



Report on the

APLAC Transition Training Course on ISO/IEC 17011

Brea, USA

27-28 September 2017

Contents

1	Acknowledgements	3
2	Background and Objectives	4
3	Course description	5
4	Trainers, Participants and Programme	6
5	Presentations, Discussions and Outcomes	7
	 Annex 1 – Attendance List	 12

1. Acknowledgements

We are indeed grateful to have three experienced experts, Mr Ned Gravel of IAS, Convener of the APLAC ETWG, Ms Anne Hofstra of IANZ, Member of the APLAC ETWG and Ms Roxanne Robinson, former Chair of the APLAC MRA Council and Member of ISO CASCO WG42, to share with us their experience and insight in the development and application of the revision of ISO/IEC 17011 based on the FDIS version issued in August 2017. And, gratitude for the hard work done by the Working Group, convened by Mr Ned Gravel of IAS, on the course material development of this training course. Special thanks also go to the International Accreditation Service (IAS) for hosting this transition training course in Brea, USA; and for the efforts made by Mr Raj Nathan, Senior Vice President, Ms Nancy Libby and other IAS 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 17011 is the key international standard for accreditation bodies (ABs) as it stipulates specifies requirements for the competence, consistent operation and impartiality of accreditation bodies assessing and accrediting conformity assessment bodies. 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 2017. One training course was conducted on 21-22 September at the Harbourview Hotel, Hong Kong, China, hosted by HKAS, in a consecutive manner with the Lead Evaluator training; the other was conducted on 27-28 September 2017 at the Embassy Suite by Hilton, Brea, USA, hosted by IAS, combined with the Lead Evaluator training due to the number of registrants.

The training course is designed to enable participants to have a better understanding of the new version of International Standard ISO/IEC 17011. The training aims

- to learn about the revision to international standard for accreditation bodies;
- 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
- clarifications of meaning
- when risk is needed
- how is risk evaluated
- what support for implementation (Quality Manager to sell the idea)
- how to implement new standards
- internal training
- how changes impact other CASCO standards
- PT-AB relations
- ILAC transition plan
- what not to do (during an evaluation)
- Option A vs. Option B

Harmonisation of the interpretation and application of ISO/IEC 17011 among the APLAC MRA signatories will no doubt benefit the upholding of the APLAC Mutual Recognition Arrangement (APLAC-MRA).

3. Course Description



APLAC Transition Training - Revision to ISO/IEC 17011

Two Training Days

What?

Learn about the revision to international standard for accreditation bodies. Examine underlying concepts and how they relate to accreditation operations. Understand the implications of implementation.

For Whom?

For all APLAC evaluators and accreditation body staff who manage the operation of a laboratory accreditation program. Personnel are normally concerned with the following operations.

- Operation and delivery
- Working within regulatory requirements
- Impartiality
- Assessor selection and assignment
- Assessor conduct and monitoring.
- Assessment reports
- Assessment frequency
- Specifying proficiency testing and inter-laboratory comparison requirements.
- Ensuring traceability of measurement to the SI through CIPM MRA Signatories.

How?

This 2-day Training Course examines the changes in both the quality system and recognition requirements within the revised standard, including conditions for accreditation, conduct of assessments and impartiality. It includes approaches for undertaking risk-based thinking and using risk to examine assessment requirements.

Syllabus

Day 1 - (09:00-16:30)

Introduction and Objectives

- Course Aims
- Approaches to Learning

Changes to 17011

- Introduction

Introduction to Risk-Based Thinking

- Revision of 17011 and Risk
- Risk Based Thinking Exercises

General AB QMS requirements

Day 2 - (09:00-16:30)

Impartiality Requirements

Personnel requirements

Accreditation process requirements

Accreditation information requirements

Implementation Discussion

Course Close out

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

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. Representatives from SANAP Project eligible economies were sponsored by SANAP Project funding for travel and accommodation. In total, 19 representatives from 14 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 Brea, USA from 27th to 28th September 2017. It was divided into eight modules covering the following topics in two days:

Day 1 - (09:00-16:30)

Introduction and Objectives

- Course Aims
- Approaches to Learning

Changes to 17011

- Introduction

Introduction to Risk-Based Thinking

- Revision of 17011 and Risk
- Risk Based Thinking Exercises

General AB QMS requirements

Day 2 - (09:00-16:30)

Impartiality Requirements

Personnel requirements

Accreditation process requirements

Accreditation information requirements

Implementation Discussion

Course Close out

5. Presentations, Discussions and Outcomes

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

Summary of Day One (27 September 2017)

Module One – Introduction and Objectives

The two trainers first introduced themselves and their involvement in APLAC peer evaluations as well as the current revision of ISO/IEC 17011, and mentioned about the training course conducted in Hong Kong a few days ago. Participants were then invited to introduce themselves. 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

Participants were first briefed on the development of ISO/IEC 17011 and the revision process. The new version has adopted the CASCO high level structure for standards and common elements. ISO/IEC 17021-1:2015 was also referred in the development of this standard. 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, and some would need to seek further advice from APLAC:

- Accreditation schemes, assessment programme and assessment plan
- Assessment techniques
- Remote assessment – it would require extensive preparation, maybe suitable for accreditation for PTPs, labs in mining sites, etc. Some ABs are already performing remote assessment. Need to seek APLAC’s 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 – replacing the term “lead assessor”, pulling out the need of management skills and responsibility of team management, must demonstrate capabilities,
- Independently - familiar vs. knowledgeable. Need more clarification from the APLAC MRA Council (ILAC A5)
- Extending of accreditation – referring to the scope, not the period

It was noted that the new terms/definitions should be documented but it’s not necessary for an AB to change the existing document.

The risk-based thinking, which seems a new element in the standard but is something we have been doing, was introduced next. Emphasis was put on the major steps for risk assessment, and the clauses linking with risk-based thinking, such as 4.4.6 to 4.4.9 – impartialities risk, 4.5.2 – coverage for risk (insurance etc.), 4.6 – scheme development, 6.1.2.4 – assessment personnel knowledge of risk, 6.1.3.4 – competence of personnel to consider risk, 7.4.6 – assessment sampling to consider risk, and 7.9.3 – assessment program to consider 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. 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 – General AB QMS requirement

In this session, the major changes in General AB 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 (4.1) 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).
- Suspended CABs must now “inform affected clients of the suspension, reduction or withdrawal of accreditation and the associated consequences without undue delay.” (4.3 e))
- 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.
- Appeals (7.13) is still in the Accreditation Process section but has been greatly expanded as a result of the mandatory wording transferred to Section 7 of the Common Elements in CASCO standards from ISO/PAS 17003 (Complaints and Appeals

Summary of Day Two (28 September 2017)

Module Four – Impartiality

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. The following points were especially discussed in this session:

- Who is top management?
- Mr Gravel suggested referring to the document developed by NATA for assessors assessing option A and option B for IB.
- ISO/IEC 17011 does not stop ABs from using measurement audit. Some ABs still let assessors bring in an artefact/PT sample to a lab for measurement audit during an assessment.
- Discussions on "enforceable" arrangement
- Conflict of interest vs. impartiality

Module Five – Personnel Requirements

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 fulfil 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).
- Using another MRA signatory's assessment report (Note 2 of 6.4.6) – not subcontracting/outsourcing but "acceptance" – as long as you protect the integrity of your own programme by due diligence. Need to consider not only the standard, but also the requirements of that specific scheme. AB makes its own accreditation decision. If you are providing across the border – G21 applies.
- Who has the proprietary ownership of the assessment report? The CAB does.

Module Six – Accreditation Process Requirements

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.

- The review shall also include the ability of the accreditation body to carry out the initial assessment in a timely manner (Clause 7.3.2) – “a timely manner” is to be defined by an AB.
- 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).
- 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. It was felt the expression in 7.8.3 c) “calibration or measurement method or procedure” is not the language in use.
- 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. There was a need for further clarifications and distinctions between “not applicable” and “not possible”.
- 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).
- In the case where a CAB applies for multiple disciplinary, the decision making may be divided into several decision makers.
- In clause 7.7.2 it was suggested that “where maintaining is not related to a reassessment (see 7.9.4) and there is no modification to the scope” needs further clarifications on “to which extent is considered no modification”.
- Voluntary suspension or withdrawal is not regarded as AB’s decision-making.

Module Seven – Accreditation Information Requirements

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

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.

Wrap Up and Presentation of Attendance Certificates

Mr Ned Gravel and Ms Roxanne Robinson 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 17011 and meet the objectives of this training course.

Annex 1 Attendance List

	Name Family name in bold	Organisation
Trainers	Mr Ned Gravel	IAS
	Ms Roxanne Robinson	
Rapporteur	Ms Wanji Yang	TAF
Participants	Ms Janice Nolan	IQMH
	Ms Debra Penn	DAP
	Mr James Empeno	PAB
	Ms Dana Leaman	NVLAP
	Ms Rhonda Banks	ANAB
	Ms Cheryl Morton	AIHA
	Ms Julie Langlois	Accreditation Canada
	Mr Doug Berg	PJLA
	Mr John Davey	SCC
	Mr Carlos Alejandro Archila Azurdia	OGA
	Ms Vilanova Duberly Barillas Galán de Hernández	OGA
	Dr Jonathan David Agnew	DAP
	Dr Cristina Draghici	SCC
	Dr George Anastasopoulos	IAS
	Ms Aisha Fallatah	GAC
	Mr Karthik Easwar	IAS

