

Key:

Notes in RED indicate their inclusion in the next New Evaluator Training Course material

OVERALL NOTES:

Here are the issues the Lead Evaluators raised for resolution:

- FMRA-012 is not called out in IAF/ILAC A3 and evaluators want to know the justification for its use, especially the second half of the form. We know it is called out in both MR 001 and MR 006, but not IAF/ILAC A3, which is supposed to be the basis of an evaluation report. It may also be considered to include the information from this form within the narrative portion of the evaluation report.
- The ECR does not include FMRA-012 in the list of records to submit with the evaluation report
- Evaluators need guidance in applying risk assessment during an evaluation. Guidance in the form of factors to consider in their risk assessment is needed (perhaps in MR 006)- such as:
 - accreditation schemes reviewed last time
 - numbers of CABs in affected schemes
 - impact of affected schemes on recognition - or other regulatory specification/recognition
 - experience of the evaluation team and type of evaluation visit
- Trace will take the issue to ILAC regarding the ability of evaluators to make subjective determination of conditions not impacting the equivalence of accreditations and therefore not raising a clear non-conformance when its impact is not an issue.
- Some APAC document should contain guidance to the effect that evaluators should not provide feedback to assessors (other than for clarification of issues in accordance with page 38 of A3) following witness activities as their issues are for the AB and not the assessors - and promote this idea in the evaluator training.
- MRA 005 contains wording that the conduct of evaluations from multiple regions should result in the appointment of either the lead from APAC, or a deputy lead from APAC - someone with enough experience to ensure APAC regional requirements are examined. If the TL is from APAC, consideration should be given to request a deputy TL from the other region.
- Wording in MRA006 may contain wording that TLs of complex, multi-disciplinary evaluations, may wish to consider their workload of both leading the team and evaluating specific conformity assessment disciplines. It is possible that a TL of a very large team may only conduct TL duties.
- Modify MRA 004 clause 3.2.3.1 (b) to require nominated evaluators to have 3 years of assessment experience, with a current grade of lead assessor, prior to nomination.
- While the definitions of findings are fairly clear, it appears that evaluators need some formal permission to exercise discretion that is not offered to auditors and assessors - based on their assessment of the risk that a noted condition or circumstance may have on:
 - The equivalence of their accreditations to those of their MRA Partners
 - The equivalence of the CAB results generated within their accreditation schemes
 - The impartiality of the AB decisions
- It is felt that evaluators should have the latitude to downgrade NCs (those that meet the definition) but do not provide any risk to the AB, its operations, or the equivalence of its CABs and their accreditations. At the same time, no evaluator should be allowed to upgrade a finding without clear and objective evidence that links a requirement to an observed condition unless a risk assessment of the condition presents a clear and present threat to the AB, its operations, or the equivalence of its CABs and their accreditations.
- Add wording in MR 001, clause 19.5 that allows Lead Evaluators to relax the timeline for the receipt of Set A and B documents. Any relaxed timeline is at the discretion of the Lead Evaluator. If the AB cannot provide the documentation within the three months specified or the relaxed timeline agreed, then the Lead Evaluator can inform the Secretariat of the inability to conduct the evaluation because of lack of sufficient preparation.

- Extra-national evaluation activities are not covered very well in our current processes. MRAMC (raised by Jennifer) should look at ways to allow an evaluation to include some continuous activities, including witnessing of foreign CABs, during the four years of the evaluation. Reporting to MRA Council may now include witnessing reports separate from the full report.
- Some folks want us to allow time to examine the effectiveness of the evaluated AB and not just collect evidence of conformance/compliance. This might be a project that APAC can undertake. This may include witnessing internal AB activities, committee meetings, board meetings, accreditation decision making etc.
- APAC may consider modifying MR 006 to allow witnessing of previously witnessed CABs depending on the aim of the specific evaluation and the other considerations of that evaluation.

DAY 1 NOTES

Issue 1 – Sufficiency of CAB file review - See Comments Above

- ECR needs to be updated to include the need to complete FRMA-0012 and provide with the assessment records
- Expand MRA-006 to include additional guidelines with regard to the records to be reviewed re CAB files.

Issue 2 – Review of transition plans from revisions of CAB standards

- Clearly identify in IAF/ILAC A3 what the status of transitioned labs may be, at the time of the evaluation – recommendation that IAF/ILAC A3 be expanded / amended
- Include in MRA-006, for the evaluation team to confirm the status and report on transitioned CAB's where a transition may be undertaken in the period since the last evaluation
- Answer to question 3 – no instances (other than a very limited number of CAB's), would there be any circumstances where the only files reviewed would be those witnessed.

Issue 3 – Review of assessor understanding and implementation of AB requirements

- No issues raised.

Issue 4 – Debriefing of the assessment teams by witness evaluators

- To provide information to the new evaluator training what feedback can/cannot be provided to assessment teams (none) and the difference between this and seeking clarification with regard to the activities witnessed (as indicated by the witnessing report in IAF/LAC A3).

Issue 5 – Grading of evaluation findings

- No feedback to secretariat required.

DAY 2

Objectives review

- Discussion around flexible scopes:
 - With regard to IB scopes – not really done or completely possible but some options in the draft G28
- Confirmed that the requirements for competence of the decision makers as per 17011 was to ensure a robust process was in place and was not intended for the decision makers needing to be technically competent to review (reassess) each parameter for which accreditation is recommended / granted. By ensuring that all Lead Evaluators are clear on how this is applied will hopefully suffice to ensure consistency of review.
- Do we need something in MRA-006 to remind evaluators to look at how decisions are made where they fall outside the scope of the accreditation decision makers – exceptions to the rule?
- Knowing more about the other side (ILAC/IAF) – now we have deputy team leaders, they should be appointed to cover whatever the team leader is not i.e. TL from ILAC, DTL from IAF.
- Clarification that the evaluation team is evaluating that the AB has conducted an evaluation of their risks.
- Ensure that the next evaluator training covers evaluation of processes, without necessarily requiring a documented procedure. 17011 is clear about this which processes require a **documented procedure**; not every requirement requires a document procedure.

Issue 6 – Ensuring conformance to requirements from all affected regions in multi-regional joint evaluations

- See MRA-005
- Add note to MRA-006 re have sufficient input from IAAC and APAC to the make-up of the team

Issue 7 – Allowing enough time for team leader evaluation duties

- Add wording in MR 001, clause 19.5 that allows Lead Evaluators to relax the timeline for the receipt of Set A and B documents. Any relaxed timeline is at the discretion of the Lead Evaluator. If the AB cannot provide the documentation within the three months specified or the relaxed timeline agreed, then the Lead Evaluator can inform the Secretariat of the inability to conduct the evaluation because of lack of sufficient preparation.

Issue 8 – Competence of the appeal decision makers

- If the AB has not needed to implement their procedures for the appeals etc. there should at least be a discussion with the AB as to what would happen and how this would be implemented.
- As the new standard is less prescriptive the evaluation teams may need to probe further as to how different processes have been implemented.

Issue 9 – Mechanism to safeguard impartiality

- See Overall Comments Above

Issue 10 – Management of large evaluation teams

- See Overall Comments Above

Issue 11 – Records of technical competence

- Nothing additional that can be added to our processes to ensure a literal interpretation of instructions from the TL is applied by a TM. Review competency of assessment staff should be sufficient.

Issue 12 – Ensuring AB documents are received on time

- Provide documents within the set date or date to be negotiated, and failure to do so could result in the cancellation of the evaluation- add to MRA-001 section 19.
- Applicant AB's would be expected to provide documents within 3 months

DAY 3

Issue 13 – Ensuring different CABs are witnessed

- See Overall Comments Above

Issue 14 – Ensuring review of AB ballot history

- MRA-001 (19.4) states what information shall be provided to the TL. This should be done at the time of the appointment as a package deal (i.e. previous evaluation reports, ballot history, complaints against the AB, etc.). The TL should not need to request this information and should assist in ensuring this is then covered as part of the evaluation

Issue 15 – Ensuring review of evidence of suspensions

- No issues raised.

Issue 16 – Ensuring IAF/ILAC A3 completed before the evaluation

- No change, but need to ensure that the team comments on deviations from the stated AB's commentary are included in the text box.
- Incomprehensible / incorrect information / padding with non relevant material - make it more clear about what was changed by the team.
- Useful to compare information in the previous report's commentary – with what was provided for the upcoming evaluation.