TEMPLATE REPORT FOR THE PEER EVALUATION OF AN ACCREDITATION BODY BASED ON ISO/IEC 17011:2017

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FURTHER INFORMATION

For further information on this document or other Global Accreditation Cooperation Incorporated (Global ACI) documents, contact the Global ACI Secretariat.

Email: secretariat@global-aci.org

Phone: +1 (571) 569-2614

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PART 1. INTRODUCTION

1.1 The Purpose of This Document in the Peer Evaluation Process

1.1.1 Peer evaluation aims at establishing confidence whether accreditation bodies (ABs) are reliable and competent to deliver services according to standards or normative documents. As a result of a positive evaluation outcome, the AB can join an Arrangement between ABs, confirming reliability and competence to the market.

1.1.2 The purpose of this document is to provide a tool for the evaluation and report preparation process, allowing an AB under evaluation to present information, facts and figures about its performance and to provide a means for the evaluation team to present confirmation of this information within the evaluation report. This document indicates where information is needed to provide a complete description and full picture of the operations of the AB. Thus, facts and the results of the implementation of policies should be reported on, and supported by evidence gathered by the evaluation process.

1.1.3 While findings can only be raised against the requirements of the Arrangement, descriptions of the details of the AB operations in regards to these identified requirements shall also be provided in appropriate detail. Such reporting provides the evaluation team and the decision-making group of the Arrangement with a concise picture of the capabilities and performance of the signatories and applicants and enables sound recommendations and decisions.

1.1.4 This reporting template shall be used by the Regional Cooperation Bodies, as a template to assist the evaluation teams in providing a consistent reporting mechanism for an AB under evaluation and the decision-making groups.

1.1.5 Not all the specific items included in this document are applicable to all situations and the AB under evaluation. The peer evaluation team shall verify that the facts stated in the AB's submitted description are valid for all Arrangement scopes of the AB. If the policies, procedures or outcomes in the Arrangement scopes are different, the situation shall be clearly described.

1.2 The Use of This Document for the Application and Peer Evaluation Process

1.2.1 Prior to the evaluation, the AB shall complete the relevant sections of the evaluation report template included as Part 2, section 3, 4 and 5 of this document, including:

- Fully addressing all ISO/IEC 17011 requirements and other Global ACI mandatory documents; and
- Also addressing any other requirements as determined by their Regional Cooperation Body.

This draft report will be submitted to the peer evaluation team as part of the application documents. The peer evaluation team will thus be able to verify the accuracy of the text provided by the AB and obtain a sense of the AB's comprehension of the requirements and their approach for conformance to those requirements.

1.2.2 The sections and clauses included in the report template in Part 2 of this document are accompanied with specific explanations to assist the AB and evaluation team to complete the report template. A concise picture of the accreditation body's activities assists in the effective review and planning of the evaluation and helps the Arrangement members to understand the processes in the AB.

1.2.3 The target audience for this report is the Decision-Making Group 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, though inclusion of the full content of referenced documents or procedures is not required.

1.2.4 The evaluation team, as part of its preparation, 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. The output of this process, functions as a summary of the policies and process found in the accreditation body's documents.

1.2.5 During the evaluation visit, the team shall explore whether the information provided by the accreditation body is evident in the records and other evidence they encountered. The evaluation team shall record its conclusions in the specific report sections. The evaluation team should also include a description about other Arrangement requirements not mentioned in the narrative provided by the AB if those are essential to understand the AB's operations and performance. The findings or reference to the findings shall be included in the description, where applicable. The final revised report template as amended during the peer evaluation process shall constitute the evaluation report.

1.2.6 Global ACI-FMRA-018 *Reporting on the Performance of an AB* can be found on the Global ACI website as a Word document to assist the AB and the evaluation team in their preparation of the report.

Note: The blue text provides guidance/instructions for the AB and the red text indicates guidance/instructions for the TL when using the report template. This text will be deleted from the final report.

PART 2. TEMPLATE REPORT ON PERFORMANCE OF THE AB

<<insert report status (draft #, final)>> REPORT ON THE *<<type of>>* EVALUATION OF THE

<<insert AB full name (and acronym)>>

BY THE

<<REGIONAL COOPERATION BODY>>

<<insert dates of on-site evaluation>>

EVALUATION TEAM MEMBERS:

<<insert name, accreditation body, economy & role for each team member e.g. Mrs Eve Aluator (AB1, New Zealand) – Team Leader
Mr E.M.C. Nerd (AB2, USA) – Evaluator
Dr Cal Ibrator (NMI, Australia) – Technical Expert A.N Other (LOTR AB, Middle Earth) – Evaluator Etc., etc.>>

OBSERVERS:
Ms N.O.Z. Parker (AB 4, USA)
A. Regulator (Japan) Department of Good Regulatory Practice, etc.
etc.

This Report is
CONFIDENTIAL
to the
<<insert name of AB>>
Evaluation Team Members
Members of the Regional Cooperation Body Decision Making Group

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Note: This template is to assist evaluation teams provide a consistent reporting framework for decision-making groups. Individual regions may include additions (as necessary) to meet their needs without changing the content of this document.

SECTION 1: SUMMARY OF FINDINGS

<<This section must be completed by the evaluation team, and presented to the AB, normally on the last day of the on-site evaluation. It would normally be produced and signed as a separate document and inserted into the evaluation report in this section. Once accepted by the AB at the conclusion of the on-site evaluation and signed by all members of the evaluation team it cannot be changed. The following is a possible template for presentation of the Summary of Findings but the evaluation team must ensure the wording is relevant to the scope of the evaluation. This template does not attempt to cover all eventualities.>>

(Note: This summary was presented to *<<insert acronym of AB>>* on *<<insert date>>* following conclusion of the evaluation. The original signed copy is maintained by the Regional Cooperation Body Secretariat.)

This is a report on the *<<type of evaluation e.g. initial, periodic re-, etc.>>* evaluation of the *<<insert full name and (acronym) of AB>>* on behalf of Regional Cooperation Body for the purpose of obtaining evidence to determine:

(a) *<<for a re-evaluation>>* Whether the Regional Cooperation Body Mutual Recognition Arrangement (MLA/MRA) signatory status of *<<insert acronym of AB>>* for the accreditation of *<<insert MLA/MRA scope of the AB e.g. testing laboratories (ISO/IEC 17025, ISO 15189), calibration laboratories, inspection bodies, reference material producers, proficiency testing providers, biobanking, managements system certification bodies for QMS, EMS, FSMS, ISMS, MDMS, product certification bodies, certification bodies of persons, validation and verification bodies>>* should be maintained; *<<and/or>>*

(b) *<<for an initial evaluation or MLA/MRA scope extension evaluation>>* Whether *<<insert acronym of AB>>* should be recommended as a full signatory to the Regional Cooperation Body MRA/MLA for the accreditation of *<<insert evaluated scope for which AB has applied e.g. testing laboratories (ISO/IEC 17025, ISO 15189), calibration laboratories, inspection bodies, reference material producers, proficiency testing providers, biobanking, managements system certification bodies (ISO/IEC 17021-1) e.g. for QMS, EMS, FSMS, ISMS, MDMS, product certification bodies, certification bodies of persons, validation and verification bodies >>.*

The evaluation was conducted in accordance with, and against the requirements specified in *<< Global ACI MRA-005 Requirements and Procedures for Evaluation of a Single Accreditation Body or Regional Cooperation Body Procedure xxx >>.*

<<The next section should give overview statements on the general level of compliance with MRA/MLA criteria, and should be itemised to reflect the evaluation criteria listed in Section 2.3 of this report. The statements must be factual and representative of the situation as observed by the evaluation team. The following is an example of an Accreditation Body (AB) that has performed well – actual statements used in your report may not be so positive.>>

The evaluation team has the pleasure to confirm that the overall operation of *<<insert acronym of AB>>* is in accordance with the requirements of *<<Global ACI MRA-005 or Regional Cooperation Body Procedure xxx.>>* In particular:

(a) *<<insert acronym of AB>>* operates its *<<insert MRA/MLA scope e.g. testing laboratory, calibration laboratory, inspection body, reference material producer, proficiency testing providers>>* accreditation programme(s) substantially in accordance with the requirements of ISO/IEC 17011:2017;

(b) *<<where relevant>>* Laboratories accredited by *<<insert acronym of AB>>* have been assessed against and found to comply with the requirements of ISO/IEC 17025;

(c) *<<where relevant>>* Medical testing laboratories accredited by *<<insert acronym of AB>>* have been assessed against and found to comply with the requirements of ISO 15189;

(d) *<<where relevant>>* Inspection bodies accredited by *<<insert acronym of AB>>* have been assessed against and found to comply with the requirements of ISO/IEC 17020 and Global ACI-TECH-2-001 *Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies*;

(e) <<where relevant>> Reference material producers accredited by *<<insert acronym of AB>>* have been assessed against and found to comply with the requirements of ISO 17034;

(f) *<<where relevant>>* Proficiency testing providers accredited by *<<insert acronym of AB>>* have been assessed against and found to comply with the requirements of ISO/IEC 17043;

(g) *<<where relevant>>* Biobanks accredited by *<<insert acronym of AB>>* have been assessed against and found to comply with the requirements of ISO 20387;

(h) *<<where relevant>>* Management System Certification Bodies accredited by *<<insert acronym of AB>>* have been assessed against and found to comply with the requirements of ISO/IEC 17021-1, and the relevant standards for each scope of certification: *<<as relevant>> e.g. ISO/IEC 17021-3 and* ISO 9001 (QMS), ISO/IEC 17021-2 and ISO 14001 (EMS), ISO 22003-1 and ISO 22000 (FSMS), ISO/IEC 27006-1 and ISO/IEC 27001 (ISMS), ISO 13485 (MDMS) and relevant Global ACI Mandatory Applications;

(i) *<<where relevant>>* Product Certification Bodies accredited by *<<insert acronym of AB>>* have been assessed against and found to comply with the requirements of ISO/IEC 17065;

(j) *<<where relevant>>* Certification Bodies of Persons accredited by *<<insert acronym of AB>>* have been assessed against and found to comply with the requirements of ISO/IEC 17024;

(k) *<<where relevant>>* Validation and Verification bodies accredited by *<<insert acronym of AB>>* have been assessed against and found to comply with the requirements of ISO/IEC 17029;

(l) *<<where relevant>>* *<<insert acronym of AB>>* adopts and *<<substantially>>* implements the Global ACI policy on traceability of measurement results (Global ACI-TECH-1-011 *Policy on Metrological Traceability of Measurement Results*), and a satisfactory measurement support can be provided to *<<insert acronym of AB>>* accredited *<<as relevant>>* laboratories, inspection bodies, reference material producers, proficiency testing providers and biobanks in the basic physical units;

(m) *<<insert acronym of AB>>* adopts and *<<substantially>>* implements the supplementary requirements and guidelines for the use of accreditation symbols and for claims of accreditation status, and implements the general principles for the use of the MRA Mark, in accordance with Global ACI-MRA-006 *Use of the MRA Mark and Claims of Accreditation Status by Accredited Conformity Assessment Bodies*;

(n) *<<insert acronym of AB>>* permanent staff are skilled and satisfactorily technically qualified for the functions they perform, and the organisation has accreditation experience. *<<insert acronym of AB>>* has access to a sufficient number of well-qualified, experienced and competent external Technical Assessors and Experts;

(o) *<<insert a brief overview description of the accreditation process, its maturity and its application in practice e.g.>>* *<<insert acronym of AB>>* has a well-established accreditation process which is applied consistently to the accreditation of its *<<where relevant>>* laboratories, inspection bodies, reference material producers, proficiency testing providers, management system certification bodies for QMS, EMS, FSMS, ISMS, MDMS, product certification bodies, certification bodies of persons, validation and verification bodies;

(p) *<<insert acronym of AB>>* has the necessary commitment, financial and other resources to continue to operate an independent (suite of) accreditation programme(s);

(q) *<<insert acronym of AB>>* and its accredited calibration laboratories meet the Global ACI-TECH-1-009 *Policy for Measurement Uncertainty in Calibration* requirements for uncertainty in calibration;

(r) *<<insert acronym of AB>>* and its accredited laboratories meet, as far as practicable, the Global ACI-TECH-1-008 requirements for proficiency testing activity and has participated in a number of PT programmes if applicable. The performance of their accredited laboratories since *<<insert date of last Regional Cooperation Body evaluation>>* has been generally satisfactory and outliers have been investigated;

(s) *<<insert acronym of AB>>* has documented and implemented an appropriate cross-frontier accreditation policy taking into account ILAC-G21;

(t) *<<insert acronym of AB>>* fulfils its MRA/MLA obligations under *Regional Cooperation Body Procedure xxx* and the Global ACI MRA-001 *Multilateral Recognition Arrangement: Structure, Scope and Obligations*; and

(u) The assessment and surveillance activities of *<<insert acronym of AB>>* provide a degree of assurance such that the results and data obtained by *<<insert acronym of AB>>* accredited organisations are equivalent to those issued by organisations accredited by other (potential *<<for MRA/MLA scope extensions>>*) *Global ACI and Regional Cooperation Body* MRA/MLA partners.

<<as relevant>> In addition, the evaluation team has verified the implementation of the actions taken by *<<insert acronym of AB>>* to address the findings of the previous evaluation and found that they were *<<generally>>* addressed satisfactorily.

During this evaluation the *<<insert acronym of AB>>* offices in *<<insert city and economy>>* were visited, and the team witnessed a number of assessments as detailed in Section 2.4.

<<insert statement(s) as to the witnessed conduct of the assessments e.g. All the assessments witnessed were, without exception, of a high standard in terms of their scope and depth.>>

The evaluation team was impressed with *<<list those elements that are especially noteworthy e.g. the expertise of staff and/or assessment teams; the quality and/or thoroughness of assessments; knowledge of and adherence to procedures; etc. etc.>>*

<<insert brief summary of the findings in relation to non-conformities and comments, as appropriate e.g.>>

<<number>> non-conformities and *<<number>>* comments were raised by the evaluation team. The *<<number>>* non-conformities relate to *<<brief statement on the area of ISO/IEC 17011 they relate to e.g. assessor monitoring, related body analysis, etc., etc.>>*. Full details of all non-conformities and comments are given in Annex 1 to this report.

<<as relevant>> *<<insert acronym of AB>>* is required to provide a Corrective Action and Response Report to the Team Leader (within *<<1 month for re-evaluations; within 3 months for initial evaluations>>* of receipt of this Report) before the evaluation team can:

(i) *<<for re-evaluation>>* forward any recommendation to the Regional Cooperation Body Decision Making Body on reaffirming its Regional Cooperation Body signatory status for *<<insert existing MRA/MLA scope>>*;

(ii) *<<for initial or MRA/MLA scope extension evaluations>>* forward any recommendation to the Regional Cooperation Body Decision Making Group on entry into the MRA/MLA for *<<insert evaluated MRA/MLA scope extension>>*.

The Corrective Action and Response Report must include details of the cause analysis, including the extent of the non-conformity(ies) and its impact, and the 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.

<<insert acronym of AB>> is also encouraged to respond to the Comments.

The evaluation team would like to thank *<<insert acronym of AB>>* and its staff for their co-operation in the arrangements for, and conduct of the evaluation and for the hospitality shown to the team during the evaluation. The evaluation team would also like to thank the *<<insert acronym of AB>>* external assessors, and the accredited and applicant organisations involved in the witnessing of assessments for their co-operation and hospitality.

……..
<<Mr E.M.C. Nerd (Team Member; AB2, USA)>>

……..
<<Dr Cal Ibrator (Team Member; NMI, Australia)>>

……
<<A.N. Other (Team Member; LOTR AB, Middle Earth)>>

……
<<Mrs Eve Aluator (Team Leader; AB1, New Zealand)>>

<<insert date of evaluation exit meeting>>

<as relevant>> <<*if a follow-up visit is done before a final decision by the* <<Regional Cooperation Body>>

1.1 Summary of the Follow Up

*<<TL: If the follow-up visit aims at checking implementation of corrective actions **before** <<Regional Cooperation Body>> makes a decision on granting or maintaining recognition, the information on the activities done in the follow-up visit shall be included in the summary section of the Final Report of that evaluation as follows:*

a) The report shall include a section with a summary of the follow-up visit, including the reasons for the follow-up visit; reference to the decision authorising the visit, the evaluators participating in the visit and dates of the visit; a summary of the activities performed by the evaluation team: confirmation whether or not all findings have been closed; and the next steps of the process.

b) An annex with the follow-up visit program.

c) An annex with the report on any assessments witnessed using the report as presented in annex V.

d) Information about the evidence obtained by the evaluation team for each of the findings that was checked, if relevant confirmation that the finding is closed or information on the actions that are still pending.

The summary section about the follow-up visit shall be provided to the AB at the end of the follow-up visit.>>

1.2 Recommendation of the Evaluation Team

For initial evaluation and for extensions of the MRA/MLA scope the recommendation shall indicate whether or not the AB should be accepted into the MRA/MLA and the scope of recognition.

For re-evaluations, this recommendation shall indicate whether or not the AB should be maintained in the MRA/MLA and the scope of recognition.

The recommendation shall also indicate when the next re-evaluation should be done. Normally the next re-evaluation will be done within 4 years from the last evaluation; if a shorter interval is recommended the evaluation team shall provide the reasons for that and the proposed scope of the evaluation.

In the case where the team recommends suspension of the AB from the MRA/MLA, the recommendation shall indicate the reason for the suspension including the MRA/MLA scopes that are affected, with reference to the relevant findings.

The recommendation to the MRA/MLA Decision Making Group should reflect the consensus of the evaluation team. If the evaluation team cannot reach consensus, the recommendation shall reflect the different views of the team members and include the reasons for the difference.>>

<<As relevant>> for example:
<<The evaluation team recommends that *<<insert acronym of AB>>* be recognised for the MRA/MLA for *<<list the relevant MRA/MLA scopes>>*.
<<The evaluation team recommends that *<<insert acronym of AB>>* maintains its signatory status of the MRA/MLA for *<<list the relevant MLA scopes>>*.

<<It is recommended that the next re-evaluation be done in the normal 4-year period, by *<<month/year>>.*
<<<It is recommended that the next re-evaluation for *<<list the relevant MRA/MLA scopes>>* be done two years from the date of the initial evaluation because <<provide the relevant reasons>>.
<<The evaluation team recommends that a follow-up visit should be done within a year, for *<<insert the relevant MRA/MLA scopes>>* so as to check implementation of actions for *<<list the findings and provide any additional reason>>.*

SECTION 2: GENERAL INFORMATION

2.1 Objectives of the Evaluation

This was a *<<insert type of evaluation e.g. initial, periodic re-, etc.>>* evaluation conducted on behalf of the *<<Regional Cooperation Body>>* to:

(i) *<<for re-evaluations>>* Reconfirm conformity with specified criteria for the continuation of *<<insert acronym of AB>>* Signatory Status in the Regional Cooperation Body Mutual Recognition Arrangement (MLA/MRA) for the accreditation of *<<insert existing MLA/MRA scope of the AB>>* (and thus also continuation of *<<insert acronym of AB>>* Signatory Status in the Global ACI MRA *<<insert existing MRA scope>>* by virtue of *<<insert acronym of Regional Cooperation Body>>*'s status as a Recognised Regional Cooperation Body by Global ACI);

(ii) *<<and/or for initial evaluations and MLA/MRA scope extension evaluations>>* Establish conformity with specified criteria for *<<insert acronym of AB>>* possible entry into the Global ACI MRA for the accreditation of *<<insert evaluated MRA scope extension>>*.

2.2 <<List name and position of (at least) AB staff involved in the evaluation>>

<<List name and organisation of any observers to the evaluation>>

2.3 Evaluation Criteria

This evaluation was conducted in accordance with the procedures specified in Global ACI MRA-005 *or Regional Cooperation Body Procedure xxx (<<insert date of issue). <<insert acronym of AB>>* was evaluated to confirm compliance with the criteria listed in the annex prepared by the TL. Requirements are specified on the websites of Global ACI and regional cooperation bodies and include all relevant Global ACI requirements documents and GA resolutions and the regional specific requirements.

2.4 Evaluation Activities

<<insert acronym of AB>> provided the requisite documentation *<<as required for; well in advance of>>* the on-site evaluation. These were reviewed by the evaluation team prior to the on-site evaluation. The evaluation visit took place from *<<insert day and date>>* to *<<insert day and date>>* inclusive, according to the programme detailed in Annex II.

During the evaluation, the *<<insert acronym of AB>>* offices in *<<insert city and economy>>* were visited, along with the witnessing of accreditation assessments.

The summary description of the scopes of accreditation of the witnessed assessments is given in Annex IV.

Full commentaries on the structure and organisation of *<<insert acronym of AB>>*, and on the performance of their accreditation systems are given in Sections 3 and 4 respectively.

<<If the findings detailed in Annex I are repeated in the main body of the report (Sections 3 & 4) they must be an exact reproduction of the content of Annex I and be clearly highlighted>>.

2.5 List of Economies where the AB Performs Assessments or Provides Accreditation

Any economies outside of its own in which the AB provides accreditation, and the number of respective accreditations. A description of the AB's cross frontier accreditation policy shall be provided.

2.6 Follow-up on Previous Evaluation Findings

<<TL: Where relevant, the evaluation team should 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.

<<AB: Sections 3, 4 and 5 of this report template are to be written by the AB prior to the evaluation. The target audience for the text is the Decision-Making Group, not only the evaluation team – so the text should be a full and complete narrative. References to documents and procedures the Decision-Making Group will not have access to must be avoided. This text can often be obtained in English from the translated version of the AB's quality manual.

Comments by the peer evaluation team will be recorded in the specific placeholders. The AB will be given the opportunity to comment on draft versions of any amendments made by the evaluation team.>>

<<TL: One of the roles of the evaluation team is to verify the accuracy of the text provided by the AB. When the team evaluates that the text provided by the AB does not fully describe the situation observed, then this shall be reflected in the findings and comments boxes. The team shall add the objective evidence and conclusions in the boxes.>>

SECTION 3: BACKGROUND AND HISTORY OF *<<insert acronym of AB>>*

<<AB: As suggested by the title, the text shall include a description of the history and background of the AB – when it was established, when the first accreditation was granted in each accreditation programme under the MRA, significant milestones, etc.

An organisational chart is provided in Annex III.>>

SECTION 4: PERFORMANCE OF THE SYSTEM

4. General Requirements

[ISO/IEC 17011:2017; Clause 4, Global ACI MRA-005; Section 4]

4.1. Legal Entity

[ISO/IEC 17011:2017; 4.1]

<<AB: The AB shall provide a full description of the following:

The legal status of the AB and of its owners.

- *Governmental ABs shall describe the Ministries and/or Departments, of which it is part; describe its legal status and structure as formally documented by government, and refer the Acts, Regulations or other statutory instruments which describe the authority under which the AB operates.*
- *Private sector ABs shall describe in full their legal status under the local laws; whether they are not-for-profit or profit-returning, who the owners are, and the documents that prescribe the authority under which they operate.*

Non-Governmental ABs shall also describe their relationship with Government, such as any legal or contractual arrangements, memoranda of understanding, recognition by regulatory agencies, etc.

In case the AB is a separate legal entity within or owned by a larger body, the related bodies shall be identified (see Section 4.4 below).

The discussion under each of the above points must be made with reference to, and be fully consistent with the organisation charts in Annex III which the AB must also provide in this report.>>

Team Conclusions	

4.2 Accreditation Agreement

[ISO/IEC 17011:2017; 4.2]

<<AB: With reference to clause 4.2 of ISO/IEC 17011:2017, the AB shall provide a brief overview of its conformity with the requirements of this clause, and how these rules are published and made available to applicant and accredited CABs.>>

Team Conclusions	

4.3 Use of Accreditation Symbols and Other Claims of Accreditation

[ISO/IEC 17011:2017; 4.3, Global ACI MRA-006]

<<AB: With reference to clause 4.3 of ISO/IEC 17011:2017 and Global ACI MRA-006, the AB shall provide a brief overview of its conformity with these, and how these rules are published and made available to applicant and accredited CABs. The AB shall describe what measures it uses to ensure CABs conform with these rules, and the action taken in the case of misuse of accreditation and/or the accreditation symbol.>>

Team Conclusions	

4.4 Impartiality Requirements

[ISO/IEC 17011:2017; 4.4]

<<AB: A description of the processes by which the AB ensures the impartiality and independence of the accreditation process needs to be given. With reference to ISO/IEC 17011, clause 4.4, this should include brief descriptions on:

How the organisation and operation of the AB safeguards objectivity and impartiality;
How the structure provides the opportunity for effective involvement of interested parties in a balanced way, how this involvement of interested parties assures threats to impartiality are minimised;
The AB's policies not being discriminatory;
How is top management commitment to impartiality to be guaranteed;
How are identified risks to impartiality eliminated or minimised;
How is the decision-making by top management on the acceptability of level of risk defined/executed;
How objectivity of personnel is assured and is free from undue pressure; This includes personnel such as AB staff, assessors, experts, committees, and/or decision-making bodies, as well as processes such as accreditation decision-making;
The competence of accreditation decision-makers and their independence from the assessment process;
Other activities of the AB that may affect impartiality, if applicable. The AB shall provide a description of all other activities it is involved in outside of accreditation; e.g. training services, etc
The activities of related bodies, and the identification and analysis of the relationship with these related bodies. The AB shall identify the types of related bodies, the types of risk and how the AB has mitigated the potential for conflict of interest;
Particularly for the accreditation of Proficiency Testing Providers, policies and actions taken to avoid conflicts of interest.>>

Team Conclusions	

4.5 Financing and Liability

[ISO/IEC 17011:2017; 4.5]

<<AB: The AB shall describe:

Its arrangements to cover liabilities;

How it receives funds for undertaking its accreditation and other activities, and an overall indication of how these funds are allocated e.g. what kind of activities are funded.>>

Team Conclusions	

4.6 Establishing Accreditation Schemes

[ISO/IEC 17011:2017; 4.6, *Global ACI MRA-005* Section 4 (ILAC-G21:09/2012)]

<<AB: The AB shall provide the following information:

The types of accreditation programmes offered i.e. the type of CAB activity it accredits, and when these programmes were launched (see also 3 above);

The sub-scopes or fields within each programme in which accreditation is offered and how they relate to the scopes of the Arrangement, including which fields are not considered part of the MRA/MLA;

The set of criteria that is used in each programme or field;

The policy on the determination of the suitability of the conformity assessment schemes and standards for accreditation purposes and how interested parties are included;

If appropriate, approved resolutions regarding the implementation date for a particular standard;

The number of CABs in each programme and field (Level 4 and/or 5), including the current number of active accreditations and the number of applicants. Where considered appropriate and of value to the Regional Cooperation Body Decision Making Group, commentary relating to the AB's conformity with Global ACI MRA-005, section 4 may be provided;

The current rate of growth e.g. statistics such as the number of new accreditation in each field since the last evaluation, or since inception for a new applicant AB;

*The AB must provide information about the level 4 or level 5 schemes **that it operates for certification bodies and validation / verification bodies**, in the following table:*

Accreditation Activity (Level 2) *(To be filled out by the AB)*	**Accreditation Standard (Level 3)** *(To be filled out by the AB)*	**Subscope Level (Level 4 or Level 5,)** *(To be filled out by the AB)*	**Number of accredited CAB** *(To be filled out by the AB)*	**Team Conclusions and type of evaluation activity *e.g.* records review or witnessing.** *(To be filled out by the Peer Evaluation Team)*
e.g. Management Systems Certifications	*ISO/IEC 17021-1*	*ISO 22003-1 (FSMS) and ISO 22000*	*5*	*Witnessing*
e.g. Management Systems Certifications	*ISO/IEC 17021-1*	*ISO/IEC 17021-2 (EMS) and ISO 14001*	*5*	*File review*
e.g. Product Certification	*ISO/IEC 17065*	*GLOBAL G.A.P IFA General Regulations, GLOBAL G.A.P IFA CPCCs*	*1*	*Interview*

Note: Expand the table if necessary. For information about levels refer to Global ACI MRA-003

The AB shall also give an overview of the policies and processes for extension of the described scope – both into the accreditation of new conformity assessment activities, and extending current programmes into new fields of technology. The policies and processes described should address the following elements:

Analysis of the suitability of the extension, including compliance with international harmonised decisions on what may be accredited and what should be accredited; The use of national and international guides for the operation of CABs;
Access to expertise;
Selection and training of AB staff and assessors; Requirements/cooperation with interested parties, such as regulators;
International mutual recognition issues, including cooperation with other ABs (e.g. by joint assessments, use of assessors).

Examples of extensions into new areas since the last evaluation should be described.>>

Team Conclusions	

5. Structural Requirements

[ISO/IEC 17011:2017; 5; Global ACI MRA-005 section 4.]

<<AB: The structure and organisation discussion shall be described with reference to, and be fully consistent with the organisation charts in Annex III (which the AB also must provide for in this report). The discussion of the structure must explain the structure represented by the organisation chart(s), including the relationship with related bodies (e.g. what conformity assessment activities the related body undertakes, if any; whether they are accredited and by whom; management structures, etc) and any organisations to which assessment activities are subcontracted (either routinely or from time to time). Each of the groups directly associated with the AB and identified on the organisation chart(s) should be described (such as Governance Boards, committees, and the like) i.e. what is their composition? What is their role in the accreditation process? What are their terms of reference?

The internal organisation of the AB must also be discussed, explaining the staff organisation chart e.g. what is the overall role and responsibility of each position? What level of authority does each position hold? What interactions do they have with external parties in the organisation chart? In particular, a description of the duties, responsibilities and authorities of top management, including the names of top management i.e. who has overall authority and responsibility and who has been assigned day-to-day management responsibilities (for each of items under clauses 5.7 and 9.1.1, 9.1.2. 9.2.1 of ISO/IEC 17011:2017), and where authorities and responsibilities may be held by more than one individual.

The AB shall also:

Describe the mechanisms by which it accesses its expertise. This should be a description focussed on the expertise to provide policy advice to the AB. Examples include, but are not necessarily limited to:

- *Its own internal staff. An overview of the technical qualifications and experience should be given.*
- *External assessors/experts.*
- *Technical committees that are part of the AB structure; their membership and an overview of their technical qualifications.*

- *Cooperation with external institutions, such as professional institutions, universities, research institutes (both government and private sector).*
- *Cooperation with international experts and institutions.*
- *Adoption of international and regional guidance documents.*

The AB shall describe how it identifies the need for expertise; how this expertise is recruited and how it is managed and used in establishing accreditation requirements (for both existing and new accreditation programmes) and advising the AB. The commentary should provide some indication of the expertise available to advise the AB in type, range and volume of the accreditation services offered.>>
If applicable, a description of the rules for the appointment, terms of reference and operation of committees, including a list of committees currently in place and a brief overview of the role that they play.>>

Team Conclusions	

6. Resource Requirements

[ISO/IEC 17011:2017; Clause 6]

6.1 Competence of Personnel

[ISO/IEC 17011:2017; 6.1]

<<AB: The AB shall provide a description of the mechanisms for determining of competence criteria for groups of personnel involved and for ensuring the competence of each of the groups of personnel associated with the AB. Such mechanisms may include person specifications competencies for each position, how individuals are selected and trained (both initially and ongoing). Examples of such a commentary may include the following:
<<insert acronym of AB>>

Staff

With reference to Section 5 and the organisation chart in Annex III, a brief overview of the role of each position within the AB;
A summary of qualifications and experience of key managerial and supervisory staff;
Availability of job descriptions and/or person specifications competencies for each position;
Induction and training processes for key operational staff involved in the accreditation process.

Committees

A list of the committees currently in place and a brief overview of the role that they play and the qualifications, training and experience held;
Where relevant, how committee members are recruited, inducted, trained (initial and ongoing) and qualified;
What support systems are in place for committees to competently fulfil their functions e.g. access to AB personnel, provision of requirements documents (and any international resource material from which these are developed).>>

Team Conclusions	

6.2 Personnel Involved in the Accreditation Process

[ISO/IEC 17011:2017; 6.2]

<<AB: The AB shall provide a description of the mechanisms for ensuring the competence of each of the groups of personnel involved in the accreditation process (particularly the assessment). Such mechanisms may include person specifications competencies for each position, how individuals are selected and trained (both initially and ongoing), and monitored. Examples of such a commentary may include the following:

Assessors

How assessors are recruited/selected, trained and qualified, including the qualification for the technical scopes they are deemed competent to assess;
The total number of currently qualified assessors, preferably broken down by accreditation sub-scopes, programmes or fields of technology, and an overview of their technical and assessment qualifications, training and experience;
Assessor support systems in place, including access to AB personnel, provision of requirements documents and assessment instructions and documents, exchange of experience among assessors and access to technical committees;
Ongoing training for assessors.

Technical Experts

As relevant, the same commentary as for Assessors, plus;
The mechanisms for supervision of technical experts by qualified assessors during the assessment process.>>
How are instructions given to technical experts

<<AB: For each of the groups of personnel identified in Sections 6.1 and 6.2 above, the AB shall provide a description of the procedures for monitoring their competence. Examples of such commentary may include the following:

<<insert acronym of AB>>

Staff

Monitoring of the competencies of staff involved in the accreditation process, the identification of training needs, and the delivery of such training.

Monitoring of Assessors and Technical Experts

How assessors and experts are systematically monitored, and what actions are taken when training needs are identified;
Other forms of monitoring and feedback that ensure the ongoing competencies of assessors.
Ongoing training for assessors.

Decision Making

Particularly where committees and individuals are involved in the accreditation decision, the AB shall describe how they are monitored, and what actions are taken when training needs are identified.>>

Team Conclusions	

6.3 Personnel Records

[ISO/IEC 17011:2017; 6.3]

<<AB: The AB shall provide an overview of the personnel records maintained in support of Sections 6.1 and 6.2 above, and how they are kept up to date.>>

Team Conclusions	

6.4 Outsourcing

[ISO/IEC 17011:2017; 6.4]

<<AB: The AB shall describe its outsourcing policy and, where relevant, its outsourcing processes, including the conditions under which outsourcing takes place and how it meets the requirement of this clause. A list of organisations with which it has an outsourcing agreement shall be given.>>

Team Conclusions	

7. Process Requirements

[ISO/IEC 17011:2017; Clause 7]

7.1 Accreditation Requirements

[ISO/IEC 17011:2017; 7.1; Global ACI MRA-005 section 4 (TECH-1-011: Policy on Metrological Traceability of Measurement Results, TECH-1-009 Policy for Measurement Uncertainty in Calibration, TECH-1-008 Policy for Participation in Proficiency Testing Activities)]

<<AB: The AB shall describe the general criteria for accreditation that its accredited CABs are required to meet, including additional detail relating to measurement traceability, and detail where and how the requisite information specified in clause 8.2.1 of ISO/IEC 17011:2017 is made publicly available.>>

Team Conclusions	

7.2 Application for Accreditation

[ISO/IEC 17011:2017; 7.2]

<<AB: The application content shall be described, and how applications are reviewed, and by whom, for adequacy. How the AB responds to the operation of the CAB in more than one site or whether it operates cross-frontier. Actions to be taken if fraudulent behaviour is detected shall be described >>

Team Conclusions	

7.3 Resource Review

[ISO/IEC 17011:2017; 7.3]

<<AB: The AB's processes for the review of applications for their ability to carry out the assessment (including in a timely manner) shall be described.>>

Team Conclusions	

7.4 Preparation for Assessment

[ISO/IEC 17011:2017; 7.4]

<<AB: The AB shall provide a description of its policies and procedures, as relevant, for:
Preliminary visits;
Coverage of the applicant's scope by on-site and other assessment techniques;
Selection of the assessment team. The AB shall provide information on the policies/mechanisms for deciding on team composition to ensure effective coverage of the requested scope of accreditation and depth of assessment;
Ensuring the impartiality of the assessment team selected; CAB objections to the assessment team;
Defining the assignment for the assessment team and development of an assessment plan;
Sampling of the (proposed) accreditation scope. The AB shall provide information on the policies for sampling of the scope for all assessment types (e.g. initial, surveillance and reassessment) and how the AB demonstrates fulfilment of these policies and ISO/IEC 17011; Assessing activities taking risk into account; (see also Section 7.4.6)
Setting the assessment date; Provisions for the assessors.>>

Team Conclusions	

7.5 Review of Documented Information

[ISO/IEC 17011:2017; 7.5]

<<AB: The AB shall provide a description of the processes for review of the CAB's assessment documentation by the assessment team, and the actions taken on prior review outcomes.>>

Team Conclusions and Objective Evidence of Compliance	

7.6 Assessment

[ISO/IEC 17011:2017; 7.6]

<<AB: A general description of the assessment process steps needs to be provided, including:
Procedures describing the assessment techniques used;
Rules for determining assessment durations;

The opening meeting;
The conduct of the assessment;
Conduct of assessment based on the assessment plan.

<<TL: In addition to the above, each of the evaluation team members needs to complete a Report on Witnessed Assessment for each of the assessments witnessed (see Annex V). In this Section the team may give an overview of its observations from the witnessed assessments i.e.
Were they in general conducted consistently in accordance with the AB procedures?
Were the assessors/experts suitably matched to the CAB being assessed?
Were the CABs assessed in sufficient depth to make an informed decision as to their competence?

Care should be taken when drawing conclusions from the individual Reports on Witnessed Assessment. Isolated good or bad findings cannot and should not be used to conclude that all the assessments are generally good or bad.>>

<<AB: A description of the following needs to be provided:
How and when assessment teams analyse the information and evidence gathered;
How findings are formulated and graded (if applicable), and what happens in the event a consensus cannot be reached;
How non-conformities with accreditation criteria are conveyed to the assessed CAB (e.g. closing meeting procedures, written reporting procedures);
How these are to be addressed by the CAB and assessed and cleared by the AB, including any involvement by the assessment team;
How such actions are used in the accreditation decision-making (recognising that decision making includes granting, suspension, withdrawal, continuation, scope reduction, scope extension);
What actions are taken on unsatisfactory resolution.>>

Team Conclusions	

7.7 Accreditation Decision-Making

[ISO/IEC 17011:2017; 7.7]

<<AB: The accreditation decision-making process shall be described, including:
Confirmation that requirements for accreditation have been met, including as appropriate, information supplied from subcontracted assessments;
The effective separation of the assessment team and the accreditation decision-maker(s);
The accreditation decision-making process for assessments and reassessments use / acceptance of decision-making without independent decision-making, i.e. by 2 eyes only;
The issuance of accreditation information and their content for different types of CABs.>>

Team Conclusions	

7.8 Accreditation Information

[ISO/IEC 17011:2017; 7.8]

<<AB: With reference to ISO/IEC 17011, clause 7.8, this should include brief descriptions on:
where and how the information on the accreditation is provided,
how fulfilment of clauses 7.8.1 a to g and 7.8.3.a to h are assured,
description for CABs accredited with flexible scopes and what is considered by the AB as a flexible scope.>>

Team Conclusions	

7.9 Accreditation Cycle

[ISO/IEC 17011:2017; 7.9, ILAC-G21:09/2012; Global ACI mandatory documents, applicable]

<<AB: The AB shall describe its assessment and reassessment programme for its accredited CABs, including:
The term of accreditation, and whether or not expiry dates are used;
The reassessment frequency;
Development and application of an assessment programme for the accreditation cycle;
How and when changes to the assessment programme are required;
How is ascertained, that all relevant accreditation fields are assessed within an accreditation cycle;
The nature, frequency and scope of assessment activities, with particular emphasis on on-site assessment and the associated sampling of sites (see below), personnel (see below), and the scope of accreditation. Other forms of assessment activity shall also be described;
Information on the policy for sampling premises taking risk into account;
How the AB responds to the operation of the CAB in more than one site or whether it operates cross-frontier;
Use of witnessing of testing, calibration, inspection, verification, validation and certification activities in assessment and reassessment, if applicable;
How the AB judges the proven stability that the services of the CAB have reached in its decision on the intervals for the assessments and reassessments;
The AB policies and procedures for the conduct of extra-ordinary visits;
The accreditation decision-making process (or continuation of accreditation) for each of the assessment/reassessment activities.>>

Team Conclusions	

7.10 Extending Accreditation

[ISO/IEC 17011:2017; 7.10]

<<AB: The AB shall provide a description of its policies and procedures for extending scopes of accreditation when requested by the CAB, including the options available for assessing these requests and the decision-making procedures.>>

Team Conclusions	

7.11 Suspending, Withdrawing or Reducing Accreditation

[ISO/IEC 17011:2017; 7.11 and TECH-3-025: Harmonisation of sanctions and dealing with fraudulent behaviour]

<<AB: The AB shall provide a description of its policies and procedures (and associated authorities) for the suspension including its lifting provisions, withdrawal or reduction of accreditation, including the number of non-voluntary suspensions and withdrawals over the last four years.>>

Team Conclusions	

7.12 Complaints

[ISO/IEC 17011:2017; 7.12]

<<AB: The AB shall provide a summary of the complaint management process including numbers of total complaints since the last evaluation, those considered valid and major reasons for the complaints.>>

Team Conclusions	

7.13 Appeals

[ISO/IEC 17011:2017; 7.13]

<<AB: The AB shall provide a summary of the appeals process including the numbers of appeals and appeals considered valid since the last full evaluation (or last 4 years for initial evaluations).>>

Team Conclusions	

7.14 Records on Conformity Assessment Bodies

[ISO/IEC 17011:2017; 7.14]

<<AB: The AB shall provide a description of what records are maintained on its applicant and accredited CABs, how these are maintained, and how confidentiality is assured.>>

Team Conclusions	

8. Information Requirements

8.1 Confidential Information

[ISO/IEC 17011:2017; 8.1]

<<AB: The AB shall describe its arrangements to safeguard the confidentiality of information obtained.>>

Team Conclusions	

8.2 Publicly Available Information

[ISO/IEC 17011:2017; 8.2]

<<AB: With reference to clause 8.2 of ISO/IEC 17011:2017 the AB shall provide a brief overview of its conformity with the requirements of this clause, and how this information is made publicly available and if any exceptional limitations to certain information are applied.>>

Team Conclusions	

9. Management System Requirements

[ISO/IEC 17011:2017; Clause 9, Global ACI MRA-005; Section 4]

9.1 General

[ISO/IEC 17011:2017; 9.1; Global ACI MRA-005; 4]

<<AB: An overview description of the management system; its conformity with ISO/IEC 17011 and Global ACI MRA-005, section 4; how the documentation of the system is structured; and its maturity. Is Option B used and if YES, how are the ISO 9001 requirements adapted to ISO/IEC 17011:2017 Management System requirements>>

9.2 Management System

[ISO/IEC 17011:2017; 9.2]

<<AB: Overview description of:
how policies and objectives are defined and documented;
their appropriateness to the type, range and volume of work;
how they are communicated to, understood by, and implemented at all levels of the AB;
the authorities and responsibilities of the management system representative;
how the management system is continuously improved in terms of effectiveness >>

Team Conclusions	

9.3 Document Control

[ISO/IEC 17011:2017; 9.3]

<<AB: Overview of document control policies and procedures.>>

Team Conclusions	

9.4 Records Control

[ISO/IEC 17011:2017; 9.4]

<<AB: A brief description of how records are maintained; how long they are retained for; their disposition; and confidentiality arrangements.>>

Team Conclusions	

9.5 Nonconformities and Corrective Actions

[ISO/IEC 17011:2017; 9.5]

<<AB: Overview of non-conformities and corrective action policies and procedures.>>

Team Conclusions	

9.6 Improvement

[ISO/IEC 17011:2017; 9.6]

<<AB: Overview of improvement policies and procedures.>>

Team Conclusions	

9.7 Internal Audits

[ISO/IEC 17011:2017; 9.7]

<<AB: A description of the internal audit policies and procedures shall be provided, including qualification of internal auditors, internal audit scope and schedules and how outcomes of internal audits are used for the continual improvement of the accreditation system. The AB shall also provide a summary of the internal audit programme and the audit results for the last two years.>>

Team Conclusions	

9.8 Management Reviews

[ISO/IEC 17011:2017; 9.8]

<<AB: A description of the management review policies and processes shall be provided, including inputs and outcomes, and how these are used for the continual improvement of the accreditation system. The AB shall also provide a summary of the management review activities and main outputs for the last two years.>>

Team Conclusions	

SECTION 5: ARRANGEMENT OBLIGATIONS

[Regional Cooperation Body Requirements; Global ACI MRA-001; Global ACI MRA-005]

The AB should provide a commentary on the following types of activities it undertakes in support of the Global ACI or the Regional Cooperation Body MLA/MRAs:

Level of attendance and participation in Global ACI or/and Regional Cooperation Body meetings, and any positions of office held therein;
How the AB ensures participation in Regional, Global ACI MRA-005 ballots;
Provision of peer evaluators and Lead Evaluators to the Regional/Global ACI MRA-005 evaluator list, and the numbers of evaluations for which evaluators have participated in since the last evaluation; how the AB ensures fulfilment of its obligations regarding the regular provision of peer evaluators?
Promotional activities of the Regional Cooperation Body/Global ACI, including supporting its role through participation in international trade facilitation forums;
Acceptance policies for test, calibration, certification and inspection certificates from organisations accredited by MLA/MRA partners;
Adoption of and protection of the Combined MRA mark, where used.>>

<<TL: The team shall add the objective evidence and conclusions in the box below that will aid in the Decision-Making Group's understanding of the AB, including where appropriate, any comment on activities such as Global ACI or Regional Cooperation Body voting participation, provision of evaluation reports to interested parties, etc.

Team Leaders are reminded that MLA/MRA obligations only apply if the AB is a member of the MLA/MRA i.e. compliance with the Global ACI or Regional Cooperation Body MLA/MRA is not mandatory for initial evaluation. However, the Decision-Making Group will be interested in the adoption of MLA/MRA principles (under the Global ACI or Regional Cooperation Body MoU) for applicant ABs.>>

Team Conclusion	

A. Regional Cooperation Body Requirements Specific to the AB Under Evaluation

<<AB: The AB shall list any specific regional Cooperation Body requirements (ie, APAC, ARAC, EA, IAAC, AFRAC & SADCA) that have not already been addressed and provide a description of the AB's compliance to the requirements.

<<TL: The evaluation team should review and confirm compliance with the specific regional requirements listed.>>

Team Conclusions	

ANNEX I: NON-CONFORMITIES AND COMMENTS

<<This section must be completed by the evaluation team, and presented to the AB, at the closing of the on-site evaluation. It would normally be produced as a separate document (with the Summary of Findings in Section 1) and inserted into the evaluation report in this section. Once accepted by the AB at the conclusion of the on-site evaluation the text cannot be changed – any changes are to be addressed through the ABs Corrective Action and Response Report. The following is a possible template for presentation of the Summary of Findings. Each non-conformity must be correctly cited against a clause in ISO/IEC 17011 or other MRA requirements document. Each finding must be presented in sufficient detail so that it can be interpreted without reference to the main body of the report e.g. with reference to the documented requirement and description of the objective evidence demonstrating why the finding is a non-conformity. All findings must avoid promoting a possible means of corrective action.>>

Non-conformities

<<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 Cooperation Body requirements.>>

1. <<insert description of non-conformity>>
   [ISO/IEC 17011:2017; <<insert clause/sub-clause number(s)>>]

Comments

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

1. <<insert description of comment>>
   [ISO/IEC 17011:2017; <<insert clause/sub-clause number>>]

<<Not all Comments need to refer a clause in ISO/IEC 17011 or other requirements document. Evaluation teams should feel free to make suggestions that may assist an AB in developing their accreditation systems, without suggesting a comment that may be questioning the compliance status of a current practice of the AB.>>

<<The Team Leader should present these findings in a tabular form incorporating the AB's Corrective Action and Response Report and the Evaluation Team Reply in a single document. A recommended format is given in Annex VI.>>

ANNEX II: EVALUATION PROGRAMME AND AGENDA FOR THE VISIT

<<TL: Normally completed by the Team Leader. The schedule should show the activities of each member of the evaluation team over the course of the on-site evaluation. The schedule should be presented in the past tense – what actually happened, rather than what was planned prior to the evaluation. Every care must be taken to ensure the full anonymity of the organisations hosting the witnessed assessments i.e. organisation names, accreditation numbers, address, contact persons, etc. must be removed.

ANNEX III: ORGANISATION CHARTS OF *<<INSERT ACRONYM OF AB>>*

<<AB: This section is to be produced by the AB prior to the evaluation. The target audience for the charts is the Decision-Making Group, not the evaluation team – so the charts should be a full and complete picture of the overall organisation. The AB needs to be aware that the evaluation team has full editorial control over the content of this section and is free to add to, remove or otherwise amend the text as they see fit.>>

It is preferred if at least two charts are provided – one for the structure of the AB and another for the internal staffing. The structure chart should show such things as (where relevant):

- *The position of the AB within a parent body,*
- *The structural relationship with related bodies,*
- *Reporting lines within Government departments, up to Ministerial level,*
  Ownership & governance structures,
- *Committee structures.*

The staff organisation chart should show how the internal structure of the AB is organised (up to Director/President level), including:

- *Levels of management/supervision, with names of incumbents in key positions,*
- *Relationship with outside parties in the accreditation process e.g. external assessors/experts, committees, etc.*

ANNEX IIIa: *<<INSERT ACRONYM OF AB>>* Structure Chart

ANNEX IIIb: *<<INSERT ACRONYM OF AB>>* Staff Organisation Chart

ANNEX IV: LIST OF WITNESSED ASSESSMENTS

<<AB: Prior to the evaluation, the AB will have provided the complete scopes of accreditation to the evaluation team as separate documents. The AB should provide a summary description also, either during or immediately following the evaluation. The information should include the type of CAB and field of technology(ies), the type of assessment witnessed, the number of test/calibrations/inspections/etc. in each technology on the scope and/or sought as part of the assessment.>>

<<TL: Each evaluation team member should verify the information provided by the AB for incorporation into the report. Care must be taken to ensure the full anonymity of the organisations hosting the witnessed assessments i.e. organisation names, accreditation numbers, address, contact persons, etc. must be removed.>>

The following are summary descriptions of the assessed scopes of accreditation (either current or draft) of the *<<insert acronym of AB>>* assessments witnessed during the evaluation, as provided prior to the evaluation team. These have been edited to protect the identity of the accredited/applicant organisations.

<<insert type of CAB>>: *<<insert type of assessment; field of technology; duration of assessment>>*

<<description of scope>> e.g.

Laboratory A: *Initial assessment; Chemical Testing (2 days), or*

Inspection Body B: *Surveillance assessment; Engineering safety (1 Day)*

Reference Material Producer C: Initial Assessment; gases (1 day)

Management System Certification: Surveillance Assessment; QMS, EMS (1 day)

Product Certification E: Initial Assessment: Electrical Products (2 days), etc.

Note: there is no need to introduce the full scope of the CABs witnessed in the report.

ANNEX V: REPORT ON WITNESSED ASSESSMENTS

<<TL: Team Leaders must ensure each of their Team Members completes an "Information on Witnessed Assessment" template below for each of the AB assessments witnessed during the evaluation. A MS Word version of the template is available in the Members area of the Global ACI and Regional Cooperation Body websites. Completed templates are inserted into this Annex of this report.

Section 2 of the template highlights those key areas of the operation of a CAB that are considered critical to ongoing technical competence in relation to the relevant accreditation standard. These specific aspects are the key information the Regional Cooperation Body Decision-Making Group wishes to know when making decisions on the competence of an AB, particularly in regard to:

- *whether the AB assessment team assessing the CAB understands the intent of an accreditation standard;*
- *whether they understand the critical elements of technical competence of the accreditation standards that lead to comparability of conformity assessment results under the MRA; and*
- *whether these are applied by the AB in the assessment process and implemented by accredited CABs.*

The sub-sections of the templates prompt the evaluator to provide some commentary on how well these aspects were assessed by the witnessed assessment team. Where a sub-section is not relevant to the type of CAB being assessed, it must be deleted by deleting the row in the table. Team Members should be instructed that the commentary provided must be based on objective observation and formulated in the context of internationally accepted practices and the overall operation of the AB's accreditation programme(s). Expressions of personal preferences and comparisons with other AB practices are to be avoided.>>

Global ACI WITNESS REPORT

Information on witnessed assessment	
AB being evaluated	
Team member doing the witnessing	
Date(s) of assessment:	
Accreditation standard(s):	
Scope of assessment:	
Level 4 and 5, according to Global ACI MRA-001.	
Type of assessment	Initial / Re-assessment / other assessment activities / Scope extension / … (If other assessment activities are witnessed, please indicate if all requirements of the standard are to be assessed.)
Composition of the assessment team *(Only indicate number of people on the assessment team, whether they are from the AB or external and areas of activity. Do not mention their names or the name of the CAB in this report)*	Team leader: internal / external Assessor(s): number and areas Technical Expert(s): number and areas

Guidance for filling out this report:	
The issues that are considered relevant are indicated in brackets with keywords or phrases. Describe your positive and negative observations for each of the given issues, as applicable. The report should be drafted during or at the end of the witnessing. After the end of the witnessing and before concluding this report the (current) TM shall discuss the result of the witnessing with the AB assessment team and the AB so as to give them the opportunity to clarify any misunderstanding.	
1. Preparation by the accreditation body (ISO/IEC 17011, clauses 7.5 and 7.6)	
1.1	Consider: Assignment of team, Time allocated, Team composition related to scope of assessment, Information provided to the team, special arrangements; amount of planned witnessing, Document review. Competence and suitability of team nominated in relation to the particular assessment. Adequacy of documents used for preparation; information on results of previous assessments; other relevant information.
2. Conducting of the assessment	
2.1	Opening meeting (Presentation of participants; clarification of roles and responsibilities; purpose of assessment; accreditation criteria; assessment schedule, scope for the assessment, accreditation process; reporting)
2.2	(Adequacy of assessment in general: internal audits; corrective and preventive actions; management review; use of marks, scope of accreditation)
2.3	**Adequacy of assessment related to specific accreditations (Delete rows if not applicable):**
a	Laboratories: (contract review, traceability; uncertainty; validation; quality control; PT performance, data-processing, reporting; environmental conditions)
b	Medical laboratories (pre-examination; post-examination; method validation; quality control; PT performance; reporting; environmental conditions, Specifically clinical oversight / pathologist input & focus on patient care):
c	Inspection: (professional judgment; type A, B or C; monitoring and harmonising inspectors; selection and conduct of witnessing; quality assurance; calibration and traceability; testing and sampling

d	Proficiency Testing Provider: (planning, statistical design, instructions to participants, evaluation of performance & authorisation of final report not subcontracted; assurance of competence of subcontractors, subcontracting services, homogeneity and stability)
e	Reference Materials Producer: (production planning, material processing, metrological traceability & measurement uncertainty / CMC, subcontracting services, homogeneity and stability, characterisation, assignment of property values and their uncertainties)
f	QMS / EMS / FSMS / ISMS / MDMS certification: (competence management, qualification of auditors; man-days calculation; impartiality and independence; audit reports and decision making, witnessing).
g	Product certification: (compliance with ISO/IEC 17020 and ISO/IEC 17025; professional judgment; impartiality and independence; subcontracting, certification schemes, surveillance regime; competence; evaluation and decision making; witnessing)
h	Certification of persons: (assessment of competence of CB to perform examination; impartiality; witnessing; certification schemes, surveillance and recertification)
i	Validation/verification (impartiality; agreement, selection of the validation or verification team, planning, competence; reporting, review and validation or verification statement; communication, compliance with ISO/IEC 17029 and applicable level 4 and/or 5 normative documents. Facts discovered after the validation or verification statement)
2.4	Assessment of additional or specific requirements in the regulated area or sector schemes (e.g. WADA, GLOBALG.A.P. etc) and Consider coverage and interpretation of the normative documents for the subscope level 4 and 5.
2.5	Methods of collecting evidence and sampling techniques (interviews; observation of activities, locations, sufficient personnel; investigation of documents and records; appropriateness of techniques)
2.6	Depth and width of assessment (Coverage of the whole or planned part of the scope; means of deciding on focus points; dealing with extension or limitation of scope)
2.7	Recording of non-conformities (formulating the NCs; objective evidence; identification of true problems of the CAB; communicating with appropriate representative of the CAB)
3. Closing meeting	
3.1	(Assessment team interaction; preparation of closing meeting; agree on conclusions; agree on roles and tasks for meeting, evidence based on sampling, findings clearly explained with requirements for responses. Method & timeframe for reporting, complaints & appeals.)

3.2	(Presentation of findings and conclusions; understanding and acknowledgement; unresolved diverging opinions)
4. Conclusions	
4.1	Depth and width of assessment; findings relevant to the body assessed; competence issues duly addressed; points of focus relevant to the operation of the body. Assessor performance.
4.2	Do you agree with the overall conclusions of the assessment team? If this CAB is accredited, are they worthy of their accreditation status?)
5. Critical issues observed during the witness If any findings are raised based on this report, the critical issue that is related to the finding shall be described in this section and a reference to the number of the finding shall be made.	

ANNEX VI: *<<INSERT ACRONYM OF AB>>* CORRECTIVE ACTION AND RESPONSE REPORT AND EVALUATION TEAM REPLY (CURRENT EVALUATION)

<<TL: This section would not be included in the finalised "interim" report provided to the AB prior to the AB's response to the evaluation findings i.e. the report as agreed by the team and the AB. It will be reincorporated as per this template once the Corrective Action and Response Report is received from the AB. In accordance with Global ACI recommendations, Team Leaders are encouraged to present the findings, the AB response and the evaluation team comments in a readily assimilated format for the Decision-Making Group. The following table formats should be used for each of the non-conformities and comments, showing the wording of the finding (from Annex I), the AB response, the team comments, and any further iteration of the latter two entries.>>

<<AB: The AB response to the non-conformities detailed in Annex I is prepared by the AB. It is provided after the receipt of the main body of this report (the "interim" report). It can be inserted directly into the tables below (or as a single document suitable for cutting and pasting into the tables), and provide a narrative summary of the actions taken (correction and/or corrective action) and/or proposed. The description shall include a cause analysis, including the extent of the finding and its impact.

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.

The AB may refer to supporting documents as objective evidence, but as the target audience is the Decision-Making Group who may not be provided with direct access to the supporting documents, this response should be able to stand alone in explaining the actions/changes made or proposed.>>

The AB is encouraged to respond to the comments.

<<TL: Where the AB response is provided as a separate file to this report, this should be inserted into the tables without any change to its content. Due to vagaries in the different versions of MS Word, inserting a file from another AB is not always a complete success and editorial (fonts, etc) and formatting changes do need to be made. In such cases an appropriate disclaimer should be made (see below) but no changes to the content are permitted.

Editorial Note: This document has undergone some editorial and formatting amendments from that supplied by <<insert acronym of AB>> for ease of assimilation into this report.

The evaluation team's response to the AB's response is inserted in the appropriate rows in the following tables. It should summarise whether the team considers the AB has adequately addressed the non-conformities identified by the evaluation, and should acknowledge the response to Comments.>>

NONCONFORMITIES

Number	Description of Nonconformity and requirements reference (from Annex I)
NC#1	*<<copied from Annex I>>*

Date	First response from ***<<insert acronym of AB>> (with cause analysis, including the extent of the finding and its impact, 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.)***
dd/mmm/yy (i.e. 01 Jan 11)	
Date	**Response from evaluation team**
dd/mmm/yy	

Date	Second response from ***<<insert acronym of AB>>***
dd/mmm/yy	
Date	**Response from evaluation team**
dd/mmm/yy	

<<If additional responses are required, more lines should be added to the table>>

<<Copy and paste NC table template here for additional non-conformities>>

COMMENTS

Number	Description of Comment (from Annex I)
Cm#1	*<<copied from Annex I>>*

Date	Response from ***<<insert acronym of AB>>***
dd/mmm/yy (i.e. 01 Jan 11)	
Date	**Comment from evaluation team if any**
dd/mmm/yy	

<<If additional responses are required, more lines should be added to the table>>

<<Copy and paste Cm template (the table above) here for additional Comments>>

PART 3. EVALUATION REPORTING ON A SINGLE ACCREDITATION BODY

A. Steps in Evaluation Reporting on a Single Accreditation Body

1. **Preparation of the summary section of the report** including as an appendix the non-conformities and comments presented, preferably in table format. This shall be completed and confirmed with the AB at the end of the on-site evaluation visit.

2. **Preparation of the draft report of the on-site evaluation visit** (within 2 months after closing of the on-site evaluation). This report is the agreed report of the evaluation team and the accreditation body and includes the results of the witness activities. This includes the full text of the summary section of the report.

3. **Formal response of the accreditation body to the findings** (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). Ideally, the accreditation body's response can simply be inserted text under each finding presented in table format with attachments of supporting evidence of corrective action as appropriate.

   The evaluated AB must respond to each non-conformity 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.

   The evaluated AB is encouraged to respond to comments.

4. **Formal reaction of the evaluation team to this response** (within one month of receipt by the team of the AB's formal response to the findings). The evaluation team's reaction to each response to every finding shall be submitted in writing to the accreditation body for consideration.

5. **Steps 3 and 4 may be repeated.**

   NOTE: Any problems completing steps 3 or 4 should be reported to the Chair of the Management Committee.

6. **Preparation of a final report to the Arrangement Group** (within one month of completion of steps 2, 3 and 4). This report consists of the items identified under steps 2, 3 and 4 (i.e., formal evaluation team report, formal AB response and formal evaluation team reaction). In addition, the recommendation of the evaluation team is stated as the leading page of the evaluation team's final report. Items included in steps 3 and 4 should be combined into one table stating the non-conformities, the formal AB response including corrective actions, and the evaluation team's reaction. This will ease the review process of the Decision-Making Group.

B. Classification of Findings

Finding: To be used as a general term.

Non-conformity: Finding where the AB does not meet a requirement of the applicable standard (ISO/IEC 17011), its own management system or the Arrangement requirements.

Comment: Finding where the requirements related to the AB's practices or documented information are fulfilled but there is potential for improvement.

Note for information - This is a standalone document under the responsibility of the region secretariats:

DECLARATION OF CONFIDENTIALITY AND IMPARTIALITY FROM THE EVALUATION TEAM AND OBSERVERS

AMENDMENT TABLE

Section	Previous Version	Summary Of Changes
All	-	Initial issue of document.
1.2.6	1.0	Form number changed from Global ACI-FMRA-017 to Global ACI-FMRA-018.