



**IAF/ILAC Multi-Lateral
Mutual Recognition Arrangements
(Arrangements):
Key Performance Indicators
A Tool for the Evaluation Process**

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PREAMBLE

The international community of accreditation Regional Groups, recognized Accreditation Bodies and their stakeholders cooperate through the International Laboratory Accreditation Cooperation (ILAC) and the International Accreditation Forum, Inc. (IAF). A principal objective of ILAC and IAF is to put in place world-wide, multi-lateral Mutual Recognition Arrangements (Arrangements). Both ILAC and IAF 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.

ILAC and IAF are linking the existing multi-lateral, mutual recognition Arrangements of the regional accreditation cooperations (Regional Groups) and are encouraging the development of new Regional Groups to complete world-wide coverage. For the purposes of their Arrangements, both ILAC and IAF delegate authority to their “recognized” Regional Cooperation Body Members (Regional Groups) for the evaluation, surveillance and re-evaluation of full Member Accreditation Bodies within their defined territory and associated decision making relating to the membership of the ILAC and IAF Arrangements in that territory. Formal “Recognition” of a Regional Group with respect to the ILAC and IAF 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 ILAC and IAF Member Regional Groups and Accreditation Bodies.

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

- the Evaluation of the competence of single Accreditation Bodies to accredit;
- the Evaluation of a Regional Group’s competence in managing the operations of regional mutual recognition Arrangements.

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

The requirements to be used by ILAC and IAF when evaluating the competence of a Regional Group in managing, maintaining, and extending a regional mutual recognition Arrangement for the purposes of ILAC and IAF “Recognition” are set out in IAF/ILAC A1.

PURPOSE

This document provides a tool in the evaluation process: (1) to allow an evaluated accreditation body (AB) to present information about how it addresses eleven topics important to its performance; (2) to focus the evaluation agenda on important topics; and (3) to provide a framework to present this information in an evaluation report. The effective date for application of this document is the date of publication.

AUTHORSHIP

This publication was prepared by a joint ILAC/IAF working group on Harmonization of Peer Evaluation Processes, endorsed for publication by the respective General Assemblies of ILAC and IAF in 2004 and reviewed by a joint ILAC/IAF working group on maintenance of A-series documents in 2006. This latest version was endorsed by letter ballot in ILAC and IAF in 2007.

INTRODUCTION

The KPIs in the Peer Evaluation Process

Peer evaluation aims at establishing confidence whether accreditation bodies are reliable and competent to deliver services according to harmonised standards. As a result of a positive evaluation outcome, the accreditation body can join a multilateral agreement (MLA/MRA)¹ between accreditation bodies, confirming reliability and competence to the market.

The purpose of the KPIs is to provide a balanced and detailed picture of the performance of the accreditation body at core processes and focal points of its operation. The KPIs are not to be used as a checklist but to stimulate thought in the design of the evaluation, to give hints to crucial points and to encourage the reporting of a full picture of the AB. Thus, only facts and the results of the implementation of policies should be reported, not the policies themselves as they are evaluated at another place.

Findings can only be raised against the standards or agreements between the MLA/MRA signatories but they can be explained in the KPIs in appropriate detail. Such reporting, together with the other documents, provides the evaluation team and the committee of the MLA/MRA with a true picture of the capabilities and performance of the signatories and applicants and enables sound decisions.

Since the KPIs deliver a true picture of the AB, they can be used

- as a tool for the peer evaluation team
- for benchmarking between the MLA/MRA members
- as a tool for the AB for improvement.

Not all the KPIs included in this document are applicable to all situations. They sometimes extend beyond the confines of the accreditation standard, and it will be a question of judgement for each peer evaluation team to decide how much to focus on a particular KPI in a specific evaluation. For example, proficiency testing may be appropriate in more situations that have been traditionally identified, but not in others. On the other hand, the peer evaluation team must verify that the facts stated in the KPIs are valid for all fields of activity of the AB. If the procedures or outcomes in the fields are different, the situation should be clearly described.

The Use of KPIs for Evaluation

Prior to the evaluation, the AB will be asked to make a narrative self-assessment, addressing all points in the KPIs. It will be submitted to the peer evaluation team as part of the evaluation documents. The peer evaluation will thus be able to have a picture of how the AB performs from its own point of view. This description will make it easier to understand the core processes of the accreditation body.

The evaluation team will use the KPIs as part of its preparation. During the evaluation visit, the team will find out whether the description given by the accreditation body in the KPIs is compliant with the reality that it encounters. The evaluation team will comment on the description of the KPIs so that it is clear what the AB's presentation is and what is the opinion of the evaluation team on the KPIs and performance of the AB. The presentation in the final report should clearly reflect both the AB's and the evaluation team's views.

¹ The term MLA/MRA (Multilateral Agreement /Mutual Recognition Arrangement) is used in this document because different terms are used in ILAC and IAF. In some regions the term MRA is used exclusively for denominating Arrangements between states or economies covering only the mandatory area of conformity assessment.

In other words, the KPIs will start off as a report submitted by the accreditation body under evaluation and end up as a report written and confirmed by the evaluation team.

This tool, if submitted in a comprehensive manner by the accreditation body prior to an evaluation, could save considerable time during an evaluation. The peer evaluators would only have to verify on-site the facts in the KPI report submitted by the accreditation body. A broader picture of the accreditation body activities would also assist in planning the evaluation more effectively and will help the MLA/MRA members to understand better the processes in the AB.

Abbreviations

AB	Accreditation Body
CAA	Conformity Assessment Activities
CAB	Conformity Assessment Body
PT	Proficiency Testing
RM	Reference Material

KPI 1: ACCESS TO EXPERTISE

References: ISO/IEC 17011: 4.2.6, 4.2.7, 4.2.8, 4.6.2, 4.6.3

Purpose:

Accreditation is essentially an assessment and confirmation of the competence of CABs to perform specific tasks.

Therefore, it has to be ensured that the AB has established effective ways to communicate with organisations and institutes (national and internationally) which will provide the necessary expertise in order to give added value to the customer and to develop specific accreditation criteria.

Aspects to evaluate:

- 1.1 Identification of the needs for expertise and the acquisition of the expertise by AB.
- 1.2 The amount and quality of the expertise for the scopes accredited by the AB
- 1.3 Organisation of the access to expertise.

Notes:

Please indicate whether the access to expertise is equal for the different kinds of conformity assessment activities.

There is a variety of ways to secure the necessary expertise by:

- ◆ internal staff
- ◆ external staff
- ◆ committees
- ◆ cooperation with professional associations, universities etc.
- ◆ cooperation with regional and international experts and organisations
- ◆ use of regional and international documents (standards, guidance from ILAC/IAF)

KPI 2: SCOPE OF THE AB, EXTENSION OF SCOPE AND ACCREDITATION CRITERIA

References: ISO/IEC 17011: 4.6.1, 4.6.2, 4.6.3, 7.1.1, 7.1.2 a, 7.1.2 b, 7.1.2 j, 8.2.4

Purpose:

In order to demonstrate competence to clients and stakeholders (e.g. government, industry), the AB should have a description of its present scope and a policy how to extend into new CAAs (e.g. extension to inspection, ISO 15189) or into technical fields (e.g. extension in testing which is not yet covered by the AB or into a customer specified certification scheme). Decisions to accredit or not to accredit a certain CAA should be taken based on such a policy and should not discriminate against parties on the market.

The AB should have accreditation criteria for all implemented fields and should have implemented procedures for establishing accreditation criteria in the new fields of activities.

Aspects to Evaluate:

- 2.1 description of the present scope, including statistics on activities (refer to list).
- 2.2 procedures for the extension of the scope including elements as:
 - ◆ analysis of the suitability of extensions
 - ◆ access to expertise in a new area (refer to KPI 1)
 - ◆ initial selection and training of assessors and AB staff for extensions (refer to KPI 3)
 - ◆ requirements of and cooperation with regulators/authorities
 - ◆ MLA/MRA issues
- 2.3 use of national and international guides for the operation of CABs.
- 2.4 co-operation with other national and international ABs (e.g. by joint assessments, use of assessors).
- 2.5 compliance with international harmonized decisions on what may be accredited and what should not be accredited.
- 2.6 description of the general requirements for accreditation (accreditation criteria).

Notes:

KPI 3: COMPETENCE OF AB STAFF, ASSESSORS, EXPERTS AND COMMITTEES

References: ISO/IEC 17011: 4.3.5, 4.6.2, 6.1.1-6.1.3, 6.2, 6.3, 6.4, 7.5.2

Purpose:

The competence of the AB is essentially based on its staff, assessors, experts and committees who have a central role in the operation of the AB systems. They have to be supported properly through training, monitoring and other means so that the AB can deliver consistent and competent services to its customers, independently of the individuals in the assessment team. The AB should also be able to offer consistent and competent services in cases where a combination of CAAs is performed by a CAB.

Aspects to evaluate

- 3.1 maintenance of personnel records and description of each function in the AB.
- 3.2 the number of staff related to the volume of work.
- 3.3 support by the AB in administrative matters including provision of relevant information, access to documents of Cab's, provision of work-related equipment, etc.
- 3.4 support by the AB in technical fields under assessment, including communication with the technical committees, access to databases etc.
- 3.5 initial and ongoing training for example about:
 - standards
 - AB rules
 - technical fields
 - personal skills
 - regional and international guidance documents
 - assessment techniques
 - competence of lecturers
 - frequency of training
- 3.6 Effectiveness of training and coverage of training needs.
- 3.7 procedures for systematical monitoring for assessors and experts and follow-up.
- 3.8 selection and appointment of qualified staff, assessors and experts.
- 3.9 preparation of the assessment with respect to technical requirements, forms, procedures.
- 3.10 recourse to experience in the AB during preparation or assessment.
- 3.11 recourse to documents, standards and guidance papers.
- 3.12 possibilities of communication with the AB during assessment.
- 3.13 exchange of experience among assessors, with lead assessors and with the ABs management.
- 3.14 feedback system for improvements.

Notes:

Monitoring could comprise of a combination of formal and informal observations, reviewing of reports and feed-back of the customer.

KPI 4: THE ASSESSMENT AND THE ASSESSMENT TEAM

References: ISO/IEC 17011: 7.2, 7.3, 7.5 - 7.7, 7.8.1 - 7.8.5, 7.9.3

Purpose:

The assessment is the ABs core activity. A competent team gives the CAB the satisfaction to have received added value (objective statement of its competence or of aspects to be improved) and provides the AB with evidence and information for its decisions or actions regarding the CAB and creates trust in the ABs activities to all interested parties. An undue focus on formalities devalues the accreditation processes.

The assessment team must have sufficient competence to assess the quality system and all technical activities of the CAB for which accreditation is requested in the necessary detail and depth. This includes special demands from regulators/authorities and sector specific requirements. It is necessary to ensure economic feasibility without jeopardising the quality of evaluation. Assessment activities should cover all geographic regions in which the CAB operates under accreditation.

Aspects to evaluate:

- 4.1 The AB has to ensure that each assessment:
- ◆ covers sufficiently the full scope (activities and sites) in depths for which the CAB has requested accreditation.
 - ◆ covers additional requirement from regulators and sector specific schemes.
 - ◆ covers technical and quality aspects well balanced.
 - ◆ equally treats the CAB's as to the width and depth.
- 4.2 The AB has to ensure that each assessment team:
- ◆ collects sufficient evidence about the CAB's competence.
 - ◆ provides reports giving a true and comprehensive picture of the activities of the CAB and allowing for sound decisions.
 - ◆ is able to evaluate the criticality of findings, in particular the non-conformities.
 - ◆ spends enough man-days to cover the scope in sufficient depth (preparation, on-site and reporting).
 - ◆ performs sufficient witnessing.
- 4.3 The AB has to ensure that the specific elements related to laboratories, certification and inspection bodies are well covered and documented. Examples of specific elements are:
- ◆ identification of type of inspection body (A, B, C).
 - ◆ capability to make professional judgement (inspection body).
 - ◆ branch offices and activities abroad are well under control by the main office.
 - ◆ use of IAF Guidance for certification and IAF/ILAC Guidance for inspection.

Notes:

Observations and witnessing give the evaluators opportunities to judge whether the rules of the AB are applied appropriately, whether the assessors are suited to do their job on a personally and technically acceptable level and whether the competence of the clients is assessed in sufficient depth.

Care should be taken when drawing conclusions. Isolated good or bad findings can not and should not be used to conclude that the all assessments are generally good or bad.

KPI 5: IMPARTIALITY

References: ISO/IEC 17011: 4.2.1 – 4.2.5, 4.2.7, 4.2.8, 4.3, 4.4, 4.5.2, 4.6.2, 5.2.1, 5.9, 6.1.4, 7.1.2 g, 7.1.2 k, 7.4, 7.5.3, 7.5.4, 7.9.3

Purpose:

The market place and the MLA/MRA members must have full confidence that accreditation is granted on the basis of full impartiality of the AB, its committees, assessors, experts and decision making bodies.

Aspects to evaluate

- 5.1 Procedures and evidence for ensuring the impartiality and independence of the decision-making process, decision-making bodies, committees, assessors, experts and other AB staff.
- 5.2 Complaints relating to assessor performance with regard to impartiality and independence.
- 5.3 Commercial independence of the AB in its operational and decision-making process, including its financial relationship between the AB and the assessors, committees etc.
- 5.4 Whether the AB and its personnel are free from undue influence from government and industrial/financial groupings in their operation and decision-making processes.
- 5.5 Impartiality with respect to related bodies.

Notes:

Self-declarations of impartiality and independence are insufficient; evidence must be given for all involved parties.

Intimate knowledge of a restricted sector (e.g. forensic science) may be a rare and valuable attribute and can, by its nature, give rise to charges of partiality, for example if a small number of assessors have to be involved in assessing each other's accredited activities. However, this in itself cannot be a reason for exclusion.

KPI 6: DEALING WITH NON-CONFORMITIES, CORRECTIVE ACTIONS OF THE CAB'S AND DECISION MAKING BY THE AB'S

References: ISO/IEC 17011: 4.3.7 b, 7.4, 7.6.2, 7.8.1 – 7.8.5, 7.8.6, 7.9.1 - 7.9.3, 7.11.5, 7.11.6, 7.12, 7.13, 8.3.2, 8.3.3

Purpose:

Decision-making regarding the granting, withdrawal, suspension, reinstatement, extension, reduction and termination of accreditation depends on the ABs' judgement regarding the non-conformities and the way these non-conformities are resolved by the CAB. There needs to be absolute consistency amongst all signatories of an agreement on reaching the decision as to whether or not a body has met the criteria.

Aspects to evaluate:

- 6.1 Rules for classification of findings and their homogeneous application.
- 6.2 Closing of the findings: Involvement of assessors and experts, timeframe, reporting.
- 6.3 Impact of the remaining findings and non satisfactory corrective actions on the decision making process.
- 6.4 Adequate separation of the assessment from the decision-making process.
- 6.5 Use of results from proficiency testing in decision making process (refer to KPI 8).
- 6.6 Use of complaints against the CABs as part of the decision making process.

Notes:

KPI 7: INTERNAL AUDITS AND MANAGEMENT REVIEWS

References: ISO/IEC 17011: 5.2.3, 5.5 - 5.9, 7.10

Purpose:

Internal audits and management reviews give good indication about the capability of an AB to identify elements for improvement, in which way it develops and how it does learn.

Aspects to evaluate:

- 7.1. Scope and effectiveness (does the audit system address the most important issues, is a feedback system in place, have evaluation results been addressed, are assessment of on-site activities considered?).
- 7.2. Improvements due to feedback (internal and external) or “what has been learned?”

Notes:

KPI 8: PROFICIENCY TESTING

References: ISO/IEC 17011: 7.8.1, 7.8.6 j, 7.15

Purpose:

Successful participation in proficiency tests and Inter-Laboratory Comparisons demonstrate the ability of a laboratory to produce credible results. They are important tools for laboratories to monitor its quality and are a further tool for the AB to check the assessment process and in the case of calibration laboratories the specification of the effectiveness between proficiency tests and their best measurement capability (BMC).

Aspects to evaluate:

- 8.1 implementation of the ABs' policies and procedures on selection, frequency and use of PTs.
- 8.2 means by the AB to allow the laboratory to demonstrate its technical competence practically.
- 8.3 use of mandatory PTs for the assessment of the laboratories competence.
- 8.4 monitoring of the corrective actions of the laboratory by the AB.
- 8.5 ABs' competence to properly analyse PT results.

Notes:

AB's should ensure that laboratories, which are integrated in inspection bodies also participate in PTs.

KPI 9: CALIBRATION, TRACEABILITY, AND REFERENCE MATERIALS

References: ISO/IEC 17011: 4.2.6, 7.1.1, 7.1.2 b, 8.2.2

Purpose:

Calibration, traceability and use of RMs are fundamental means for achieving consistency in testing and measurement results, for proper function of technical equipment and for validation. The level to which these tools are employed should be adapted to the needs of the conformity assessment bodies, their availability and their applicability to different CAAs.

Aspects to evaluate:

- 9.1 whether the AB has a stringent policy and pays proper attention to the implementation of its policy on calibration, traceability and the use of RMs.
- 9.2 appropriate access to international traceability and RMs by the accredited CABs.
- 9.3 the ABs specific policies and guidelines in areas where traceability is difficult to achieve.
- 9.4 whether the uncertainty budgets of the CABs relate to their use of calibration and RMs.
- 9.5 ABs training of its assessors on these issues.

Notes:

ABs should make sure that certification and inspection bodies implement the concept of calibration and traceability in process, product control and in inspection where appropriate.

KPI 10: SURVEILLANCE AND RE-ASSESSMENT

References: ISO/IEC 17011: 7.5.8, 7.5.9, 7.11, 8.1.2

Purpose:

Surveillance and reassessment activities must provide confidence that accredited CABs continue to provide reliable results over their full scope of accreditation (including the geographical regions in which they operate) and continue to operate an effective quality management system.

Aspects to evaluate:

- 10.1 Whether the AB has a stringent policy on surveillance and reassessment.
- 10.2 Methods of surveillance applied by the AB.
- 10.3 Coverage of scope of the CAB, frequency and rigour, considering multiple accreditation if applicable.
- 10.4 Use of previous experience, initiatives for work improvement and complexity of the scope.
- 10.5 The way the AB uses information from other sources (e.g. other accreditation bodies) in its surveillance program.
- 10.6 Reaction of the AB to operation of the CAB in more than one site or whether it operates cross-frontier.
- 10.7 Use of witnessing of inspection and certification activities in surveillance and reassessment programs.

Notes:

It needs to be recognised by evaluators that different combinations and frequency of surveillance activities are applied by an AB with equivalent achievement of confidence.

KPI 11: SUPPORTING ACTIVITIES

References: ISO/IEC 17011: 4.3.6, 4.3.7, 8.2

Purpose:

The primary objective of an AB is to provide an independent recognition of CAB conformance to standards and competence in performing various activities. In addition, ABs have the opportunity to provide supplementary service that benefits the AB, its clients, its stakeholders, and other interested parties. These services must not cause loss of impartiality and independence and they shall not interfere with accreditation activities.

Aspects to evaluate:

- 11.1 Supporting activities offered.
- 11.2 The way the AB makes sure that the services do not endanger impartiality and independence.
- 11.3 Liaison to MLAs/MRAs and MLA/MRA signatory partners and provision of appropriate materials for use by ABs, their clients, their governments and their industries.

Notes:

The AB may provide supporting activities, such as:

- ◆ Provision of information services through newsletters, web-sites, and promotional brochures on topics of interest and relevance to the accredited bodies;
- ◆ Provision of advice on access to suitable providers of PT schemes, certified reference materials etc. needed to support the operations of the ABs (note that for some ABs this may be mandatory);
- ◆ Promoting the benefits of accreditation and the accreditation symbol to third party customers and regulators in order to provide optimal added value for the CAB;
- ◆ Non-prescriptive advice to the CABs on technical, managerial and quality improvement in their operations;
- ◆ Cooperation with national and international expert organizations;
- ◆ Promotion of specialized training services (seminars etc.) relevant to the expertise of ABs and its network of technical experts;
- ◆ Submissions to government, client groups, standard writing bodies, etc. on issues of significance to the bodies they accredit.