, and a question was raised as to whether there really is a need for this document. <u>Raj Nathan noted that the document states in its scope as a 'Comprehensive Specific Requirements' and this may need to be revised.</u> However, the consensus was to review the comments, update the document, and to send it back out for 60-day comment.	updated software document to the TC for 60-day comment.
8	Review of APLAC Technical Committee Documents		
8.1	Update of TCxxx Series Documents	The APLAC TC documents were reviewed and discussed. The TC member responsible for the document at the time of this meeting is in brackets following the name of the document. TC002/TC003 - Internal Audits / Management Reviews for Labs and IBs (Kelvin Shih) – Kelvin provided a presentation on proposed changes to both these documents. The proposed changes are relatively minor (e.g., updates to newer versions of standards, some editorial corrections, changing APLAC contact details, and aligning some wording with wording in other standards (e.g., annually vs every 12 months)). Kelvin proposed to have an update to both TC002 and TC003 by the end of 2016. He also recognizes that a further update will be required following the new version of ISO/IEC 17025. TC004 - Method of Stating Test and Calibration Results and Compliance with Specification (Yoshi Uematsu) – under review; see Item 7.7 (above).	Action Item 16-5: Brahim Houla and Kathryn Lockyer to determine the relevance and applicability of TC009, and pending the results, to lead a review of TC009. Action Item 16-6: Natarajan to determine the relevance and applicability of TC011, and pending the results, to lead a review of TC011.

		TC005 - Interpretation and Guidance on the Estimation of Uncertainty of Measurement in Testing (Yoshi Uematsu) – under review; see Item 7.7 (above). TC006 - Guidance Notes on ISO/IEC 17020 (Geoff Hallam) – under review; see 7.1 (above). TC007 - APLAC Guidelines for Food Testing Laboratories (Roger Brauning) – this document was reviewed fairly recently, so no action is currently needed or assigned. TC008 - APLAC Requirements and Guidance on the Accreditation of a Reference Material Producer (WW Wong) – will be reviewed after the workshop in November 2016; see Item 7.2 (above). TC009 - Guidance on Assessing Laboratories Inspection Bodies to meet Foreign Regulatory Requirements – Brahim Houla and Kathryn Lockyer assumed joint ownership of this document. TC010 - General Information on Uncertainty of Measurement (Yoshi Uematsu) – Yoshi reported that the contents of this document are valid, though it does include some information that is in TC004. Therefore, it is proposed that this document is revised after the revision of TC004. The Chair noted that at one time, there was discussion around giving this document to the PIC; see 7.4 (above). TC011 - The importance of testing methods in chemical and microbiological testing – Natarajan from NABL assumed ownership of this document.	
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		TC012 - Guidelines for acceptability of chemical reference materials and commercial chemicals for calibration of equipment used in chemical testing (WW Wong) – WW indicated that there will be a better sense of the need and applicability of TC012 following the workshop in November 2016; see 7.2 (above). TC013 - Guidance for the assessment, reassessment, and surveillance of "key activities" at laboratories with multiple locations (Colleen Cotter) – There is no value in reviewing this document until after ISO/IEC 17011 is published; once ISO/IEC 17011 is published, the WG (which is currently disbanded) may need to be reinstated to determine if this document is still needed or not.	
9	Work Items under ILAC AIC Initiative		
9.1	BIPM	The Chair included some information from the ILAC AIC Frankfurt April 2016 meeting in the agenda. In particular, there were summaries on the following topics: BIPM/ILAC Working Group (Bipartite Meeting) BIPM/ILAC/ISO/OIML (Quadripartite) Meeting BIPM Workshop on Global to Urban Scale Carbon Measurements There was no questions or discussion on these items.	
9.2	Other ILAC Issues	None.	
10	TC Training Needs	Zhang Mingxia asked the TC to consider whether training on both ISO/IEC 17025 and ISO/IEC 17011 was needed in 2017. She noted that a joint training program with PAC was being considered for ISO/IEC 17011, recognizing that training a	

		large group of evaluators would not be easy. Nonetheless, the Joint Executive committee members will discuss this possibility during this week of meetings. Ned Gravel reported that a Lead Evaluator Training for transition to ISO/IEC 17011 is being planned for 2017. Brahim suggested WebEx or Skype training for ABs might be appropriate, and less costly. Mingxia also asked for input on whether training on Medical Image Accreditation and/or POCT is needed, and if so, the feasibility of using a web conference tool such as SKYPER to provide this training.	
11	Other Business • Previous TC Action Items • TC report to GA • Confirmation of decision and motion(s) to GA		Open Actions remaining from previous APLAC Technical Meetings: Action 14-4: Yoshi Uematsu to forward the draft document on uncertainty in measurement in testing to the Chair of the TC. Action 14-5: Chair of the TC to forward the guidance document on uncertainty in measurement in testing to the APLAC TC. Action TC(13)5: Yoshi will send a draft of TC005 to the Chair of the TC and the AIC WG in the near future. ACTION TC(12)3 – The SC is to

			consider including a reference to JCGM106, and re-scoping the document for testing only. Following the issuance of G8, the relevance and on-going need for TC004 will be reviewed.
12	Next Meeting	The Chair announced that the 23 rd meeting of the Technical Committee will be held in Thailand in 2017. Details on the date and location were not known at this time.	