ISSUE 15 – ENSURING REVIEW OF EVIDENCE OF SUSPENSIONS

APAC Lead Evaluator Training Objectives:

Examine appropriate approaches in ensuring the AB has appropriate policies for the suspension and withdrawal of CABs and that they are implemented.

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

ITEM	CONSIDERATION
OBS4 - NC 1	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: • 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.) IAF/ILAC A2, 2.1.1 and APLAC MR 001 3.1.1
Date	Response from the Region
2018/04/23	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. 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.
Date	Reaction from the IAF / ILAC evaluation team
2018/05/21	Thank you for this this response. 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.

	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). APLAC is requested to reconsider their response to this finding.
Date	Response from the Region
2018-09-03	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. The issue is covered by Case Study 8 *Sufficiency of examination of CAB files,* part of the APLAC Evaluator Training syllabus. 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.

ILAC Finding: NC-01 of AB#3 and APAC Response

ITEM	CONSIDERATION
DM NC # 1	The APLAC peer evaluator did not consider the following requirements during evaluation: 1. The AB suspension and withdrawal of accreditation for medical labs 2. Checking CAB files other than those witnessed (2 labs), which is considered to be insufficient. 3. The transition of all accredited labs to the new ISO 15189:2012 by the end of the transition period; although the previous APLAC evaluation was conducted in 2013 before the end of the transition period. In addition, the ILAC evaluator had noticed that there were two labs on the AB website that were accredited according to the old version of the standard while the accreditation renewal was after the end of transition by nearly 6 months. IAF/ILAC A2, Clause 2.1.1
Date	Response from the Region
26 March 2018	Point number 1. is acknowledged. A specific check on this was overlooked. Point number 2. is noted. The response is that the demonstration of the two files that were checked showed confident knowledge of the process. Information was easily found and able to be discussed. The fact that the process needed to be done through a translator did mean that file review took longer and could not be done in quite the same way as usual. I was however satisfied with what I saw. I do not think trawling more files would have added useful information to the evaluation. Files to be reviewed are a matter for judgement and if there is nothing to indicate a problem then reviewing more is of no value. I also do not see how this is an NC against ILAC A2 Clause 2.1.1. Point number 3. This is correct. I did not make a special check as the transition period had ended and the region had received a declaration that all had been converted. I stand corrected that I did not check this conversion. I am not clear though what the ILAC observer is saying. Did she identify two facilities that were still not converted at the time of this evaluation in November 2017? Or did she identify two that had not been converted by the deadline of mid-2016? I am disappointed that this was not pointed out to me at the time if there were in fact facilities that were not yet converted.

Date	Reaction from the IAF / ILAC evaluation team
2018/05/30	§1 – No correction or corrective action is presented, APLAC should clarify what it intends to do; §2 –Although the number of files to be reviewed is not specified in ILAC A2, the ILAC Team doesn't agree that reviewing only those that will be witnessed can be regarded as sufficient – point number 3 already indicates that additional files would require a review; if translation is an issue, then additional time should have been planned. No correction or corrective action is presented, APLAC should clarify what it intends to do; §3 – The self-declaration of completeness by the ABs should be checked during the peer-evaluation to see what happened, namely if CABs were not suspended at the end of the transition deadline. Regarding the discussion on-site, the ILAC Team is required not to intervene or change the normal peer-evaluation, so this could only be presented after the peer-evaluation has ended. No correction or corrective action is presented, APLAC should clarify what it intends to do; The finding cannot be closed due to the absence of corrective actions and evidences.
Date	Response from the Region
2018/09/04	§1 APLAC Secretariat contacted AB#3 in relation to whether there were any accredited medical testing facilities suspended or withdrawn in the period between the 2013 and 2017 evaluations. AB#3 advised that 13 Medical laboratories have been withdrawn and 5 laboratories have been suspended since 2013. Please find attached the list of withdrawn and suspended medical laboratory by JAB. JAB does not release the reason of suspension or withdrawal. Information on suspension and withdrawal are available at the JAB website (Japanese only) https://www.jab.or.jp/service/clinical_examination/report/list02.html . Whilst the records were not specifically checked for Medical laboratories, the procedure was reviewed. Records were checked for other types of CABs by other members of the evaluation team. It is not clear why this evaluator, who is in fact an experienced Lead Evaluator, did not review records of suspensions and withdrawals of accreditation but proposed the broader issue of sampling CAB files will be addressed at forthcoming evaluator workshops. §2 APAC MRA MC procedures will not specify anything more than a sampling of CAB files in accordance with a risk-based approach. However, Lead Evaluators will examine this issue during training as a Case Study for Lead Evaluator Training in 2019. See Case Study 8. §3 APLAC Secretariat contacted AB#3 to determine the number of facilities accredited to ISO 15189:2009 still being listed on the AB's website. AB#3 advised that the transition to ISO 15189:2012 had been completed by the end of 2015 and currently no laboratory is accredited to ISO 15189:2009. Accreditation certificates are available at JAB website both in Japanese and English. https://www.jab.or.jp/en/system/service/medicallaboratories/accreditation/
Date	Reaction from the IAF / ILAC evaluation team
2018/10/28	The update on the current status of transition is appreciated. The issue has been further discussed in a meeting between the ILAC Team and APLAC and it was clarified that APLAC verifies and ascertains that their signatories are meeting the transition deadlines and suspending CABs that have not transitioned in time. It was further clarified that the mismatch came from the AB website information that would not have been updated after several months past the deadline. So APLAC is requested to ensure that their PE Teams check the transition information from the ABs appropriately.
Date	Response from the Region
2018/11/19	APAC will request APAC signatories to provide a self declaration of the transition status for their accredited CABs every six months until the full implementation date of the standard has passed. The APAC MRA MC will ensure that all non-transitioned CABs are suspended. The Lead Evaluator Training in 2019 will emphasise the need for the evaluation team leader to review the self-declarations provided, check that all accredited CABs have been transitioned to the new standard and document the status of the transition in the evaluation report..

Date	Reaction from the IAF / ILAC evaluation team
2018/12/26	Corrective action accepted and finding closed.

IAF/ILAC A2:2014, 2.1.1 and APLAC MR 001:2014 3.1.1 – refers to ISO/IEC 17011:2004 generically and ISO/IEC 17011:2004, 7.13 (used during ILAC evaluation)

7.13 Suspending, withdrawing or reducing accreditation

7.13.1 The accreditation body shall establish procedures for the suspension, withdrawal or reduction of the scope of accreditation.

NOTE Depending on the type of conformity assessment, the rules set by the accreditation body may differ.

7.13.2 The accreditation body shall make decisions to suspend and/or withdraw accreditation when an accredited CAB has persistently failed to meet the requirements of accreditation or to abide by the rules for accreditation.

NOTE The CAB may ask for suspension or withdrawal of accreditation.

7.13.3 The accreditation body shall make decisions to reduce the scope of accreditation of the CAB to exclude those parts where the CAB has persistently failed to meet the requirements for accreditation, including competence.

NOTE The CAB may ask for reduction of its scope of accreditation

IAF/ILAC A2:2018, 2.1.1 and APAC MR 001:2019, 5 and APAC FMRA-001 – refers to ISO/IEC 17011:2017 generically and ISO/IEC 17011:2019, 7.11 (current versions of requirements)

7.11 Suspending, withdrawing or reducing accreditation

7.11.1 The accreditation body shall have documented procedure(s) and criteria to decide in which circumstances the accreditation shall be suspended, withdrawn or reduced when an accredited conformity assessment body has failed to meet the requirements of accreditation or to abide by the rules for accreditation or has voluntarily requested a suspension, withdrawal or reduction.

7.11.2 Where there is evidence of fraudulent behaviour, or the conformity assessment body intentionally provides false information or conceals information, the accreditation body shall initiate its process for withdrawal of accreditation.

7.11.3 The accreditation body shall have a documented procedure and criteria for lifting suspension of accreditation.

Acceptable / Possible solutions

Discuss most appropriate approaches in ensuring the AB has appropriate policies for the suspension and withdrawal of CABs and that they are implemented.

Case Study 5 – Evaluating impartiality (see Issue 9)

Case Study 8 – Sufficiency of examination of CAB files (see Issue 2)