

ISSUE 08 – COMPETENCE OF APPEAL DECISION MAKERS

APAC Lead Evaluator Training Objectives:

Examine competence of appeal decision-makers.

ILAC Finding: NC-01 of AB#4 and APAC Response

ITEM	CONSIDERATION
OBS4 - NC 1	<ul style="list-style-type: none"> The APLAC evaluation team evaluated the procedure for suspension and confirmed that no CAB are suspended at the time of the evaluation. However, no records of previous suspensions were reviewed by the team to confirm compliance with clause 7.13 of ISO/IEC 17011:2004. The APLAC evaluation team did not properly assess clauses 4.2.2, 4.2.5d) and f), and 7.10.2a) of ISO/IEC 17011:2004 and no findings was raised about the following issues: <ul style="list-style-type: none"> ✓ The AB uses a Committee for the decision making process. The members of that Committee are subject to approval by the Director of the AB (identified as the AB's top management), as well as by the Director General of the Governmental Organization where the AB belongs. That Director General is responsible for the whole Governmental Organization that also carries out conformity assessment activities. That Decision Making Committee is subsequently appointed by the Permanent Secretary of the Ministry where the Government Organization belongs. ✓ Appeals against AB's decisions are addressed to the Permanent Secretary of the Ministry where the AB belongs. Appeals are investigated by a Committee appointed by the Permanent Secretary, who is responsible for decisions on Appeals. (It should be noted that there has never been any appeal against AB's decisions.) <p>IAF/ILAC A2, 2.1.1 and APLAC MR 001 3.1.1</p>
Date	Response from the Region
2018/04/23	<ol style="list-style-type: none"> Regarding the issue of not reviewing records of previous suspensions, one of team members asked about cases for suspension, the reply was that there was no current suspension for PTP, and she further asked if there was any previous suspension cases, AB also replied that there was never a suspension for PTP. The TL checked the list of suspension on the AB website, there was no current suspension, the TL did not review the records of previous suspensions for Testing. After the evaluation, the TL confirmed with the AB that there was no case of suspension CAB from 2014 to 2017. To improve the TL's evaluation skills, the TL considered that review of both previous and current suspension cases would be emphasized in future evaluations. Regarding the issue on assessing the AB's top management, the TL reviewed the responsibility of Director General and the Permanent Secretary of the Ministry against the law of the Government Organization focused on the accreditation activities. The AB's quality manual indicated that the AB's top management was the Director of DSS-BLA, not including Director General of DSS and the Permanent Secretary of the Ministry. It was suggested that the AB revised the top management to include Director General of DSS and the Permanent Secretary of the Ministry in the quality manual.
Date	Reaction from the IAF / ILAC evaluation team
2018/05/21	<p>Thank you for this this response.</p> <p>The response given above focuses only on actions related to the evaluation observed. Has APLAC done any review of the finding in order to identify the root cause and to investigate whether nonconformities exist, or could potentially occur in other peer evaluations? Please provide that review as well as information and evidence on any additional actions determined as a result of that review.</p>

	<p>In relation to the second issue raised in the finding, the explanation provided by APLAC does not actually address the finding. The Director General of the Governmental Organization where the AB belongs (DSS) and the Permanent Secretary of the Ministry are from related bodies outside the AB. Revising the Quality Manual to include the Director General of DSS and the Permanent Secretary of the Ministry as part of top management of the AB would only document in the Quality Manual the non conformity against clauses 4.2.2, 4.2.5d, 4.2.5f, and 7.10.2 of ISO/IEC 17011:2004 raised by the ILAC evaluator, and would also be against clause 4.3.7 of ISO/IEC 17011. APLAC is also requested to consider in their response to this particular issue the fact that the Evaluation Report of the previous evaluation performed in March 2015 includes the same information about the issues raised by the ILAC evaluator (see items 4.3.1 and 4.4.11 on pages 27 and 38 of that evaluation report).</p> <p>APLAC is requested to reconsider their response to this finding.</p>
Date	Response from the Region
2018-09-03	<p>1. It is not clear how this could be classified as a non-conformity when both the TM and TL ascertained that there had not been any suspensions of accreditation (for any CABs) in the previous three years i.e the period under review at this evaluation. If the AB is asked to show records of suspensions but there are no records to review, the team can only note this for attention at future evaluations. There is nothing to indicate from other witnessed assessments that there is a systemic issue so it is unclear why a root cause analysis is required. Furthermore, IAF-ILAC A1 in effect at the time, does not require a root cause analysis.</p> <p>The issue is covered by Case Study 8 Sufficiency of examination of CAB files, part of the APLAC Evaluator Training syllabus.</p> <p>2. AB #4 has provided copies of the relevant documentation in relation to its decision making and appeals processes for review by the APLAC Quality Manager (QM). The review by the QM indicates that the AB may not be in compliance with the clauses in ISO/IEC17011:2004 as noted by the evaluation team. Further clarification is being sought from the AB before a final determination can be made and, if necessary, suitable corrective action requested of the AB. A further response to this matter will be provided as soon as possible.</p>
Date	Reaction from the IAF / ILAC evaluation team
2018-10-26	<p>In relation to issue 1 of the finding, Case Study 8 Sufficiency of examination of CAB files, included as part of the APLAC Evaluator Training syllabus addresses the issue.</p> <p>1) Please provide information on when the Evaluator Training syllabus was used or will be used with those evaluators already qualified by APLAC.</p> <p>In relation to Issue 2 of the finding.</p> <p>2) The ILAC evaluation team awaits for a further response by APLAC as a result of the review done by APLAC Quality Manager.</p> <p>3) We also request APLAC to inform what actions have been taken or will be taken to ensure that APLAC evaluators properly evaluate clauses 4.2.2, 4.2.5d) and f), and 7.10.2a) of ISO/IEC 17011:2004 (or corresponding clause in ISO/IEC 17011:2017).</p>
Date	Response from the Region
2018-11-19	<p>1). Whilst APAC will invite all current Lead Evaluators to the Lead Evaluator Training in 2019 the outcome s from the training will be shared amongst all APAC evaluators using the Evaluator Resources pages on the APAC website.</p> <p>2). APLAC is still waiting on further information from the AB. The APLAC designated Representative has retired recently and we are following the mater up with the new incumbent.</p> <p>3). The Lead Evaluator Training in 2019 will emphasis the need to ensure that the impartiality requirements 4.2.2, 4.2.5d) and f), and 7.10.2a) of ISO/IEC 17011:2004 (or corresponding clause in ISO/IEC 17011:2017) are fully implemented. The issue is covered by Case Study 5 Evaluating impartiality, part of the APLAC Evaluator Training syllabus. As detailed above the</p>

	outcome s from the training will be shared amongst all APAC evaluators using the Evaluator Resources pages on the APAC website.
Date	Reaction from the IAF / ILAC evaluation team
2019/01/10	Accepted under the conditions presented - it is recommended that APLAC/APAC provides a progress report to ILAC on this issue within 6 months.

ILAC Finding: NC-03 of AB#3 and APAC Response

ITEM	CONSIDERATION
DM NC #03	<p>The RG Team did not make an investigation/examination of:</p> <ul style="list-style-type: none"> - 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. <p>[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]</p>
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	<p>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.</p> <p>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.</p> <p>No corrective action or evidence, or sufficient clarification is presented, and the finding cannot be closed.</p>
Date	Response from the Region
2018/08/06	1&2). APLAC Evaluator Training will emphasise the necessity for making a determination of an appropriate sampling size for assessor records. See Case Study 4 attached.

2018/09/25	<p>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.</p> <p>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.</p> <p>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 <i>Provision for Dealing with Appeals and Complaints Relating to Accreditation</i> and JAB SG 201:2017 <i>Rules on Monitoring Panel</i> are attached.</p>
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.</p> <p>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:</p> <p><i>"(1) Understanding the social significance of the accreditation system, and from this perspective, making synthetic judgment on the accreditation activities for conformity assessment bodies;</i> <i>(2) Having insights on the entire conformity assessment system including accreditation; and</i> <i>(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.)."</i></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	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. 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.
Date	Reaction from the IAF / ILAC evaluation team
2018/12/26	Accepted and closed

IAF/ILAC A2:2014, 2.1.1 and APLAC MR 001:2014 3.1.1 – refers to ISO/IEC 17011:2004 generically

ISO/IEC 17011:2004 7.10.2 (Appeals) (used during ILAC evaluation)

7.10.2 The accreditation body

- shall appoint a person, or group of persons, to investigate the appeal who are competent and independent of the subject of the appeal,
- shall decide on the validity of the appeal,
- shall advise the CAB of the final decision(s) of the accreditation body,
- shall take follow-up action where required, and
- shall keep records of all appeals, of final decisions, and of follow-up actions taken.

IAF/ILAC A2:2018, 2.1.1 and APLAC MR 001:2014 3.1.1 – refers to ISO/IEC 17011 generically

ISO/IEC 17011:2019 6.1.2.3-6.1.2.5 and Annex A (Competence in accreditation disciplines) (current versions of requirements)

6.1.2.3 The accreditation body shall ensure the assessment team, and the accreditation body personnel who review applications, select assessment team members, review documents, review assessment reports, **make accreditation decisions** and manage accreditation schemes, demonstrate knowledge of the following:

- accreditation body's rules and processes;
- accreditation and accreditation scheme requirements and relevant guidance and application documents;
- conformity assessment scheme requirements, other procedures and methods used by the conformity assessment body.

6.1.2.4 The accreditation body shall ensure the assessment team, and the accreditation body personnel who review assessment reports, **make accreditation decisions** and manage accreditation schemes, demonstrate knowledge of risk based assessment principles.

6.1.2.5 The accreditation body shall ensure the assessment team, and the accreditation body personnel who review documents, review assessment reports, **make accreditation decisions** and manage accreditation schemes, demonstrate knowledge of general regulatory requirements related to the conformity assessment activities.

Acceptable / Possible solutions

Determine if the APLAC response to ILAC provides sufficient guidance to TLs.

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?

Case Study 5 – Evaluating impartiality (reserved for Issue 09)

Scenario:

During a re-evaluation, the team did not appear to have sufficiently examined impartiality requirements:

- The existence and operation of a structure (body or process) to safeguard the impartiality of the AB' activities and its conformance with the applicable requirements of ISO/IEC 17011 was not discussed with the AB and could not be demonstrated;
- The existence and appropriateness of the measures taken by the AB to address the risks to impartiality arising from its financial situation were not discussed;
- The nature of the main sources of income and expenses were not checked to allow the confirmation that no potentially conflicting activity was being conducted by the AB;
- The AB's declaration that no related bodies existed was not discussed nor verified

Questions to Lead Evaluators:

- Does this circumstance/condition conform to evaluation requirements?
- Is a separate body or process, such as the “mechanism to safeguard impartiality” required for product certification bodies also required for ABs conformant to 17011?
- What financial conditions may present risks to impartiality of an AB? How can these be identified?
- Is an evaluation team required to audit financial records and identify the actual sources of income or the expenses incurred by the AB? Is the acceptance of audited financial statements sufficient for the determination of the financial situation of an AB?
- Are there circumstances where an AB may not have any related bodies? Describe these.