

## LEAD EVALUATOR TRAINING COURSE CASE STUDIES

OUTCOMES FROM THE ILAC EVALUATION OF APLAC				
	Identified Issue (NC / Concern / Comment)	Requirement (Old or new as appropriate)	Acceptable / Possible solutions	Comments – general
1	Only 2 CAB files were selected – those of the CAB’s witnessed - for review.	There is currently no set requirement for the number of files reviewed. A representative number needs to be reviewed.	Records of what was reviewed now needs to be captured on APAC FRMA-012	NC from witnessing of AB #3, observation #4.  NC from witnessing of AB #3, observation #3  Comment from witnessing AB #5, observation #5
2	The transition of CAB’s to an updated standard ISO 15189:2012 was not reviewed by the APLAC evaluator and it was noted (by the ILAC evaluator) that 2 CAB’s had not transitioned in the timeframe specified by ILAC.	Lead Evaluators need to review the self-declarations provided by the AB with regard to the deadline set by ILAC	Include consideration of AB policies regarding the transition of CABs caused by revisions to CAB standards on APAC FRMA-012  Document the status in the evaluation report.	NC from witnessing of AB #3, observation #4
3	The assessment team witnessed did not follow the AB’s procedures (a technical assessor provided the laboratory being assessed with a sample for analysis as part of the competency assessment of the lab), which was not permitted by the AB. The evaluator commented on this but no finding was made with regard to the AB not following their own procedures.	AB’s need to follow their own documented procedures, and where they don’t a non-conformance raised by the evaluation team (according to ILAC).	Review methods of evaluating assessor understanding of AB requirements during the witness portion of an evaluation.	Comment from witnessing of AB #3, Obs #4

OUTCOMES FROM THE ILAC EVALUATION OF APLAC				
	Identified Issue (NC / Concern / Comment)	Requirement (Old or new as appropriate)	Acceptable / Possible solutions	Comments – general
4	Debriefing of the assessment team witnessed, by the evaluator	Expectations by the assessment team (and not just the AB) that they will be provided with feedback – this came up three times.	Discuss ramifications. If discussion is animated, then perhaps guidance is needed.	Do we need to clarify what is permitted around this – I know it varies between evaluators
5	Inconsistency of grading findings of the evaluation team re: NC's, Concerns and Comments	IAF-ILAC A1 Annex 3.B	Discuss definitions of findings and establish common ground	NC from the evaluation of the secretariat.  NC from witnessing of AB #3, observation #3  Comment from witnessing AB #5, observation #5  While IAF-ILAC JWG A-series may be changing on this, we are required to follow the latest current publications.
6	Consideration not given to requirements of other regional bodies were a joint evaluation is carried out.	Consider differences between APAC MRA-001 and IAAC MD 002 – TL responsibility?	Check with TLs to see if APLAC approach works for them	Concern from the Evaluation of the secretariat

OUTCOMES FROM THE ILAC EVALUATION OF APLAC				
	Identified Issue (NC / Concern / Comment)	Requirement (Old or new as appropriate)	Acceptable / Possible solutions	Comments – general
7	Planning for the evaluation and allowance of sufficient time for TL's to cover their assignment.  Timetable did not include clear assignment of all clauses to the team.	IAF-ILAC A2 Annex 2 Section 3.2	Discuss issues that may be caused by potential overloading in the psyche of our vaunted and intrepid TLs	Concern from witnessing of AB #3, observation #3.  Comment from witnessing of AB#1, observation #1.
8	Competency requirements of accreditation decision makers (of appeals) not adequately defined or reviewed by the evaluation team.	ISO/IEC 17011:2004, 7.10.2 (Appeals)	Discuss methods of determining competence of decision makers.	NC from witnessing of AB #3, observation #3  NC from witnessing of AB #5, observation #5
9	The evaluation did not sufficiently confirm the "existence of a structure (body or process) to safeguard" the impartiality of the AB's activities	ISO/IEC 17011:2004, 4.3.2 (Impartiality)	Discuss methods of evaluating impartiality	NC from witnessing of AB #3, observation #3  NC from witnessing of AB #5, observation #5  Need to see Case Study #5
10	Management of large evaluation teams with the combination of APLAC and PAC - either a combined team or 2 teams working alongside each other	APAC MR006, Clause 3	Appointing a TL without a scope for witnessing / review so they can focus of the management system and managing the team (Bruce and I saw this in action with the recent ILAC evaluation of EA)	NC from witnessing of AB #3, observation #3 (also see No.9 Identified Issues)  Need to see what Case Study 6 contains, as provided with the response to the ILAC evaluation.

OUTCOMES FROM THE ILAC EVALUATION OF APLAC				
	Identified Issue (NC / Concern / Comment)	Requirement (Old or new as appropriate)	Acceptable / Possible solutions	Comments – general
11	Records of competency for Technical Experts were not reviewed by the evaluator (for Inspections Bodies). Records for assessors were reviewed.  The evaluator did not ensure that the AB were responsible for the inspections and inspectors selected for witnessing as part the AB's assessment process.	ISO/IEC 17011:2004, 6.4 (Personnel records)  IAF-ILAC A5 M.6.3.1.1 IAF-ILAC A5 M.7.3.3.1	Records of what was reviewed now needs to be captured on APAC FRMA-012	NC from witnessing of AB #1, observation #1
12	Receipt of documentation from the AB being evaluated was provided to the team only the week prior to the evaluation.	IAF-ILAC A2 APAC-MRA 006.3.2  "not less than 3 months prior"	We were reminded of this requirement at the 2018 MRA meeting but would not hurt to confirm we all understand the same thing by this	NC from witnessing of AB #2, observation #2
13	Witnessing of the same CABs at consecutive evaluations	IAF-ILAC A2 3.1.5 APAC-MRA 001, 19.9	We were reminded of this requirement at the 2018 MRA meeting – reminder to check as soon as practical what was covered last time and forward plan accordingly?	NC from witnessing of AB #2, observation #2
14	The team did not receive the ballot history of the AB (this came up twice) and in one case did not receive the list of AB's witnessed at the last evaluation	APAC MRA 001:2019, 19.4 APAC MRA 011:2019, 3.2	Discuss most appropriate methods in determining the evaluated body's ballot history as part of the evaluation.	Comment from witnessing AB #5, observation #5

OUTCOMES FROM THE ILAC EVALUATION OF APLAC				
	Identified Issue (NC / Concern / Comment)	Requirement (Old or new as appropriate)	Acceptable / Possible solutions	Comments – general
15	Records as evidence of implementation of suspension process were not reviewed (there had been no suspensions in the period under evaluation)  Records of suspensions and withdrawals for medical testing laboratories were not reviewed by the evaluator covering the medical testing scheme of the AB.	IAF-ILAC A2, 2.1.1 APLAC MR 001, 3.1.1  ISO/IEC 17011:2004, 7.13 ISO/IEC 17011:2019, 7.11	Discuss most appropriate approaches in determining if the AB has appropriate policies for the suspension and withdrawal of CABs and that they are implemented.	NC from witnessing of AB #3, observation #4  NC from witnessing of AB #5, observation #5
16	The AB's self-evaluation report was not reported on the correct template, MR009, now as per IAF-ILAC A3	IAF-ILAC A3	Discuss most appropriate methods for ensuring the AB self-evaluation is complete before the evaluation is undertaken.	Comment from witnessing AB #5, observation #5

POSSIBLE TOPICS FOR OTHER AREAS			
Suggested topics	Requirement	Possible solutions	Comments – general
Use of the Evaluation Review Panel (ERP)			
30 day comment period – not sure where this at			
Electronic balloting			