APLAC

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, proficiency testing providers>>* 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, proficiency testing providers>>*.

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, proficiency testing providers>>* accreditation programme(s) substantially in accordance with the requirements of ISO/IEC 17011 and IAF/ILAC-A5; and for its proficiency testing provider accreditation programme, substantially in accordance with the requirements of ILAC-P13;

(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;

(f) 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) *<<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, reference material producers, and proficiency testing providers in the basic physical units;

(h) *<<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);

(i) *<<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;

(j) *<<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, and proficiency testing providers;

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

(l) *<<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;

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

(n) *<<insert acronym of AB>>* fulfils its MRA obligations under the APLAC MR 002 and the ILAC MRA document ILAC-P5, and;

(o) 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)>>*
Proficiency Testing Provider:	*<<e.g. 1 reassessment (2 days; food chemistry and microbiology>>*

<<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 details of the corrective actions to address the Nonconformities and evidence of their effective implementation, and an appropriate action plan and a time schedule to address the Concern(s). *<<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>>

Section 2: INTRODUCTION

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 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 whether *<<insert acronym of AB>>* meets and applies the requirements of *<<Section 3>>* of MR 001, including,

(a) 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 IAF/ILAC-A5 *"IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Application of ISO/IEC 17011:2004"*;
- IAF/ILAC-A2 *"IAF/ILAC Multi-Lateral Mutual Recognition Arrangements (Arrangements): Requirements and Procedures for Evaluation of a Single Accreditation Body"* (Section 2), and;
- ILAC-P13 *"Application of ISO/IEC 17011 for the Accreditation of Proficiency Testing Providers"* in the accreditation of its proficiency testing providers.

(b) 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;

(c) The adoption and application of ILAC-P14 "ILAC Policy for Uncertainty in Calibration" by its accredited calibration 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"* by its accredited reference material producers;

(f) The adoption and application of ISO/IEC 17043 "*Conformity assessment – General requirements for proficiency testing*" by its accredited proficiency testing providers;

(g) The adoption and application of ILAC-P10:*"ILAC Policy on Traceability of Measurement Results"* by its accredited organisations;

(h) 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 and Inspection Bodies"*;

(i) The adoption and application of ILAC-P9: *"ILAC Policy for Participation in Proficiency Testing Activities"* by *<<insert acronym of AB>>* and its accredited organisations;

(j) The documentation and implementation of a cross-frontier accreditation policy taking into account ILAC-G21: *"Cross Frontier Accreditation – Principles for Cooperation"*;

(k) The satisfactory fulfilment of 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. 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 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 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.

<<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 VII 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 VII 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 VII 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 AND HISTORY OF *<<insert acronym of AB>>*

<<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 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.>>

<<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.

Descriptions of the following topics previously required in this section in past issues of this document are now to be provided in later sections of this report as indicated:

- *Legal status and relationship to government (Section 4.1.1)*
- *Current scope of accreditation activity (Section 4.1.6)*
- *Structure, management and staffing of the AB (Section 4.1.2).>>*

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. In accordance with IAF/ILAC-A3:01/2013, *<<insert acronym of AB>>* provided a written narrative for each of the clauses of ISO/IEC 17011:2004 (and associated APLAC/ILAC requirements) 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 below is to be written by the AB prior to the evaluation to describe how the AB meets the requirements of that clause (and sub-clauses) of ISO/IEC 17011:2004. 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.>>

4.1 ACCREDITATION BODY

[ISO/IEC 17011:2004; Clause 4, IAF/ILAC-A2:01/2013; Section 2.2.1]

4.1.1 Legal Responsibility

[ISO/IEC 17011:2004; 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 reference 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 accreditation body is a separate legal entity within or owned by a larger body, the related bodies shall be identified (see Section 4.1.3 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.>>

4.1.2 Structure

[ISO/IEC 17011:2004; 4.2; IAF/ILAC-A2:01/2013; 2.2.1.2]

<<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 4.2.5 and 5.2.3 of ISO/IEC 17011:2004), 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 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.>>
- *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.>>*

4.1.3 Impartiality

[ISO/IEC 17011:2004; 4.3]

<<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 4.3, 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 minimized;*
- *The AB's policies not being discriminatory;*
- *How objectivity of personnel is assured and is fee 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;*
- *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 based on the requirements of ILAC-P13.>>*

4.1.4 Confidentiality

[ISO/IEC 17011:2004; 4.4]

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

4.1.5 Liability and Financing

[ISO/IEC 17011:2004; 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.>>*

4.1.6 Accreditation Activity

[ISO/IEC 17011:2004; 4.6, IAF/ILAC-A2:01/2013; 2.2.1.1, 2.2.1.2, 2.2.1.8 (ILAC-G21:09/2012)]

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

- *The scopes of the Arrangement in which the AB accredits;*

- *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-programmes 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;*
- *The set of criteria that is used in each programme or field;*
- *The number of CABs in each programme and field (sub-programme), including the current number of active accreditations and the number of applicants. Where considered appropriate and of value to the APLAC MRA Council, commentary relating to the AB's conformity with IAF/ILAC-A2, sections 2.2.1.1 and 2.2.1.2 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;*
- *Any economies outside of their 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;*
- *What other related activities the AB is involved in outside of accreditation e.g. training services, etc.*

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 discussed.>>

4.2 MANAGEMENT

[ISO/IEC 17011:2004; Clause 5, IAF/ILAC-A2:01/2013; Section 2]

4.2.1 General

[ISO/IEC 17011:2004; 5.1; IAF/ILAC-A2:01/2013; 2.1]

<<AB: An overview description of the management system; its conformity with ISO/IEC 17011 and IAF/ILAC-A2, section 2.1; how the documentation of the system is structured; and its maturity.>>

4.2.2 Management System

[ISO/IEC 17011:2004; 5.2]

<<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 accreditation body;*
- *the authorities and responsibilities of the management system representative.>>*

4.2.3 Document Control

[ISO/IEC 17011:2004; 5.3]

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

4.2.4 Records

[ISO/IEC 17011:2004; 5.4]

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

4.2.5 Nonconformities and Corrective Actions

[ISO/IEC 17011:2004; 5.5]

<<AB: Overview of nonconformities and corrective action policies and procedures.>>

4.2.6 Preventive Actions

[ISO/IEC 17011:2004; 5.6]

<<AB: Overview of preventive action policies and procedures.>>

4.2.7 Internal Audits

[ISO/IEC 17011:2004; 5.7]

<<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.>>

4.2.8 Management Reviews

[ISO/IEC 17011:2004; 5.8]

<<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. >>

4.2.9 Complaints
[ISO/IEC 17011:2004; 5.9]

<<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.>>

4.3 HUMAN RESOURCES
[ISO/IEC 17011:2004; Clause 6]

4.3.1 Personnel Associated With The Accreditation Body
[ISO/IEC 17011:2004; 6.1]

<<AB: The AB shall provide a description of the mechanisms for ensuring the competence of each of the groups of personnel associated with the accreditation body. Such mechanisms may include person specifications 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 4.1.2. 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 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).>>*

4.3.2 Personnel Involved With The Accreditation Process
[ISO/IEC 17011:2004; 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 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 programmes and 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.*

Experts

- *As relevant, the same commentary as for Assessors, plus;*
- *The mechanisms for supervision of experts by qualified assessors during the assessment process.>>*

4.3.3 Monitoring

[ISO/IEC 17011:2004; 6.3]

<<AB: For each of the groups of personnel identified in Sections 4.3.1 and 4.3.2 above, the AB shall provide a description of the mechanisms for monitoring their competence. Examples of such commentary may include the following:

***<<insert acronym of AB>>* Staff**

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

Assessors and 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.*

Committees

- *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.>>*

4.3.4 Personnel Records
[ISO/IEC 17011:2004; 6.4]

<<: The AB shall provide an overview of the personnel records maintained in support of Sections 4.3.1, 4.3.2 and 4.3.3 above, and how they are kept up-to-date.>>

4.4 ACCREDITATION PROCESS
[ISO/IEC 17011:2004; Clause 7]

4.4.1 Accreditation Criteria and Information
[ISO/IEC 17011:2004; 7.1; IAF/ILAC-A2:01/2013; 2.2.1.3 (ILAC-P10:01/2013, ILAC-P14:01/2013)]

<<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 (see below), and detail where and how the requisite information specified in clause 7.1.2 of ISO/IEC 17011:2004 is made publically available.>>

Measurement Traceability
[IAF/ILAC-A2:01/2013; 2.2.1.3 (ILAC-P10:01/2013, ILAC-P14:01/2013)]

<<AB: The AB shall describe:

- *its policies for achieving satisfactory measurement traceability by its accredited CABs in compliance with ILAC-P10;*
- *access to international traceability and reference materials (RMs) by the accredited CABs (including a summary of the local NMI status in relation to the CIPM MRA);*
- *Its specific policies and guidelines in areas where traceability is difficult to achieve;*
- *Its policies on the use of reference materials to achieve measurement traceability, where the concept applies, and;*
- *Its policies on the estimation or measurement uncertainty, including how these are used in the traceability chain in compliance with ILAC-P14.>>*

4.4.2 Application for Accreditation
[ISO/IEC 17011:2004; 7.2]

<<AB: The application content shall be described, and how applications are reviewed, and by whom, for adequacy.>>

4.4.3 Resource Review
[ISO/IEC 17011:2004; 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.>>

4.4.4 Subcontracting the Assessment

[ISO/IEC 17011:2004; 7.4]

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

4.4.5 Preparation for Assessment

[ISO/IEC 17011:2004; 7.5]

<<AB: The AB shall provide a description of its policies and procedures, as relevant, for:

- *Preliminary visits;*
- *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;*
- *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 key activities for initial assessments;*
- *Premises assessed in surveillance and reassessments (see also Section 4.4.11)*
- *Setting the assessment date;*
- *Provisions for the assessors.>>*

4.4.6 Document and Record Review

[ISO/IEC 17011:2004; 7.6]

<<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 poor review outcomes.>>

4.4.7 On-site Assessment

[ISO/IEC 17011:2004; 7.7]

<<AB: A general description of the on-site assessment process steps needs to be provided, including:

- *The opening meeting;*
- *The conduct of the assessment;*
- *Witnessing the performance of conformity assessment activities. The AB shall provide the policies for determining the amount of conformity assessment services to witness, and which criteria for selecting the CAB locations and personnel are used.>>*

<<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 4.4.7 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.>>

4.4.8 Analysis of Findings and Assessment Report

[ISO/IEC 17011:2004; 7.8]

<<AB: Following on from Section 4.4.7, 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 nonconformities 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, reinstatement, continuation, scope reduction, scope extension);*
- *What actions are taken on unsatisfactory resolution;*
- *At the completion of the assessment process, what information is provided to the AB's accreditation decision-makers.>>*

4.4.9 Decision-Making and Granting Accreditation

[ISO/IEC 17011:2004; 7.9]

<<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 use of PT in the decision-making process;*
- *The accreditation decision-making process for surveillance and reassessments;*
- *The issuance of accreditation certificates and their content for different types of CABs.>>*

4.4.10 Appeals

[ISO/IEC 17011:2004; 7.10]

<<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.>>

4.4.11 Reassessment and Surveillance

[ISO/IEC 17011:2004; 7.11, ILAC-G21:09/2012]

<<AB: The AB shall describe its surveillance and reassessment programme for its 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 (see below), personnel (see below), and the scope of accreditation. Other forms of surveillance activity shall also be described;*
- *Information on the policy for sampling premises from which one or more key activities are performed;*
- *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 and certification activities in surveillance 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 surveillances and reassessments;*
- *The AB policies and procedures for the conduct of extra-ordinary visits;*
- *Corrective action time limits for surveillance and reassessment findings;*
- *The accreditation decision-making process (or continuation of accreditation) for each of the surveillance/reassessment activities.>>*

4.4.12 Extending Accreditation

[ISO/IEC 17011:2004; 7.12]

<<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.>>

4.4.13 Suspending, Withdrawing or Reducing Accreditation

[ISO/IEC 17011:2004; 7.13]

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

4.4.14 Records on CABs

[ISO/IEC 17011:2004; 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.>>

4.4.15 Proficiency Testing and Other Comparisons for Laboratories

[ISO/IEC 17011:2004; 7.15, IAF/ILAC-A2:01/2013, 2.2.1.4 (ILAC-P9:11/2010)]

<<AB: For ABs accrediting laboratory and inspection CABs, a description of the AB's implementation of ILAC-P9 shall be provided (e.g. policies on frequency of participation; CAB PT Plans; policies on selection of PT activities; how the AB uses PT results in the assessment process, the determination of surveillance plans and in accreditation decision-making; how the AB monitors corrective action on unsatisfactory performance). This description shall include any mandated PT programmes and programmes mandated and organised by the AB. The description shall cover participation of its accredited CABs in PT organised by APLAC and reference the details of this participation included in Annex VI.>>

4.5 RESPONSIBILITIES OF THE ACCREDITATION BODY AND THE CAB

[ISO/IEC 17011:2004; Clause 8, ILAC-P8:12/2012]

4.5.1 Obligations of the CAB

[ISO/IEC 17011:2004; 8.1]

<<AB: With reference to clause 8.1 of ISO/IEC 17011:2004, 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.>>

4.5.2 Obligations of the Accreditation Body

[ISO/IEC 17011:2004; 8.2]

<<AB: With reference to clause 8.2 of ISO/IEC 17011:2004, the AB shall provide a brief overview of its conformity with the requirements of this clause, and how this information is made publically available.>>

4.5.3 Reference to Accreditation and Use of Symbols

[ISO/IEC 17011:2004; 8.3, ILAC-P8:12/2012]

<<AB: With reference to clause 8.3 of ISO/IEC 17011:2004 and ILAC-P8, 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.>>

Section 5: MUTUAL RECOGNITION ARRANGEMENT (MRA) OBLIGATIONS

[APLAC MR002; ILAC-P5; IAF/ILAC-A2: 01/2013, 2.2.1.5, 2.2.1.6, 2.2.1.7, 2.3]

<<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, where used.>>*

<<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, including where appropriate, any comment on activities such as APLAC voting participation, provision of evaluation reports to interested parties, etc.

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 [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 [MR001].>>

1. <<insert description of concern>>
   [ISO/IEC 17011:2004; <<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 [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 that may be questioning the compliance status of a current practice of the AB.>>

<<As suggested by MR001, 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 X.>>

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.

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	AB Offices • Introductions • Presentation Commence evaluation **17011 clauses/KPIs/MR-docs** *Detail elements covered* Evaluation Team meeting	AB Offices • Introductions • Presentation Commence evaluation **17011 clauses/KPIs/MR- docs** *Detail elements covered* Evaluation Team meeting	AB Offices • Introductions • Presentation Commence evaluation **17011 clauses/KPIs/MR- docs** *Detail elements covered* Evaluation Team meeting	AB Offices • Introductions • Presentation Commence evaluation **17011 clauses/KPIs/MR- docs** *Detail elements covered* Evaluation Team meeting	AB Offices • Introductions • Presentation Commence evaluation **17011 clauses/KPIs/MR- docs** *Detail elements covered* Evaluation Team meeting
Tues, dd/mm/yy	Travel to assessments Assessment Observation *Detail type of CAB, technical field, type of assessment*	Travel to assessments Assessment Observation *Detail type of CAB, technical field, type of assessment*	Travel to assessments Assessment Observation *Detail type of CAB, technical field, type of assessment*	Travel to assessments Assessment Observation *Detail type of CAB, technical field, type of assessment*	Travel to assessments Assessment Observation *Detail type of CAB, technical field, type of assessment*
Wed, dd/mm/yy	Assessment Observation *Detail type of CAB, technical field, type of assessment* Travel back to *AB Offices*	Assessment Observation *Detail type of CAB, technical field, type of assessment*	Assessment Observation *Detail type of CAB, technical field, type of assessment*	Assessment Observation *Detail type of CAB, technical field, type of assessment*	Assessment Observation *Detail type of CAB, technical field, type of assessment*
Thurs dd/mm/yy Evening 18:00 hrs	AB Offices Continuation of evaluation of **17011 clauses/KPIs/MR-docs** • Report drafting Evaluation Team meeting • Report drafting	Assessment Observation *Detail type of CAB, technical field, type of assessment* Travel back to *AB Offices* Evaluation Team meeting • Report drafting	Assessment Observation *Detail type of CAB, technical field, type of assessment* Travel back to *AB Offices* Evaluation Team meeting • Report drafting	Assessment Observation *Detail type of CAB, technical field, type of assessment* Travel back to *AB Offices* Evaluation Team meeting • Report drafting	Assessment Observation *Detail type of CAB, technical field, type of assessment* Travel back to *AB Offices* Evaluation Team meeting • Report drafting
Fri, dd/mm/yy (a.m.) (p.m.)	AB Offices • Follow-up/completion of issues from Monday and assessments • Report finalisation Presentation of evaluation team findings	AB Offices • Follow-up/completion of issues from Monday and assessments • Report finalisation Presentation of evaluation team findings	AB Offices • Follow-up/completion of issues from Monday and assessments • Report finalisation Presentation of evaluation team findings	AB Offices • Follow-up/completion of issues from Monday and assessments • Report finalisation Presentation of evaluation team findings	AB Offices • Follow-up/completion of issues from Monday and assessments • Report finalisation Presentation of evaluation team findings

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 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 IIIa: <<insert acronym of AB>> Structure Chart

Annex IIIb: <<*insert acronym of AB*>> Staff Organisation Chart

Annex IV: (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 V: 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 ongoing 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, it 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):	***Delete where not applicable*** ISO/IEC 17025; ISO 15189; ISO/IEC 17020 & IAF/ILAC-A4; ISO Guide 34 & ISO/IEC 17025; ISO/IEC 17043
(Requested) Scope of assessment: (major fields of calibration and/or fields & sub-fields of testing, inspection, RMP or PTP accreditation)	
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)***

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)*	
1.3	***(Preparation by individual assessors: studying of received documents; preparation of questions; focus on the CAB)***
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; Clause 5 of ISO/IEC 17043; 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)***
(a)	***ISO/IEC 17043 only: Delete row if not applicable*** ***(Adequacy of assessment: Specifically planning of the PT scheme(s); participant performance evaluation & authorisation of final report not subcontracted; assurance of competence of subcontractors)***
3.2	***(Adequacy of assessment: General coverage & depth of Clauses 5 of ISO/IEC 17025, ISO 15189 and/or ISO Guide 34; Clause 4 of ISO/IEC 17043; 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)***

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)*	
(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)***
(e)	***ISO Guide 34 only: Delete row if not applicable*** ***(Adequacy of assessment: General coverage & depth of ISO Guide 31 and ISO Guide 35)***
(a)	***ISO/IEC 17043 only: Delete row if not applicable*** ***(Adequacy of assessment: Specifically access to necessary technical expertise in relevant area, including statistics)***
(b)	***ISO/IEC 17043 only: Delete row if not applicable*** ***(Adequacy of assessment: Specifically assessment of homogeneity and stability of PT items, statistical design, determination of assigned values, and for calibration programmes, metrological traceability)***
(c)	***ISO/IEC 17043 only: Delete row if not applicable*** ***(Adequacy of assessment: Specifically validity of methods of evaluating participant performance)***
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)***

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)*	
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 VI: SUMMARY OF PARTICIPATION IN APLAC *(AND IAAC?)* PROFICIENCY TESTING PROGRAMMES (201*x* – 201*y*)

<<AB: The AB shall provide details of the participation of its laboratories in APLAC (and IAAC where relevant) proficiency testing programmes for at least the last four years. The following information (as set out in the template below) is expected to be provided:

- *Number and description of the programme(s);*
- *The date the programme was completed (final report date);*
- *The laboratory code – this is just a unique identifier to distinguish your laboratories in the programme; it need not be the coding used by the programme organiser i.e. it could be as simple as Lab#1, Lab#2, etc.;*
- *Whether the individual laboratory had unsatisfactory results (as published in the final PT programme report);*
- *The fraction of outliers relative to number of parameters tested in the programme. This is intended to give some sense of scale to the unsatisfactory performance e.g. a calibration programme may have 8 calibration points across a range, but the laboratory had outliers at only 2 points (2/8); a testing programme might be testing for 12 analytes, but the laboratory had an outlier for only 1 of the analyte (1/12);*
- *Whether the laboratory was accredited for the measurements covered by the PT programme;*
- *Additional comments, with particular reference to actions taken by the laboratory and the AB on outlier results.*

Some examples of how such information is typically presented are included in the template below.>>

<<TL: the evaluation team needs to verify the information provided and make additional comments as appropriate.>>

Programme & Description	Date Completed	Lab Code	Outlier? (Y/N)	Fraction outlying parameters	Accredited?	Comments
e.g. M015 Resistance	June 2008	17	**Y**	2/18	Y	Corrective action reviewed by AB
		58	N	-	Y	
		28	N	-	Y	
		47	N	-	Y	
e.g. T039 Toy Safety	March 2006	39	**Y**	3/18	Y	Corrective action reviewed by AB
		7	**Y**	15/18	Y	Accreditation suspended
		14	N	-	N	
		6	**Y**	14/18	N	Different method

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

NONCONFORMITIES

Number	Description of Nonconformity and requirements reference (from previous report)
NC#1	*<<copied from previous report>>*
Corrective Action and Response Report from *<<insert acronym of AB>>*	
<<copied from previous report>>	
Evaluation Team Observation on Effectiveness of Corrective Actions	

<<Copy and paste NC table template here for additional Nonconformities from the previous evaluation>>

CONCERNS

Number	Description of Concern and requirements reference (from previous report)
Cn#1	*<<copied from previous report>>*
Corrective Action and Response Report from *<<insert acronym of AB>>*	
<<copied from previous report>>	
Evaluation Team Observation on Effectiveness of Corrective Actions	

<<Copy and paste Cn table template here for additional Concerns from the previous evaluation>>

Annex VIII: DECLARATION OF CONFIDENTIALITY AND IMPARTIALITY FROM THE EVALUATION TEAM AND OBSERVERS

Procedures for Establishing and Maintaining the APLAC Mutual Recognition Arrangement 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 the APLAC peer evaluation team and by all observers who observe all parts of the evaluation, including the closed sessions of the evaluation team. (The accreditation body being evaluated shall be responsible for the confidentiality requirements laid on observers who observe only the open parts of the evaluation i.e. when the evaluation team is interacting with the accreditation body.)

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. After the conclusion of the evaluation I will dispose of all documents confidentially as agreed with this accreditation body either prior to, during or after the evaluation.

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

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

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

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

<<TL: The Team Leader is responsible 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 IX: *<<insert acronym of AB>>* CORRECTIVE ACTION AND RESPONSE REPORT AND EVALUATION TEAM REPLY

<<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. 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. The following table formats should be used for each of the Nonconformities, Concerns 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 Nonconformities, Concerns and Comments 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 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 response should be able to stand alone in explaining the actions/changes made or proposed.>>

<<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 summarize whether the team considers the AB has adequately addressed the Nonconformities and Concerns 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>>***
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>>

CONCERNS

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

Date	First response from ***<<insert acronym of AB>>***
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 Cn template (the table above) here for additional Concerns>>

COMMENTS

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

Date	First response from ***<<insert acronym of AB>>***
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 Cm template (the table above) here for additional Comments>>