



Asia Pacific Laboratory Accreditation Cooperation

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

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

BY THE

**ASIA PACIFIC LABORATORY ACCREDITATION COOPERATION
(APLAC)**

<<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
Ms Nosey Parker (AB1, New Zealand) - Observer
Etc., etc.>>

This Report is

CONFIDENTIAL

to the

<<insert name of AB>>

Evaluation Team Members

Members of the APLAC MRA Council

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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 (typically two pages) and inserted in to 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 APLAC 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 the Asia-Pacific Laboratory Accreditation Cooperation (APLAC) for the purpose of obtaining evidence to determine:

- (a) <<for a re-evaluation>> Whether the APLAC Mutual Recognition Arrangement (MRA) signatory status of <<insert acronym of AB>> for the accreditation of <<insert MRA scope of the AB e.g. testing laboratories, medical laboratories (ISO 15189), calibration laboratories, inspection bodies, reference material producers>> should be maintained; <<and/or>>
- (b) <<for an initial evaluation or MRA scope extension evaluation>> Whether <<insert acronym of AB>> should be recommended as a full signatory to the APLAC MRA for the accreditation of <<insert evaluated scope for which AB has applied e.g. testing laboratories, medical laboratories (ISO 15189), calibration laboratories, inspection bodies, reference material producers>>.

The evaluation was conducted in accordance with, and against the requirements specified in APLAC MR 001) .

<<The next section should give overview statements on the general level of compliance with MRA 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 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 APLAC MR 001. In particular:

- (a) <<insert acronym of AB>> operates its <<insert MRA scope e.g. testing laboratory, calibration laboratory, inspection body, reference material producer>> accreditation programme(s) substantially in accordance with the requirements of ISO/IEC 17011 and ILAC/IAF A5;
- (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 IAF/ILAC-A4;

- (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 Guide 34 and where applicable, in combination with ISO/IEC 17025;
- (f) <<insert acronym of AB>> adopts and <<substantially>> implements the International Laboratory Accreditation Cooperation (ILAC) policy on traceability of measurement results (ILAC-P10), and the <<insert economy name>> national measurement system can provide satisfactory measurement support to <<insert acronym of AB>> accredited <<as relevant>> laboratories, inspection bodies and reference material producers in the basic physical units;
- (g) <<insert acronym of AB>> adopts and <<substantially>> implements the International Laboratory Accreditation Cooperation (ILAC) supplementary requirements and guidelines for the use of accreditation symbols and for claims of accreditation status (ILAC-P8);
- (h) <<insert brief overview description of skills, experience and levels of qualification of AB staff and access to assessors and their skills, experience and qualifications e.g.>> <<insert acronym of AB>> permanent staff are skilled and satisfactorily technically qualified for the functions they perform, and the organisation has an excellent foundation of accreditation experience. <<insert acronym of AB>> has access to a sufficient number of well qualified, experienced and competent external Technical Assessors and Experts;
- (i) <<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, and reference material producers;
- (j) <<insert acronym of AB>> has the necessary commitment, financial and other resources to continue to operate an independent (suite of) accreditation programme(s);
- (k) <<insert acronym of AB>> and its accredited laboratories meet, as far as practicable, the ILAC-P9 requirements for proficiency testing activity and has participated in a number of APLAC PT programmes. The performance of their accredited laboratories since <<insert date of last APLAC evaluation>> has been generally satisfactory and outliers have been investigated. <<insert acronym of AB>> has organised a range of PT programmes for its accredited organisations;
- (l) <<insert acronym of AB>> has documented and implemented an appropriate cross-frontier accreditation policy taking into account ILAC-G21;
- (m) <<insert acronym of AB>> fulfils its MRA obligations under the APLAC MR 002 and the ILAC MRA document ILAC-P5, and;
- (n) 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 scope extensions>>) APLAC MRA 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. The following accreditation assessments were witnessed by the evaluation team: <<list type and duration of assessments observed>>

Testing:	<<e.g. 1 initial assessment (2 days; food chemical testing)>> <<e.g. 1 surveillance assessment (1 day; electrical/EMC testing)>>
Medical Testing	<<e.g. 1 reassessment (3 days)>>
Calibration:	<<e.g. 1 reassessment (3 days; dimensional, electrical, temperature)>>
Inspection:	<<e.g. 1 reassessment (2 days; engineering safety)>>

Reference Material Producer: <<e.g. 1 initial assessment (3 days; chemical solutions)>>

<<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 nonconformities, concerns and comments, as appropriate e.g.>>

<<number>> nonconformities, <<number>> concerns, and <<number>> comments were raised by the evaluation team. The <<number>> nonconformities relate to <<brief statement on the area of ISO/IEC 17011 they relate to e.g. assessor monitoring, related body analysis, etc., etc.>>, and the <<number>> concerns 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 nonconformities, concerns 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 APLAC MRA Council on reaffirming its APLAC MRA signatory status for <<insert existing MRA scope>> ;
- (ii) <<for initial or MRA scope extension evaluations>> forward any recommendation to the APLAC MRA Council on entry into the MRA for <<insert evaluated MRA scope extension>>.

The Corrective Action and Response Report must include a time schedule to address the nonconformities and a response to the concern(s).

It is also recommended <<insert acronym of AB>> to give due consideration 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>>

Section 2: INTRODUCTION

2.1 Reason for the Evaluation

This was a <<insert type of evaluation e.g. initial, periodic re-, etc.>> evaluation conducted on behalf of the Asia Pacific Laboratory Accreditation Co-operation (APLAC) to:

- (i) <<for re-evaluations>> Reconfirm conformity with specified criteria for the continuation of <<insert acronym of AB>> Signatory Status in the APLAC Mutual Recognition Arrangement (MRA) for the accreditation of <<insert existing APLAC MRA scope of the AB>> (and thus also continuation of <<insert acronym of AB>> Signatory Status in the ILAC MRA for <<insert existing ILAC MRA scope>> by virtue of APLAC’s status as a Regional Co-operation recognised by ILAC);
- (ii) <<and/or for initial evaluations and MRA scope extension evaluations>> Establish conformity with specified criteria for <<insert acronym of AB>> possible entry into the APLAC MRA for the accreditation of <<insert evaluated MRA scope extension>>;

2.2 Participants in the Evaluation

The evaluation team comprised the following members, with major areas of responsibility during the evaluation indicated:

Name	Organisation	Major area of responsibility
Mrs Eve Aluator	AB1, New Zealand	Team Leader, testing, PT, management system, APLAC requirements
Mr E.M.C. Nerd	AB2, USA	Testing
Dr Cal Ibrator	NMI, Australia	Calibration
A.N. Other	LOTR AB, Middle Earth	Testing & Inspection
Ms Nosey Parker	AB1, New Zealand	Observer

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

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

2.3 Evaluation Criteria

This evaluation was conducted in accordance with the procedures specified in APLAC MR 001 “Procedures for Establishing and Maintaining the APLAC Mutual Recognition Arrangement Amongst Accreditation Bodies” (<<insert issues number and date of issue>>). The criteria against which the evaluation of <<insert acronym of AB>> was conducted was that specified in <<insert appropriate sections e.g. Section 3>> of APLAC MR001. With respect to the objectives of the evaluation detailed in Section 2.1 above, the evaluation criteria was applied to establish:

- (a) Whether <<insert acronym of AB>> meets and applies the requirements of <<Section 3>> of MR 001, including,
- (b) The implementation of the following documents in the accreditation of its <<insert existing/proposed MRA scope of the AB>>:
 - ISO/IEC 17011 “Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies”, and ILAC/IAF A5

- IAF/ILAC-A2 “IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Requirements for Evaluation of a Single Accreditation Body” <<(Section 2)>>
 - ILAC P1: “ILAC Mutual Recognition Arrangement (Arrangement): Requirements for Evaluation of Accreditation Bodies” <<(Section 5)>>
- (c) The adoption and application of ISO/IEC 17025 “General requirements for the competence of testing and calibration laboratories” by its accredited testing and calibration laboratories, and/or the adoption and application of ISO 15189 “Medical Laboratories – Particular requirements for quality and competence” by its accredited medical testing laboratories;
- (d) The adoption and application of ISO/IEC 17020 “General requirements for the operations of various types of bodies performing inspection” and IAF/ILAC-A4 “Guidance on the Application of ISO/IEC 17020” by its accredited inspection bodies;
- (e) The adoption and application of ISO Guide 34 “General requirements for the competence of reference material producers” in combination with ISO/IEC 17025 by its accredited reference material producers;
- (f) The adoption and application of ILAC-P10: “ILAC Policy on Traceability of Measurement Results” by its accredited organisations;
- (g) The adoption and implementation by <<insert acronym of AB>> of ILAC-P8: “ILAC Mutual Recognition Arrangement (Arrangement) – Supplementary Requirements and Guidelines for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories”
- (h) The adoption and application of ILAC-P9: “ILAC Policy for Participation in National and International Proficiency Testing Activities” by <<insert acronym of AB>> and its accredited organisations;
- (i) Whether <<insert acronym of AB>> has documented and implemented a cross-frontier accreditation policy taking into account ILAC-G21: “Cross Frontier Accreditation – Principles for Avoiding Duplication”;
- (j) Whether <<insert acronym of AB>> satisfactorily meets its obligations under the APLAC MR 002 “Mutual Recognition Arrangement” and ILAC-P5: “ILAC Mutual Recognition Arrangement (Arrangement)”.

2.4 Evaluation Activities

The evaluation process followed very closely the relevant processes described in <<detail all relevant sections and appendices>> of MR 001. <<if relevant>> Under <<quote section>> of MR 001, <<insert acronym of AB>> requested special emphasis be paid to the accreditation of <<detail special emphasis>>, which was (not) able to be accommodated through the selection of a <<detail special area>> specialist as an evaluator on the evaluation team and through the witnessing of <<the number and type of relevant>> assessments.

<<insert acronym of AB>> provided the requisite documentation <<as required for; well in advance of>> the on-site evaluation. The list of documents provided is detailed in Annex II. 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 III.

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

<<list type and duration of assessments observed>>

- <<e.g. 1 initial assessment (2 days; food chemical testing)>>

- <<e.g. 1 surveillance assessment (1 day; electrical/EMC testing)>>
- <<e.g. 1 reassessment (3 days; dimensional, electrical, temperature)>>
- <<e.g. 1 reassessment (2 days; engineering safety)>>
- Etc., etc.

The summary description of the scopes of accreditation of the assessed organisations is given in Annex V.

A full commentary 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.

<<Some evaluation teams choose to repeat the findings detailed in Annex I in the main body of the report (Sections 3 & 4) in order to give them some context. When this is done, they must be an exact reproduction of the content of Annex I and be clearly highlighted. The following type of statement is recommended.>>

The evaluation team identified <<insert number>> nonconformities, <<insert number>> concerns and made <<insert number>> comments. These findings, summarised in Annex I, were provided to <<insert acronym of AB>> immediately following the evaluation and are also detailed in the text of Sections 3 and 4 as follows:

- **Nonconformities** are detailed in **bold font underlined**
- **Concerns** are detailed in **bold font** only
- Comments are detailed in underlined italicised font.

2.5 Follow-up on Previous Evaluation Findings

<<AB: Where relevant, the AB could complete this section of the report by providing an overview of the corrective action taken on the Nonconformities and Concerns identified at the previous evaluation of the AB. Annex VIII of this report can be used to provide the detail of the findings and the AB response. The AB should complete the first and second columns of the table in Annex VIII by cutting and pasting from the previous evaluation report.>>

<<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. An overview commentary in this regard needs to be included in this Section, and/or completion of the table in Annex VIII of this report. This is particularly important where the APLAC MRA Council decisions (resolutions) arising from the last evaluation specifically direct the evaluation team to follow-up on certain aspects of the AB's operation. Including the text of such resolutions (available from the Secretariat) may be worthwhile to add to this Section. Where the evaluation team identifies repeat or related findings, these should cross referenced to the findings detailed in Annex I.>>

Section 3: BACKGROUND OF <<insert acronym of AB>>

<<AB: Sections 3.1, 3.2, 3.3 and 3.4 are to be written by the AB prior to the evaluation. The target audience for the text is the MRA Council, not only the evaluation team – so the text should be a full and complete narrative. References to documents and procedures the Council 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.

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 necessary to describe the team's understanding based on the evaluation. 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 the commentary provided by the AB must be amended to reflect the observations of the team. The team is free to remove text that is not considered necessary or relevant, and is encouraged to add observations and comments that will aid in the MRA Council's understanding of the AB.>>

3.1 Legal Status, Relationship to Government and History

<<AB: As suggested by the title, the text must include a full description of the following:

- The legal status of the AB and of its owners.
 - Governmental ABs must describe the Ministries and/or Departments the AB is part of, and reference the Acts, Regulations or other statutory instruments which describe the authority under which the AB operates.
 - Private sector ABs must 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 also need to describe their relationship with Government, such as any legal or contractual arrangements, memoranda of understanding, recognition by regulatory agencies, etc.
- The discussion under each of the above points must be made with reference to, and be fully consistent with the organisation charts in Annex IV which the AB must also provide in this report).
- A brief description of the history of the AB – when it was established, when the first accreditation was granted in each accreditation programme under the MRA, significant milestones, etc.>>

3.2 Current Scope of Accreditation Activity

<<AB: The commentary must contain (but should not be limited to) 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 3.1 above);
- The sub-programmes or fields within each programme in which accreditation is offered;
- The criteria that is used in each programme;
- The number of organisations in each programme and field (sub-programme), including the current number of active accreditations and the number of applicants;

- *The current rate of growth e.g. statistics such as the number of new accreditation is each field in the last year or since the last evaluation, or the like;*
- *Which accreditation activities (particularly fields) the AB considers to be part of the MRA, and which fields are not;*
- *Any economies outside of their own in which the AB provides accreditation, and the number of accreditations in each.*
- *What other related activities the AB is involved in outside of accreditation e.g. training services, etc.>>*

3.3 Structure, Management and Staffing of <<insert acronym of AB>>

<<AB: The structure and organisation discussion must be made with reference to, and be fully consistent with the organisation charts in Annex IV (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?>>

3.4 Other General Provisions (Financing & Liability Provisions)

<<AB: The AB must describe 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. Liability insurance provision should also be indicated i.e. government body protection, insurance for private sector ABs.>>

Section 4: PERFORMANCE OF THE SYSTEM

The performance of the <<insert acronym of AB>> system was evaluated against the standards and requirements specified in Section 2.3, using the IAF/ILAC Key Performance Indicators stated in IAF/ILAC-A3:05/2007 as a tool. <<insert acronym of AB>> provided a written narrative for each Key Performance Indicator before the evaluation, which was used by the evaluation team in preparation for the evaluation. The narrative from <<insert acronym of AB>> may have been edited and/or added to where required to reflect actual observation and to provide a brief summary of the highlights of the <<insert acronym of AB>> system and/or points of difference with common practices in other accreditation bodies.

<<AB: Each section is to be written by the AB prior to the evaluation. The target audience for the text is the MRA Council, not only the evaluation team – so the text should be a full and complete narrative. References to documents and procedures the Council will not have access to must be avoided. The AB needs to be aware that the evaluation team is free to add to, remove or otherwise amend the text as necessary to describe the team’s understanding based on the evaluation. This text can often be obtained in English from the translated version of the AB’s quality manual.>>

<<TL: One of the roles of the evaluation team is to verify the text provided by the AB prior to the evaluation. Where the evaluation team is not fully satisfied that the text provided by the AB fully represents the situation then the commentary needs to be amended to reflect the understanding of the team. The team is free to remove text that is not considered necessary or relevant, and is encouraged to add observations and comments that will aid in the MRA Council’s understanding of the AB, both its strengths and possible weaknesses and/or points of difference with common practices in other accreditation bodies.>>

<<Both the AB and the TL are reminded to review the introduction to IAF/ILAC-A3 for guidance as to the purpose of the KPIs and considerations when writing the narrative. In order for the evaluation team to be able to make the most effective use of the narrative KPI descriptions, the AB is reminded that while the KPIs are an opportunity to describe their organisation in a positive manner, the performance statements must reflect as closely as possible the objective evidence that can be observed by independent parties. This will avoid excessive rewriting on the part of both the team and AB. >>

4.1 Access to Expertise (KPI 1)

[ISO/IEC 17011:2004: 4.2.6, 4.2.7, 4.2.8, 4.6.2, 4.6.3]

<<AB: The AB should describe the mechanisms by which it accesses its expertise, as outlined in the IAF/ILAC-A3 KPI 1. 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 should describe how it identifies the need for expertise; how this expertise recruited and how it is managed and used in establishing accreditation criteria (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.>>

4.2 <<insert acronym of AB>> Scope, Extension of Scope, and Accreditation Criteria (KPI 2)

[ISO/IEC 17011:2004: 4.6.1, 4.6.2, 4.6.3, 7.1.1, 7.1.2(a)(b)(j), 8.2.4]

<<AB: For the current scope of accreditation (and other) activities, see Section 3.2 above. In addition the AB needs to give an overview of the policies and processes for possible 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 indicated in the KPI:

- Analysis of the suitability of the extension;
- Access to expertise (see KPI 1 above);
- Selection and training of AB staff and assessors;
- Requirements/cooperation with interested parties, such as regulators;
- International mutual recognition issues.

This KPI also needs to describe the accreditation criteria used in its current scope of activities and how it is established for extensions of scope, with particular reference to international standards, APLAC MRA requirements documents, and other international harmonised guides. A description of any programme or field specific accreditation criteria should also be described, with an indication of how it has been developed and why.

See also IAF/ILAC-A3 KPI 2.>>

4.3 Competence of <<insert acronym of AB>> Staff, Assessors, Experts and Committees (KPI 3)

[ISO/IEC 17011:2004: 4.3.5, 4.6.2, 6.1.1-6.1.3, 6.2, 6.3, 6.4, 7.5.2]

<<AB: The AB needs to provide a full description of the mechanisms for ensuring the competence of each of the groups of personnel stated in the title. Such mechanisms may include person specifications for each position, how individuals are selected, inducted, trained (both initially and on-going), and monitored. Examples of such a commentary may include the following but should also address all the relevant elements detailed on the IAF/ILAC-A3 KPI 3.

<<insert acronym of AB>> Staff

- With reference to Section 3.3. and the organisation chart in Annex IV, 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 person specifications and job descriptions for each position;
- Induction and training processes for key operational staff involved in the accreditation process;
- Monitoring of the competencies of operational staff involved in the accreditation process, the identification of training needs, and the delivery of such training.

Assessors

- How assessors are recruited and qualified;
- The total number of currently qualified assessors, preferably broken down by accreditation programmes and fields of technology, and an overview of their technical and assessment qualifications, training and experience;

- *How assessors are inducted, trained and qualified, including the qualification into the technical scopes they are deemed competent to assess;*
- *How assessors are systematically monitored, and what actions are taken when training needs are identified;*
- *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;*
- *Other forms of monitoring and feedback that ensures the on-going competencies of assessors.*
- *On-going training for assessors.*

Experts

- *As relevant, the same commentary as for Assessors, plus;*
- *The mechanisms for supervision of experts by qualified assessors during the assessment 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 and qualified;*
- *Particularly where committees are involved in the accreditation process (most commonly, in the accreditation decision), how committees are monitored, and what actions are taken when training needs are identified;*
- *What support systems are in place for committee 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).>>*

4.4 The Assessment and the Assessment Team (KPI 4)

[ISO/IEC 17011:2004: 7.2, 7.3, 7.5-7.7, 7.8.1-7.8.5, 7.9.3]

<<AB: A general description of the accreditation process needs to be provided. It needs to contain sufficient detail to give a clear picture to the mode of operation of the AB. The key elements and actions in the overall process need to be identified, and a description of the controls in place at these points (which ensures the on-going integrity of the competence of the process) should be included. Such a commentary would typically include:

- *The content of the application documentation and the personnel involved in its initial review and acceptance;*
- *Preliminary visits, where relevant;*
- *Selection and appointment of an assessment team, with particular emphasis on its constitution to ensure effective coverage of the requested scope of accreditation and depth of assessment;*
- *Specific arrangements with respect to subcontracting of the assessment, where relevant;*
- *Review of the assessment documentation by the assessment team prior to the on-site assessment;*
- *Conduct of the on-site assessment process, including an overview on policies regarding the sampling of sites and sampling of CAB personnel;*
- *Maintenance of records of the assessment process;*
- *The assessment report.*

See also IAF/ILAC-A3 KPI 4.>>

<<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 witness (see Annex VI). In this

Section 4.4 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.>>

4.5 Impartiality (KPI 5)

[ISO/IEC 17011:2004: 4.2.1-4.2.5, 4.2.7, 4.2.8, 4.3, 4.4, 4.5.2, 4.6.2, 5.2.1, 5.9, 6.1.4, 7.1.2(g), 7.1.2(k), 7.4, 7.5.3, 7.5.4, 7.9.3]

<<AB: A description of the processes by which the AB ensures the impartiality and independence of the accreditation process needs to be given. 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 processes described need to address such factors as commercial independence and financial relationships, other potential forms of undue influence on the integrity of the accreditation process, and how the involvement of interested parties assures such influences are minimized. Where relevant, the commentary should also include a discussion on the analysis of related bodies to the AB. See also IAF/ILAC-A3, KPI 5.>>

4.6 Dealing with Nonconformities and Corrective Actions of the CABs, and Decision making by <<insert acronym of AB>> (KPI 6)

[ISO/IEC 17011:2004: 4.3.7(b), 7.4, 7.6.2, 7.8.1-7.8.5, 7.8.6, 7.9.1-7.9.3, 7.11.5, 7.11.6, 7.12, 7.13, 8.3.2, 8.3.3]

<<AB: Following on from Section 4.4, a description of the following needs to be provided:

- *How nonconformities with accreditation criteria are conveyed to the assessed CAB;*
- *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, reinstatement, continuation, scope reduction, scope extension;*
- *What actions are taken on unsatisfactory resolution?*

The accreditation decision making process should be fully described, including:

- *The effective separation from the assessment and assessment team;*
- *The use of PT in the decision making process;*
- *The use of complaints in accreditation decision making;*
- *Processes for consideration of appeals against accreditation decisions.*

See also IAF/ILAC-A3 KPI 6.>>

4.7 Internal Audits and Management Reviews (KPI 7)

[ISO/IEC 17011:2004: 5.2.3, 5.5-5.9, 7.10]

<<AB: A full description of the internal audit and management review processes should be given, including scope and schedules and how outcomes of both internal audits and management review are used for the continual improvement of the accreditation system. See

also IAF/ILAC-A3 KPI 7. The description may also include an overview of other related generic management system processes such as non-conformance/corrective action, preventive action, complaints, etc. >>

4.8 Proficiency Testing (KPI 8)

[ISO/IEC 17011:2004: 7.8.1, 7.8.6(j), 7.15]

<<AB: A description of the AB's policies on the frequency of participation in PT activities by applicant and accredited laboratories and inspection bodies needs to be given, including reference of any mandated PT programmes. The policies described should indicate how PT activities are selected and how the AB uses these results in the assessment process, the surveillance programme and in the accreditation decision making, and how the AB monitors the corrective actions by CABs on unsatisfactory performance.

See also IAF/ILAC-A3 KPI 8.>>

4.9 Calibration, Traceability and Reference Materials (KPI 9)

[ISO/IEC 17011:2004: 4.2.6, 7.1.1, 7.1.2(b), 8.2.2]

<<AB: The AB needs to describe its policies for achieving satisfactory measurement traceability by its accredited CABs. Where it may not be possible to meet the requirements of ILAC-P10 domestically, the AB needs to describe its policies for managing such situations.

Included in the commentary should be AB policies on the use of reference materials to achieve measurement traceability, where the concept applies.

The AB's policies on the estimation of measurement uncertainty should also be described, including how these are to be used in the traceability chain.

See also IAF/ILAC-A3 KPI 9.>>

4.10 Surveillance and Re-assessment (KPI 10)

[ISO/IEC 17011:2004: 7.5.8, 7.5.9, 7.11, 8.1.2]

<<AB: The AB needs to describe in full its surveillance and reassessment programme for accredited CABs, including:

- The term of accreditation, and whether or not expiry dates are used;
- The reassessment frequency;
- The nature, frequency and scope of surveillance activities, with particular emphasis on on-site surveillance and the associated sampling of sites, personnel, and the scope of accreditation. Other forms of surveillance information should also be described in full i.e. what information? Where is it sourced from?
- The accreditation decision making process for each of the above activities.

See also IAF/ILAC-A3 KPI 10.>>

4.11 Supporting Activities (KPI 11)

[ISO/IEC 17011:2004: 4.3.6, 4.3.7, 8.2]

<<AB: The AB needs to describe its non-accreditation activities that support its accreditation function and discuss the potential impact of these on its impartiality and independence. Such activities may include:

1. Provision of training services in conformity assessment and related activities;

2. *Advice on, and promotion of accreditation to interested parties in accreditation e.g. regulators, specifiers;*
3. *Publications of general and specific interest e.g. newsletters, registers of PT providers or reference material producers;*
4. *Participation in standards writing bodies;*
5. *etc., etc.*

See also IAF/ILAC-A3 KPI 11.>>

Section 5: MUTUAL RECOGNITION ARRANGEMENT (MRA) OBLIGATIONS

<<AB: This section is to be written by the AB prior to the evaluation. The target audience for the text is the MRA Council, not only the evaluation team – so the text should be a full and complete narrative and references to documents and procedures the Council will not have access to must be avoided. The AB needs to be aware that the evaluation team is free to add to, remove or otherwise amend the text as necessary to describe the team’s understanding based on the evaluation. For non-English speaking ABs, this text can often be obtained in English from the translated version of the AB’s quality manual.

The AB should provide a commentary on the following types of activities it undertakes in support of the APLAC and other MRAs:

- Level of attendance and participation in APLAC and ILAC meetings, and any positions of office held therein;
- Participation of its accredited organisations in APLAC and other regional PT programmes;
- Participation/membership on APLAC/ILAC committees and Working Groups, and any positions of office held therein;
- Provision of peer evaluators and Lead Evaluators to the APLAC evaluator list, and the numbers of evaluations for which evaluators have participated in since the last evaluation;
- Promotional activities of the APLAC/ILAC MRA, including supporting its role through participation in international trade facilitation forums;
- Acceptance policies for test, calibration and inspection certificates from organisations accredited by MRA partners;
- Adoption of and protection of the ILAC Combined MRA mark.>>

<<TL: The team is free to remove text that is not considered necessary or relevant, and is encouraged to add observations and comments that will aid in the MRA Council’s understanding of the AB.

Team Leaders are reminded that MRA obligations only apply if the AB is a member of the MRA i.e. compliance with the APLAC and ILAC MRA is not mandatory for initial evaluation. However, the MRA Council will be interested in the adoption of MRA principles (under the APLAC MoU) for applicant ABs.>>

Annex I: NONCONFORMITIES, CONCERNS 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 in to 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 Nonconformity and Concern 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 nonconformity or concern. All findings must avoid promoting a possible means of corrective action.>>

Nonconformities

<<Finding where the AB does not meet a requirement of the applicable standard(s) e.g. ISO/IEC 17011, its own management system or the APLAC MRA requirements in a way that discredits its competence or jeopardises the quality of its work [MR001].>>

1. <<insert description of nonconformity>>
[ISO/IEC 17011:2004; <<insert clause/sub-clause number(s)>>]

Concerns

<<Finding where the AB's practice may develop into a nonconformity or the team is not fully satisfied [MR001].>>

1. <<insert description of concern>>
[ISO/IEC 17011:2004; <<insert clause/sub-clause number(s)>>]

Comments

<<Finding about documents or the AB's practices with a potential of improvement but still fulfilling the requirements [MR001].>>

1. <<insert description of comment>>
[ISO/IEC 17011:2004; <<insert clause/sub-clause number>>]

<<Not all Comments need to reference 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 may be questioning the compliance status of a current practice of the AB.>>

<<As suggested by MR001, the Team Leader may choose to 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 possible format is given in Annex VIII.>>

Annex II: LIST OF DOCUMENTS SUPPLIED BEFORE THE EVALUATION

<<AB: This should/must be prepared by the AB prior to the evaluation. The list is included for possible future reference so each individual document should uniquely and fully identified (with version numbers/issue dates where relevant). 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.>>

<<TL: The Team Leader should verify the receipt of the listed documents as they arrive, or else prepare the list him/herself as the documents are received. The list is included for possible future reference so each individual document should uniquely and fully identified (with version numbers/issue dates where relevant).>>

The following documents were provided as part of the official submission of the Set A and Set B documents required under MR001, plus additional follow-up documents requested by the Team Leader or volunteered by <<insert acronym of AB>>.

1. Initial Set A and Set B submission
 - (i)

2. Additional documentation
 - (i)

Annex III: EVALUATION SCHEDULE 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.

Often the evaluation schedule is presented as a table in landscape format. An example follows.>>

	Mrs Eve Aluator	Mr E.M.C. Nerd	Dr Cal Ibrator	A.N Other	Ms Nosey Parker
Sun, dd/mm/yy 15:00hrs	Evaluation Team meeting	Evaluation Team meeting	Evaluation Team meeting	Evaluation Team meeting	Evaluation Team meeting
Mon, dd/mm/yy Evening; 18:00hrs	<u>AB Offices</u> • Introductions • Presentation Commence evaluation 17011 clauses/KPIs/MR-docs <i>Detail elements covered</i> Evaluation Team meeting	<u>AB Offices</u> • Introductions • Presentation Commence evaluation 17011 clauses/KPIs/MR- docs <i>Detail elements covered</i> Evaluation Team meeting	<u>AB Offices</u> • Introductions • Presentation Commence evaluation 17011 clauses/KPIs/MR- docs <i>Detail elements covered</i> Evaluation Team meeting	<u>AB Offices</u> • Introductions • Presentation Commence evaluation 17011 clauses/KPIs/MR- docs <i>Detail elements covered</i> Evaluation Team meeting	<u>AB Offices</u> • Introductions • Presentation Commence evaluation 17011 clauses/KPIs/MR- docs <i>Detail elements covered</i> Evaluation Team meeting
Tues, dd/mm/yy	Travel to assessments <u>Assessment Observation</u> <i>Detail type of CAB, technical field, type of assessment</i>	Travel to assessments <u>Assessment Observation</u> <i>Detail type of CAB, technical field, type of assessment</i>	Travel to assessments <u>Assessment Observation</u> <i>Detail type of CAB, technical field, type of assessment</i>	Travel to assessments <u>Assessment Observation</u> <i>Detail type of CAB, technical field, type of assessment</i>	Travel to assessments <u>Assessment Observation</u> <i>Detail type of CAB, technical field, type of assessment</i>
Wed, dd/mm/yy	<u>Assessment Observation</u> <i>Detail type of CAB, technical field, type of assessment</i> Travel back to AB Offices	<u>Assessment Observation</u> <i>Detail type of CAB, technical field, type of assessment</i>	<u>Assessment Observation</u> <i>Detail type of CAB, technical field, type of assessment</i>	<u>Assessment Observation</u> <i>Detail type of CAB, technical field, type of assessment</i>	<u>Assessment Observation</u> <i>Detail type of CAB, technical field, type of assessment</i>
Thurs dd/mm/yy Evening 18:00 hrs	<u>AB Offices</u> Continuation of evaluation of 17011 clauses/KPIs/MR-docs • Report drafting Evaluation Team meeting • Report drafting	<u>Assessment Observation</u> <i>Detail type of CAB, technical field, type of assessment</i> Travel back to AB Offices Evaluation Team meeting • Report drafting	<u>Assessment Observation</u> <i>Detail type of CAB, technical field, type of assessment</i> Travel back to AB Offices Evaluation Team meeting • Report drafting	<u>Assessment Observation</u> <i>Detail type of CAB, technical field, type of assessment</i> Travel back to AB Offices Evaluation Team meeting • Report drafting	<u>Assessment Observation</u> <i>Detail type of CAB, technical field, type of assessment</i> Travel back to AB Offices Evaluation Team meeting • Report drafting
Fri, dd/mm/yy (a.m.) (p.m.)	<u>AB Offices</u> • Follow-up/completion of issues from Monday and assessments • Report finalisation Presentation of evaluation team findings	<u>AB Offices</u> • Follow-up/completion of issues from Monday and assessments • Report finalisation Presentation of evaluation team findings	<u>AB Offices</u> • Follow-up/completion of issues from Monday and assessments • Report finalisation Presentation of evaluation team findings	<u>AB Offices</u> • Follow-up/completion of issues from Monday and assessments • Report finalisation Presentation of evaluation team findings	<u>AB Offices</u> • Follow-up/completion of issues from Monday and assessments • Report finalisation Presentation of evaluation team findings

Annex IV: ORGANISATION CHARTS OF <<inset acronym of AB>>

<<AB: This section is to be produced by the AB prior to the evaluation. The target audience for the charts are the MRA Council, 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.>>

Often it is clearer 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.

<<TL: One of the roles of the evaluation team is to verify the text provided by the AB prior to the evaluation. Where the evaluation team is not fully satisfied that the text provided by the AB fully represents the situation then the commentary needs to be amended to reflect the understanding of the team. The team is free to remove text that is not considered necessary or relevant, and is encouraged to add observations and comments that will aid in the MRA Council's understanding of the AB.>>

Annex IVa: <<inset acronym of AB>> Structure Chart

Annex IVb: <<inset acronym of AB>> Staff Organisation Chart

Annex V: (DRAFT) ACCREDITATION SCOPES 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. Traditionally, the full scope of accreditation as provided by the AB prior to the evaluation has been incorporated into the report. While this may be practical in some circumstances, often the size of the evaluation report can become unnecessarily large as a result of multi-page scopes of accreditation. In either case, but particularly the latter, 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.>>

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)

Annex VI: REPORTS 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 APLAC website. Completed templates are inserted into this Annex of this report.

Section 3 of the template highlights those key areas of the operation of a CAB that are considered critical to on-going technical competence in relation to the relevant accreditation standard. These specific aspects are the key information the APLAC MRA Council 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, these should 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.>>

Information on witnessed assessment	
Evaluation Team Member:	
Date(s) of assessment:	
Accreditation standard(s):	<i>Delete where not applicable</i> ISO/IEC 17025; ISO 15189; ISO/IEC 17020 & IAF/ILAC-A4; ISO Guide 34 & ISO/IEC 17025
(Requested) Scope of assessment: (major fields of calibration and/or fields & sub-fields of testing or inspection)	
Type of assessment:	Initial / Re-assessment / Surveillance /
Composition of the assessment team:	Lead Assessor: internal / external Assessor(s): <<number and areas>> Expert(s): <<number and areas>>

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
1. Preparation by the accreditation body	
1.1	(Adequacy of documents used for preparation; information on results of previous assessments; other relevant information)
1.2	(Time allocated; team composition; coverage of scope; special arrangements; amount of planned witnessing)
1.3	(Preparation by individual assessors: studying of received documents; preparation of questions; focus on the CAB)

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
1.4	(Competence and suitability of team nominated in relation to this assessment)
2. Opening meeting	
2.1	(Presentation of participants; clarification of roles and responsibilities; confidentiality matters; accreditation criteria; specific supplementary documents used; accreditation process; reporting)
3. Conduct of the assessment (Considering the type and scope of the assessment)	
3.1	(Adequacy of assessment: General coverage & depth of Clauses 4 of ISO/IEC 17025, ISO 15189 and/or ISO Guide 34; or of Clauses 3 – 7 of ISO/IEC 17020)
(a)	ISO 15189 only: Delete row if not applicable (Adequacy of assessment: Specifically clinical oversight / pathologist input & focus on patient care)
(a)	ISO/IEC 17020 only: Delete row if not applicable (Adequacy of assessment: Specifically Type A, B, C)
(b)	ISO/IEC 17020 only: Delete row if not applicable (Adequacy of assessment: Specifically supervision & monitoring of inspectors by the IB)
(a)	ISO Guide 34 only: Delete row if not applicable (Adequacy of assessment: Specifically definition of roles of collaborators for each RM)
3.2	(Adequacy of assessment: General coverage & depth of Clauses 5 of ISO/IEC 17025, ISO 15189 and/or ISO Guide 34; or of Clauses 8 – 16 of ISO/IEC 17020)
(a)	ISO/IEC 17025 &/or ISO Guide 34 only: Delete row if not applicable (Adequacy of assessment: Specifically traceability of measurement & measurement uncertainty / CMC & assignment of RM values)
(b)	ISO/IEC 17025 (incl RMP) or ISO 15189 only: Delete row if not applicable (Adequacy of assessment: Specifically PT / EQA participation & performance)
(c)	ISO/IEC 17025 (incl RMP) or ISO 15189 only: Delete row if not applicable (Adequacy of assessment: method validation / verification & internal quality control)
(d)	ISO 15189 only: Delete row if not applicable (Adequacy of assessment: Specifically pre-examination procedures)
(e)	ISO 15189 only: Delete row if not applicable (Adequacy of assessment: Specifically pathology reporting)
(a)	ISO/IEC 17020 only: Delete row if not applicable (Adequacy of assessment: Specifically qualification of inspectors and ability to make valid professional judgements)
(b)	ISO/IEC 17020 only: Delete row if not applicable (Adequacy of assessment: Selection of inspection methods)
(d)	ISO Guide 34 only: Delete row if not applicable (Adequacy of assessment: Specifically assessment of collaborator competencies)

Subject (with key words or phrases the issues that are at least considered relevant are indicated between brackets; describe your positive and negative observations for each of the given issues, as applicable)	
(e)	ISO Guide 34 only: Delete row if not applicable (Adequacy of assessment: General coverage & depth of ISO Guide 31 and ISO Guide 35)
3.3	(Adequacy of assessment: AB rules e.g. accreditation documents, use of symbols)
3.4	(Sampling techniques: LAB/RMP: observed / assessed activities; locations, CAB staff; INSPECTION: sufficient inspectors witnessed? Sufficient key locations visited?)
3.5	(Methods of collecting evidence: interviews; observation of activities; investigation of documents and records; appropriateness of techniques)
3.6	(Interviews of relevant personnel; adapted to the situation)
3.7	(Coverage of the whole or planned part of the scope; means of deciding on focus points; dealing with extension or limitation of scope; for ISO 15189, adequacy of accreditation scope to meet clinical needs)
3.8	(Recording of nonconformities; formulating the NCs; objective evidence; identification of true problems of the CAB; communicating with appropriate representative of the CAB)
3.9	(For surveillance and re-assessments: plan of surveillance for the accreditation cycle; following this plan for this particular visit; use of reports from previous assessment; follow up of findings from previous assessments)
4. Closing meeting	
4.1	(Assessors interaction; preparation of closing meeting; agree on conclusions; agree on roles and tasks for meeting.
4.2	(Relevant representation of the CAB; participating in closing meeting)
4.3	(Presentation of findings and conclusions; understanding and acknowledgement; unresolved diverging opinions)
4.4	(Explanation of consequences of outcome for the accreditation process. Reporting procedures; positive and negative reporting; thoroughness of reports; explanation of decision-making processes)
5. Conclusions	
5.1	(Scope & depth of assessment; findings relevant to the CAB assessed & for ISO 15189 findings relevant to patient care; competence issues duly addressed; points of focus relevant to the operation of the CAB)
5.2	(The attitude and skill of assessors; consistency in following AB's assessment policies)
5.3	(Did the assessment team identify the key issues for this CAB?)
5.4	(Do you agree with the overall conclusions of the assessment team? If this CAB is accredited, are they worthy of their accreditation status?)

Annex VII: MISCELLANEOUS

<<TL: This Annex is available for the inclusion of any other material that does not fit within the other headings in the report, or where it is practical to remove the material from the main body of the report into an Annex. An example may include a detailed history of participation, performance and follow-up by the AB in APLAC and other regional PT programmes since the last evaluation. The title of the Annex should reflect its actual content and be reproduced in the table of contents.>>

Annex VIII: FOLLOW-UP ON PREVIOUS EVALUATION FINDINGS (<<state month and year of previous evaluation>>)

Finding		<<insert acronym of AB>> Corrective Action and Response Report	Evaluation Team Observation on Effectiveness of Corrective Actions
Nonconformities			
NC1	<<copied from the previous report>>	<<copied from the previous report>>	
NC2	<<copied from the previous report>>	<<copied from the previous report>>	
Concerns			
Cn1	<<copied from the previous report>>	<<copied from the previous report>>	
Cn2	<<copied from the previous report>>	<<copied from the previous report>>	

Annex IX: DECLARATION OF CONFIDENTIALITY AND IMPARTIALITY FROM THE EVALUATION TEAM

Establishing and Maintaining Mutual Recognition Arrangements Amongst Accreditation Bodies - APLAC MR 001



**DECLARATION OF CONFIDENTIALITY AND IMPARTIALITY
(TEAM MEMBERS & OBSERVERS)**

This form shall be signed by all members and observers of an APLAC peer evaluation team.

I declare that I will not reveal confidential information gained through peer evaluations or peer evaluation reports to anyone who does not have the right of access to such information and who has not signed an APLAC Confidentiality Declaration Form.

I further declare that I have no conflicts of interest with this accreditation body that would compromise impartiality and have not undertaken consultancies to it during the last four years.

Date: <<insert dates of on-site evaluation>>

Name	Affiliation	Role	Signature
<i>Mr E.M.C. Nerd</i>	<i>AB2, USA</i>	<i>Evaluator</i>
<i>Dr Cal Ibrator</i>	<i>NMI, Australia</i>	<i>Expert</i>
<i>A.N Other</i>	<i>LOTR AB, Middle Earth</i>	<i>Evaluator</i>
<i>Ms Nosey Parker</i>	<i>AB1, New Zealand</i>	<i>Observer</i>
<i>Mrs Eve Aluator</i>	<i>AB1, New Zealand</i>	<i>Lead Evaluator</i>

(Note: The original signed copy is maintained by the APLAC Secretariat.)

<<TL: The Team Leader is responsibility for ensuring the signature of all team members and observers. If the AB also invites domestic observers, the Team Leader should ensure they too are subject to the same provisions, preferably by signature of the APLAC form above.>>

Annex X: <<insert acronym of AB>> CORRECTIVE ACTION AND RESPONSE REPORT AND EVALUATION TEAM REPLY**(a) <<insert acronym of AB>> Corrective Action and Response Report**

<<TL: This section would not be included in the finalized “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.>>

<<AB: This Annex is written by the AB in response to the Nonconformities, Concerns and Comments detailed in Annex I. It is provided after the receipt of the main body of this report (the “interim” report). It should be single document suitable for insertion into this report, and provide a narrative summary of the actions taken and/or proposed. It may refer to supporting documents as objective evidence, but as the target audience is the MRA Council who may not be provided with direct access to the supporting documents, this document should be able to stand alone in explaining the actions/changes made or proposed.>>

<<TL: The AB Corrective Action and Response Report should be inserted here without any change to its content. Due to vagaries in the different version 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. In accordance with IAF/ILAC recommendations, Team Leaders are encouraged to present the findings, the AB response and the evaluation team comments in a readily assimilated format for the MRA Council. This may include a table showing (across the page) the wording of the finding, the AB response, the team comments, and any further iteration of the latter two entries. Alternatively, this may be in standard format with the various iterations inserted between entries.>>

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

(b) Evaluation Team Response

<<A copy of the evaluation team’s response to the AB’s Corrective Action and Response Report is inserted here. It should summarize whether the team consider the AB has adequately addressed the Nonconformities and Concerns identified by the evaluation. If the AB has responded to any Comments made by the team this should be acknowledged but should not be further commented upon.>>

As suggested by MR001, the Team Leader may choose to present the findings (Annex I) in a tabular form incorporating the AB’s Corrective Action and Response Report and the Evaluation Team Reply (this Annex VIII) in a single document. The format could be as follows:

Annex X: <<insert acronym of AB>> CORRECTIVE ACTION AND RESPONSE REPORT AND EVALUATION TEAM REPLY

Finding		<<insert acronym of AB>> Corrective Action and Response Report	Evaluation Team Comment
Nonconformities			
NC1	<<copied from Annex I>>		
NC2	<<copied from Annex I>>		
Concerns			
Cn1	<<copied from Annex I>>		
Cn2	<<copied from Annex I>>		
Comments			
Cm1	<<copied from Annex I>>		
Cm2	<<copied from Annex I>>		