Guidance for ARAC Peer Evaluators for use in ARAC Peer Evaluations

CLASSIFICATION

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AVAILABILITY

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1. Purpose:

This document is intended to provide guidance for ARAC evaluation teams to assist them in conducting the peer evaluations in accordance with the requirements of ARAC MD002.

It is considered necessary for the harmonization of the work of ARAC evaluators during the evaluation process, which includes preparing for, planning and conducting of evaluations in a consistent and comparable manner.

Accreditation Bodies (AB’s) that are subject to evaluations by ARAC evaluation teams against the ARAC MLA requirements can also use this Guidance.

Note: Where it is necessary to perform an evaluation or part thereof remotely, please use this guidance document in conjunction with ARAC GD 002 “ARAC MLAG Policy and Procedure for Guiding Remote Peer Evaluations”.

2. References:

ARAC MD 001 ARAC MLA
ARAC MD 002 Policies and Procedures for a Multi-Lateral recognition arrangement among accreditation bodies.
ARAC PR 025 Structure of the ARAC MLA and procedure to extend the MLA
ARAC PR 030 Procedure for conduct of joint evaluation with another Regional Cooperation
ARAC GD 002: ARAC MLAG Policy and Procedure for Guiding Remote Peer Evaluations
ARAC FM 001: ARAC MLA Application form
ARAC FM 003: ARAC Checklist for Peer Evaluation
ARAC FM 004: ARAC Evaluation Plan Template
ARAC FM 007: ARAC Performance Log for Team Member
ARAC FM 008: Team Leader Evaluator Monitoring Form
ARAC FM 009: ARAC Form for Evaluation Team Performance Review and ARAC Decision Making Process by the Evaluated Accreditation Body
ARAC FM 011: ARAC declaration of impartiality and confidentiality
ARAC FM 020: List of applicable documents and ILACIAFARAC resolutions for the ARAC Peer evaluation purposes

ISO/IEC 17011 Conformity Assessment–Requirements for accreditation bodies accrediting conformity assessment bodies
IAF/ILAC A3 Template report for the peer evaluation of an accreditation body based on IAF/ILAC 17011:2017
IAF/ILAC A-series documents can be accessed at: https://ilac.org/publications-and-resources/joint-ilac-iaf-series/
ILAC P series documents can be accessed at: https://ilac.org/publications-and-resources/ilac-policy-series/
ILAC guidance documents can be accessed at: https://ilac.org/publications-and-resources/ilac-guidance-series/
3. Key issues prior to evaluation

3.1. Information and Documents sent to the Evaluation Team

Each member on the evaluation team will be required to sign and submit to the Secretariat the ARAC FM 011 “Declaration of Impartiality and Confidentiality” before receiving any of the AB’s information.

Thereafter, a complete set of AB documents, as listed in ARAC FM 001 is sent to the PE team by ARAC Secretariat at least three months in advance of the evaluation. The documents of the AB shall include:

- The AB’s management system documentation in which its policies and procedures, and the responsibility for implementation of the quality system are clearly described.
- Full details of the staffing of the AB, including numbers and functions of its operational staff, their backgrounds and length of experience in assessment and accreditation of conformity assessment bodies;
- Accreditation criteria and associated applicable technical criteria that the AB publishes;
  - All other published criteria, including formal rules or regulations that apply to the AB’s operation and the responsibilities and obligations of its accredited bodies;
  - A completed ARAC FM 003 containing a cross-reference table between each clause, sub-clause or specific requirement of the recognition criteria in IAF/ILAC A2 section 2 and the documentation of the AB;
  - The AB’s self-evaluation report against ISO/IEC 17011 and other ARAC requirements. The AB shall complete the relevant parts in sections 3, 4 and 5 of IAF/ILAC A3 Part 2. During the document review, the evaluation team shall review the text and the related/referenced documents provided by the AB to determine, in principle, conformance to the requirements and comment on the text as appropriate;
- ABs for laboratories/inspection bodies:
  - A report on interlaboratory comparisons & proficiency testing activities; and
  - Information about the available sources of metrological traceability, e.g. a list of recent international comparisons in which the economy’s national metrology institute (NMI) or designated institutes have been involved and/or, when applicable, reference to the NMI’s calibration and measurement capabilities (CMC) as published on the BIPM website;
- AB’s for certification bodies – a list of foreign critical locations;
- All procedures and policies required by ISO/IEC 17011;
- In case of re-evaluation – the full report from the previous evaluation, a copy of the ARAC MLA Group’s resolution decision on the previous evaluation, and a list of CABs whose assessments were witnessed at the previous evaluation;

The TL will allocate the relevant documents to the TM’s as needed, who should confirm
receipt and start reviewing the adequacy of the documents to the requirements of ISO/IEC 17011 directly after receipt.

The TL should be able to prepare a part of the report, using IAF/ILAC A3, with background information as provided by the AB before the evaluation. This part of the preparation is the same for all types of evaluations. The total time involved in studying the documentation may take an average of 3 to 5 days for the TL and 2 to 4 days for the team members.

The evaluation team should use the same checklist ARAC FM 003 completed by the AB to record their observations.

3.2. Selection of witnessing activities

It is important that a representative sample of the range of accreditation activities under evaluation is witnessed by the team.

The time schedule and its time span will depend on the scope of the AB’s activities and the geographical area it covers. In case of a multi-economy accreditation body or widespread economy, travelling time and logistics are critical and have to be carefully planned. Additional time may have to be allocated when necessary.

The TL will request the AB to provide a list of assessments in each scope which can be witnessed by the evaluators during the evaluation. This list should include the names of CABs for each accreditation scheme, location, the types of assessment, the technical scope, date of assessment and names of the assessment teams.

The team must select the most appropriate assessments in each scope, where the assessment of all accreditation requirements can be witnessed (see section 4.2).

If it is difficult to identify suitable assessments to witness during the evaluation, witnessing may have to be arranged in the weeks before or after the AB’s office evaluation.

When selecting the assessments to be witnessed, the evaluation team will consider the witnessed assessments in the previous evaluation to avoid selecting the same CAB’s or assessment team.

3.3. Planning and Managing Observers and Trainees in the Evaluation Team

3.3.1. Trainee evaluators

Trainees should be involved in all stages of the evaluation process as if they are members of the evaluation team, including the pre- and post-evaluation activities. The AB under evaluation is responsible to seek the agreement of its CABs for trainees to attend the assessments to be witnessed.

A qualified mentor (an evaluator with experience in more than two evaluations) will be appointed to mentor the trainee evaluators in addition to his/her evaluation tasks. The level of supervision will depend on the experience of the trainee evaluator in performing evaluations.
The mentor will allocate the trainee such tasks that he/she is capable of performing, and will supervise, observe and provide a report to the MLA Group about the performance of the trainee.

Based on the performance report, the MLA Group will decide whether the trainee can be qualified, or whether further training, mentoring or other action is required.

3.3.2. IAF/ILAC observers for the evaluation of ARAC

In the framework of ARAC MLA’s recognition by IAF/ILAC, the regional evaluators of IAF/ILAC will witness the conduct of ARAC evaluations, collectively covering the ARAC evaluations of all scopes of recognition under the IAF MLA and ILAC MRA.

The IAF/ILAC regional evaluators are involved in all stages of the evaluation process, as if they are members of the evaluation team.

This will include the provision of the AB’s documentation, development of the evaluation timetable, logistical arrangements, observation of closed evaluation team meetings, observation of the evaluation opening meeting and the AB’s office evaluation, observation of the evaluation team’s witnessing of the AB’s assessments of CABs, observation of the evaluation closing meeting and lastly the evaluation of ARAC’s decision-making process.

The role of IAF/ILAC regional evaluators is to observe the ARAC evaluation process and not to involve themselves in any way in the evaluation of the AB.

The ARAC evaluation team and the AB under evaluation are required to afford the IAF/ILAC evaluator the necessary cooperation as long as it does not interfere in the evaluation process.

3.4. Team Leader Responsibilities

The team leader shall have the ultimate responsibility for all phases of the evaluation and is delegated by the MLA Group to make final recommendations regarding the conduct of the evaluation.

3.4.1. Assignment after team selection:

The TL shall:
- Obtain from the ARAC Secretariat all the AB’s documentation as per clause 3.1;
- Agree with the AB on all logistical, travel and accommodation arrangements;
- Obtain a list of possible assessments for witnessing from the AB; and
- Agree with the AB on agenda for the evaluation, specifically:
  - The number of days for the evaluation, which may exceed 5 days if necessary;
  - Any need to conduct a witnessing before the AB’s office evaluation;

Guidance for ARAC Peer Evaluators for use in ARAC Peer Evaluations
• Geographical and inter-country flight considerations (for witnessing);
• Assign tasks to team members;
• Obtain the acceptance of the AB to include any observers onto the team.

3.4.2. Assignment prior to the evaluation:

The TL shall:

- Prepare a detailed evaluation plan using ARAC FM 004 for the evaluation and have it endorsed by AB at least one week before the commencement of the evaluation.
- In preparing the evaluation plan, the following shall be considered:
  • Assignment of tasks to each TM;
  • Including a half-day team meeting prior to the start of the evaluation;
  • Allowing for team meetings each evening, if necessary;
  • Allowing extra time for the TL's evaluation in the AB’s office;
  • Advising the AB of days that are not convenient for any formal hospitality functions, e.g. evening of day 1, evening prior to last day
  • Any other arrangements such as the provision of a meeting room at the team’s hotel, the need for interpreters, any dietary requirements for team members, etc.

- Ensure the team members have all necessary AB documents and other briefing documents, as well as evaluation plan FM 004.
- Allocate the AB’s documentation to the TM’s and ensure each member’s participation in the document review, including timeous submission of their feedback on the ARAC FM 003; and
- Ensure that the document review report FM 003 is provided to the AB in sufficient time to allow the AB to respond to any queries or take corrective measures before the evaluation.

3.5. Deputy Team Leader Responsibilities

The role of the Deputy TL is to assist the TL in the planning, preparation and management of the evaluation. The Deputy TL can replace the TL in case of illness or unforeseen circumstances.

4. Key issues during the evaluations

The evaluation team shall take into consideration the following issues during an evaluation.
4.1. Conduct an opening meeting

The TL will start the evaluation with an opening meeting that should covers:
- The team members and the AB staff are introduced.
- The TL outlines the aims, objectives criteria and procedures to be adopted by the evaluation team.
- Impartiality and confidentiality
- A presentation by the head of the AB is given.
- Logistics and any updates to the evaluation arrangements are agreed upon.
- Classification of findings

4.2. Witnessing activities

- It is very important to spend ample time to check on how the AB selects its assessors and experts for a particular assessment. Thorough checking of records from assessments is required, including matching the assessor’s expertise to the scope of the conformity assessment body being assessed and checking that on-site assessment time is adequate to cover the scope of accreditation being assessed.

- The evaluation team shall witness at least:
  - one initial assessment or a re-assessment for every scope. When the witnessing of other on-site assessment activities takes the place of the witnessing of a full assessment or re-assessment, then those activities must include all of the accreditation requirements and assessment of a portion of the scope of accreditation.
  - or two other assessment activities including a portion of the accreditation scope which may each only include parts of the accreditation requirements.

- For certification:
  - The evaluation team should witness the AB assessment team performing the assessment of the body only at the office location.
  - The PE team shall pay particular attention on how the assessment team is assessing the competencies of the CB auditors: competence criteria shall be determined with regard to the requirements of each type of management system standard or specification, for each technical area as defined in ISO/IEC 17021-1 (NACE codes or IAF sub-codes) and that can be define, and for each function in the certification process.

- The assessments witnessed shall involve a range of technical scopes’ representative of the accreditations granted by the AB.

- The evaluation team shall pay particular attention to the procedures used by the assessment team and shall note deviations by the assessment team from the specified requirements when they are observed.

- The evaluation team members shall maintain the role of observer at all times during the witnessing to avoid influencing the performance or procedures of the assessors and the responses by staff of the conformity assessment body being assessed. Any observations made by the evaluation team regarding the organizations under assessment, the assessors, the AB’s staff or the AB’s
procedures may be made after the assessment.
- The IAF/ILAC Witness Report in Annex V of ILAC/IAF F1.1 A3/2018 “Reporting on the Performance of an AB” shall be used by the evaluation team to report on the witnessing activities. The report can be found on the IAF and ILAC websites.

4.3. AB’s offices evaluation:
- The evaluation team shall set aside sufficient time for this part of the evaluation. During this time the team shall hold discussions with a cross-section of the staff operating at all levels in the organization and shall discuss the documentation used by the AB, i.e. quality manual, accreditation criteria, specific procedures, etc., and shall make an appraisal of the effectiveness of the implementation of the documented policies and procedures of the AB, as set out in its quality manual and associated documents. Files, records and archives of the AB shall be checked. The evaluation team shall also evaluate the relationship of the AB with technical and other organizations in its economy, and the existence and content of any MLAs with other accreditation bodies.
- The evaluation team shall follow-up on the findings from the previous evaluation and evaluate the effectiveness of the corrective actions taken. If the effectiveness of the corrective action could not be confirmed that shall cause a new finding in which the history shall be described as well. The team shall use the table described in Annex II to describe the follow-up on the findings from the previous evaluation.
- When the evaluated AB is operating across borders the PE need to have evidences that the AB’s personnel involved in the accreditation process, including who are responsible for the application review, have the knowledge regarding the applicable general regulatory requirements, including the legal entity of the CABs, in the countries where the accredited CAB is located.
- The evaluation team shall decide on sampling of activities and files to be selected and persons to be interviewed based on the analysis of risks and related to the scope of work and the scope of the ARAC MLA;
- The evaluation team shall evaluate how the AB consider the risks related to the operation of a conformity assessment body (CAB) when planning assessments, assessment programs or scope extensions, as referred to in ISO/IEC 17011 clause 7.4.6, 7.9.3 and 7.10.1: Annex I gives a list of risks that may be used to plan assessments (focus and case review), preparation time, assessment time and team.
- The evaluation team shall check that the AB has implemented all the requirements of the relevant ISO (IEC) standard(s). After examination of the management system documentation (or at the same time) the team shall check the extent to which the AB’s accreditation criteria incorporate the requirements of the appropriate ISO (IEC) standard(s) and any ARAC MLA supplementary requirements. A record shall be made of any requirements not covered and of any alternative or additional requirements used.
- For initial evaluations, the evaluation team shall check the internal audit and management review for the last two years, taking into consideration the date in
which the AB has applied for ARAC MLA.

- The evaluation team shall examine any guidance documents provided to the staff of the AB detailing the use and implementation of the accreditation criteria, and any rules or regulations issued by the AB.
- The evaluation team shall check the availability and content of any documents containing additional requirements or guidance to assessors, and conformity assessment bodies.
- The evaluation team shall check the AB’s procedures for issuing accreditation documents, defining the scope for which accreditation has been granted, identifying approved signatories or key personnel, as appropriate, and maintaining such information up-to-date.
- The evaluation team shall evaluate the AB’s ability to address risks and opportunities in its operations and to assess the CABs ability to address their own risks and opportunities.
- For certification, in case of the validation audits are considered by the evaluated AB, the PE team needs to check if the agreement require CABs to allow AB to conduct validation audits.
- Form FM003 can be used to record the team notes or findings.

4.4. Evaluation of Assessors’ competencies

- The AB’s policies and procedures for selecting, training, contracting and appointing internal and external assessors shall be examined. Checks shall be made to ensure that up-to-date records detailing the qualifications, experience, expertise, training and performance monitoring of assessors and, as appropriate, technical experts are maintained. The evaluation team shall ensure that each assessment is conducted by competent personnel familiar with the requirements of the accreditation system, trained in the techniques of assessment, and possessing appropriate technical expertise for their assignment. The evaluation team shall check that the assessment team leader or a member of each assessment team has sufficient knowledge in the evaluation of quality systems appropriate for the accredited or applicant conformity assessment bodies.
- For the monitoring of the AB’s assessors the PE team need to be sure that the AB is monitoring each assessor considering each accreditation scheme for which the assessor is authorized.
- For certification the PE team should pay attention where the AB is considering the audit experience in allocating IAF codes.
- Where accreditation bodies use a staff member as the assessment team leader or as part of the assessment team the same requirements apply.

4.5. Evaluation of assessment reports

The evaluation team shall examine the procedure for reporting the findings of assessment teams. In particular, the evaluation team shall check that any corrective actions required of assessed conformity assessment bodies are carried out within the required time frame, particular attention should be paid if the AB assessment team can accept correction as corrective action (e.g. training activities cannot be
accepted as corrective actions). For certification activities, attention should be paid
on the effective implementation of the witnessing rules as per the IAF MD 16 and MD
17 (e.g. for FSMS if CBs are granting certificates in C1 or C2 etc, witnessing of higher
risk sub categories as part of assessment program should be carried out).

If the assessment findings are subject to endorsement by a committee before a
decision on accreditation is made, records of the decisions of such committees shall
be examined. The evaluation team shall review the AB’s records of the accreditation
process to ensure these are sufficient to justify the accreditation decision.

4.6. Evaluation of committees

Where committees are used to review the reports of assessments, to assist in the
decision-making process or to provide technical advice on criteria, assessors, etc.,
their terms of reference and the procedures for appointment of committee members
and committee members’ competencies shall be examined.

4.7. Evaluation of Proficiency Testing Activities

The policies and procedures of the AB (accreditation of Laboratories and where
relevant, inspection bodies) for proficiency testing shall be evaluated.
The way in which the results of proficiency testing activities are used by the AB shall
be examined.
The evaluation team shall discuss with the relevant members of the AB staff the
following matters:

- Identification of areas where proficiency testing activities are available or
  should be initiated;
- Criteria for selection, organization and use of proficiency testing activities;
- Criteria for accepting proficiency testing activities provided by PT providers;
- Policies and procedures for corrective action when participant results are
  outside the predefined criteria;
- Policies and procedures for Proficiency testing plans developed by
  participants; and
- Criteria for alternative tools when proficiency testing programs are not
  available or not appropriate.

The evaluation team shall establish whether the AB has adequate policies and
procedures to ensure the requirement of Proficiency Testing as addressed in ILAC P
9 are fulfilled.

4.8. Evaluation of Metrological Traceability

If the AB offers accreditation to CABs that use measuring equipment, the evaluation
team shall check the relationship between the accreditation system and the national
or regional measurement system, and the arrangements made to ensure metrological
traceability of the measurement results.

The evaluation team shall evaluate how metrological traceability and associated
estimates of measurement uncertainty are established, wherever applicable, in
accordance with the provisions of applicable ILAC documents and ISO (IEC)
standard(s).
The evaluation team shall establish whether the AB has adequate policies and procedures to ensure the requirement of metrological traceability as addressed in ILAC P10 are fulfilled.

4.9. Classification of findings

All findings from the office evaluation and witnessing activities are discussed by the evaluation team during the evening meetings. The Team Leader comes to a final conclusion of the classification of these findings in consultation with the team members in the last team meeting before the day of the closing meeting.

The PE team shall pay particular attention on the clause(s) of the ISO/IEC 17011 and other mandatory documents for each finding raised by the team.

The classification of some findings may be changed as a result of the comments and discussion with the AB before the closing meeting. The AB may provide evidence or justification in this regard.

The classification of findings is based on the guidance in Part 3 of IAF/ILAC A3:

- **Nonconformity**: Finding where the AB does not meet a requirement of the standard ISO/IEC 17011, its own management system and the Arrangement requirements. The AB must respond to each nonconformity by undertaking a cause analysis, including the extent of the finding and its impact, and by taking appropriate action (correction and/or corrective action).

  The AB must provide the peer evaluation team with evidence of the cause analysis and an action plan and time schedule for implementation of the action. Based on the risk associated with a finding, the AB may also be required to provide evidence of the effective implementation of the action.

  Wherever possible, the need for the provision of such evidence will be stated in the report.

- **Comment**: Finding where the requirements related to the AB’s practices or documented information are fulfilled but there is a potential for improvement. The evaluated AB is encouraged to respond to comments.

The IAF/ILAC Corrective Action and Response Report and Evaluation Team Reply (Current Evaluation) in Annex VI of the ILAC/IAF A3 “Template report for the peer evaluation of an accreditation body based on IAF/ILAC 17011:2017” shall be used by the evaluation team to record the findings and to comment on the AB response to evaluation findings in the same form. The report can be found on the IAF and ILAC websites.
4.10. **Conducting the closing meeting**

Prior to the closing meeting, the AB is given an opportunity to comment on and discuss the evaluation team’s findings and recommendations and to clarify any misunderstandings that may have arisen. The team presents and discusses the findings with the AB.

The AB agrees with the team on the next steps to respond to findings. The evaluation team leaves a draft of the summary report with the AB, which includes the nonconformities and comments presented.

If a follow-up visit is recommended to verify corrective actions, this should be stated if possible, and documented in the draft summary report.

In case of conducting a peer evaluation at different phases the reporting should be done at the end of each phase.

4.11. **Team Leader responsibilities during the evaluation**

- Lead the opening meeting and ensure any queries from team members have been clarified with AB.
- Ensure the evaluation remains on track.
- Ensure team members gather sufficient objective evidence to support their findings.
- Mentor less experienced team members.
- Ensure the AB receives feedback, as appropriate, throughout the evaluation.
- Gather information from the team members each evening (if geographical location and channels of communication allow):
  - Main meeting in the evening of the evaluation period to allow areas for follow-up to be identified and assigned to team members;
  - an evening meeting prior to the last day when findings should be finalized as far as possible
- Ensure team discussions remain on track.
- Ensure team members’ findings are based on clear and objective evidence, are correctly classified and correctly assigned to clauses of ISO/IEC 17011.
- Prepare the summary section of the evaluation report including as an appendix the nonconformities and comments presented, preferably in table format, for presentation to the AB at the closing meeting.
  - The draft of the summary report should highlight any findings that are recurrences of findings from the previous evaluations.
  - The draft of the summary report should be reviewed for comment by the AB prior to the closing meeting.
- Ensure during closing meeting that any misunderstandings are clarified, disagreements resolved.
5. Key issues after evaluation

5.1. Team responsibilities after the evaluation

- The team members receive feedback and responses to findings from the AB through the TL.
- The AB responds to the TL on all nonconformities by providing evidence of a cause analysis and an action plan and time schedule for implementation of the action. Based on the risk associated with a finding, the AB may also provide evidence of the effective implementation of the action.

  Note: Responses from the AB must be received:

  - within one month of receipt by the AB of the draft report for re-evaluations; and
  - within three months of receipt by the AB of the draft report for initial evaluations and extensions of scope.

- The evaluation team needs to spend time on reviewing the AB’s response and/or corrective actions as well as on the preparation of the evaluation team’s comment to these corrective actions.
- The evaluation team’s reaction to each response to every finding is submitted in writing to the AB for consideration.

  Note: The evaluation team’s responses must be submitted within one month of receipt of the AB’s formal response to the findings.

  This process may be repeated until acceptance of the corrective actions by the team.

5.2. Team Leader responsibilities after the evaluation

- Provide a draft full report, agreed among the team members, to the AB for comment and correction of factual errors (if necessary) within two months of the closing of the evaluation visit.
- This draft report includes the results of the witnessed activities and the full text of the summary report that has been provided at the end of the evaluation visit.
- Review the AB’s corrective action and response report, assigning parts to team members, as applicable.
- Ensure the AB provides evidence of identification of correction and/or corrective actions with the root cause(s) of nonconformities.
- Advise the AB if the response is acceptable within one month of its receipt.
- Once the team is satisfied that the AB’s response is satisfactory and all necessary corrective action has been taken, prepare a recommendation to the ARAC MLA Group.
- Prepare the final evaluation report within one month from the team’s satisfaction with the AB’s response. The report is prepared as included in IAF/ILAC A3 Part 2 “Template report for the peer evaluation of an accreditation body based on IAF/ILAC17011:2017”. This template is to assist evaluation teams to provide a consistent reporting framework for ARAC decision-making.
- Communicate the final evaluation report with the evaluation team members for their review and any amendments before sending it to the AB for final review.
- Send the full final evaluation report and a list of the CABs whose assessments
were witnessed during the evaluation in a separate file to ARAC MLA secretariat.

5.3. Important aspects of the final peer evaluation report

- The ILAC/IAF A3 “Template report for the peer evaluation of an accreditation body based on IAF/ILAC 17011:2017” can be found on the members area of the IAF and ILAC websites as a word document to assist the AB and the evaluation team in their preparation of the report.
- Ensure that the report is written fully in English.
- Ensure that the blue texts which provide guidance/instructions for the AB and the red texts which indicate guidance/instructions for the TL when using the report template are deleted from the final report.
- Ensure that all parts including the annexes of the report do not include names of the assessors or names of the CABs whose assessments were witnessed during the evaluation.
- Ensure that the "Team Conclusion" text box after each major section includes:
  
  o Sufficient objective evidence of conformance (or non-conformance) obtained during the evaluation;
  o Information regarding requirements not mentioned in the narrative provided by the AB;
  o The results of verification of the information provided by the AB as evident in records and other evidence;
  o The findings or reference to the findings, where applicable; and
  o Conclusions related to each major section.

- Ensure that the report includes updated information including numbers, figures, charts, etc.
- Remember that the target audience for this report are the ARAC decision-makers, so the text shall be a comprehensive narrative. If references are made to the AB’s documents or procedures, a sufficient description shall also be provided.

6. Key issues during and after the decision making process

The ARAC MLA Group is responsible for reviewing the PE report and they can request additional information and/or evidences, the PE team is expected to provide all the requested additional information and to amend the report if needed.

6.1. Team Leader responsibilities

- Respond to any queries or requests for information by the MLA Group. The TL may need to refer to the evaluation team or the AB under evaluation before responding to the MLAG.
- Revise the final evaluation report, if needed and provide the revised report to the MLAG as part of his response.
- Present a verbal report to the ARAC MLA Group when required, summarizing the team’s findings and reporting on the team’s recommendations.
- Within one month of completion of the decision-making process, provide the MLA Secretariat with reports on the performance of each team member, using the ARAC form “FM 007: ARAC Performance Log for Team Member”.

6.2. Team members responsibilities

- Cooperate with the TL and respond with the information that may be needed to provide clarification to the MLA Group.
- Within one month of completion of the decision-making process, each team member must provide the Secretariat with a report on the performance of the TL, using the ARAC form “FM 008: Team Leader Evaluator Monitoring Form”.
### Risk area

<table>
<thead>
<tr>
<th>Activities</th>
<th>Risks to the fulfilment the accreditation requirements by CAB</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>• complexity of the scope of accreditation (e.g. number of different competences required by the AB to cover the scope);</td>
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<tr>
<td></td>
<td>• organisation of CAB (e.g. number of sites, geographical distribution, foreign sites, multiple management system for different departments/standards);</td>
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<tr>
<td></td>
<td>• complexity and criticality of external requirements and rules for specific sector (e.g. diversity of regulatory texts and requirements);</td>
</tr>
<tr>
<td></td>
<td>• general levels of competence and compliance in the sector the CAB operates in (e.g. critical findings, complaints, market surveillance that occur in CABs operating in the same sector);</td>
</tr>
<tr>
<td></td>
<td>• volume and frequency of services provided to clients i.e. number of certificates, testing reports etc.;</td>
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<td>• outsourcing of activities that form part of the CAA process including use of use agencies, auditing companies, franchisees etc.;</td>
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<td>performing other activities which can possibly interfere or conflict with CAAs (e.g. consultancy, regulatory activities – both legislative and executive, manufacture of product under test);</td>
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<tr>
<td>Risk area</td>
<td>Risks to the fulfilment the accreditation requirements by CAB</td>
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<td>• changes to factors critical to the ongoing validity of CAAs the CAB is accredited for, such as:</td>
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<td>- company ownership;</td>
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<td>- key personnel;</td>
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<td></td>
<td>- location;</td>
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<td></td>
<td>- equipment.</td>
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<td>• use of remote working/virtual locations (i.e. when individuals spend a high proportion of their time working independently away from a centralized location);</td>
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<td>• CAB operates a flexible scope;</td>
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<td>• historical performance in external monitoring activities (e.g. proficiency testing or interlaboratory comparisons);</td>
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<td>• historical performance on the effective and prompt clearance of non-conformities;</td>
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<td>• historical performance in conducting effective root cause analysis;</td>
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<td>• historical performance in relation to significant non-conformities;</td>
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<td></td>
<td>• history of sanctions (full or partial) e.g. suspension, scope reduction, etc.;</td>
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<td>• history of requiring supplementary or extraordinary assessments during the accreditation cycle;</td>
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<td>• upheld complaints, sector feedback, whistleblowing, etc. in relation to the operation of the CAB;</td>
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</table>
### Risk area
<table>
<thead>
<tr>
<th>Risk area</th>
<th>Risks to the fulfilment the accreditation requirements by CAB</th>
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</thead>
</table>
| **Personnel** | - competence and experience of CAB's personnel;  
|           | - turnover of CAB's personnel (in comparison to industry norms);  
|           | - resource capacity and capability to provide CAAs in timely and competent manner;  
|           | - ratio of newly employed to experienced personnel for specific functions (especially related to conformity assessments activities).  |
| **Locations** | - level of control and monitoring demonstrated by the CAB for any satellite location;  
|           | - criticality of activities performed at satellite locations (e.g. process development and approval, contract review, decision making, competence approval and monitoring of personnel);  
|           | - type of location – permanent, temporary, mobile;  
|           | - geographical spread of locations results in differences in language and culture, particularly consistency in application of policies, procedures & methods.  |
## Annex II_ Follow-up on Previous Evaluation Findings

<table>
<thead>
<tr>
<th>Number and Classification of the finding from previous peer evaluation</th>
<th>Team Comments / Conclusions</th>
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<tbody>
<tr>
<td>NC #xx</td>
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<td>Cm #xx</td>
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