



**IAF/ILAC Multi-Lateral
Mutual Recognition Arrangements
(Arrangements):
Narrative Framework for Reporting on the
Performance of an Accreditation Body (AB)**

A Tool for the Evaluation Process

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PREAMBLE

The International Accreditation Forum, Inc. (IAF) and the International Laboratory Accreditation Cooperation (ILAC) is an international community where member Regional Groups, Accreditation Bodies (AB) and their stakeholders cooperate. A principal objective of IAF and ILAC is to put in place world-wide, multilateral Mutual Recognition Arrangements (Arrangements). Both IAF and ILAC aim to demonstrate the equivalence of the operation of their Member Accreditation Bodies through these Arrangements. As a consequence, the equivalent competence of conformity assessment bodies accredited by these accreditation bodies is demonstrated. The market can then be more confident in accepting certificates and reports issued by the accredited conformity assessment bodies.

IAF and ILAC are linking existing multi-lateral, mutual recognition Arrangements of the regional accreditation cooperations (Regional Groups; also called Regional Cooperation Body Members) and are encouraging the development of new Regional Groups to complete world-wide coverage. For the purposes of their Arrangements, both IAF and ILAC recognize Regional Groups for the evaluation, surveillance and re-evaluation of Accreditation Bodies within their defined territory and associated decision making relating to the membership of the IAF and ILAC Arrangements in that territory. Formal recognition of a Regional Group with respect to the IAF and ILAC Arrangements is based on an external evaluation of the Regional Group's competence in mutual recognition Arrangement management, practice and procedures by a team composed of evaluators from other IAF and ILAC Member Regional Groups and Accreditation Bodies.

Evaluations relating to the development and maintenance of the IAF and ILAC Arrangements operate at two levels:

- Evaluation of a single accreditation body to accredit;
- Evaluation of a Regional Group's management and operation of the Regional Group's Arrangement.

The general requirements to be used by IAF and ILAC and their recognized Regional Groups, when evaluating a single accreditation body for the purpose of qualifying to sign the applicable Arrangement(s) are set out in IAF/ILAC A2. The terms used in this document are defined in IAF/ILAC A2.

The requirements to be used by IAF and ILAC, when evaluating a Regional Group's management and operation of its Arrangement are set out in IAF/ILAC A1.

The effective date for mandatory implementation of this document is two years after publication. ABs and Regional Groups are encouraged to adopt this document at their earliest convenience.

AUTHORSHIP

This publication was prepared by a joint IAF/ILAC working group on Harmonization of Peer Evaluation Processes, endorsed for publication by the respective General Assemblies of IAF and ILAC in 2004 and reviewed by the joint IAF/ILAC working group on maintenance of A-series documents in 2006 and in 2010. This latest version was endorsed by letter ballot in IAF and ILAC in 2011.

1. INTRODUCTION

1.1 The Purpose of this Document in the Peer Evaluation Process

- 1.1.1 Peer evaluation aims at establishing confidence whether ABs are reliable and competent to deliver services according to harmonized standards. As a result of a positive evaluation outcome, the AB can join an Arrangement between ABs, confirming reliability and competence to the market.
- 1.1.2 The purpose of this document is to provide a tool for the evaluation and report preparation process, allowing an AB under evaluation to present information, facts and figures about its performance and to provide a framework for the evaluation team to present confirmation of this information within the evaluation report. This document indicates where information is needed to provide a complete description and full picture of the operations of the AB. Thus, facts and the results of the implementation of policies should be reported, supported by evidence gathered by the evaluation process.
- 1.1.3 While findings can only be raised against the requirements of the Arrangement, descriptions of the details of the AB operations in regards to these identified requirements shall also be provided in appropriate detail. Such reporting provides the evaluation team and the decision making group of the Arrangement with a concise picture of the capabilities and performance of the signatories and applicants and enables sound recommendations and decisions.
- 1.1.4 This reporting framework shall be used
 - ◆ as a tool for the peer evaluation process; and
 - ◆ as a self- evaluation tool for the improvement of the AB.
- 1.1.5 Not all the specific items included in this document are applicable to all situations. For example, proficiency testing is appropriate for the accreditation of some types of CABs, but not for others. On the other hand, the peer evaluation team shall verify that the facts stated in the AB's submitted description are valid for all Arrangement scopes of the AB. If the policies, procedures or outcomes in the Arrangement scopes are different, the situation shall be clearly described.

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

1.2.1 Prior to the evaluation, the AB shall complete this narrative self-evaluation report using section 2 of this document as the framework, including:

- ◆ Fully addressing all ISO/IEC 17011 requirements and other IAF and ILAC mandatory documents; and
- ◆ Also addressing by self-evaluation any other requirements as determined by their Regional Group.

This self-evaluation will be submitted to the peer evaluation team as part of the application documents. The peer evaluation team will thus be able to review the AB's self-evaluation and obtain a sense of the AB's comprehension of the critical requirements and their approach for conformance to those requirements.

1.2.2 The typical structure and content of an evaluation report on a single accreditation body is provided in Annex 5B of IAF/ILAC-A2. Clauses 5, 6 and 7 of Annex 5B of IAF/ILAC A2 are addressed through completion of this narrative framework as follows:

- ◆ **Clause 5: Background on the Accreditation Body** This clause is covered by section 2.1 of this document.
- ◆ **Clause 6: Performance of the system** is covered by section 2.2 of this document.
- ◆ **Clause 7: Arrangement obligations** are covered in section 2.3 of this document. For re-evaluations, the steps taken by the signatory to implement the obligations stated in the Arrangement document are covered.

Certain clauses identified in section 2 of this document are accompanied with specific explanations to assist the accreditation body to complete the self-evaluation. All clauses mentioned in section 2 shall be considered by the evaluation team.

1.2.3 The target audience for this narrative is the evaluation team and the Decision-Making Group so the text shall be a comprehensive narrative. If references are made to the AB's documents or procedures, a sufficient description shall also be provided. If the AB uses this document to provide the cross reference information required in IAF/ILAC A2, Annex 1 then there is no need to provide a separate cross reference document.

1.2.4 The evaluation team, as part of its preparation, shall review the narrative framework and the related/referenced documents provided by the AB to

determine, in principle, compliance to the requirements and revise or comment on the narrative, as appropriate. The output of this process, an amended narrative, functions as a summary of the policies and process found in the accreditation body's documents.

- 1.2.5 During the evaluation visit, the team shall explore whether the narrative provided by the accreditation body is evident in the records and other evidence they encountered. The evaluation team shall provide comments on the narratives prepared by the AB, based on the evidence found during the evaluation, and/or make further amendments and additions. The evaluation team should also include a description about other Arrangement requirements not mentioned in the narrative provided by the AB if those are essential to understand the AB's operations and performance. The findings or reference to the findings shall be included in the description, where applicable. The final revised narrative as amended during the peer evaluation process shall be included in the evaluation report.
- 1.2.6 In other words, this narrative framework will start off as a self-evaluation report submitted by the accreditation body under evaluation and end up incorporated in and confirmed as a report written by the evaluation team.
- 1.2.7 This tool, if submitted in a comprehensive manner by the accreditation body prior to an evaluation, could save considerable time during an evaluation. A concise picture of the accreditation body's activities assists in the effective review and planning of the evaluation and helps the Arrangement members to understand the critical processes in the AB.

2. REPORT ON PERFORMANCE OF THE AB

2.1 Background on The AB

This should state the history and background of the accreditation body.

2.2 Report on all ISO/IEC 17011 Clauses (in *italics below*)

4. ACCREDITATION BODY

4.1 *Legal Responsibility*

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 that describe the authority under which the AB operates.

Private sector ABs shall describe 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 authorities, 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 4.3.7).

Multi-economy ABs (as defined in the S2-ILAC Rules) shall describe their relationship with the relevant economies' governments and where applicable, Regional Group.

4.2 Structure

4.2.1 A document (e.g. an organization chart) describing the AB structure and place within a larger entity, if applicable, shall be provided as Appendices.

4.2.2 Authority and responsibility for decisions

4.2.3 Description of legal status

4.2.4 Document duties, responsibilities and authorities of top management

4.2.5 Identification of Top Management

Names of top management shall be provided, i.e. who has overall authority and responsibility and who has been assigned day-to-day management responsibilities (for each of the items under 4.2.5 and 5.2.3, and where authorities and responsibilities may be held by more than one individual).

4.2.6 Access to Expertise for Advising the AB

The AB shall describe the mechanisms by which it accesses its expertise. This should be a description focused on the expertise to provide policy advice to the AB.

The AB shall describe how it identifies the need for technical expertise; how this expertise is recruited, and how it is managed and used in establishing accreditation criteria (for both existing and new accreditation programs) 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 list of the committees currently in place and a brief overview of the role that they play shall also be described.

4.2.7 *Rule for appointment, terms of reference and operation of committees*

4.3 Impartiality

4.3.1 *Safeguard objectivity and impartiality*

4.3.2 *Structure to provide opportunity for effective involvement by interested parties*

The AB shall provide an explanation for why the structure is considered to provide effective involvement by interested parties in a balanced way.

4.3.3 *Non-discriminatory and accessible*

4.3.4 *Free from undue pressures*

4.3.5 *Competent accreditation decisions*

4.3.6 *Provision of other services which affect impartiality*

The AB shall provide a description of all other activities it is involved in outside of accreditation.

4.3.7 *Activities of related bodies and identification and analysis of relationship with 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.

4.4 Confidentiality

4.5 Liability and Financing

4.5.1 *Arrangements to cover liabilities*

4.5.2 *Adequate financial resources*

The AB shall describe how it receives funds for undertaking its accreditation and other activities, and provide an overall indication of how these funds are allocated.

4.6 Accreditation Activity

4.6.1/4.6.2 *Normative documents, application and guidance documents*

The information provided by the AB shall contain (but should not be limited to) the following:

- *The scopes of the Arrangement in which the AB accredits;*
- *The types of accreditation programs offered, i.e. the type of CAB activity it accredits, and when these programs were launched;*
- *The fields within each program in which accreditation is offered and how they relate to the scopes of the Arrangements;*
- *The set of criteria that is used in each program or field;*
- *The number of CABs in each program and field, 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 accreditations in each field since the last evaluation or since inception for a new applicant;*
- *Which accreditation activities (particularly fields) the AB considers to be part of the Arrangement, and which fields are not;*
- *Any economies outside of their own in which the AB provides accreditation and the number of the respective accreditations. A description of the AB's cross frontier accreditation policy shall be provided.*

4.6.3 Extension of AB's activities

The AB shall 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 programs into new fields of technology.

The description should include, where applicable:

- *Use of national and international guides for the operation of CABs;*
 - *Co-operation with other ABs (e.g. by joint assessments, use of assessors);*
 - *Compliance with international harmonized decisions on what may be accredited and what should not be accredited; and*
 - *Examples of extension into new areas in the last four years.*
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5. MANAGEMENT

5.1 General

5.1.1 *Establishment of a management system*

5.1.2 *Documented procedures*

5.2 Management System

5.2.1 *Documented policies and procedure understood and implemented*

5.2.2 *Type, range and volume of work addressed; accessible*

5.2.3 *Management system representative appointed*

5.3 Document control

5.4 Records

5.4.1 *Procedures for record keeping*

5.4.2 *Procedures for retaining records*

5.5 Nonconformities and corrective actions

5.6 Preventive Action

5.7 Internal Audits

5.7.1 *Procedure for internal audit*

5.7.2/5.7.3 *Internal audit schedule, process and results*

The AB shall provide a summary of the internal audit program and the audit results for the last two years.

5.8 Management Reviews

5.8.1 *Procedure for management review*

5.8.2/5.8.3 *Input and output to management review*

The AB shall provide a summary of the management review process and the main outputs for the last two years.

5.9 Complaints

The AB shall provide a summary of the complaint process including numbers of total complaints, those considered valid and major reasons for the complaints.

6. HUMAN RESOURCES

6.1 Personnel associated with the AB

6.1.1 Sufficient number of competent personnel

- *A brief overview of the role of each position having influence on the process of accreditation shall be provided.*

Staff- *A summary of the level of competence of key managerial and supervisory staff, and the number of staff, including any staff changes since the last full evaluation, shall be provided.*

6.1.2 Sufficient number of assessors

The total number of currently qualified assessors and experts, broken down by accreditation programs and broken down by internal/own staff and external/contracted staff shall be provided.

6.1.3 Extent and limit of responsibilities for each person

6.1.4 Commitment to confidentiality, and conflict of interest avoidance

6.2 Personnel involved in the accreditation process

6.2.1 Description of each accreditation activity

The AB shall provide a description of the mechanisms for ensuring the competence of each of the groups of personnel. Such mechanisms may include how individuals are selected and trained (both initially and on-going). Examples of such a commentary may include the following:

Staff

Training processes (initial and on-going) for operational staff involved in the accreditation process.

Committees

Where relevant, how committee members are recruited, trained (initially and on-going) and qualified.

6.2.2 *Procedures for recruiting, training, qualifying assessors and experts*

- *How assessors are selected, trained and qualified, including the qualification for the technical scopes they are deemed competent to assess;*
- *An overview of assessors' technical and assessment qualifications, training and experience; and*
- *On-going training of assessors.*

Experts

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

6.2.3 *Identifying competence of assessors by scope*

6.2.4 *Assessor familiarity with accreditation documents*

6.3 Monitoring

6.3.1 *Procedure for monitoring competence of assessors, experts and decision makers*

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.

6.3.2 *Monitoring assessors*

- *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 on-going competencies of assessors.*

6.4 Personnel records

6.4.1 *Record maintenance*

6.4.2 *Content of personnel records*

7. ACCREDITATION PROCESS

7.1 Accreditation criteria and information

7.1.1 General criteria

7.1.2 Publicly available information

7.2 Application for Accreditation

7.2.1 Application content

7.3 Resource Review

7.3.1 Review of ability to carry out the assessment

7.3.2 Carry out in timely manner

7.4 Subcontracting the Assessment

7.4.1 Subcontracting policy and agreements

7.4.2 Subcontracting process

The AB shall describe the conditions under which subcontracting takes place, and how it meets the requirements of this clause.

7.4.3 List of subcontractors

The AB shall provide the list of organizations with which it has a subcontract agreement.

7.5 Preparation for Assessment

7.5.1 Preliminary visit

7.5.2 Selection of the assessment team

The AB shall provide information on the policies/mechanisms for deciding on the team composition.

7.5.3 Impartiality of the assessment team

7.5.4 CAB objections to the assessment team

7.5.5 Defining the assignment for the assessment team

7.5.6 *Sampling of the 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 fulfillment of these policies and ISO/IEC 17011.

7.5.7 *Assessing key activities for initial assessments*

7.5.8 *Premises assessed in surveillance and reassessments*

See section 7.11.

7.5.9 *Setting the assessment date*

7.5.10 *Provisions for the assessors*

7.6 *Document and Record Review*

7.6.1 *Assessors' document review*

7.6.2 *Poor review outcome reported to CAB*

7.7 *On-site Assessment*

7.7.1 *Opening meeting*

7.7.2 *Conduct of the assessment*

The AB shall provide a description of the steps of the on-site assessment.

7.7.3 *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 are used.

7.8 *Analysis of Findings and Assessment Report*

7.8.1 *The assessment team's analysis of documents*

7.8.2 *Assessment team's referral back to the AB*

7.8.3 *AB's reporting procedures*

7.8.4 *AB retains responsibility for the assessment report*

7.8.5 *Resolution of the nonconformities*

A description of the following shall be provided by the AB:

- *How findings are graded;*
- *How non-conformities with accreditation criteria are communicated to the assessed CAB;*
- *How these findings 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; and*
- *What actions are taken on unsatisfactory resolution.*

7.8.6 *Information provided for the AB's decision makers*

7.9 Decision-Making and Granting Accreditation

7.9.1 *Confirmation that requirements have been met*

7.9.2 *The AB's decision*

The accreditation decision-making process shall be described, including:

- *The effective separation of the assessment team and the decision maker(s);*
- *The use of proficiency testing in the decision making process (see 7.15.1); and*
- *The accreditation decision making process for surveillance activities and reassessments.*

7.9.3 *Using results from assessment by another AB*

7.9.4 *Content of the accreditation certificate*

7.9.5 *Accreditation certificate content for different types of CABs*

7.10 Appeals

7.10.1 *Procedure to address appeals*

7.10.2 *Details of the appeals process*

The AB shall provide a summary of the appeals process including numbers of appeals and of appeals considered valid since the last full evaluation/4 years for initial evaluations.

7.11 Reassessment and Surveillance

7.11.1/7.11.2 The AB shall describe its surveillance and reassessment program for its accredited CABs, including the term of accreditation, and whether or not expiry dates are used;

7.11.3 Surveillance and reassessment plans

The AB shall describe its surveillance and reassessment plan for its accredited CABs, including:

- 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;*
- The 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; and*
- Use of witnessing of testing, calibration, inspection and certification activities in surveillance and reassessment, if applicable.*

7.11.4 Planning surveillances and taking account of other surveillance activities.

The AB shall describe how it judges the proven stability that the services of the CAB have reached in its decision on the intervals for the surveillances and reassessments.

7.11.5 Corrective action time limits for surveillances and reassessments.

7.11.6 Continuation of accreditation based on surveillances and reassessments results

7.11.7 Conducting extraordinary assessments

7.12 Extending Accreditation**7.13 Suspending, Withdrawing or Reducing Accreditation****7.13.1 Procedure for suspension, withdrawal or reduced accreditation**

The AB shall detail the number of non-voluntary suspensions and withdrawals over the last four years.

7.13.2 Decision to suspend or withdraw based on persistent failure by CABs in meeting requirements**7.13.3 Decision to reduce accreditation based on persistent failure by CABs in meeting requirements****7.14 Records on CABs****7.14.1 Maintenance of records on CABs****7.14.2 Confidentiality of record keeping****7.14.3 Content of CAB records****7.15 Proficiency Testing and Other Comparisons for Laboratories****7.15.1 Procedures for considering CAB's proficiency testing (PT) activities during assessment****7.15.2 List of PT programs (internal or external)****7.15.3 Laboratories participation in PT; corrective actions for PT (see also ILAC P9)**

For ABs accrediting testing, calibration and inspection CABs, a description of the AB's implementation of ILAC P9 shall be provided. This description shall include any mandated PT programs and programs mandated and organized by the AB. The description shall cover the AB's fulfillment of any regional requirements including participation of its accredited CABs in PTs organized by Regional Groups.

8. RESPONSIBILITIES OF THE ACCREDITATION BODY AND THE CAB**8.1 Obligations of the CAB****8.1.1 AB's requirements of the CAB****8.1.2 AB's requirements that the CAB report significant changes**

8.2 *Obligations of the AB*

8.2.1 Information publicly available

8.2.2 Information on obtaining traceability of measurements

8.2.3 Information on international arrangements

8.2.4 Alerting CABS to changes in the AB's requirements

8.3 *Reference to Accreditation and Use of Symbols*

8.3.1 AB policy governing protection and use of the accreditation symbol

8.3.2 Measures to ensure CAB conforms with rules for claiming accreditation

8.3.3 Action taken by AB

The AB shall describe the action taken in the case of misuse of the accreditation and/or the accreditation symbol.

2.3 Other Arrangement Requirements to be Addressed (as detailed in italics below)

IAF/ILAC A2

2.1 *Standards*

2.1.1 Compliance with ISO/IEC 17011; operating in accordance with IAF and ILAC guidance

2.1.2 Compliance with A2, section 2.2 (see below) and Regional requirements (see below)

2.2 *Supplemental requirements*

2.2.1/2.2.1.1 Experience in assessment/one accreditation in each scope

2.2.1.2 Access to expertise

2.2.1.3 Measurement Traceability (See also ILAC P10)

The AB (that accredits testing, calibration, and inspection CABs) 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 (summary of the 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 of measurement uncertainty shall also to be described, including how these are to be used in the traceability chain in compliance with ILAC P14.*

2.2.1.4 PT requirements (see section 7.15)

2.2.1.5 Abide by requirements/obligations of region/international arrangements

2.2.1.6 Program to promote the arrangement

2.2.1.7 Contribute to peer evaluations

2.2.1.8 Cross frontier in accordance with IAF documents/taking into account ILAC G21

2.4 Other Regional Requirements to be Addressed (if relevant)