



Report on the

APLAC Transition Training Course on ISO/IEC 17025

Frederick, USA

14-16 November 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 American Association for Laboratory Accreditation (A2LA) for hosting this transition training course in A2LA's office in Frederick, USA; and for the efforts made by Mr Trace McInturff, Senior Director – Accreditation Services, Mr Tim Osborne, Senior Director – Training Services and other A2LA 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 standard was at the stage of FDIS (with 99% positive votes from ISO P members 100% positive votes from IEC P members) while this training course was 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 other was conducted 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

- The new requirements
- Impartiality and confidentiality
- How other people interpret
- To get assurance
- Consistency (*2)
- Differences between the old and the new versions
- Making sure we are on the same page
- To get clear understanding and consistency of application
- To get knowledge to deal with questions
- To hear everybody's viewpoints
- To learn different viewpoints from European's and how risk-based approach is implemented (EA will have a 17025 training in Jan 2018)
- Option A vs. Option B

3. Course Description

OBJECTIVES OF THE TRAINING COURSE

ISO/IEC 17025, the standard for calibration and testing laboratories, is 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 will sponsor the venue, lunch and refreshments but participants need to 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.

DATES AND VENUES

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

1. A2LA Training Room, 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 A2LA 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, 18 representatives from 10 accreditation bodies 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 Frederick from 14th to 16th November 2017. It was divided into seventeen sessions covering the following topics in three days:

Day 1 – Tuesday, 14 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 – Wednesday, 15 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 – Thursday, 16 November 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 (14 November 2017)

Session 0 – Welcome and Introduction

Mr Trace McInturff, representing the host A2LA and also the APLAC Board of Management, welcomed all the participants and briefly introduced the two trainers, Mr Tim Osborne and Ms Colleen Cotter. 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. 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. Although the new version does not change dramatically from the previous version, it was agreed that there would be a learning curve due to the mind-set change. 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:

- Why a special chapter for impartiality and confidentiality?
- PDCA, process-based approach, process flow
- Root cause analysis – risk-based
- Find evidences showing risks that are not addressed
- Records of risk identification
- Definition of risk (in ISO 9001 and ISO 31000, not in 17000)
- Assessing the results rather than assessing the risks
- Mind-set shift: taking ownership
- Pre-assessment preparation time could be shorter while on-site assessment time could be longer, which might affect the assessment fees.

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.

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. It was noted that currently some ABs accredit laboratories performing sampling activities against ISO/IEC 17025 or ISO/IEC 17020. Discussions on “competence” were brought up, such as “how to ensure the validity of results of sampling?” Ms Cotter later mentioned about common elements in section 4, which was added to the standard to meet ISO Directives. A group exercise (scenario) 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. The following points were discussed:

- The term “scope” has been replaced by “range of laboratory activities”
- Lab activities constantly outsourced (externally provided) shall be excluded from accredited range of activities
- The job title “Quality Manager” has been removed as all related requirements are in the standard.
- PDCA for personnel
- 6.2: getting assessors to ask questions, not too focused on the checklist.
- 6.3 facilities and environment: the appropriateness and deviation of activities performed at the customer's facility shall be communicated and documented.

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

The following points were discussed:

- Defining equipment – If the item affects the validity of the result in any way.
- The word “furnished” was replaced by “have access to” – there was sufficient evidence that equipment could be borrowed.
- PDCA for equipment
- Readily available
- 6.5 Traceability (5.6 in 2005 version): unbroken chain
- Adjusting vs. calibration: by adjusting, the traceability could be lost

Summary of Day Two (15 November 2017)

Session 6 – ISO/IEC 17025:2017 Section 6.6

The last clause of section 6 was introduced in this session and it generated lots of discussions. The following points were discussed:

- “Suitable” – depending on the criticality, and the results fits the purpose.
- An AB providing assessment is regarded as an external provider. In the case of one-man lab, internal auditing and complaint handling must be outsourced.
- Clause 6.6.2 b) a procedure for defining should be a procedure for doing
- Re-evaluation of the external providers – RBT and continuous improvement.
- The frequency of re-evaluation of external providers – it depends (RBT). The frequency should be defined.

- If a customer specifies a specific contractor to be used to supply the services: unlike in the 2005 version, the 2017 version requires the lab to be responsible for evaluating the vendor – communicating all the way up to the chain in the flow. (also refer to clause 5.4)
- If the subcontracted scope is a lab activity and the subcontracted lab is not in conformance with the standard, the lab cannot claim conformance to 17025.

This session ended with a group exercise on clause 6.4. Participants suggested such kind of exercise would be more suitable for labs than for ABs.

Session 8 & 9 & 10 – ISO/IEC 17025:2017 Sections 7.1 – 7.11

The trainers talked through the clauses in section 7.1 to 7.5, with cross references of the corresponding clauses in the 2005 version. It was noted that there are not many changes in the requirements in this section, but some have been re-organised. The following points were discussed:

- Statement of conformity: decision rule shall be clearly defined and communicated.
- Verify vs. validate: also refer to clause 3.8 and 3.9.
- Definition of a non-standard method – standard method used outside of its intended scope.
- 7.3 sampling: notes in 2005 version have become requirements in 2017 version.
- 7.5 Technical records: the lab has to keep track of what the change was.
- Any wording that implies paper records has now been removed.
- What is the relationship between measurement uncertainty and “risk”? According to ISO 9001:2015, Risk (3.7.9) is the effect of uncertainty.
- 7.6: Estimation (2005 version) vs. Evaluation (2017 version) – consistency with the use in the GUM.
- 7.8 Reporting of results: Lab shall be responsible for all information in the report, except when information is provided by the customer. Decision rules shall be clearly defined in case when a statement of conformity to a specification or standard is provided.
- 7.9 (Complaints) and 7.10 (Nonconforming work) in this section and not the management requirements section, because the laboratory shall be responsible for all decisions at all levels of the handling process for complaints.
- 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.

Summary of Day Three (16 November 2017)

Session 13 – ISO/IEC 17025:2017 Option A and Option B

The trainers introduced “Option A and Option B”, which are also included in ISO/IEC 17020, ISO/IEC 17065 and ISO/IEC 17021-1. Participants shared the real practices in assessing CABs with option B. For instance, an IB chooses option B because when changes need to happen, it's easier to have option B which will affect a smaller group of people. However, it's agreed by the class that there is no option A or B because all the requirements in this standard need to be met. Although 8.2 ~8.9 are basically reflecting the management requirements in ISO 9001, it is critical to find evidences of technical competence and have records revealing all the requirements (Section 4~7) are met. An ISO 9001 internal audit would not be sufficient as it does not cover the technical components. The following points were discussed:

- We accredited 17025, not 9001. The lab has to demonstrate their 9001 system meets the requirements of 17025.
- The meaning of the last sentence of clause 8.1.3: 8.2 ~ 8.9 reflects 9001 requirements but more specific to laboratories. Labs can use the system of 9001, but still need to look at the technical aspects. For example, 9001 does not mention about “laboratory activities”.
- It might be possible that an AB says it only recognises option A. ILAC has not had a decision on this yet.
- It’s possible to take into account the results of auditing; however, based on 17011, taking into account of results done by others is regarded as outsourcing.
- Consistency matters. ISO has developed some document for training on option A and option B. IAAC consensus can also be referenced.

Session 14 – ISO/IEC 17025:2017 Sections 8.2 – 8.5

- 8.2.1: Policies may be overarching. Because of PDCA, a policy might be written and unwritten and doesn’t have to be called “a policy”.
- 8.2.2: Based on RBT, a policy is not necessary; however, 8.2.2 requires policies to address competence, impartiality and consistent operation.
- The training course on ISO/IEC 17020 usually begins with section 8. This can be considered to apply on ISO/IEC 17025 training course.
- 8.3.1: one of the top 10 nonconformities identified by A2LA – control of external document, which should be readily available.
- 8.3.2: move from paper-based to web-based.
- 8.4.1 Objective evidences – evidences and records are not the same thing. Participants were suggested to search the word “record” on ISO website.
- Synonym to “address to”? Perhaps “deal with” or “manage”.
- To prevent or reduce “undesired impact of risks” rather than “risks”
- 8.5.3 is only place that has a definition of “opportunities”. Not found in 31000 or 17000. What’s the difference between “opportunities” and “risks”? They are the same.
- Group exercise: to consider the “impact” and “risks” of a business decision, e.g. scope expansion.
- It’s the mind-set change – labs are already doing risk analysis, just need to raise the awareness

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

- 8.7.1 b) “root cause” is gone – because the need to eliminate the cause is evaluated by doing risk analysis.
- 8.8 “procedure” is gone, but you still need to have a “programme” for internal audit. 19011 defines “programme” as “a documented information (procedure + schedule)”
- 8.8.1 a) ...including the “laboratory activities” – not in 9001.
- 8.9.3: “predetermined schedule and procedure” is gone.

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 this very first transition training course on the new version of ISO/IEC 17025. Fortunately, many participants are also very experienced assessors and trainers, and have contributed a lot to a better understanding by active interactions during the three-day training. Constructive suggestions would be considered to improve the design of the training programme and training materials for accommodating a larger group in the Seoul training course.

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 Trace McInturff	A2LA
	Mr Tim Rasinski	NVLAP
	Ms Melissa Kennedy	ANAB
	Mr Pavel Nosek	CAI (EA)
	Mr Michael Kramer	PJLA
	Mr Ronald Peters	AIHA
	Mr Kulasingham Vivekananthan	SCC
	Mr Abdel Kassou	SCC
	Mr Chris Gunning	A2LA
	Mr Robert Knake	A2LA
	Ms Elizabeth Carbonella	A2LA
	Mr Andrew Bohan	A2LA
	Mr Robert Miller	A2LA
	Mr Takashi Arai	IAJapan
	Ms Pam Wright	A2LA



