



**ILAC Mutual
Recognition Arrangement
(Arrangement): Requirements for
Evaluation of Accreditation Bodies**

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The ILAC Secretariat,
c/- NATA,
7 Leeds Street,
Rhodes, NSW, Australia, 2138,
Fax: +61 2 9743 5311,
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**ILAC Mutual Recognition
Arrangement (Arrangement):
Requirements for Evaluation of
Accreditation Bodies by ILAC-
recognised Regional Cooperations**

PREAMBLE

The international community of accreditation cooperations, recognised laboratory accreditation bodies and their stakeholders cooperate through the International Laboratory Accreditation Cooperation (ILAC). A principal objective of ILAC is to put in place a world-wide mutual recognition Arrangement (Arrangement). ILAC aims to demonstrate the equivalence of the operation of its Member Accreditation Bodies through this Arrangement. As a consequence, the competence (within the accredited scopes) of laboratories accredited by these bodies is demonstrated and recognized by all signatory accreditation bodies. The market can then be more confident in accepting certificates and reports issued by the accredited laboratories.

At present, this Arrangement covers the accreditation of calibration and testing laboratories. It is envisaged that a mutual recognition Arrangement will evolve to cover the accreditation of inspection bodies. ILAC expects to cooperate with IAF (International Accreditation Forum) and the inspection industry and its stakeholders in the development of such an Arrangement and its associated procedures.

ILAC is linking the existing regional mutual recognition Arrangements of the regional accreditation Cooperations and is encouraging the development of new Cooperations to complete world-wide coverage. For the purposes of its Arrangement, ILAC shall delegate authority to its "recognized" ILAC Regional Cooperation Body Members (Cooperations) for the evaluation, surveillance and re-evaluation of ILAC full Member Accreditation Bodies within their defined territory and associated decision-making relating to the membership of the ILAC Arrangement in that territory. Formal "recognition" of a Cooperation for the ILAC Arrangement is based on an external evaluation of the Cooperation's competence in Mutual Recognition Arrangement management, practice and procedures by an ILAC team composed of evaluators from other ILAC Member Cooperations and Accreditation Bodies.

Evaluation relating to the development and maintenance of the ILAC Arrangement operates at two levels:

- ◆ the evaluation of competence of individual ILAC Member Accreditation Bodies to accredit; and

- ◆ the evaluation of a Cooperation's competence in managing the operations of regional mutual recognition Arrangements.

The procedures to be used by ILAC for the second of these are set out in document ILAC-P2.

The requirements for procedures to be used by ILAC "recognized" Cooperations when evaluating individual Accreditation Bodies for the purposes of the ILAC Arrangement are set out in this document.

PURPOSE

This document provides the ILAC Arrangement Council with criteria for evaluating the procedures used by Cooperations in their mutual recognition Arrangement evaluation process. The effective date for application of these requirements in evaluations is the date when membership is notified of its availability on the ILAC Website. Clauses 5.2.1.7 and 5.2.1.8 were revised in 2001 and again in this edition with effective enforcement dates of December 31, 2005.

AUTHORSHIP

This publication was prepared by the ILAC Accreditation Policy Committee and initially endorsed for publication by the ILAC General Assembly in 2000. This revision addresses several improvements since the implementation of the Arrangement.



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1. SCOPE

This document identifies requirements for procedures used by ILAC-recognised Regional Cooperation Body Members (Cooperations) in evaluating individual Accreditation Bodies for its mutual recognition Arrangements.

The topics to be covered by evaluation procedures are listed in paragraph 3. Subsequent paragraphs 4-16 set out ILAC's minimum requirements for each of these topics. In many cases, these requirements are followed by "*NOTES*" (in italic script) which offer advice and guidance, based on evaluator experience to date. These notes may be used by Cooperations when drafting their evaluation procedures which, however, must at least include the minimum requirements.

Procedures and requirements specified below are equally applicable to initial evaluation of an Accreditation Body and to subsequent re-evaluations.

2. DEFINITIONS

- 2.1 Accreditation Body:** an organisation that operates an accreditation system for calibration laboratories and/or testing laboratories.
- 2.2 Applicant Body:** an Accreditation Body that applies to become a Signatory to the recognized Arrangement of an ILAC recognised Cooperation.
- 2.3 Cooperation: A Regional Cooperation Body of ILAC.** This term can also refer to a group of Accreditation Bodies (possibly involving other stakeholders) whose purpose is to develop and maintain a mutual recognition Arrangement (Arrangement).
- 2.4 ISO/IEC standard:** An ISO/IEC standard, guide or technical report related to accreditation or conformity assessment.
- 2.5 Member:** An Accreditation Body that is a Signatory to the ILAC Arrangement.
- 2.6 Associate:** An Accreditation Body that has voting rights at the ILAC General

Assembly but is not yet an Arrangement Signatory to qualify as a full Member.

- 2.7 Affiliate:** An Accreditation Body that has no voting rights at the ILAC General Assembly but is allowed to participate.
- 2.8 Signatory:** An Accreditation Body who has signed a mutual recognition Arrangement of a Cooperation.
- 2.9 Recognition:** the action taken by ILAC, following an evaluation conducted according to the ILAC P2 procedures, whereby ILAC acknowledges a Cooperation's competence to manage a regional mutual recognition Arrangement which can then be integrated into the ILAC Arrangement, or the action taken after an evaluation, conducted according to the procedures of ILAC P3, whereby ILAC acknowledges an unaffiliated body's competence to qualify for signatory status under the ILAC Arrangement.
- 2.10 Arrangement:** the ILAC Mutual Recognition Arrangement: This term, also can refer to the Arrangements (MRAs or MLAs) of recognised Cooperations which pre-date the establishment of the ILAC Arrangement and which, as a consequence of the Recognition process, will be accepted as a subset of the ILAC Arrangement.
- 2.11 Arrangement Council:** The ILAC decision-making body on recognition of Cooperations and on the Signatory status of individual Accreditation Bodies.
- 2.12 Proficiency Testing Activity:** for the purpose of this document, all those activities used by Accreditation Bodies to assess performance including proficiency tests (refer to ISO/IEC Guide 43, "Proficiency testing by means of interlaboratory comparisons" and ILAC G13, "Guidelines for the Requirements for the Competence of Providers of Proficiency testing Schemes") interlaboratory comparisons and measurement audits conducted by Cooperations, Accreditation Bodies, commercial organisations, or other providers.



3. CONTENTS OF PROCEDURES

Evaluation procedures used by Cooperations shall address at least the following topics:

- Objective(s) of evaluation see Para.4
- Criteria for an evaluation see Para.5
- Costs see Para.6
- Confidentiality see Para.7
- Application for evaluation see Para.8
- Appointment of team leader see Para.9
- Documentation to be supplied by Applicant Body see Para.10
- Pre-evaluation see Para.11
- Composition of evaluation team see Para.12
- Evaluation see Para.13
- Corrective action and decision see Para.14
- Appeals see Para.15
- Formal monitoring and re-evaluation see Para.16

4. OBJECTIVE(S) OF EVALUATION

- 4.1 The objective(s) of a Cooperation's evaluation procedure shall be clearly stated to include the goal of establishing cross-border stakeholder confidence in the reports and certificates issued by accredited laboratories. The evaluation shall be focused on how the Applicant Body ensures the competence of accredited laboratories.
- 4.2 In order to achieve this objective for Applicant Bodies, the evaluation procedure shall include the following:
 - 4.2.1 An initial appraisal of the documented policies and procedures of the Applicant Body as set out in its quality manual and associated documentation;
 - 4.2.2 An initial appraisal of the documented policies and procedures on traceability of measurement results, including acceptable routes to stated references (see ILAC P-10) and measurement uncertainty as well as participation in Proficiency Testing Activity;
 - 4.2.3 An evaluation, on-site, of the implementation of these policies and procedures; and

- 4.2.4 An evaluation of an Applicant Body's ability to accredit laboratories, including an appraisal of whether the Applicant Body obtains sufficient evidence that laboratories are technically competent to perform the work for which they have been accredited.

5. CRITERIA FOR AN EVALUATION

5.1 Standards

- 5.1.1 The procedures shall require Applicant Bodies to comply with provisions of ISO/IEC Guide 58 (and future versions thereof) for calibration and testing laboratory accreditation.

5.2 Supplementary Requirements

- 5.2.1 Additionally, the procedures shall require Applicant Bodies to:
 - 5.2.1.1 Demonstrate the ability of accredited organisations to obtain valid results with reference to the appropriate ISO/IEC standards;
 - 5.2.1.2 Demonstrate compliance to those relevant ILAC P-series documents which state requirements for the Arrangement (available on the web <http://www.ilac.org>).
 - 5.2.1.3 Have a permanent secretariat;
 - 5.2.1.4 Employ a head of the Applicant Body, or senior support staff with sufficient experience in the operation of an accreditation system;
 - 5.2.1.5 Be fully operational (i.e., having carried out surveillance and reassessment);
 - 5.2.1.6 Neither offer nor provide, any conformity assessment service covered by any ILAC or IAF arrangements. -This does not exclude related bodies from providing the above conformity assessment activities subject to the conditions of 5.2.1.8.) (effective December 31, 2005);

5.2.1.7 Ensure that activities of related bodies do not affect the confidentiality, objectivity or impartiality of its accreditation operations (The accreditation body and any related body shall be effectively separate in terms of both accreditation management and decision-making, and shall have distinctly different names and logos/marks.) (Note: The word “distinctly” means different enough to avoid market confusion when the corporate identity is used in combination with the accreditation logo/mark.) (effective December 31, 2005);

5.2.1.8 Ensure that it meets the suitable requirements for Proficiency Testing Activity (see 5.3); and

5.2.1.9 For re-evaluations, abide by the requirements and obligations of the applicable regional and ILAC Arrangements.

5.3 Proficiency Testing Activity

Note: Proficiency testing is one of the important tools used by laboratories and Accreditation Bodies for monitoring test and calibration results and for verifying the effectiveness of the accreditation process. As such, it is an important element in establishing confidence in the competence of Signatories and their accredited laboratories covered by this Arrangement.

5.3.1 The procedures shall require an Applicant Body for calibration and/or for testing to demonstrate the technical competence of its accredited laboratories by their satisfactory participation in Proficiency Testing Activity. The minimum amount of appropriate proficiency testing required per laboratory shall be specified.

Note: One activity prior to gaining accreditation and one activity relating to each major sub-area of major disciplines of a laboratory's scope of accreditation at least every four years is recommended. It is recognised that there are particular areas where proficiency testing is just not practical.

5.3.2 An Applicant Body shall demonstrate that the Proficiency Testing Activity that its

accredited or applicant laboratories undertake is effective, linked to the assessment process and that appropriate corrective action is carried out when necessary.

5.3.3 Every applicant or Signatory to the Arrangement for calibration and testing shall participate in and use, as far as available and practicable, Proficiency Testing Activity offered by Cooperations, in order to verify the competence of its accredited laboratories and to demonstrate the Accreditation Body's ability to take appropriate actions if necessary.

6. COSTS

6.1 There shall be a documented policy on the costs associated with the evaluation process.

Note: Travel and hotel costs of the evaluation team could be covered by the Applicant Body, either directly to the team members' organisations or indirectly through a fee charged by the Cooperation (e.g., as part of a contract of cooperation). It is normal practice for observers to cover their own costs.

7. CONFIDENTIALITY

7.1 All confidential information received, both in writing and by spoken word, during pre-evaluations, evaluations, re-evaluations and interim visits shall be treated as such by all parties and persons concerned. This includes information relating to both the Applicant Body and the organisations visited. Provision shall be made to ensure that all members of the team agree to or sign a declaration of confidentiality. Reports on pre-evaluations, evaluations, re-evaluations and interim visits shall only be copied on a “need to know” basis to the representatives of Cooperation members who have a role to play in decision-making.

7.2 The Applicant Body and evaluation team shall agree on the storage and safe disposal of documents that have been provided as part of the evaluation process.

8. APPLICATION FOR EVALUATION

8.1 The procedures shall describe the application process.



8.2 The Applicant Body shall, having been supplied with documented evaluation procedures and criteria, indicate its familiarity with the Arrangement requirements and procedures.

8.3 The Applicant Body shall declare its operational status, the accreditation criteria it uses, its staffing, the fields of accreditation in which it operates, the number of accreditations granted and the number of assessment, surveillance/re-assessment visits already performed. The Applicant Body shall also indicate its relationship to government and its authority to operate. Its involvement in the mandatory sector should be made clear.

8.4 Applications shall be acknowledged and handled in an expeditious, non-discriminatory manner.

9. APPOINTMENT OF TEAM LEADER

9.1 In appointing team leaders for a specific evaluation, a Cooperation shall:

9.1.1 avoid the appointment of team leaders that may give rise to their mutual evaluation of their respective Accreditation Bodies in a relatively short period; and

9.1.2 not appoint the same team leader for two successive evaluations of the same Applicant Body.

Note: It is normal practice that evaluators from as many members as possible are used.

9.2 Team leaders shall comply with the minimum qualifications of evaluation as given in Appendix A.

9.3 An Applicant Body shall be informed of the name of the team leader nominated to carry out the evaluation and the scope of the evaluation, with sufficient notice, so that the Applicant Body is given the opportunity to appeal against the appointment of the team leader.

10 DOCUMENTATION TO BE SUPPLIED BY THE APPLICANT BODY

10.1 The documents to be supplied to the team leader shall be specified in the evaluation procedures so that a complete document review can be performed against the documentation requirements of the applicable ISO/IEC standard(s). These documents typically include:

10.1.1 a listing of all documents, forms, checklists, etc., used by the applicant body;

10.1.2 the Applicant Body's quality manual in which the policies and procedures of the Applicant Body and the responsibility for implementation of the quality system are clearly designated. Full details of the staffing of the Applicant Body including their backgrounds and length of experience in each type of accreditation shall also be provided if not given in the quality manual;

10.1.3 accreditation criteria and associated generally applicable criteria that the Applicant Body publishes;

10.1.4 all other general criteria published which include formal rules or regulations affecting the Applicant Body's operation and the responsibilities and obligations of its accredited laboratories;

10.1.5 a document giving a clause-by-clause cross-referencing of the Applicant Body's requirements and those of the appropriate ISO/IEC standard(s) and ILAC P1 clauses 5.2 and 5.3;

10.1.6 the policy for traceability of measurement results;

10.1.7 in the case of a calibration laboratory accreditation Applicant Body, the written requirement document(s) provided to those laboratories for the calculation and reporting of measurement uncertainty (this may be a simple

- reference to a document prepared by another international/regional body;
- 10.1.8 the policy on the surveillance and re- assessment of accredited laboratories;
- 10.1.9 the policy on the implementation and use of Proficiency Testing Activity;
- 10.1.10 summary listing of all Proficiency Testing Activity over the past five years, including a list all programs organized by of Cooperations in which accredited and applicant laboratories have participated;
- 10.1.11 operational procedures covering Proficiency Testing Activity including criteria for statistical evaluation and corrective action procedures (where available);
- 10.1.12 if available, a list of recent international comparisons in which the economy's national metrology institute or designated bodies have been involved (e.g., BIPM or regional metrology organisation) or, when applicable, reference to the NMI's capabilities as published by the BIPM website;
- 10.1.13 any other documentation that describes the mechanics of operation of the accreditation system, including annual reports, questionnaires, newsletters, guidance documents, etc;
- 10.1.14 a copy of the body's directory or other listings providing the name and scope of accreditation of each accredited laboratory;
- 10.1.15 detailed scopes of accreditation and draft scopes of accreditation of all laboratories to be visited during the pre-evaluation or and evaluation visits;
- 10.1.16 descriptions of any separate functions or affiliations of the body to activities other than accreditation (such as standards writing, etc);
- 10.1.17 details of any formal arrangement or recognition to which the body is
- party either nationally or internationally, including government authorities, private sector organisations, other accreditation systems, etc;
- 10.1.18 reports on any recent evaluations carried out by other relevant organisations, if applicable;
- 10.1.19 self-evaluation report against the KPIs;
- 10.1.20 latest internal audit report; and
- 10.1.21 latest management review report.
- 10.2** Provisions shall be made for the process of document review. The document shall be reviewed by the team leader. A report stating any documentation nonconformities shall be issued with a request for correction before proceeding with the evaluation.
- Note. For example, the team leader should confirm that all necessary documents have been provided by examination of the matrix references and the list of all documents. The team leader should request any additional documents considered necessary for the document review, to be provided in an official language of the Cooperation and with copies also to other team members. The document review should be conducted by the team leader, liaising as appropriate with the team members and using ISO Guide 58 (in future ISO/IEC 17011) and ILAC P1 as the requirements. The record should indicate conformity or nonconformity with the requirements and identify any gaps in the documentation of the system. For nonconforming areas, the reason for the nonconformity should be indicated in a report. The team leader should submit the document review report to the applicant body with a request for a response on clarifications, corrective actions and an estimate of the time-scale to submit revised documents if required. Where feasible, the applicant body should provide all amended or additional documents to the team for a further review. The team members should review the documents, and if necessary seek further clarification. When the document review is complete and satisfactory the team leader should issue a report confirming the documents are acceptable and that the evaluation (or pre-evaluation) of the accreditation body can*



commence. The team leader should agree mutually convenient dates for the evaluation (or pre-evaluation) with all parties concerned.

11. PRE-EVALUATION

- 11.1** Provisions shall be made for a pre-evaluation if requested by the Applicant Body or deemed appropriate by the Cooperation before a full evaluation would take place. The purpose of a pre-evaluation is to determine whether the Applicant Body is ready for evaluation.

Note 1 Before any evaluation takes place, the team leader should ensure that the head of the Applicant Body understands and accepts that the evaluation will be conducted in accordance with the requirements and procedures set out in the Cooperation's documents and relevant ILAC P-series documents.

Note 2: A minimum interval for supply of the required documentation in advance of the visit should be specified.

- 11.2** The team leader shall propose an agenda for the pre-evaluation visit and ask for assurance that key personnel be available during the visit.

Note 1: A team leader should normally be accompanied by at least one other team member for a pre-evaluation visit to ensure more than one person is involved in establishing an Applicant Body's readiness for a full evaluation visit. Evaluation of the documentation shall take place before the team visits the Applicant Body. During a pre-evaluation visit, the team shall discuss at least the quality system, quality documentation and its implementation and make recommendations, where necessary, on actions to be taken before the full evaluation. The team shall also indicate how many days the full evaluation will take.

Note 2: A part of the pre-evaluation shall be an assessment of the existence of laboratories providing traceability on the highest level in the economy or region. This is especially necessary where traceability of measurement results is not clear and where participation in BIPM and related activities is not fully known. The participation in international Proficiency Testing Activity should also be covered.

Note 3: During the pre-evaluation visit, the team should be allowed to observe the Accreditation Body carrying out an assessment of one or two accredited laboratories, as appropriate, to gain an initial impression of the operation of the accreditation system and of the competence of its accredited laboratories. A pre-evaluation visit should normally be from two to three days.

- 11.3** At the end of the pre-evaluation visit, the team leader shall submit a short written report to the Applicant. The report shall indicate the degree of the Applicant Body's documents and procedures that comply with the requirements of the appropriate ISO/IEC standard(s) and any other relevant documents. In particular, the report shall highlight any nonconformities with the standards, what actions are needed, and any areas of concern.

Note: The report should, as a minimum, contain the following information:

- ♦ a recommendation or decision whether to continue, suspend or terminate the evaluation process;
- ♦ a recommendation or decision on the type and number of team members necessary and the estimated duration of any proposed evaluation visits; and
- ♦ the conditions to be fulfilled before the full evaluation visit is conducted.

- 11.4** The Applicant Body shall be given the opportunity to comment on any factual errors in the report. On the basis of the report, the Applicant Body shall be required to describe the corrective actions to be taken.

Note: The report should normally be issued to the Applicant Body for guidance only on the steps to be taken before the full evaluation. The procedures should prohibit its use to claim that the Applicant Body has been evaluated by the Cooperation.

12. COMPOSITION OF EVALUATION TEAM

- 12.1** For the full evaluation visit, members of the team shall be chosen as needed to cover the types of accreditation, the technical fields, size and complexity of the accreditation system under evaluation.

Team members shall be chosen from a list of team members prepared and kept up-to-date by the Cooperation. This list should record the experience of team members. At least one member of the team shall have sound experience with these evaluations. One member of the team should be familiar with proficiency testing.

The minimum qualifications of team members shall be as described in Appendix A.

- 12.2** The team chosen shall consist of representatives from a cross-section of Accreditation Body members of the Cooperation. The team shall be chosen to provide a balanced set of skills so as to be able to conduct an effective evaluation of the key components of the system under examination.

Note 1: There should only be one team member from each member body taking part.

Note 2: The team members should have working knowledge of the English language. Knowledge of the local language should be taken into account.

- 12.3** The Applicant Body shall be informed of the names of the team members nominated to carry out the evaluation and any observers, with sufficient notice so that the Applicant Body is given the opportunity to appeal against the appointment of any particular team member or observer.

- 12.4** No team member should be associated with any Accreditation Body that has provided consultancy service to the body being evaluated for the last four years.

13 EVALUATION

13.1 Preparation

- 13.1.1 If a pre-evaluation has taken place, the full evaluation visit shall not be carried out before the Applicant Body has undertaken all the actions agreed at the pre-evaluation visit and before it appears from the documentation supplied by the Applicant Body to meet the criteria.

- 13.1.2 The team leader shall organise the full evaluation. The evaluation team shall

conduct a full evaluation of the operational practices and procedures:

- of the Applicant Body at its offices; and
- in organisations undergoing assessment/re-assessment and surveillance.

Identification of suitable assessments to witness during the evaluation visit shall be arranged before the visit to the office takes place. Suitable assessments to witness are for instance those that are representative of the technically critical activities of the Accreditation Body including in particular any in which export-related, technically-critical testing or calibration is taking place.

Note: It is acceptable that some of the evaluation team members may have as their only task to perform witnessing at different geographical places or at different times than the rest of the team.

The possibility to exchange views among team members and to discuss observations of any of them during the evaluation period is, however, considered quite important and should be ensured wherever possible.

- 13.1.3 The team leader shall be responsible for the document review.

Note: The team leader may delegate specific tasks associated with this review to the other team members.

- 13.1.4 All members of the team shall be supplied with copies of the necessary documentation at least one month in advance of the evaluation visit.

Note: If the documentation is supplied too late, the team leader could arrange to postpone the visit

- 13.1.5 The team leader (when necessary in consultation with the team members) and the Applicant Body shall decide upon the agenda for the evaluation visit taking into account the scope of the accreditations offered and the time needed to conduct an effective evaluation. The agenda shall include the itinerary and assessments/re-assessments, and surveillance visits to be observed. The agenda shall also include an examination of the Proficiency Testing Activity used by the Applicant Body and the participation of its accredited laboratories.



Note 1: It is important that a representative sample of the accreditation work under evaluation can be witnessed by the team.

Note 2: The team leader also obtain confirmation that:

- (i) the key personnel of the Applicant Body will be available during the visit;*
- (ii) visits have been arranged to organisations as requested and that the team will be able to observe the Applicant Body's assessors carrying out surveillance or assessment/ reassessment visits;*
- (iii) that any extra technical visits, where applicable, have been arranged;*
- (iv) when requested, the team is provided with the opportunity of attending a meeting of the committee concerned with decisions on accreditation if such a committee exists and is due to meet during the visit;*
- (v) provisions for the evaluation team are made, such as rooms, personal computer, facilities for copying etc; and*
- (vi) where requested, arrangements have been made for translators.*

13.2 Conduct of the Evaluation Visit

13.2.1 All of the requirements of the appropriate ISO/IEC standard(s) and Arrangement supplementary requirements require appraisal. Three other key tasks of an Arrangement evaluation team are to:

13.2.1.1 Use ILAC P7: Key Performance Indicators (KPIs) as a guide to collect information on the performance of the Applicant Body;

Note: KPIs should not be considered as requirements.

13.2.1.2 evaluate the effectiveness of the Applicant Body's assessment team by observing:

- (a) whether the Applicant Body's requirements are implemented;
- (b) whether the Applicant Body's procedures for assessment are implemented;
- (c) whether the requirements of the appropriate ISO/IEC standard(s) are implemented satisfactorily by accredited organisations; and

13.2.1.3 verify whether the competence of the laboratories is appropriate to the accredited scope.

Note: The team members should be allocated specific tasks during the evaluation and that visits to organisations be made after preliminary discussions have been held with the Applicant Body and after any initial queries about the operational procedures and technical requirements of the body have been answered. The team should allow itself sufficient time to discuss its findings in private at the end of each day or session and should leave time at the end of the visit to follow up any outstanding queries arising from visits, etc, before presenting its findings to the Applicant Body.

13.2.2 Opening meeting

An initial meeting shall be held with the senior management of the Applicant Body.
Note: Such meetings should address the objectives of the visit, the criteria to be used, the visit agenda, and the arrangements for reporting the observations and outcome of the on-site visit. After this meeting, the team should split up so that each member proceeds to that part of the evaluation assigned.

13.2.3 Evaluation of the administration

13.2.3.1 Part of the evaluation visit shall be devoted to establishing confidence in the Applicant Body's permanent secretariat and the administrative and organizational arrangements for overall operation of the system.

Note 1: The evaluation team should set aside sufficient time for this part of the evaluation. During this time they should hold discussions with a cross-section of the staff operating at all levels in the organisation and should discuss the documentation used by the Applicant Body, and should make an appraisal of the effectiveness of the implementation of the documented policies and procedures of the Applicant Body as set out in its quality manual and associated documents. Part of the evaluation should be to check files, records and archives of the Applicant Body. The

team should also appraise The relationship with technical and other organisations in the economy and the existence and content of any Arrangements with other Accreditation Bodies.

- 13.2.3.2 Due attention shall be given to the requirements of the appropriate ISO/IEC standard(s) to check that all the necessary elements are in place and being implemented. After examination of the quality system documentation (or at the same time) the team shall check the extent to which the accreditation criteria for the system incorporate the requirements of the appropriate ISO/IEC standard(s) and Arrangement supplementary requirements. A record should be made of any requirements not covered and of any alternative or additional requirements used.

Note 1: The team should examine the guidance documents provided to the staff of the Applicant Body and to external assessors, detailing the use and implementation of the accreditation criteria, and any rules or regulations issued by the Applicant Body.

Note 2: The team should check the availability and content of any documents containing additional requirements or guidance to assessors and laboratories.

Note 3: The team should check the Applicant Body's procedures for issuing accreditation documents, defining the scope for which accreditation has been granted, identifying approved signatories or key personnel, as appropriate, and maintaining such information up-to-date.

13.2.4 Assessors

- 13.2.4.1 The body's policies and procedures for selecting, training, contracting, appointing and monitoring the performance of internal and external assessors shall be examined.

Note: Checks should be made to ensure that up-to-date records detailing the qualifications, experience, expertise, training and performance monitoring of assessors are maintained. The evaluation team should ensure that each assessment is conducted by personnel familiar with the requirements of the accreditation system and trained in the techniques of assessment, and possess appropriate technical expertise for their

assignment. The team should check that the team leader or a member of the assessment team has sufficient knowledge in the evaluation of quality systems appropriate for the accredited or applicant laboratories. Where applicant bodies use a staff member as leader or part of the team, the same requirements apply.

- 13.2.5 Evaluation of performance of assessors and competence of laboratories

- 13.2.5.1 The evaluation team shall attend at least two full assessments (including an initial assessment where possible) and a combination of re-assessments and surveillance visits.

Note 1: The visits should involve a range of export-related technically critical fields representative of the accreditations granted by the Applicant Body.

Note 2: The evaluation team should pay particular attention to the procedures adopted by the assessment team and note deviations from the specified requirements by the Applicant Body's assessment team when they are observed.

- 13.2.5.2 The evaluation team members shall maintain the role of observer at all times during the assessment, re-assessment and surveillance assessments to avoid influencing the performance or procedures of the assessors and the responses by staff of the laboratory under assessment. Any observations made by the evaluation team regarding the laboratories under assessment, the assessors, the Applicant Body's staff or the Applicant Body's procedures shall be provided to the Applicant Body after the assessment.

13.2.6 Assessment reports

The evaluation team shall examine the procedure for reporting the findings of assessment teams.

Note: In particular, the team should check that any actions required of laboratories assessed are carried out within the required time scale. If the assessment findings are subject to endorsement by a committee before a decision on accreditation is made, records of the decisions of such committees should be examined. The evaluation team should review the Applicant Body's records of the accreditation process to ensure these are sufficient to justify the decision to accredit.



13.2.7 Committees

Where committees are used to assess the reports of assessments, to assist in the decision-making process or to provide technical advice on criteria, assessors, etc., then their terms of reference and the procedures for appointment of committee members shall be examined in accordance with the provisions of ISO/IEC Guide 58 (in future ISO/IEC 17011).

13.2.8 Proficiency testing activity

13.2.8.1 The way in which the results of Proficiency Testing Activity are used by the Applicant Body shall be established.

Note: The evaluation team should discuss with the relevant members of the Applicant Body's staff the following matters:

- ♦ identification of areas where Proficiency Testing Activity is available or should be initiated;
- ♦ criteria for the selection, organisation and use of Proficiency Testing Activity
- ♦ criteria for accepting Proficiency Testing Activity provided by external bodies;
- ♦ policies and procedures, including corrective action, for implementing proficiency testing results in the assessment process; and
- ♦ criteria for the selection of laboratories when access to a particular Proficiency Testing Activity is limited.

13.2.9 Traceability and measurement uncertainty

The team shall evaluate how traceability of measurement results and associated estimates of measurement uncertainty are established wherever applicable in accordance with the provisions of ILAC P10 and the ISO Guide for the Expression of Uncertainty in Measurement or equivalent.

Note: If the calibration laboratories providing measurement support to the testing laboratories are accredited by a separate Accreditation Body, it may be necessary to hold discussions with the secretariat of that body as part of the overall agenda for the evaluation, particularly if the Accreditation Body is not a Member of the Cooperation.

13.3 Evaluation Report

13.3.1 The evaluation team shall make provision in the visit agenda for time to prepare a draft of the final report (see Appendix B), identifying nonconformities, concerns, and comments included as an Annex; to be presented to the Applicant Body before leaving. This draft should be based on observations made and agreed by the team during the evaluation and on other factual information.

Note 1: A nonconformity is defined by ISO 9000:2000 as a nonfulfilment of a requirement. For peer evaluations, requirements are those of the Arrangement. Arrangement requirements are from ISO/IEC standards and guides, other normative references, supplementary requirements as supported by the documents from Cooperations, Arrangement obligations, an Applicant Body's own rules, policies and procedures, and peer evaluator judgments of competence. A nonconformity is supported by objective evidence identified by the peer evaluation team. The Applicant Body would be expected to provide evidence of successful implementation of corrective action to resolve nonconformities.

Note 2: A concern is a statement questioning the practice or competence of the Applicant Body, but not supported by enough objective evidence to justify a nonconformity. Concerns are often the type of findings a peer evaluation team has given the limited time and samples involved on a peer evaluation. The Applicant Body would be expected to respond to resolve concerns.

Note 3: A comment is any of a number of less negative or more neutral findings such as suggestions for improvement, recommendations regarding the practice of an Applicant Body. The Applicant Body would not be expected to respond to comments.

13.3.2 The team shall prepare a short summary (typically two pages) of the report identifying any conclusions with the findings appended as an Annex. This shall be signed by all team members and presented to the Applicant Body at the final meeting. The team leader shall give the Applicant Body an opportunity to comment on and discuss the team's findings and conclusion on the next step(s) and to clear up any misunderstandings that may have arisen.

Note 1: The team leader should also present a more detailed oral summary of the content of the draft final report to the Applicant Body at the final meeting at the end of the visit.

Note 2: The team should also determine the method of follow-up of all nonconformities and concerns identified, including any follow-up visit, if applicable, with agreement of the Applicant Body.

- 13.3.3 After the visit, the team leader shall complete the report and, subject to the approval of the final draft by the team members, provide it to the Applicant Body, within two months. The report should basically follow the format described in Appendix B.

Note: It should clearly highlight the compliance with the requirements of the relevant ISO/IEC standard(s), when relevant the Arrangement supplementary requirements and the Applicant Body's own requirements.

- 13.3.4 The Applicant Body shall be given the opportunity to correct any misunderstandings or errors appearing in the report.

14. CORRECTIVE ACTION AND DECISION

14.1 Corrective Action

- 14.1.1 The Applicant Body shall report on any corrective actions, including a time schedule, to the team leader (in the case of re-evaluations within one month) of receiving the final report.

NOTE The team leader should state within one month of receiving the response of the Applicant Body whether the corrective actions are acceptable.

- 14.1.2 The team leader shall, after consultation with other members of the evaluation team, provide a written recommendation on whether the Applicant Body fulfils the requirements for Signatory status together with the evaluation report and the response(s) from the Applicant Body to the decision-making body. This recommendation might include a follow-up visit to verify corrective actions.

Note: This would normally occur within one month of receiving the response(s) from the applicant. The recommendation should take into consideration the evaluation findings and the response from the applicant. The justification should also be stated.

14.2 Decision-making Regarding Evaluations

- 14.2.1 The evaluation report, the corrective actions and the recommendations of the team leader shall be submitted together as the final report to the listed members of the decision-making body.

- 14.2.2 The decision-making body shall decide: in the case of an initial evaluation,

- ♦ whether or not the Applicant Body may enter the Cooperation's Arrangement;

in the case of a re-evaluation,

- ♦ whether or not the Applicant Body will remain a Signatory to the Arrangement. Positive decisions can be accompanied by conditions: (see Appendix C).

Note 1: In the case of an existing Signatory, the decision-making body may recommend, if major non-conformities have been found, to withdraw recognition of reports from laboratories accredited by the Signatory, until the non-conformities and concerns have been resolved.

Note 2: The decision-making body may decide to carry out a re-evaluation, partly or totally prior to the normal 4 year period. Normally this would be the case after initial evaluations or fundamental re-organisations.

14.3 Scope of Recognition

- 14.3.1 The Cooperation may wish to further delineate the scope of an Applicant Body's recognition in order to satisfy its stakeholder needs.

- 14.3.2 The Applicant Body may also request that the evaluation emphasize certain areas in its accreditation activities to satisfy stakeholder needs. In such cases, the organisation of the evaluation team and the mode of the evaluation process may be specially tailored to serve such needs. Observers, such as regulators from the



economies served by the Applicant Body, may be invited.

14.3.3 The evaluation report should detail the Applicant Body's capabilities in these specific areas.

14.3.4 The decision-making body should decide on how to denote such areas in its scope of recognition.

15. APPEALS

15.1 The procedures shall provide for an appeals process by which an Applicant Body may appeal any adverse decision including pre-evaluation recommendations.

15.2 The appeals process shall be documented and provide for an objective statement of the facts of the initial decision and adequate due process.

16. FORMAL MONITORING AND RE-EVALUATION

16.1 Periodic monitoring and re-evaluation of the Arrangement is necessary.

16.2 All Arrangement Signatories shall be formally re-evaluated at maximum intervals of four years.

16.3 Formal re-evaluation shall take place at an earlier date should there be due cause such as notification of significant changes in administration, finances, operational practices or an extension in the scope of accreditation available.

16.4 Re-evaluation visits should be led by a team other than that which undertook the previous evaluation.

APPENDIX A: REQUIREMENTS FOR THE QUALIFICATIONS OF EVALUATORS

A1. Selection of Evaluators

A1.1 A regional Cooperation shall approve and appoint evaluators, maintain a list of the qualified evaluators, and oversee their performance in accordance with the criteria in the following sections.

A1.2 Members of the regional Cooperations may nominate evaluators (i.e., team leaders and team members) in writing, including a description of the experience and the scope of each proposed evaluator to the appropriate committee of the Cooperation.

A2. Team Leaders

A2.1 A team leader shall be able:

A2.1.1 to lead the evaluation in an efficient and effective way, including the distribution of the tasks among the team members;

A2.1.2 to evaluate whether an Accreditation Body complies with the requirements of the appropriate ISO/IEC standard(s) and its accredited laboratories comply with the requirements of the appropriate ISO/IEC standard(s);

A2.1.3 to organize an evaluation team with an appropriate composition (maximum coverage of scope of the Accreditation Body and minimum number of members);

A2.1.4 to decide from the submitted documentation any features requiring special study during the evaluation;

A2.1.5 to report clearly and succinctly the findings of all team members, in compliance with the Cooperation's procedures;

A2.1.6 to evaluate whether the corrective actions decided by the

Accreditation Body are likely to be effective and to evaluate the corrective actions carried out;

A2.1.7 to determine the criticality of the findings;

A2.1. to adapt quickly and easily to different accreditation cultures.

A2.2 In order to meet these criteria, a team leader shall:

A2.2.1 be an experienced (at least three years) person within an Accreditation Body or organisation which has relevant working experience (at least three years) with accreditation and have the appropriate technical background and experience (at least three years) of assessment; A2.2.2 have participated in at least two evaluations of Accreditation Bodies as a team member;

A2.2.3 have sound knowledge of the application of the appropriate ISO standards and relevant Arrangement supplementary requirements;

A2.2.4 be able to understand and to express him/herself clearly, in speaking and writing;

A2.2.5 have experience in chairing meetings and in reaching consensus on delicate points;

A2.2.6 have good interpersonal skills.

A2.3 The Cooperation shall appoint team leaders for a three-year term.

A2.4 The Cooperation shall arrange periodic meetings for team leaders in order to improve and maintain the harmonization of the evaluations.

A3. Team Members

A3.1 A team member shall be able:

A3.1.1 to evaluate whether an Accreditation Body complies with the requirements of the

appropriate ISO/IEC standard(s) and its accredited laboratories comply with the requirements of the appropriate ISO/IEC standard(s) and other documents;

A3.1.2 to report clearly and succinctly the findings;

A3.1.3 to determine the criticality of the findings.

A3.2 A team member shall:

A3.2.1 be an experienced person within his/her Accreditation Body or an experienced assessor used by an Accreditation Body, or an experienced person of another organisation knowledgeable in his/her assigned areas of the evaluation;

A3.2.2 successfully completed a relevant training course(s) or have experience in evaluating laboratory Accreditation Bodies;

A3.2.3 have sound knowledge of the application of appropriate ISO/IEC standard(s), and relevant Arrangement supplementary requirements;

A3.2.4 have good interpersonal skills; and

A3.2.5 be able to be understood and to express him/herself clearly.

A4 Evaluator-Attributes

(based on clause 7.2 of ISO 19011:2002)

A4.1 Evaluators should be:

A4.1.1 ethical, I.e, fair, truthful, sincere, honest and discreet;

A4.1.2 open minded, i.e., willing to consider alternative ideas or points of view;

A4.1.3 diplomatic, i.e., tactful in dealing with people;

A4.1.4 observant, i.e., actively aware of physical surroundings and activities;



- A4.1.5 perceptive, i.e., instinctively aware of and able to understand situations;
- A4.1.6 versatile, i.e., adjusts readily to different situations;
- A4.1.7 tenacious, i.e., persistent, focused in achieving objectives;
- A4.1.8 decisive, i.e., reaches timely conclusions based on logical reasoning and analysis; and
- A4.1.9 self-reliant, i.e., acts and functions independently while interacting effectively with others.

**APPENDIX B:
GUIDANCE ON THE STRUCTURE AND
CONTENT OF AN EVALUATION REPORT**

B1 Cover Page

The cover page states the type of evaluation, the name of the Accreditation Body that has been evaluated, the dates of evaluation visit(s), the names of the team leader, other team members and observers, specifying the body or organisation they belong to, and a clear indication that the report is confidential.

B2 Contents

For a full evaluation, a page giving the report contents, including the annexes.

B3 Summary Page

(about 2 pages), for a full evaluation, the name and type of applicant and the organisations involved in the evaluation. The summary must include the main conclusions with respect to section 5 of this document and be signed by the team members, indicating the organisations to which they belong. The summary report shall be handed over to the applicant on the last day of the evaluation visit.

B4 Introduction

The introduction should give the reason for the evaluation, the participants, a summary of the content of the evaluation, criteria against which the evaluation was performed, activities undertaken during the evaluation, provisions of documentation and translations, type of assessments observed and institutions visited.

B5 Background of the Applicant Body

This section shall give the history and background of the Applicant Body, including fields of accreditation, relationship to government, responsibilities, management, number of accreditations, staffing levels and arrangements with other bodies.

B6 Performance of the System

Subsections based upon ILAC P7, Key Performance Indicators

B7 Arrangement Obligations

For re-evaluations, the steps taken by the signatory to implement the obligations stated in the Arrangement document(s).

Annexes

- ♦ Nonconformities, concerns and comments (to be left at the end of the evaluation visit);
- ♦ List of documents supplied before evaluation;
- ♦ Evaluation programme and agenda for visit;
- ♦ Organisation chart of the Applicant Body;
- ♦ Identification of accreditation scopes of organizations visited;
- ♦ Declaration of confidentiality statement signed by all team members and observers.

APPENDIX C: DECISION-MAKING REGARDING EVALUATIONS OF A SINGLE ACCREDITATION BODY

C1.0 Decision-making Regarding Evaluations

C1.1 The evaluation report, the corrective actions and the recommendations of the team leader shall be submitted as the final report to the listed members of the decision-making body.

C1.2 The decision-making body shall decide:

- ♦ in the case of an initial evaluation, whether or not the Applicant Body may enter the Cooperation's Arrangement;
- ♦ in the case of a re-evaluation, whether or not the Applicant Body will remain a Signatory to the Arrangement. Positive decisions can be accompanied by conditions (see 2.0 Hierarchy of Decisions).

Note 1: The decision-making body may decide to carry out a re-evaluation, partly or totally prior to the normal 4 year period. Normally this would be the case after initial evaluations or fundamental re-organisations.

C2.0 Hierarchy of Decisions

C2.1 Decisions made as a result of peer evaluations can take many forms. Implicit in these decisions is the possibility of a variety of "sanctions". This guidance outlines a hierarchy of the major types of decisions from the most positive decision to the least positive decision (i.e., conditions or sanctions of increasing severity are imposed).

C2.2 Decisions on new applicants from affiliated bodies of ILAC-recognized Regional Accreditation Body Cooperations are made by the decision-making body of their respective multi-lateral mutual recognition arrangements. Decisions on the on-going re-evaluations of Signatory affiliated bodies also reside with the recognized Regional Cooperation. This becomes a prerequisite to signing and maintaining Signatory status with the Arrangement.¹

C2.3 The ILAC Arrangement Council makes all decisions on unaffiliated bodies, unless the unaffiliated body elects to apply for Signatory status through a bilateral mutual recognition with an ILAC-recognised Regional Cooperation. There are primarily two situations to address: *New Applicant Unaffiliated Single Accreditation Bodies* and *Signatory Unaffiliated Single Accreditation Bodies*. A third situation that is not addressed below is the possibility of adverse decisions or sanctions imposed on a signatory which fails to abide by its obligations under the Arrangement itself.

C2.4 Decisions on New Applicant Unaffiliated Single Accreditation Bodies:

C2.4.1 Approval without conditions (re-evaluation to occur 4 years hence);

C2.4.2 Approval with conditions (e.g., shortened interval for re-evaluation, completion of one or more ILCs);

C2.4.3 Defer approval pending submittal of required evidence of corrective actions and/or re-visit by one or more members of the evaluation team to confirm implementation of corrective actions;

C2.4.4 Disapproval with a new evaluation required².

C2.5 Decisions on Signatory Unaffiliated Single Accreditation Bodies:

C2.5.1 Approval without conditions (re-evaluation to occur 4 years hence);

C2.5.2 Approval with conditions (e.g., shortened interval for re-evaluation, completion of one or more ILCs);

C2.5.3 Defer re-approval pending submittal of required evidence of corrective actions and/or re-visit by one or more members of the evaluation team;

C2.5.4 Reduction of recognition for one or more types of accreditation;

C2.5.5 Withdrawal of Signatory status (subject to Appeals Process) — if ultimately a Signatory were withdrawn, a new application and evaluation would be required to re-enter the Arrangement.

¹ Provided that ILAC dues are paid and other obligations are fulfilled

² Disapproval should rarely happen for New Applicant Unaffiliated Single Accreditation Bodies since an evaluation report is normally only submitted for a decision once a consensus of the Evaluation Team and the ILAC Arrangement Management Committee have concluded that all requirements have been met.

The International Laboratory Accreditation Cooperation (ILAC) is the principal international forum for the exchange of ideas and information on laboratory accreditation. Established in the late 1970s, ILAC membership has grown rapidly and includes representatives from the world's major laboratory accreditation systems in Europe, Asia, North America, Australia and the Pacific. Countries that are developing their own laboratory accreditation systems are also welcome to participate and contribute.

ILAC operates a series of committees which investigate issues such as the harmonisation of international laboratory accreditation practices, the effectiveness of mutual recognition agreements in facilitating trade and the promotion of the aims and awareness of laboratory accreditation around the world. There are regular meetings of individual ILAC committees as well as a major plenary meeting of all ILAC members.

The activities of ILAC affect a diverse range of areas including standardisation, accreditation, certification, testing, calibration, and regulation in both the public and private sectors.

ILAC has a comprehensive website at www.ilac.org which contains a wealth of information regarding accreditation, testing, trade related publications and other information of interest to industry, regulators, government, trade bodies, laboratories, accreditation bodies, and users of testing and calibration services.

The following ILAC publications are available free of charge on the ILAC website at www.ilac.org:

Brochures

ILAC Information Brochure

Why Use An Accredited Laboratory?

Why Become An Accredited Laboratory?

How Does Using an Accredited Laboratory Benefit Government & Regulators?

The Advantages of Being An Accredited Laboratory (86 kb)

Information Documents (I Series)

ILAC-I1:1994 Legal Liability in Testing

ILAC-I2:1994 Testing, Quality Assurance, Certification and Accreditation

ILAC-I3:1996 The Role of Testing and Laboratory Accreditation in International Trade

ILAC-I4:1996 Guidance Documents for the Preparation of Laboratory Quality Manuals

Guidance Documents (G Series)

ILAC-G2:1994 Traceability of Measurement

ILAC-G3:1994 Guidelines for Training Courses for Assessors

ILAC-G4:1994 Guidelines on Scopes of Accreditation

ILAC-G7:1996 Accreditation Requirements and Operating Criteria for Horseracing Laboratories

ILAC-G8:1996 Guidelines on Assessment and Reporting of Compliance with Specification

ILAC-G9:1996 Guidelines for the Selection and Use of Certified Reference Materials

ILAC-G10:1996 Harmonised Procedures for Surveillance & Reassessment of Accredited Laboratories

ILAC-G11:1998 Guidelines on Assessor Qualification and Competence

ILAC-G12:2000 Guidelines for the Requirements for the Competence of Reference Material Producers

ILAC-G13:2000 Guidelines for the Requirements for the Competence of Providers of Proficiency Testing Schemes

ILAC-G14:2000 Guidelines for the Use of Accreditation Body Logos and for Claims of Accreditation Status

ILAC-G15:2001 Guidance for Accreditation to ISO/IEC 17025

ILAC-G17:2002 Introducing the Concept of Uncertainty of Measurement in Testing in Association with the Application of the Standard ISO/IEC 17025

ILAC-G18:2002 The Scope of Accreditation and Consideration of Methods and Criteria for the Assessment of the Scope in Testing

ILAC-G19:2002 Guidelines for Forensic Science Laboratories

ILAC-G20:2002 Guidelines on Grading of Non-Conformities

ILAC-G21:2002 Cross Frontier Accreditation — Principles for Avoiding Duplication

Secretariat Documents (S Series)

ILAC-S1:2000 Guidelines for the Proposal, Drafting, Approval and Publication of ILAC Documents

ILAC-S2:2003 Rules

Procedural Documents (P Series)

ILAC-P1:2003 ILAC Mutual Recognition Arrangement (Arrangement): Requirements for Evaluation of Accreditation Bodies by ILAC-recognised Regional Cooperations

ILAC-P2: 2003 ILAC Mutual Recognition Arrangement (Arrangement): Procedures for the Evaluation of Regional Cooperation Bodies for the Purpose of Recognition

ILAC-P3: 2003 ILAC Mutual Recognition Arrangement (Arrangement): Procedures for the Evaluation of Unaffiliated Bodies for the Purpose of Recognition

ILAC-P4:2003 ILAC Mutual Recognition Arrangement (Arrangement): Policy Statement

ILAC Mutual Recognition Arrangement (Arrangement): Terms of Reference and Composition of the Arrangement Management Committee

ILAC Mutual Recognition Arrangement (Arrangement)

ILAC-P7: 2003 ILAC Mutual Recognition Arrangement (Arrangement): Key performance Indicators (KPIs)

ILAC-P10:2002 ILAC Policy on Traceability of Measurement Results

