

Lead Evaluator Training Course Case Studies

Case Study 1 – Grading Findings.

Definitions currently contained in IAF-ILAC A3 02 2018.

Nonconformities

Finding where the AB does not meet a requirement of the applicable standard(s) e.g. ISO/IEC 17011, its own management system or the Regional Body requirements.

Concerns

Finding where the AB's practice may develop into a nonconformity.

Comments

Finding about the AB's documents or practices with a potential of improvement but still fulfilling the requirements.

Questions to Lead Evaluators:

- Which of these definitions point to a condition that clearly does not meet written specification?
- Which of these definitions is really only a suggestion about how an AB may improve or enhance their operations, without there being any current problem with meeting written specification?
- Which of these definitions point to a condition that currently meets specification, but demonstrates a risk to not doing so in the future?

Case Study 2 – Determining Conformance to A5

Scenario:

During an evaluation, the peer evaluator for inspection did not appear to consider the following requirements of IAF-ILAC A5- “Multi-Lateral Mutual Recognition Arrangements Application of ISO/IEC 17011:2004,” specifically:

- M.6.3.1.1 Personnel to be monitored also includes experts involved in the assessment.
- M.7.7.3.1 Inspection body Accreditation

As part of the pre-evaluation meeting (and post-witnessing meeting), the Team Leader asked the evaluators to examine monitoring records of the assessors. The Team Leader assumed that the evaluators would include the review of technical experts, but they did not specifically ask them to review the records for technical experts.

As well, the Team Leader instructed the AB on how many and what type of assessments to be witnessed but they did not follow up to ensure that the AB were responsible for the selection of the inspections and the inspectors to witness. This was an oversight of the Team Leader and not one that the evaluator would be expecting to be responsible for checking.

Questions to Lead Evaluators:

- Does this circumstance/condition conform to evaluation requirements?
- Which member of the evaluation team is responsible for ensuring that sufficient assessment personnel records are examined to provide evidence of conformance by the AB?
- At which planning or execution points, could communication have been used to avoid these two conditions? Who would be expected to participate in this communication?

Case Study 3 – Re-visiting CABs for witnessing assessments

Scenario:

During a re-evaluation, the AB selected the same CABs as those witnessed in the last peer-evaluation, although the AB had 22 CABs accredited in this conformity assessment discipline.

It was noted that, with small programs, the availability for witnessing activities is limited and depending on the ABs surveillance intervals the same facilities may be the only facilities due to witness.

Questions to Lead Evaluators:

- Does this circumstance/condition conform to evaluation requirements?
- Who provides the Team Leader with the information on CABs visited during the previous evaluation?
- At which planning or execution points, could communication have been used to avoid a potential problem described in this scenario? Who would be expected to participate in this communication?

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

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 6 – Working with other Evaluation Teams operating concurrently

Scenario:

During a re-evaluation, the timetable prepared by the Team did not contain sufficient detail to ensure that the office evaluation covered all the relevant requirements and accessed the relevant AB staff in a coordinated and efficient way, which was occurring at the same time as another evaluation team from another region was present and conducting their own.

Each team member was given a list of clauses and documents to review. It would have been difficult to provide more detail in the schedule so far before the office visit as the AB staff members dealing with each aspect were unknown. With two evaluation teams looking at similar issues and a limited number of AB personnel this was difficult to coordinate.

The peer-evaluation from the other region provided significant challenges to coordination

Questions to Lead Evaluators:

- Does this circumstance/condition conform to evaluation requirements?
- Does the presence of another evaluation team onsite at the same time enhance the need for detailed planning as foreseen in APLAC MR011?
- What steps can be taken to ensure that the work of the two teams is sufficiently coordinated to ensure the success of the APLAC, if not both, evaluations, with a minimum of difficulty caused to the AB staff?

Case Study 7 – Overloading the work of the Team Leader

Scenario:

During a re-evaluation, the TL assigned themselves several other functions (calibration, PTP and RMP, plus mentoring a provisional evaluator for calibration and PTP). This restricted their availability to perform in a thorough and complete manner all the functions assigned, specifically those of the Team Leader. The actual onsite effort was also complicated by differences of approach between the APLAC team and a concurrent evaluation team from another region.

An observer questioned whether there would be sufficient effort from the TL for the conduct of TL functions, or whether an extension of the duration of the peer-evaluation for the TL would be considered, given the need for complete dependence on interpreters for reading and communicating.

In fact, the RMP evaluation took place a full month after the observer raised their concern.

Questions to Lead Evaluators:

- Does this circumstance/condition conform to evaluation requirements?
- Does the presence of another evaluation team onsite at the same time increase the workload of the TL?
- Does the requirement for simultaneous interpretation during an evaluation increase the workload of the team?
- Under conditions such as described in this scenario, discuss how much of the work of the TL can be directed to actual evaluation of conformity assessment disciplines and how much can be directed to the coordination function associated with leadership of the team.

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 which renew 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?