

Report on the
APLAC Transition Training - Revision to ISO/IEC 17011
Held in Hong Kong, China
21-22 September 2017

Contents

	Page
Background and objectives	3
Summary of Day One	4
Summary of Day Two	6
Annex – List of participants	9

Background and objectives

ISO/IEC 17011 is a very important international standard for accreditation bodies (ABs) as it stipulates requirements on their operation, impartiality and competence. ABs have to comply with this standard in order to be a signatory to the mutual recognition arrangements (MRA) established by APLAC and ILAC. This standard is currently under revision by the ISO CASCO Working Group 42 (WG42). It is now at the stage of FDIS and the new version is anticipated to be published before the end of 2017.

To help APLAC member bodies prepare for the transition to the revised ISO/IEC 17011, the APLAC Training Committee had decided to organise two training courses for ABs' staff in September 2017. One of the training courses was conducted on 21-22 September at the Harbourview Hotel, Hong Kong, China. HKAS was the host of the course.

The objectives of the training, as determined by the participants at the course, were to:

- Introduce the key changes between the versions of the standard, including those involved legal considerations, their challenges and implementation;
- Introduce risk management requirements and their implementation;
- Introduce the changes in management system requirements and their implementation;
- Discuss 'Option A' and 'Option B' implementation;
- Introduce the ILAC transition plan, including timing for each to meet new requirements;
- Discuss the need for ILAC or APLAC application/interpretation documents;
- Obtain consensus on the application including frequency of assessment activity;
- Discuss the impact on restructures of ABs;
- Introduce new top management requirements;
- Discuss advantages of the new version and the intention behind the changes;
- Introduce requirements on flexible scopes and discuss how ILAC G18 could be met;
- Introduce requirements on remote assessment;
- Discuss what the evaluators will look for with regards to the revised standard;
- Discuss the impact of new requirements on different types of scopes; and
- Discuss the impact on proficiency testing (PT) and determination of alternatives.

The trainers of this training course were:

- Mr Ned GRAVEL, IAS, Convener of the APLAC Evaluator Training Working Group
- Ms Anne HOFSTRA, IANZ, Member of the APLAC Evaluator Training Working Group
- Ms Roxanne ROBINSON, Former Chairperson of the APLAC MRA Council and Member of ISO CASCO WG42

In addition, 29 delegates from 22 ABs attended the course. A list of participants is provided in Annex. Dr Daria Wong of HKAS was the rapporteur of the training. APLAC sponsored the lunch and refreshments of the event while attendees were responsible for travel and accommodation.

The programme and training materials are provided as attachments.

Summary of Day One (21 September 2017)

Module One – Introduction and Objectives

The trainers first introduced themselves and their involvement in APLAC peer evaluations as well as the current revision of ISO/IEC 17011. Participants were then invited to introduce themselves and outline their role in their corresponding AB. Mr Gravel then asked participants to share their objectives of attending the training, which were summarised above.

Module Two – Revision of ISO/IEC 17011 and New Risk-Based-Thinking Concept

Speaker: Roxanne Robinson and Ned Gravel

Participants were first briefed on the development of ISO/IEC 17011 and the revision process. The new version has adopted the CASCO common structure for standards and was very much based on ISO/IEC 17021-1:2015. The Terms and Definitions in the ISO/IEC FDIS 17011 were then introduced with a focus on those that were newly added or revised from the 2004 version. Besides, it was noted that some terms in the 2004 version had been removed in the new edition, including 'accreditation certificate' and 'surveillance'. The following terms and their definitions generated further discussion:

- Accreditation schemes, assessment programme and assessment plan
- Assessment techniques
- Remote assessment - a note would be sent to APLAC to seek guidance on under what circumstances would remote assessment be considered applicable and acceptable
- Technical expert – a note would be sent to APLAC to seek clarification on how much supervision would be needed on a technical expert during an assessment
- Team leader – it has replaced 'lead assessor'

The risk-based approach, which is a new element in the standard, was introduced next. Emphasis was put on the major steps for risk assessment, i.e. identifying the condition at risk, followed by determining the impact and probability of occurrence, and finally taking action to mitigate the risk. Records of the above process should be maintained as evidence for fulfilling the requirements. Besides, the AB should also look for opportunities for improvement when conducting risk assessment.

The trainer then went through clauses in ISO/IEC FDIS 17011 that mentioned 'risk' and presented several scenarios for participants to discuss how risk-based approach could be applied. It was also noted that as per clause 6.1.2.5 of the FDIS, all personnel involved in accreditation activities shall demonstrate knowledge of risk based assessment principles.

Module Three – Changes in Quality Management System (QMS)

Speaker: Roxanne Robinson

In this session, the major changes in general, structural and QMS requirements in the ISO/IEC FDIS 17011 as compared with the 2004 version were covered. The following new requirements were highlighted in this session:

- The AB must have legally enforceable arrangements with its accredited conformity assessment bodies (CAB) that requires the CAB to conform to the requirements listed under clause 4.2.
- ABs need to ensure that its accreditation symbol is legally protected (clause 4.3.2) and have a policy to govern its use (clause 4.3.3).
- ABs must now have authority for its accredited decisions that are not subject to approval by other organisation/person (clause 5.5), implying that the 'decision maker' must be an AB personnel.
- ABs must now establish formal rules for any expansion of its scope of operation and new 'accreditation schemes' (clause 4.6). The scheme may have requirements additional to those in relevant international standards or normative documents, but cannot contradict or exclude the normative requirements.

- AB may now structure its QMS in accordance with the requirements of ISO 9001 i.e. Option B in cl. 9.1.1. This is in line with similar requirements in the current versions of ISO/IEC 17020, 17021 and 17065. Nonetheless, an AB still needs to meet all requirements under clauses 9.2 to 9.8 of the standard regardless of the QMS Option selected (clause 9.1.4 & 9.1.5).
- Requirements for complaints are now included in the 'Process requirements' section and follow the mandatory wording in 'Common Elements in ISO/CASCO Standards' (QS-CAS-PROC/33).
- AB must be responsible for all decisions at all levels of the handling process for complaints and appeals (clause 7.12.7 and 7.13.3). Such decision cannot be made by an outside party, even if it has higher authority.

Summary of Day Two (22 September 2017)

Module Four – Changes in impartiality

Speaker: Ned Gravel

This module covered the requirements under clause 4.4 of the FDIS on impartiality. The clause has been expanded and included mandatory wording from QS-CAS-PROC/33. The AB must now identify and assess risk to impartiality arising from its activities and relationships on an on-going basis, eliminate or minimize the risk identified, and then document the residual risk and review if it is acceptable. The standard now requires the AB to not provide accreditation if there is unacceptable risk arising from such accreditation that cannot be mitigated. Same as that in the 2004 version, an AB is not allowed to provide conformity assessment services and consultancy. The types of conformity assessment activities are explicitly however listed in the new edition (clause 4.4.11a). The requirements for 'related body' in the 2004 version are retained in clause 4.4.12 of the FDIS but the term 'related body' was removed.

Module Five – Changes in Personnel Requirements

Speaker: Roxanne Robinson

Requirements for personnel, which are now included in the 'Resource requirements' section of the FDIS, were discussed in this module. The following clauses were highlighted for discussion:

- ABs are required to determine and document the competence criteria for personnel involved in accreditation activities (clause 6.1.2). Knowledge and skills expected for different accreditation activities are provided in 6.1.2.2 – 6.1.2.8, as well as in informative Annex A.
- Personnel making accreditation decisions must demonstrate knowledge of accreditation scheme requirements, conformity assessment scheme requirements, as well as procedures and methods used by the assessed CAB (clause 6.1.2.3). This means that the decision making personnel should have competence in the conformity disciplines being accredited. A note would be sent to APLAC to seek further guidance on how the decision making process could be designed to fulfill this requirement.
- There are more specific requirements on evaluating monitoring the performance of personnel involved in accreditation process (clause 6.1.3). The requirement to observe assessors during an assessment at least every three years is retained in the new version.
- Requirements for subcontracting assessment are now included in clause 6.4 'Outsourcing'. They are similar to those in the 2004 version, but now ABs need to have an enforceable arrangement covering the outsourcing arrangements with each body providing the outsourced service.
- The requirement about ABs not being allowed to subcontract accreditation decision remains in the new version and it is further specified that the decision must be made by the AB's employee(s) or person(s) under enforceable arrangements with the AB (Clause 6.4.2).

Module Six – Changes in Accreditation Process Requirements

Speaker: Anne Hofstra

In this module, accreditation process requirements (Clause 7) from application review to decision making were introduced. The following key changes in the FDIS were discussed:

- There is a new requirement (Clause 7.2.3) that ABs must reject an application if there is evidence of fraudulent behaviour or the applicant intentionally provides false information or conceals information.
- Clause 7.4.4 allows ABs to assess the competence of a CAB through the use of on-site assessments as well as other assessment techniques listed in Note 1 of clause 3.24, e.g. remote assessment.

- The term 'key activity' has been removed in the new edition. An AB needs to select activities to be assessed by considering 'risk associated with the activities, locations and personnel' covered by the scope (Clause 7.4.6).
- ABs must document the rules for determining assessment durations (Clause 7.6.1).
- The assessment team shall conduct the assessment based on an assessment plan, which describes the arrangement for an assessment and the activities involved (Clause 7.6.3).
- The assessment team must report *in writing* the nonconformities identified during the assessment at the meeting conducted at the end of the assessment (Clause 7.6.6a). If the assessment is conducted at the CAB's client's premise, AB can request the CAB to make arrangement with its client to provide a venue for having such meeting (Clause 4.2 e).
- Requirements for the scopes of accreditation of different types of CABs are provided in clause 7.8.3. However, the need to issue an 'accreditation certificate' becomes optional in the FDIS. Requirements for using flexible scope is now included in the standard (clause 7.8.4).
- Clause 7.9.1 defines that an accreditation cycle starts at/after the date of the decision for granting initial accreditation or the date of making decision after reassessments. It also stipulates that an accreditation cycle must not exceed five years.
- Clause 7.9.3 requires an AB to assess a sample of the scope of accreditation of a CAB at least every two years. The time between consecutive on-site assessments must not exceed two years, but the standard now allows the AB to use other assessment techniques if on-site assessment is deemed not applicable. The alternative techniques must achieve the same objective as an on-site assessment and justification needs to be provided to support the choice.
- Clause 7.9.4 stipulates that a reassessment must cover *all* requirements of the standard(s) for which the CAB is accredited.
- Clause 7.11.2 specifies that an AB must initiate its process for withdrawal of accreditation if there is evidence of fraudulent behaviour, or the CAB intentionally provides false information or conceals information.
- ABs are now required to retain CAB records at least for the duration of the current cycle plus the previous full accreditation cycle (Clause 7.14.2).

Module Seven – Accreditation Information Requirements

Speaker: Anne Hofstra

This module covered discussions on requirements under clause 8.2 of the FDIS. Much of the wording in Clause 8.1 about confidential information came from QS-CAS-PROC/33. There are now more specific requirements on how to manage confidential information in the new version. The standard also defines the information that must be publicly available without request under clauses 8.2.1 to 8.2.4. Such information includes the scope of accreditation as well as information on the suspension or withdrawal of accreditation, unless in exceptional cases such as for security reasons.

Module Eight – Implementation Discussion and Conclusion

Speaker: Ned Gravel

Five questions regarding the implementation of the new version of ISO/IEC 17011 were discussed in this module and the outcomes are summarised as follows:

- QS-CAS-PROC/33 is not a normative reference of ISO/IEC 17011 and ABs do not need to maintain such document as a controlled document.
- The ILAC-IAF Joint General Assembly at New Delhi endorsed a three-year transition period for the revised ISO/IEC 17011, counting from the date of its official publication. According to the draft transition plan of ILAC, MRA signatories/applicants will be evaluated to the revised standard starting from July 2018. Between July 2018 and the end of the transition period, any findings based on the revised standard may be addressed later but necessary actions must be implemented before the deadline. If the next peer evaluation of a signatory takes place before July 2018 and the 2004 version has been used in the evaluation, such AB will have to provide

evidence to demonstrate conformance to the revised standard before the end of the transition period.

- The revised standard still requires onsite monitoring of assessors at least every three years, unless there is sufficient supporting evidence that an assessor is continuing to perform competently.
- The revised standard allows ABs to assess a CAB using techniques other than on-site assessment as long as they are sufficient to provide confidence in the CAB's conformance with relevant accreditation criteria. If an AB determines that an on-site assessment is not applicable, it may use other assessment techniques to achieve the same objective with justifications.
- There is a significant change in the competence requirement of personnel making the accreditation decision in clause 6.1.2.3 of the revised standard. ABs should review their post-assessment review and decision making process to ensure that they comply with the new requirement.

The training was concluded and acknowledgement was made to the staff of HKAS and the Harbourview Hotel for hosting the training course and managing the logistics.

Annex I - List of Participants

Name of participants (Surname in bold)	Organisation
Ms Anuja Anand	NABL
Ms Fajarina Budiantari	KAN
Ms Sunee Chonlanakitkul	NSC-ONSC
Dr Lillian Chow	HKAS
Dr Aparna Dhawan	NABCB
Ms Hoa Thach Quynh Duong	BoA
Ms UUGANTSETSEG Enkhsaikhan	MNAS
Mr J E J (Ned) Gravel	IAS
Ms Mithila Rangani Gunasekara	SLAB
Mr Anand Deep Gupta	NABL
Mr Phillip Hill	NATA
Dr Chun Wah Ho	HKAS
Ms Anne Hofstra	IANZ
Mr Azhar Iqbal	PNAC
Ms Ratchadatorn Kangvalklai	NSC-ONSC
Mr Shuichi Kobayashi	VLAC
Mr Alexander Litvak	RusAccreditation
Dr Lidong Liu	CNAS
Mr Paulo Lorenzo	PAB
Mr Moteb Mezani	GAC
Mr Maxut Omirkhanov	NCA
Ms Kirsty Outhred	NATA
Ms Kanika Pheap	NAFP-CANC (DA)
Ms Roxanne Robinson	-
Mr Kelvin Shih	TAF
Dr Patravee Soisangwan	BLQS-DMSc
Ms Juhee Song	KOLAS
Mr Yee Teck Tan	SAC

Ms Pataraporn Tanapavarit	BLA-DSS
Dr Yufeng Tao	CNAS
Ms Chantarat Vorasapavit	BLA-DSS
Dr Daria Ching-hang Wong	HKAS

Group photo taken at the ISO/IEC 17011 training in Hong Kong

