ISSUE 02 – REVIEW OF TRANSITION PLANS FROM REVISIONS OF CAB STANDARDS

APAC Lead Evaluator Training Objectives:

Discuss the requirements to:

- review APAC signatories' self-declaration of the transition status for their accredited CABs under ISO 15189 provided to APAC every six months until the full implementation date of the standard has passed.
- check that all accredited CABs have been transitioned to the new standard,
- document the status of the transition in the evaluation report AB 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.

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

ITEM	CONSIDERATION
Finding from AB #3, observations #3 and #4	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 Regional TL
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 AB#3. AB#3 does not release the reason of suspension or withdrawal. Information on suspension and withdrawal are available at the AB#3 website (AB#3 language only) https://www.AB#3.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 AB#3 website both in AB#3 native language and English. *https://www.AB#3/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 & ISO/IEC 17011 (2004), §7, §6.1.1, §6.3, §6.4.1 – Ensuring Conformance of Accredited CABs to MRA Requirements - PREVIOUS EDITIONS

IAF/ILAC A2:2014, clause 2.1.1 *An accreditation body shall comply with the provisions of ISO/IEC 17011 requirements and mandatory documents in IAF and ILAC where applicable.*

ISO/IEC 17011: 2004,

- ***7 ACCREDITATION PROCESS***
- ***7.1*** *Accreditation criteria and information*
- ***7.2*** *Application for accreditation*
- ***7.3*** *Resource review*
- ***7.4*** *Subcontracting the assessment*
- ***7.5*** *Preparation for assessment*
- ***7.6*** *Document and record review*
- ***7.7*** *On-site assessment*
- ***7.8*** *Analysis of findings and assessment report*
- ***7.9*** *Decision-making and granting accreditation*
- ***7.10*** *Appeals*
- ***7.11*** *Reassessment and surveillance*
- ***7.12*** *Extending accreditation*
- ***7.13*** *Suspending, withdrawing or reducing accreditation*
- ***7.14*** *Records on CABs*
- ***7.15*** *Proficiency testing and other comparisons for laboratories*

ILAC Resolution GA 16.21 (On the Transition to 15189:2012)

Noting the results of the ISO ballot completed for ISO FDIS 15189 on 11 October 2012, the General Assembly agrees that by 1 March 2016, all references to ISO 15189 in accreditation certificates (as defined and described in ISO/IEC 17011), shall refer to the latest edition of ISO 15189. Compliance will be determined during normal surveillance or reassessment activities or as a separate activity.

At the end of the transition period, accreditation of a laboratory to ISO 15189:2007 will not be recognised under the ILAC Arrangement.

Current Requirement from 17011 and IAF/ILAC A Series Documents

There is currently no set requirement for the number of files regarding suspensions, withdrawals or transitions to a new version of the applicable CAB standard to be reviewed during an evaluation contained in ISOIEC 17011: 2017. Review of the current clause 2.1.1 of IAF/ILAC A2:2018 is not useful as it also makes only generic and non-specific reference to 17011. However, a representative number of files 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:

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.

Acceptable / Possible solutions

Records of what was reviewed may now need to be captured on APAC FRMA-012 (specimen attached to Issue 01)

Case Study 8 – Sufficiency of examination of CAB files

Scenario:

During a re-evaluation, the APLAC Team Leader did not consider the following requirements during evaluation:

- The AB's suspension and withdrawal of accreditation for CABs within a specific technical discipline
- Checking CAB files other than the two which were witnessed within the same technical discipline
- The transition of accredited CABs to the new version of the applicable CASCO standard by the end of the transition period agreed by ILAC and APLAC, in this specific discipline.

Although the previous APLAC re-evaluation was conducted before the end of the transition period, no confirmation was made during this re-evaluation to determine if all applicable CABs had demonstrated conformance to the new requirements in the timeframe allotted for this change. In addition, there were two of the same type of CABs on the AB website that were accredited against the previous version of the standard for which renewal of accreditation was 6 months after the end of the transition period.

The Team Leader did not believe that reviewing more files would have added useful information to the evaluation. There was nothing to indicate a problem and reviewing more files was not considered valuable to the overall success of the evaluation. Since the AB had already declared full transition conformance, it was not deemed necessary to check this fact.

Questions to Lead Evaluators:

- Does this circumstance/condition conform to evaluation requirements?
- Does declaration to MRA Council by an AB of conformance to special requirements and timelines relieve the evaluation team of the need to confirm implementation of conformance?
- What are the conditions that a Team Leader may encounter that allows them to view only the CAB files to be witnessed and no others in order to conclude conformance to accreditation requirements?