



Report on the

APLAC Transition Training Course on ISO/IEC 17025

Seoul, Korea

29 November – 1 December 2017

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1. Acknowledgements

We are indeed grateful to have two experienced experts, Mr Tim Osborne of A2LA and Ms Colleen Cotter of CALA, both are Members of ISO CASCO WG44, to share with us their experience and insight in the development and application of the revision of ISO/IEC 17025 based on the FDIS version issued in August 2017. And, gratitude for the hard work done by the Working Group, convened by Ms Wanji Yang of TAF, on the course material development of this training course. Special thanks also go to the Korea Laboratory Accreditation Scheme (KOLAS) for hosting this transition training course in the Lotte Hotel in Seoul, Korea; and for the efforts made by Ms Juhee Song and other KOLAS Colleagues to coordinate the organisation of this training course; and Ms Wanji Yang of Taiwan Accreditation Foundation (TAF) for serving as the rapporteur of this training course.

2. Background and objective

ISO/IEC 17025 is the key international standard with the objective of promoting confidence in the operation of calibration and testing laboratories. It contains requirements for laboratories to enable them to demonstrate they operate competently, and are able to generate valid results. ABs that are signatories to the APLAC and ILAC Mutual Recognition Arrangement (MRA) have to accredit laboratories against the new version of ISO/IEC 17025 within a 3-year transition period after the publication of the new standard. This new standard was published on 29 November 2017 while this training course was being conducted.

To help APLAC member bodies prepare for the transition to the revised ISO/IEC 17025, this transition training course was developed by the APLAC Training Committee based on Members' training needs and the General Assembly's endorsement. The main objective of the course is to highlight the new and changed requirements in the newest version of ISO/IEC 17025. The training aims to assist accreditation body staff in assessing laboratories in a harmonised way within the APLAC region. As well, participants are invited to share ideas on the transition to the new version of ISO/IEC 17025 over the next three years and/or to share experience gained during the implementation and transition of other standards, with the goal of having a smooth, harmonized transition of all laboratories across the region.

In order to accommodate a large group of participants, the APLAC Training Committee decided to conduct two training courses without increasing the approved budget. One training course was conducted on 14-16 November 2017 at the A2LA office in Frederick, USA, hosted by A2LA. The outcome of the Frederick training course contributed to the conduct of the Seoul training course, held on 29 November – 1 December 2017 at the Lotte Hotel in Seoul, Korea, hosted by KOLAS.

The training course is designed to enable participants to have a better understanding of the new version of International Standard ISO/IEC 17025. The training aims

- to learn about the revision to international standard for calibration and testing laboratories;
- to examine underlying concepts and how they relate to accreditation operations;
- to understand the implications of implementation.

In addition, the objectives, as determined by the participants at the course, were to learn about

Subject	# Interested
Changes, Principles of changes	9
Risk Assessment, Risk-Based Approach	9
How to Assess Option B (Option A & B)	8
Validation	5
Verification	5
Continuity between 2005 and 2017	4
Sampling	4
Interpretation	3
Measurement Traceability	3
Competency Requirements	2
Documentation & Record Requirements	2
Assessment, Doc Review	1

Decision Rules	1
Environmental Conditions	1
Equipment Qualification	1
Flexible Scope (assess)	1
How to Train Assessors on Standard	1
Impartiality	1
Interlaboratory Comparison vs. PT	1
Laboratory Information Management Systems	1
Managing Transition from 2005 to 2017	1
Methods Requirements	1
Process Requirements	1
Reporting	1
Sampling Uncertainty	1
Validity fo Results	1
Why the revision?	1

3. Course Description

OBJECTIVES OF THE TRAINING COURSE

ISO/IEC 17025, the standard for calibration and testing laboratories, was expected to be published later this year. This transition training course was developed by the APLAC Training Committee, based on Members' training needs and the General Assembly's endorsement.

The main objective of the course is to highlight the new and changed requirements in the newest version of ISO/IEC 17025. Underlying concepts will be discussed, with the goal of enabling participants to have a better understanding of the recent changes. The training aims to assist accreditation body staff in assessing laboratories in a harmonised way within the APLAC region. As well, participants are invited to share ideas on the transition to the new version of ISO/IEC 17025 over the next three (3) years and/or to share experience gained during the implementation and transition of other standards, with the goal of having a smooth, harmonized transition of all laboratories across the region.

PARTICIPANTS

The workshop is geared to APLAC members who are responsible for and/or conduct assessments to ISO/IEC 17025. Participants are expected to have a sound level and understanding of ISO/IEC 17025:2005; the course is not designed for new accreditation body staff.

APLAC sponsored the venue, lunch and refreshments but participants need to bear their own costs of travelling, accommodation, etc. There is a restriction of one (1) participant per accreditation body, due to the limited number of places available.

SANAP Project is available for participants from the eleven eligible economies with the rule of "one participant per AB/economy".

DATES AND VENUES

This course is being offered in two (2) different locations:

1. A2LA Office, Frederick, MD, USA; 14-16 November 2017; hosted by A2LA
2. Lotte Hotel, Seoul, Korea; 29 November – 01 December 2017; hosted by KOLAS

PRESENTERS

- Mr. Tim Osborne, Senior Director of Training Services, A2LA
- Ms. Colleen Cotter, Accreditation Manager, CALA

Both Mr. Osborne and Ms. Cotter are members of ISO/CASCO/WG44.

COORDINATOR

Ms. Wanji Yang (TAF, APLAC Training Committee Chair)

4. Trainers, Participants and Programme

The training course content and programme was organised by the APLAC Training Committee and logistical arrangements organised by the host KOLAS in conjunction with the APLAC Secretariat. The training course was open to all APLAC members. An invitation was also sent to other regional and international accreditation cooperation, such as IAAC, EA, SADCA, AFRAC, ARAC, ILAC, etc.

The training course was delivered by two experienced trainers:

- Mr Tim Osborne, Senior Director – Training Services of A2LA and Member of ISO CASCO WG44
- Ms Colleen Cotter, Accreditation Manager of CALA and Member of ISO CASCO WG44

Ms Wanji Yang of TAF was the rapporteur of the training. APLAC sponsored the lunch and refreshments of the event while attendees were responsible for travel and accommodation. In total, 34 representatives from 25 accreditation bodies and the APLAC Secretariat had participated in this training course. The participant list is provided in Annex 1.

The following is a report on the training course held in Seoul from 29th November to 1st December 2017. It was divided into seventeen sessions covering the following topics in three days:

Day 1 – Wednesday, 29 November 2017 (08:30-16:30)

- Session 0 –
 - Welcome & Introductions
 - Logistics
 - Introduction of presenters & participants
 - Purpose & expectations of course
 - Objectives
 - Content & Format
 - Expected Outcomes
- Session 1 – Review of the Development & Key Changes
- Session 2 – ISO 9001:2015 Process Approach (PDCA)
- Session 3 – ISO/IEC 17025 Sections 1 – 4
- Session 4 – Sections 5 – 6.3
- Session 5 – Sections 6.4 – 6.5
- Session 6 – Sections 6.5 – 6.6

Day 2 – Thursday, 30 November 2017 (08:30-16:30)

- Session 7 – Wrap-up Activity
- Session 8 – Section 7.1 – 7.5
- Session 9 – Section 7.6 – 7.8
- Session 10 – Section 7.9 – 7.11
- Session 11&12 – Review

Day 3 – Friday, 1 December 2017 (08:30-16:30)

- Session 13 – Option A and Option B
- Session 14 – Section 8.2 – 8.5
- Session 15 – Section 8.6 – 8.9
- Session 16 – Transition Plan
- Session 17 – Wrap-up

5. Presentations, Discussions and Outcomes

The three-day training course was conducted in accordance with the programme and was structured into seventeen sessions. There were presentations, open discussions and group exercises.

Summary of Day One (29 November 2017)

Session 0 – Welcome and Introduction

Ms Wanji Yang, representing the APLAC Training Committee, welcomed all the participants and briefly introduced the two trainers, Mr Tim Osborne and Ms Colleen Cotter. Mr Michael Fraser was then invited to give a few words on behalf of the APLAC Secretariat. The two trainers introduced themselves and their involvement in the revision work of ISO/IEC 17025. Participants were then invited to introduce themselves and to share their objectives of attending the training, which were summarised above.

Session 1 – Review of ISO/CASCO/WG44 Development & Overview of Key Changes

Participants were first briefed on the development of ISO/IEC 17025 and the revision process. Mr Osborne introduced the main inputs from ISO 9001, such as risk-based thinking, less descriptive, documented information, etc. It was noted that the biggest shift is the “leadership” – a fundamental role in all aspects, requiring labs to take ownership of the lab operations. The new version is more “process-based”, which enables labs to have more flexibility in management. Mr Osborne then briefly went through the evolution of the standard from 1999 and 2005 versions to the 2017 version. He also used house building as an example to illustrate the new version, including the adoption of CASCO high level structure and common elements. Proper transition trainings for assessors will be critical because the assessment job, possibly with more interviews and interactions rather than black-and-white checklist or clear policies / procedures, might be harder. Assessors will also need guidance on how to determine the adequacy of risk evaluation. Mr Osborne later briefly went through the sections of the standard. The following points generated further discussion:

- The fact there are still more ISO 9001 labs than ISO/IEC 17025 labs
- No more requirements for quality manager and technical manager – because everyone involved in the process has the responsibility – critical points: personnel competency, authority and responsibilities.
- Process-based – let the business run itself. More focus on the competency rather than overhead administrative procedures.
- Risk – the effect of uncertainty. What would you do to mitigate the risks?
- Risk management and risk-informed decision-making.
- Instead of having a quality manual, you can have a line of PDCA.
- Leadership involvement vs. employee engagement – leadership is the key.

Session 2 – ISO 9001:2015 & Process Approach (PDCA)

Risks, Opportunities and Objectives, Application of PDCA and Risk Management concepts were introduced, followed by risk management exercises and group discussions. Mr Osborne also mentioned about the requirements of risk management in 2005 version. The following points generated further discussion:

- Does a requirement with “shall” refer to high risk? Not necessary. Regarding “where necessary”, it’s up to the lab to decide based on its risk assessment.
- No “top management” anymore. It’s about the appropriateness of management.

Mr Osborne also introduced some tools for risk management, such as Pareto process, Fishbone diagram (an excellent tool to identify where the risks come from), Logic tree, FMEA – Failure Modes and Effects (and Criticality) Analysis, etc. It was noted that everyone has his/her own risk appetite.

Session 3 – ISO/IEC 17025:2017 Sections 1-4

In this session, Ms Cotter went through sections 1-4 and explained the background of main changes, such as sampling, laboratory activities, etc. She also introduced the relevancy to ISO 9001, and the clauses comparison between 2005 and 2017 version. Ms Cotter mentioned about common elements in section 4, which was added to the standard to meet ISO Directives. The following points generated further discussion:

- Inter-laboratory comparison vs. proficiency testing
- Inter-laboratory comparison vs. intra-laboratory comparison: inter-laboratory refers to independent labs, including network/sister labs, while “intra-laboratory” refers to same lab, same location, same equipment, same test method, just different operators.
- Repeatability and reproducibility
- Verification vs. validation: it was noted that verification and validation were not included in the DIS version submitted by the WG44 but added to the FDIS version by the editorial group.
- Decision rule – not new, just better described. 5.10.4.2 just requires more documentation.

Ms Cotter talked about the definition of laboratory activities. She also mentioned about a survey sent to CASCO members on “can a standalone sampling be seen as a lab activity”? Unfortunately, there was no firmed answer to the question. It was suggested to raise the question “whether an AB can accredit a standalone sampling against 17025” to APLAC Technical Committee for discussion.

A group exercise (scenario) on “4.1 Impartiality” was introduced following the completion of section 4.

Session 4 – ISO/IEC 17025:2017 Sections 5-6.3

In this session, the trainers introduced requirements of Section 5 and part of Section 6. Clause 5.3 generated lots of discussions in particular, such as: 1) clarification of the meaning of “which excludes externally provided laboratory activities on an ongoing basis”. Lab activities constantly outsourced (externally provided) shall be excluded from accredited range of activities; 2) what to assess “to the extent necessary” to ensure the consistent application of its laboratory activities and the validity of the results? It was suggested to look at the following aspects: document review; business process flow (inputs and outputs); interview different lab staff to ask how they do the work to see whether there is consistency.

The following points were also discussed:

- The term “scope” has been replaced by “range of laboratory activities”

- The job title “Quality Manager” has been removed as all related requirements are in the standard.
- 5.6: PDCA for personnel: someone with competence and authority to do the job may not necessarily be called a quality manager. Personnel follow PDCA to carry out duties.
- 6.2: getting assessors to ask questions, not too focused on the checklist.
- 6.2.4: are there ways other than job descriptions? Yes, performance review. Questions to ask in the interview phase – how do you do the performance review? Do you have any records?
- 6.3 facilities and environment: the appropriateness and deviation of activities performed at the customer's facility shall be communicated and documented.
- If you are looking for inconsistency in the process, where is the first place you check? E.g. sample a few reports across, record of activities – data recorded by different persons, internal audits, complaints and nonconforming work, etc.

Summary of Day Two (30 November 2017)

Day two began with two group exercises (scenarios) on “4.2 Confidentiality”.

Session 5 – ISO/IEC 17025:2017 Sections 6.4-6.5

The trainers continued the sections for equipment and metrological traceability. The following points were discussed:

- 6.4.1: anything as an error or a risk component contributes to the uncertainty. Note 1 and Note 2 refer to ISO 17034; “should” is not a requirement.
- 6.4.2: how to determine “equipment outside its permanent control”?
- 6.4.4: calibration vs. verify
- 6.4.5: measurement accuracy vs. measurement uncertainty
- 6.4.6: there are significant changes in NOTE and examples.
- 6.4.8 how would you label, especially for something that cannot be labelled, e.g. a MS, a gauge block, reference material, software?
- 6.4.11: “as appropriate” – as an assessor, how would you ask the question about appropriateness? For instance, calibration certificates, errors and correction factors in the process, any specific requirement of accuracy when using the equipment, etc. Also refer to 6.4.7.
- 6.4.12: “practicable” measures – “practicable” is judgemental and risk-based.
- What's the difference between accuracy and precision? Precision and uncertainty are synonyms. Accuracy and trueness are associated. Bias and errors are synonyms. It's important to understand this because they do affect the validity of results.
- 6.5: uncertainty: metrology is a science of making measurement. Uncertainty in a sampling labs will depend on the fields.
- 6.5.2: Only three clauses in uncertainty in the 2017 version. Nearly 2 pages in the 2005 version were moved to Annex A. Normative is required, and informative is for information.

Session 6 – ISO/IEC 17025:2017 Section 6.6

This session focused on clause “6.6 Externally provided products and services”. The following points were discussed:

- Anything that will affect the output of the lab and the validity of its report should comply to this clause.

- 6.6.2: new word: b) “re-evaluation”; d) not only do the re-evaluation, but also take any actions arising from evaluations.
- 6.6.3 new word: “c) competence, including any required qualification of personnel”. What matrix do you use to consider the performance of external providers, such as PTP? Attention should be paid to complaint as it is probably one of the biggest areas showing responsiveness. What actions would you take when you have no options of vendors?

Session 8 – ISO/IEC 17025:2017 Sections 7.1 – 7.5

Ms Cotter mentioned that most requirements in sections 7.1 to 7.5 can also be found in the 2005 version. The following points were discussed:

- 7.1.1 c) if a customer requests for “pass or fail” or “whether or not within tolerance”, such request shall be considered when reviewing the contract. It’s important to keep upfront transparency and decision rule shall be communicated (see Note 1: agreement in advance).
- Verification vs. validation
- 7.2.2.4 provides examples of records of validation. There are various references on, for example, how to determine detection limits. There is no requirement for a lab to have a procedure for validation or verification, because it will depend on different situations. Ask questions when looking at the evidences of validation.
- 7.3.2: sub-sampling vs. sample pre-treatment
- Method vs. procedure: in testing, they are the same; for calibration, they are different. Most calibration labs do not sample. In calibration, there are five fundamental measurement methods.

A group exercise (scenario) was introduced following the completion of section 8.

Session 9 – ISO/IEC 17025:2017 Sections 7.6 – 7.8

Ms Cotter continued on sections 7.6 to 7.8. It was agreed that managing an uncertainty is managing risks, and the decision is made when the uncertainty is managed – then it can be called risk management. The following points were discussed:

- Evaluation vs. estimation: estimation – a process, making your best guess; evaluation – more rigorously calculated measurement uncertainty.
- No requirement for a procedure any more in section 7.6.
- 7.8: for standalone sampling lab: needs to provide certificate for sampling
- 7.8.2.1 I) anything prior to the receipt of the sample is not the lab’s liability

Summary of Day Three (1 December 2017)

Session 10 – ISO/IEC 17025:2017 Sections 7.9 – 7.11

Day three began with a group exercise (scenarios) on “7.9 Complaints”.

The trainer went through sections 7.9 to 7.11. It was discussed how an assessor would define “*defined*”. Participants shared various views, such as finding evidence of consistency through documentation check and interviews with different staff. If not consistent, then it’s not well defined. The following points were also discussed:

- PDCA for complaints handling

- 7.10 PDCA for nonconforming work; RBT – in the classification of risks and determination of actions taken
- 7.11: no procedure is required; more focused on LIMS. Use of COTS.

Session 13 & 14 – ISO/IEC 17025:2017 Option A vs. Option B and Sections 8.2 – 8.5

Before talking about option A and option B, Mr Osborne began with questions like “who is this standard written for?” and “who else uses this standard?”. The laboratory shall establish, document, implement and maintain a management system that is capable of supporting and demonstrating the consistent achievement of the requirements of this document and assuring the quality of the laboratory results. The AB shall be looking for objective evidences. He then recapped the principles of ISO 9001 introduced on Day One, including leadership involvement, risk-based thinking, employee engagement, continuous improvement, process approach, customer focus and relationship management. The class reached a consensus that there is no option A or B because all the requirements in this standard need to be met. The following points were also discussed:

- 8.2.1 & 8.2.2: how to manage those changes in electronic documents?
- 8.3: without a “master list”, what would you look for? E.g. database, files on the server, etc.
- 8.5: what are the opportunities to find out how labs manage their risks? Records of internal audit, complaints, PT results, non-conforming work, etc. In the case of repeated non-conformance found in two consecutive assessments, some aspects to be considered, such as: seriousness of the nonconformity? What’s the risk-based thinking? Did they do what they said? How would a lab like this affect your risk management as an AB?
- Risk vs. opportunity: opportunity is taking on something new (see clause 8.5.3 NOTE 2, also the slide 4 of session 2), while risk is the effect of uncertainty (see ISO 9000:2015, clause 3.7.9). Opportunity comes with risks.

Session 15 – ISO/IEC 17025:2017 – Sections 8.6 – 8.9

The trainers went through sections 8.6 to 8.9. A group exercise (scenario) on “8.8 internal audit” was introduced following the morning session. The following points were discussed:

- Why “root” cause analysis is gone? Because of risk management. It may not be necessary to go down to root cause.
- 8.7.1c) d): go back to look at risks and opportunities when taking corrective actions.
- 8.7.2 “Corrective actions shall be appropriate to the effects of the nonconformities encountered” means the effectiveness of corrective actions implemented. In the case of a major nonconformity, staff retraining might be necessary.
- 8.8: internal audit – audit programme (2017) vs. audit procedure (2005)
- The independence of the internal auditor is addressed in 4.1.3 impartiality.
- Internal audit is not a laboratory activity
- 8.9: management reviews should be organised based on the risk level
- If a lab wants to be assessed against 2017 version, but the internal audit was done in this year and did cover the new requirements in the 2017 version)? What’s risk an AB will face? Perhaps requesting for additional internal audits?

Session 16 – Transition plan

The trainers shared the transition plans of CALA and A2LA, and invited all participants to share their plans:

- First, having a small group of senior assessors (mainly staff) trained to accommodate applications against new version
- The largest obstacle is risk-based thinking. Most people in quality are very black and white people. Everybody has their own risk appetite. You need to coach them.

Mr Osborne then talked about the comparison of IS (just released) and FDIS:

- two “and/or”, both in measurement uncertainty
- harmonised titles

It was noted that ILAC G8 is under revision, linking to JCGM106.

Wrap Up and Presentation of Attendance Certificates

Mr Tim Osborne and Ms Colleen Cotter gave a wrap up of the training course and concluded that the course had been successful to address the main changes of the new version of ISO/IEC 17025 and meet the objectives of this training course.

Ms Wanji Yang, on behalf of the APLAC Training Committee, expressed sincere gratitude for all the efforts made by the two trainers, the host and all participants. She mentioned that, being the leading regional body, APLAC conducted the very first transition training courses on the new version of ISO/IEC 17025. She also mentioned about two more ISO/IEC 17025 transition trainings scheduled to take place in the first half of 2018. One of them will be hosted by BLA-DSS in Bangkok in May 2018; interested ABs are invited to be a host of the training in March 2018.

Annex 1 Attendance List

	Name Family name in bold	Organisation
Trainers	Mr Tim Osborne	A2LA
	Ms Colleen Cotter	CALA
Rapporteur	Ms Wanji Yang	TAF
Participants	Mr Michael Fraser	APLAC
	Ms Danielle Dicker	NATA
	Ms Ratchadatorn Kangvalklai	NSC-ONSC
	Ms Ratikorn Alongkornchotikul	BLA-DSS
	Mr Mohammed Abbas Alam	BAB
	Mr Awiruth Khejonnit	BLQS-DMSc
	Mr Marlon Macadamia	PAB
	Ms Rosnieh Eggat	Standards Malaysia
	Mr Landegedara Hevayalage Dias Bandusoma	SLAB
	Ms Dian Asriani	KAN
	Ms Hoang Thanh Duong	BoA
	Ms Annah Bale	PNGLAS
	Mr Nguyen Truong Danh	AOSC
	Mr Lee Yew Tian	SAC
	Mr Anil Relia	NABL
	Mr Young Cheol CHOI	KOLAS
	Mr Shuichi Kobayashi	VLAC
	Dr Hiroaki Ohtaka	IAJapan
	Ms Baasanjav Baigalmaa	MNAS
	Mr Masaki Uematsu	JAB
	Ms Zhypar Kenenbaeva	KCA
	Mr Chao-Ping (Kelvin) Shih	TAF
	Mr Vichet Yot	CANC-DA
	Mr Denis Baranov	RusAccreditation
	Ms Diane Hobday	NATA
	Ms Sirorat Thonhamkaew	NSC-ONSC
	Ms Dusadee Munkwamdee	BLA-DSS
	Ms Perla Baje	PAB
	Ms Palawinnage Hiruni Senari Kumaratunga	SLAB
	Dr Tran Thi Thu Ha (f)	BoA
	Ms Somi KIM	KOLAS
	Mr Chen Di	CNAS



