

ISSUE 01 – SUFFICIENCY OF CAB FILE REVIEW

APAC Lead Evaluator Training Objectives:

Discuss awareness of the need to review sufficient numbers of CAB files during an evaluation.

ILAC Finding: Observation #4, NC-01 and APLAC Response

ITEM	CONSIDERATION
Source of Issue	NC from witnessing of AB #3, observation #4. NC from witnessing of AB #3, observation #3 Comment from witnessing AB #5, observation #5
Finding from AB #3, Observation #3, NC 03	The [APLAC] Team did not make an investigation/examination of: - a sufficient number of file reviews to complement the witnessing (only those files witnessed were reviewed); - the AB's monitoring process for staff and assessors and corresponding records; - the competence of the members of the Appeals Panel to confirm or change accreditation decisions. [IAF/ILAC A2:2014, Annex 2, B.1, B.2.5] [IAF/ILAC A2:2014, §2.1.1 & ISO/IEC 17011, §7, §6.1.1, §6.3, §6.4.1]
Date	Response from the Region
2018/03/30	As the Regional TL was not in the AB offices on the second to last day of the evaluation and not present during the additional visit for RMP in December, these conclusions are without merit or evidence.
Date	Reaction from the IAF / ILAC evaluation team
2018/05/15	1&2) Regarding the insufficient number of file reviews and monitoring of calibration staff and assessors records statement: The ILAC TM did follow the RG TM for calibration, and did not see this being checked; the evaluation timetable confirmed on Sunday of the visit indicated that during the absence of the ILAC TM in the office, the review of files would be for RMP and not for calibration - if more calibration files were checked, please clarify how many files and when; also if calibration assessors' monitoring files were checked, please clarify how many files were reviewed and when this happened. 3) Competence of the members of Appeals Board: at the end of the observed visit, the ILAC TM asked to the RG Team if anyone had checked this, and the answer was no - the ILAC TM would appreciate to learn which documents and records were checked and when. No corrective action or evidence, or sufficient clarification is presented, and the finding cannot be closed.
Date	Response from the Region
2018/08/06	1&2). APLAC Evaluator Training will emphasize the necessity for making a determination of an appropriate sampling size for assessor records. See Case Study 4 attached.
2018/09/25	1&2). The APLAC TL reviewed several calibration laboratory files and assessors' monitoring files while she was in the JAB offices on the Thursday following the witness. The ILAC Team Leader was observing another APLAC TM (calibration) at the time and was not in the JAB offices. Prior to leaving for the witness, the APLAC TL spent time reviewing the subject laboratory's files as did the other APLAC TM (calibration). The assessors' monitoring files are maintained in an electronic database, not paper record, so the APLAC TL was at a computer with the translator so she could provide the translation for her to understand the content of the records. This process was somewhat tedious and did not allow for 100% review but she was able to sample a sufficient number of both experienced and relatively new assessors. For RMP, the technical assessor was participating in his initial assessment so the APLAC TL was able to observe the effectiveness of his training and the monitoring process as well. It should also be noted that the technical assessors are evaluated by the lead assessor at each assessment. The translator provided remarkable service and was well-versed in the requirements of the standard and also technically competent so we were able to have a very complete

	understanding of what was occurring during the assessment. She was instrumental in the APLAC TL being able to establish that the assessors were, in fact, determining and verifying metrological traceability and verifying that the content of the produced certificates contained all the required elements, thus meeting the requirements of ISO/IEC 17025:2005.
	3). In reviewing her records, the APLAC TL advised that there is no standing JAB Appeals “Board” in that it is integrated by a Monitoring Panel which is appointed from a range of qualified (by JAB process and their Secretary General) individuals in the event of the need for reviewing complaints and appeals. There was not an appeals panel active at the time of the evaluation so there was no opportunity to review the qualifications of the Monitoring Panel. The two procedures that cover this process JAB SG200:2017 Provision for Dealing with Appeals and Complaints Relating to Accreditation and JAB SG 201:2017 Rules on Monitoring Panel are attached.
Date	Reaction from the IAF / ILAC evaluation team
2018/10/26	<p>1&2) The evaluator training is accepted as corrective action and together with the clarifications provided, the related findings can be closed. However, since the reporting template of IAF/ILAC A3 does not foresee information on the file review done in PEs, the ILAC TM is unsure how APLAC will verify the effectiveness of the corrective action ...</p> <p>3) The requirements established by the AB are too generic in the competences stated and there is no mention to knowledge on ISO/IEC 17025 or ISO/IEC 17020 or ISO/IEC 17011 and ILAC documents to an appeal decision overcome without risk an accreditation decision taken previously by competent persons: “(1) Understanding the social significance of the accreditation system, and from this perspective, making synthetic judgment on the accreditation activities for conformity assessment bodies; (2) Having insights on the entire conformity assessment system including accreditation; and (3) Having a high level of interest in and consciousness of activities as well as professional knowledge related to the conformity assessment system in each field (consumers and ordinary citizens, academic experts, industry, etc.)”</p> <p>So a discussion between the PE Team and the AB was expected for understanding how these would be implemented in practice, regardless of existing or not active appeals (even past appeals or simulations could be used for comprehension of the criteria). APLAC is required to ensure that its PE Teams understand the need to check the competence requirements of the decision-making from appeals.</p>
Date	Response from the Region
2018/11/19	<p>1&2). APAC FMRA-012 has been expanded to record the number of files (CAB and assessor) reviewed out of the total number of files (CAB and assessor) to ensure that an appropriate number of records have been examined. Refer to APAC FMRA-012 as attached.</p> <p>3). APLAC Evaluator Training will emphasise the need of reviewing the competence requirements of the decision makers. The training will cover checking of the competence of decision makers for appeals that have occurred and if no appeals have been held since the last evaluation ensure that the documented procedure adequately addresses the competence of the decision makers.</p>
Date	Reaction from the IAF / ILAC evaluation team
2018/12/26	Accepted and closed

IAF/ILAC A2:2014, Annex 2, B.1, B.2.5 – Sufficiency of CAB File Review

1. Introduction

The task of an evaluation of an AB is to collect sufficient information about the assessments and decision-making process of the AB to have confidence in the conformity assessment results from CABs accredited by the AB such that the signatories to the Arrangement can promote acceptance of these results.

It is the task of the TL to create a timetable in a timely manner prior to the evaluation of the AB that allows sufficient time to collect information for obtaining such confidence.

Because there exists a large variety of circumstances under which an evaluation will take place, it is the prerogative of the TL to deviate from the examples shown in 3.2 of this annex. The TL should agree with the team members on the duration. Consultation with the accreditation body under evaluation is essential. When the proposed timetable largely differs from the examples of 3.2.2 of this annex or when additional evaluation team capacity is required, the Chair of the MC should also be consulted at an early stage.

2.5 Other Factors

Factors that may influence the duration of the evaluation include:

- *Need for translators;*
- *Extensive travel and travel circumstance; and*
- *Cultural differences.*

This annex cannot provide guidance on all these items. It is left to the team members and their experience to judge these effects and to cater to them in such a way that there is no compromise to the principle stated in the introduction to this annex.

Current Requirement from IAF/ILAC A3:2018

There is currently no set requirement for the number of files to be reviewed during an evaluation. However, a representative number probably needs to be reviewed in order to provide evidence that IAF/ILAC A3:2018, Annex 2, Section B, clause 1 is followed during an evaluation:

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Acceptable / Possible solutions

Records of what was reviewed may now need to be captured on a revised version of APAC FRMA-012 (specimen attached)

Case Study 4 – Sampling CAB, monitoring, and competence records

Scenario:

During a re-evaluation, the team did not appear to have examined a sufficient number of:

- CAB files to complement the witnessed CABs. Only those files witnessed were reviewed
- AB monitoring records for staff and assessors
- Records regarding the competence of the members of the Appeals Panel to confirm or change accreditation decisions.

Questions to Lead Evaluators:

- Does this circumstance/condition conform to evaluation requirements?
- What criteria can the team employ to give them confidence in the sampling size of assessor, monitoring and competence records?

LIST OF CABS WITNESSED AND FILES REVIEWED DURING EVALUATION

This list must be read in conjunction with the information in the report on the witnessed assessments
(Annex IV of IAF/ILAC-A3)

Accreditation Body	
Evaluation Date	

Witnessed Assessment(s)		
Coding in Report	Name of CAB	Lead Assessor
<i>Laboratory A</i>	<i>XYZ Testing Services, Downtown Laboratory</i>	<i>John Smith</i>

Assessor Files		
No of files reviewed	Total No of Assessors	Comments
<i>8</i>	<i>300</i>	<i>The files reviewed demonstrated</i>

CAB Files (ALSO NOTE IMPACT OF TRANSITIONS IN CAB STANDARDS)			
No of files reviewed	Field	Total No of CABS	Comments
<i>4</i>	<i>RMP</i>	<i>24</i>	<i>The files reviewed demonstrated</i>