

## ISSUE 09 – MECHANISM TO SAFEGUARD IMPARTIALITY

### APAC Lead Evaluator Training Objectives:

Examine appropriate approaches in evaluating mechanisms to safeguard impartiality.

### ILAC Finding: NC-05 of AB#3 and APAC Response

ITEM	CONSIDERATION
DM NC #05	<p>The RG Team addressed the impartiality requirements insufficiently:</p> <ul style="list-style-type: none"> <li>- 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;</li> <li>- 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;</li> <li>- 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;</li> <li>- the AB's declaration that no related bodies existed was not discussed nor verified.</li> </ul> <p>[IAF/ILAC A2:2014, §2.1.1 &amp; ISO/IEC 17011, §4.3]</p>
Date	Response from the Region
2018/04/18	<p>What is the evidence that the team did not address these items? The TL found no evidence to suggest that AB#3 acts in any way to compromise its impartiality. During review and in observation, the AB's policies and procedures were found to be non-discriminatory and objective. They do not offer consultancy and there was no evidence that their activities could be linked to consultancy.</p>
Date	Reaction from the IAF / ILAC evaluation team
2018/05/15	<p>1) The ILAC TM followed the APLAC TL at the observed visit and did not see this check; furthermore, at the end of the observed visit the ILAC TM asked to the APLAC Team if the existence and operation of a structure (body or process) to safeguard the impartiality had been checked, and the answer was 'No' - the ILAC TM would appreciate to learn which documents and records were checked and when.</p> <p>2&amp;3) Non-discriminatory provision of accreditation services and absence of consultancy is not sufficient to comply with all the requirements in section 4.3 of ISO/IEC 17011:2004. The ILAC TM would also appreciate to know which documents or records were seen to substantiate the claim that the AB does not provide consultancy.</p> <p>No corrective action or evidence, or sufficient clarification is presented, and the finding cannot be closed.</p>

Date	Response from the Region
2018/10/12	<p>The APLAC Team Leader has reviewed her notes, the declarations by AB#3 in MR 009 and the documents related to impartiality.</p> <p>Overall, she was not just satisfied but quite impressed by the policies as written in AB#3 S001, Articles of Association, elaborated in great detail in AB#3 Document S321, Code of Ethics and additionally supported by AB#3 S611, Rules for Information Security. AB#3 S001 requires that all staff, assessors and committee members sign agreements/covenants specifically committed to observe confidentiality and impartiality rules. When committees are formed for specific reasons (decisions, appeals, etc.) there is an additional Declaration that is signed committing or actually recommitting to the strict code of ethics.</p> <p>The APLAC Team Leader reviewed the signed declarations for the assessors and staff that she interviewed and is sure that the other team members did as well as it was part of our review of the onsite information we were given for the witnesses. The evaluators, including our regional evaluators, were required to commit to confidentiality and impartiality during the opening meetings of the assessment (our signature on the attendance sheets).</p> <p>AB#3 works to ensure that there is a balanced representation of interests for all activities associated with accreditation.</p> <p>Article 4 of S321 specifically addresses the Prohibition of providing consultancy services. Article 5 prohibits the receiving or granting of benefits and discusses eliminating any conflict of interest for a minimum of 2 years. There are supplementary provisions which describe in detail the prohibitions regarding accepting requests to deliver lectures, providing lecturers for training courses, contributing to articles for publication and the like. Participation cannot be for the sole benefit of the individual or organization making the request.</p> <p>AB#3 is no longer offer PT services RL 230: 2017 is AB#3's current policy on the participation in and implementation of proficiency testing activities.</p>
Date	Reaction from the IAF / ILAC evaluation team
2018/10/26	<p>The ILAC TM recognizes that the AB can fulfil several requirements for impartiality as stated by the APLAC TL; however, the structure required by §4.3.2 (2004 version) as an identifiable body within the AB seems to be missing and not understood as missing by the APLAC TL. Also the need to confirm the absence of related bodies and perform a risk analysis of the impartiality with the interested parties was not addressed.</p> <p>Nevertheless, although not stated in APLAC response, these items will be specifically addressed in the APAC evaluators' training in 2019, so an appropriate corrective action has been taken and the finding <b>can be closed</b>.</p>

### **ILAC Finding: NC-01 of AB#5 and APAC Response**

ITEM	CONSIDERATION
Number	Requirements and description of the non-conformity
OBS4 - NC 1	<ul style="list-style-type: none"> <li>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.</li> <li>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"> <li>✓ 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.</li> <li>✓ 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</li> </ul> </li> </ul>

	<p>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> <p>IAF/ILAC A2, 2.1.1 and APLAC MR 001 3.1.1</p>
Date	Response from the Region
2018/04/23	<p>1. 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.</p> <p>2. 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.</p>
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 <i>Sufficiency of examination of CAB files</i>, part of the APLAC Evaluator Training syllabus.</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.
Date	Reaction from the IAF / ILAC evaluation team
2018-10-26	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. 1) Please provide information on when the Evaluator Training syllabus was used or will be used with those evaluators already qualified by APLAC.  In relation to Issue 2 of the finding. 2) The ILAC evaluation team awaits for a further response by APLAC as a result of the review done by APLAC Quality Manager. 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).
Date	Response from the Region
2018-11-19	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. 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. 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 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.

**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, 4.3 (Impartiality) (used during ILAC evaluation)**

**4.3 Impartiality**

- 4.3.1** The accreditation body shall be organized and operated so as to safeguard the objectivity and impartiality of its activities.
- 4.3.2** **For safeguarding impartiality and for developing and maintaining the principles and major policies of operation of its accreditation system, the accreditation body shall have documented and implemented a structure to provide opportunity for effective involvement by interested parties.** The accreditation body shall ensure a balanced representation of interested parties with no single party predominating.
- 4.3.3** The accreditation body's policies and procedures shall be non-discriminatory and shall be administered in a non-discriminatory way. The accreditation body shall make its services accessible to all applicants whose requests for accreditation fall

within the activities (see 4.6.1) and the limitations as defined within its policies and rules. Access shall not be conditional upon the size of the applicant CAB or membership of any association or group, nor shall accreditation be conditional upon the number of CABs already accredited.

- 4.3.4** All accreditation body personnel and committees that could influence the accreditation process shall act objectively and shall be free from any undue commercial, financial and other pressures that could compromise impartiality.
- 4.3.5** The accreditation body shall ensure that each decision on accreditation is taken by competent person(s) or committee(s) different from those who carried out the assessment.
- 4.3.6** The accreditation body shall not offer or provide any service that affects its impartiality, such as
- a) those conformity assessment services that CABs perform, or
  - b) consultancy.

The accreditation body's activities shall not be presented as linked with consultancy. Nothing shall be said or implied that would suggest that accreditation would be simpler, easier, faster or less expensive if any specified person(s) or consultancy were used.

- 4.3.7** The accreditation body shall ensure that the activities of its related bodies do not compromise the confidentiality, objectivity and impartiality of its accreditations. A related body may, however, offer consultancy or provide those conformity assessment services the accreditation body accredits, subject to the related body having (with respect to the accreditation body)
- a) different top management for the activities described in 4.2.5,
  - b) personnel different from those involved in the decision-making processes of accreditation,
  - c) no possibility to influence the outcome of an assessment for accreditation, and
  - d) distinctly different name, logos and symbols.

The accreditation body, with the participation of the interested parties as described in 4.3.2, shall identify, analyse and document the relationships with related bodies to determine the potential for conflict of interest, whether they arise from within the accreditation body or from the activities of the related bodies. Where conflicts are identified, appropriate action shall be taken.

**NOTE 1** A related body is a separate legal entity that is linked by common ownership or contractual arrangements to the accreditation body as described in 4.1.

**NOTE 2** A separate part of the government, outside the governmental accreditation body as described in 4.1, is considered as a related body.



**IAF/ILAC A2:2018, 2.1.1 and APAC MR 001:2019, 5 and APAC FMRA-001 – refers to ISO/IEC 17011:2017 generically**

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

#### **4.4 Impartiality requirements**

- 4.4.1** *Accreditation shall be undertaken impartially.*
- 4.4.2** *The accreditation body shall be responsible for the impartiality of its accreditation activities and shall not allow commercial, financial or other pressures to compromise impartiality. Where an accreditation body, including a governmental accreditation body, is part of a larger entity, the accreditation body shall be organized so that accreditation is provided impartially.*
- 4.4.3** ***The accreditation body shall have top management commitment to impartiality. It shall document and make public an impartiality policy which includes the importance of impartiality in carrying out its accreditation activities, managing conflict of interest and ensuring objectivity of its accreditation activities.***
- 4.4.4** *All accreditation body personnel and committees who could influence the accreditation process shall act objectively and shall be free from any undue commercial, financial and other pressures that could compromise impartiality. The accreditation body shall require all personnel and committee members to disclose any potential conflict of interest whenever it may arise.*
- 4.4.5** *The accreditation body shall document and implement a process to provide opportunity for effective involvement by interested parties for safeguarding impartiality. The accreditation body shall ensure a balanced representation of interested parties with no single party predominating.*
- 4.4.6** *The accreditation body shall have a process to identify, analyse, evaluate, treat, monitor and document on an ongoing basis the risks to impartiality arising from its activities including any conflicts arising from its relationships or from the relationships of its personnel. The process shall include identification of and consultation with appropriate interested parties as described in 4.4.5 to advise on matters affecting impartiality including openness and public perception.*
- NOTE 1** *Sources of risks to impartiality of the accreditation body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, outsourcing, training, marketing and payment of a sales commission or other inducement for the referral of new clients, etc.*
- NOTE 2** *One way of fulfilling the consultation with the interested parties is by the use of a committee.*
- 4.4.7** *Where any risks to impartiality are identified, the accreditation body shall document and demonstrate how it eliminates or minimizes such risks and document any residual risk. The demonstration shall cover all potential risks that are identified, whether they arise from within the accreditation body or from the activities of other persons, bodies or organizations.*
- 4.4.8** *Top management shall review any residual risk to determine if it is within the level of acceptable risk.*

**4.4.9** When an unacceptable risk to impartiality is identified and which cannot be mitigated to an acceptable level, then accreditation shall not be provided.

**4.4.10** The accreditation body's policies, processes and procedures shall be non-discriminatory and shall be applied in a non-discriminatory way. The accreditation body shall make its services accessible to all applicants whose application for accreditation falls within the scope of its accreditation activities as defined within its policies and rules. Access shall not be conditional upon the size of the applicant conformity assessment body or membership of any association or group, nor shall accreditation be conditional upon the number of conformity assessment bodies already accredited.

**NOTE** It is not considered discriminatory when an accreditation body refuses services to a conformity assessment body because of proven evidence of fraudulent behaviour, falsification of information or deliberate violation of accreditation requirements.

**4.4.11** The accreditation body and any part of the same legal entity shall not offer or provide any service that affects its impartiality, such as:

- a) conformity assessment activities covered by accreditation which include but are not limited to testing, calibration, inspection, certification of management systems, persons, products, processes and services, provision of proficiency testing, production of reference materials, validation and verification;
- b) consultancy.

**4.4.12** In case the accreditation body is linked to a body offering consultancy or undertaking those conformity assessment activities mentioned in 4.4.11 bullet a), the accreditation body shall have:

- a) different top management (see 5.7);
- b) different personnel performing the accreditation decision-making processes (see Clause 5);
- c) distinctly different name, logos and symbols;
- d) effective mechanisms to prevent any influence on the outcome of any accreditation activity.

**4.4.13** The accreditation body's activities shall not be presented as linked with consultancy or other services that pose an unacceptable risk to impartiality. Nothing shall be said or implied that would suggest that accreditation would be simpler, easier, faster or less expensive if any specified person(s) or consultancy were used.

**NOTE** Accreditation bodies can carry out, for example, the following duties that are not considered a risk to impartiality:

- arranging and participating as a lecturer in training, orientation or educational courses, provided that these courses confine themselves to the provision of generic information that is freely available in the public domain, i.e. they cannot provide specific solutions to a conformity assessment body in relation to the activities of that organization;
- adding value during assessments, e.g. by identifying opportunities for improvement as they become evident during the assessment without recommending specific solutions;
- advising other accreditation bodies on development of accreditation process;
- advising scheme owners on accreditation requirements, including requirements within relevant conformity assessment standards.

### **Acceptable / Possible solutions**

With the replacement of the term "structure" from the 2004 version of the standard, evaluators can more easily interpret requirements during evaluations.

## Case Study 5 – Evaluating impartiality

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.

## Case Study 8 – Sufficiency of examination of CAB files (reserved for Issue 02)