

## ISSUE 03 – REVIEW OF ASSESSOR UNDERSTANDING AND IMPLEMENTATION OF AB REQUIREMENTS

### APAC Lead Evaluator Training Objectives:

Discuss methods to review and confirm assessor understanding of AB requirements during the witness activities of an evaluation.

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

ITEM	CONSIDERATION
DM CN # 1	<p>The APLAC peer evaluator has raised a comment regarding the availability of a procedure for test samples (from a PTP) provided by the AB to the labs; however it was noticed in witness no.2 that one of the technical assessors had introduced a test sample (qualitative) to the lab without the involvement of the AB (which is not allowed by the AB). While the representative of the AB observing the witness did not object that; the APLAC peer evaluator did not raise it in the finding.</p> <p>IAF/ILAC A2, Clause 2.1.1 &amp; 2.2.1.4</p>
Date	Response from the Region
26 March 2018	<p>I am surprised that this is recorded as a concern as I saw this approach as one assessor's mechanism for establishing the knowledge of the staff in the laboratory involved in the reading of blood films. The approach was friendly and provided a means by which the assessor and the laboratory staff could discuss and demonstrate their knowledge. It is a perfectly legitimate approach.</p> <p>The approach was however discussed with the AB to establish if this was how all assessors did this and we were advised "no" but that the AB were fine with it. The laboratory staff were too.</p> <p>The comment that the AB do not allow this approach is not understood. Perhaps this could be clarified?</p> <p>I did not raise it as a finding as I do not consider it to be a finding.</p> <p>I also wonder about the citing of ILAC A2 Clauses 2.1.1 and 2.2.1.4 in this case.</p>
Date	Reaction from the IAF / ILAC evaluation team
2018/05/30	<p>Please consider the grading for concern mentioned in ILAC A1.</p> <p>The ILAC Team clarifies that AB#3 document RM300 "Guidance on Accreditation Criteria - Medical Laboratories" states on page 18 "ANNEX A Basic Approach to Proficiency Testing" that:</p> <p>"2. Types of proficiency testing (external accuracy control survey)</p> <p>a) Proficiency testing (external accuracy control survey) programs</p> <ul style="list-style-type: none"> <li>• National Medical Association: medical examination accuracy control survey</li> <li>• National Association of Medical Technologists: medical examination accuracy control survey</li> <li>• National Registered Clinical Laboratories Association: accuracy control survey</li> <li>• National Federation of Industrial Health Organization: medical examination accuracy control survey</li> <li>• College of American Pathologists (CAP) Surveys</li> <li>• Medical examination accuracy control surveys organized by prefectural governments (associations of physicians and laboratory technologists)</li> <li>• Proficiency test provided by ISO/IEC 17043 accredited proficiency testing provider</li> <li>• Other, proficiency tests acknowledged by medical technical committee.</li> <li>• On-site practical examination provided by AB#3"</li> </ul> <p>This last option b) is stroked out in the document and not accepted anymore.</p> <p>The finding cannot be closed due to the absence of corrective actions or sufficient clarification.</p>
Date	Response from the Region

ITEM	CONSIDERATION
2018/09/04	The APLAC Secretariat contacted AB#3 in relation to the use of on-site practical examination as part of the assessment to ascertain whether this was one off occurrence and how AB#3 has advised its technical assessors of the change to the AB document RM 300. AB#3 advised that it stopped the use practical examination and also revised AB#3 QPL 702 and QPL 704 to remove such procedure. Please find attached the response to APLAC Evaluation Team for the finding in question and associated evidences including revised documents. Records and materials of medical assessor training in which AB#3 advised all medical assessors that the AB stopped practical examination at on-site assessment and revised QPL 702/QPL 704 to delete the relevant parts of relevant descriptions is attached.
Date	Reaction from the IAF / ILAC evaluation team
2018/10/28	The focus should be on why the APLAC PE Team did not recognize the non-compliance with the AB procedures.
Date	Response from the Region
2018/11/19	The Lead Evaluator Training in 2019 will emphasise that the evaluation team need to ensure that compliance against AB procedures are evaluated and any non-compliances with the AB procedures raised.
Date	Reaction from the IAF / ILAC evaluation team
2018/12/26	Corrective action accepted and finding can be closed.

### **IAF/ILAC A2:2014, §2.1.1 & 2.2.1.4**

*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.*

*2.2.1.4 Ensure that it meets the relevant requirements for proficiency testing activity (ILAC applicant and signatory ABs: see ILAC P9);*

### **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

### **Current Requirement from 17011 and IAF/ILAC A Series Documents**

While this finding appears to have been changed by the ILAC team from understanding and evaluation of AB PT policies and procedures, to be more about evaluators understanding and evaluation of AB policies and assessor implementation of them as a whole, it is noted that neither the original direction of the finding nor its re-interpretation by the ILAC team would have had any impact on either the validity of the CAB work or the equivalence of the AB accreditations – both of which must remain central to any evaluation.

The most telling requirement within ISO/IEC 17011:2017 as regards examination of evidence to determine competence of a CAB is contained in clause 7.6.1 dealing with conduct of assessments, which is itself a follow-on from 17011:2004, clause 7.7.2.

**7.6.1** *The accreditation body shall have documented procedures for describing the assessment techniques used, the circumstances in which they are to be used and the rules for determining assessment durations. The procedures shall include how the accreditation body will report the assessment findings to the conformity assessment body.*

As regards the implication that the AB assessors were not following AB policies, those requirements are contained in clause 6.2.4 of 17011:2004 and in clause 6.1.2.3 of 17011:2017.

**17011:2004, clause 6.2.4** *The accreditation body shall ensure that assessors and, where relevant, experts*

- a) are familiar with accreditation procedures, accreditation criteria and other relevant requirements,*
- b) have undergone a relevant accreditation assessor training,*
- c) have a thorough knowledge of the relevant assessment methods,*
- d) are able to communicate effectively, both in writing and orally, in the required languages, and*
- e) have appropriate personal attributes.*

**NOTE** *Guidance on personal attributes may be found in publications such as ISO 19011.*

**17011:2017, clause 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.*

### **Acceptable / Possible solutions**

The witness form in IAF/ILAC-A3:01/2018 contains consideration of the knowledge of AB policies and procedures demonstrated by assessors. Evaluators are reminded that these must be considered during an evaluation.