

## **Further Harmonisation of Activities within IAF, ILAC and the Regions**

### **I. BACKGROUND**

At its meeting held in Mexico in June 2010, the Joint ILAC/IAF Executive (JEC) started to consider further the harmonisation of activities within IAF, ILAC and the Regions following a discussion of the outcome of the ballot on the potential merger of ILAC and IAF.

The JEC noted that:

- The need to clearly identify what work is best undertaken at the international and regional levels is very important as all groups (regional and international) have resource problems and there often appears to be duplication of activity.
- The ILAC document ILAC P12 addresses this issue and is supposed to avoid these problems, but it does not appear to operate well. It was considered that ILAC P12 document could possibly be developed into a joint ILAC and IAF document, but that any revision should take into account both the earlier and current version of P12, as the first version was a stronger document.
- All the reports provided to the JEC by the regions should provide details about what is being undertaken by the region to assist in identifying and avoiding some duplication of effort.

#### **Establishment of a Task Force**

The JEC established a Task Force (TFG) with Terms of Reference to explore harmonizing work at the international and regional level through looking at what is being done now at the international level and the regional level, and seeking opportunities to streamline this. It was agreed to use the document ILAC P12 (previous and current versions) as a starting point with the possibility that this may lead to the preparation of a joint document.

At the JEC meeting in London in March 2011, the tasks were extended to include whether the global structure should contain a more specific description of obligations to be met by members and regions.

This report builds on the key messages from the regions to the enquiry regarding the future of IAF and ILAC in 2008 (a summary of which is given at Annex A), and the subsequent analysis made by the JCCC TF to consolidate the responses to focus on the key/primary activities to be held at the regional level and those exclusively to be managed at the global level. Further comments and deductions have been added to the work of the JCCC TF based upon a wider analysis - see Annex B.

### **II. PURPOSE**

This report was presented to the JEC at the meeting in Frankfurt 2 May 2013. The JEC decided to circulate the report to the IAF and ILAC memberships, and to have a preliminary discussion of the report at the Joint General Assembly in Seoul and to invite the regions, unaffiliated bodies and stakeholders to discuss the report and to provide feedback to the annual meetings in Bangkok 2014. Any decisions based on this report may have an impact on the strategic planning in ILAC and IAF.

### **III. THE CURRENT INFRASTRUCTURE FOR ACCREDITATION GLOBALLY**

#### **Overview**

The structure of global accreditation is divided into two levels: the regional level (EA, APLAC, PAC, IAAC, SADCA, AFRAC and ARAC and the global level (ILAC and IAF – throughout this document also referred to as the “global associations”).

Accreditation bodies in most economies are both members of a region and of the global associations. Exceptions are generally accreditation bodies from parts of the world where a regional cooperation has not yet been established; these accreditation bodies are members of the global associations as unaffiliated bodies. Stakeholders and other interested parties may also be members of the global associations.

#### **The Global Associations (IAF and ILAC)**

Both IAF and ILAC are associations built of membership by accreditation bodies from economies around the world; the number of members has increased over the years, where IAF now has over 100 members and ILAC 146 members from 112 different economies (as of 1 February 2013). The general assemblies are the decision-making bodies of the associations and the members hold the voting rights (in ILAC only full and associate members hold voting rights).

Except for centralised secretariat functions which are provided by (paid) contractors to IAF and ILAC, the activities of the global associations are carried out by persons from or on behalf of the members' organisations at no staff cost to the global associations.

The values and key principles of the global associations since they were founded have been active involvement by members, democracy, and decision-making by consensus. These values were, and remain, vital for the global associations in the process of establishing and enhancing confidence in the operation of accreditation activities by the accreditation body members.

The increase in number of members has several implications for the global associations:

- a. The operation and management of the global associations has become more complex.
- b. Members are to a greater degree joining associations in operation and not – as in the past – becoming attached to an association with the purpose to contribute to the development of the global system. As a result, many members are to greater degree receivers of the benefits delivered by the global associations compared to contributors to establishing and enhancing accreditation at the global level.
- c. The costs of running the global associations have increased over the years. Managing associations with the increase of total membership is more expensive and it is becoming more and more difficult to involve volunteers in the work – both at the technical level and in taking on the task to host global events. The financial risk of hosting a global event has increased and the amount of work necessary to arrange meetings has increased following the increase in numbers of participants attending meetings.
- d. Global events (such as General Assemblies) are by necessity bigger, more expensive to run, and therefore require higher registration fees to be levied; as a result they have become more expensive to attend. At the same time, many accreditation bodies and stakeholders are facing increasing budget constraints, which results in more focus on the added value of attending meetings and of volunteering to take on obligations under the global system.

The challenge IAF and ILAC face with regard to resources is to some extent being in a situation of competition for scarce resources with the regions. From an accreditation body point of view, providing resources to the activities of a region is cheaper and the benefits of involvement in regional activities may be more obvious as the regions have more commonality. In addition, tasks dealt with at the regional level are to some extent similar to those discussed at the global level; new work items are generally started up in the regions following a need being recognised but often in parallel the issue may also be taken up at the global level. This competitive situation with regard to resources needed to manage and operate the technical development of the global system means that some accreditation bodies are actually considering if resources shall be allocated to the technical work in the regions or to the global level.

An increasing proportion of the global level membership consists of accreditation bodies from developing countries, placing both IAF and ILAC structures in a position to have a developmental agenda, as a large part of these members are still in the developmental state. For Recognised Regions this issue is addressed by the regions and supported by the global level; in regions not yet recognised, the issue remains.

The complexity of dealing with global issues – where the outcome needs to be applicable to and satisfy the political and cultural environment that accreditation bodies operating in around the world – requires additional resources from each individual participating in the work and from the total resources allocated as well.

### **The Global Arrangements**

The main deliverables of ILAC and IAF are the Arrangements; the success of the global associations depends almost exclusively on the confidence and trust the marketplace has in reports issued by accredited CABs.

Confidence among accreditation bodies in the accreditation activities performed by the accreditation body members of IAF and ILAC was established by the IAF MLA in 1998 and the ILAC Arrangement in 2000. Confidence in the peer evaluation system has continuously been enhanced during the re-evaluation of existing members and by accepting new members as signatories to the MLA/Arrangement.

The international arrangements on mutual recognition of certificates and reports issued by conformity assessment bodies (CABs) accredited by signatories to the arrangements were established with the objective to provide recognised conformity assessment activities and global acceptance of conformity assessment certificates.

Realising the objective of global acceptance of certificates and reports issued by CABs accredited by signatories to the arrangements has progressed over the years and many end-users are relying on accreditation as the preferred tool to ensure the quality and reliability of conformity assessment activities. Further, regulators in many different economies have shown their confidence in accreditation by introducing provisions in national regulations for compliance with national requirements for products and services to be demonstrated through the use of conformity assessment services provided by accredited CABs.

The development in Europe and the US over the last few years, the on-going discussions in the WTO TBT committee, and the use by UNIDO of accreditation in the development of trade infrastructures confirm that regulators and the marketplace have gained confidence in accreditation; the use of conformity assessment provided by accredited CABs has been introduced in many new sectors to demonstrate compliance with specifications or agreed/adopted requirements.

The widespread use of services from accredited CABs poses, however, new challenges to the global associations as the confidence established over the years may be questioned or put at risk in cases

where individual conformity assessment reports/certificates issued by accredited CABs are defective or if a sector indicates or provides evidence that the global system has inherent weaknesses. Although accreditation confirms the competence of a CAB to carry out specific tasks and thus cannot ensure that reports/certificates will be “correct” every time, the credibility of the global accreditation system is highly dependent on a low number of erroneous conformity assessment reports and for such examples not to be considered by the marketplace as a weakness of the system but as individual instances.

The tool applied to assure the quality and integrity of accreditation and of services provided by accreditation bodies is the peer evaluation system, which is managed by ILAC and IAF but where the actual peer evaluation of accreditation bodies is delegated to the Recognised Regions (except for peer evaluation of unaffiliated accreditation bodies). IAF/ILAC conducts the peer evaluation of regions (including witnessing the region performing peer evaluation of member accreditation bodies). This system was put in place when the arrangements were formed and the basis for the global arrangements is thus the regional MLAs and the work conducted by the regions.

The management of the global peer evaluation system means that the decision-making on signatory status of accreditation bodies to the global Arrangements is with the global associations and that the policy and procedures for evaluation of an accreditation body and regions are approved by IAF/ILAC.

#### IV. ANALYSIS

A number of existing papers were analysed or taken into consideration by the TFG:

- Comments received during the ballot on future direction of ILAC and IAF and options for the future structure

The key messages from the two members providing comments during the voting process were:

- a. To align policies and to coordinate joint actions between both entities in a first step, in such a way that the desired merger can crystallize naturally soon thereafter as the result of an integration process instead of a decision made by a majority of votes.
  - b. To consider if the global organization shall be:
    - i. An “umbrella” for the regions – and tasks to be dealt with and decided at regional and global level,
    - ii. An association for members.
- Consolidated input to enquiry regarding the future of ILAC and IAF (2008) and subsequent work of the JCCC TF on the future of ILAC and IAF

An enquiry was circulated to the regions after the annual meetings in 2008. The subsequent work performed by the JCCC TF (based on input from regions, unaffiliated bodies and stakeholders) was considered to be a good basis for analysing the responsibilities and related work items to be managed at the global level, and providing principles for coordinating/harmonising the work at the global level with activities performed and managed by the regions.

- ILAC-P12:2005 and ILAC-P12:2009

The ILAC policy was adopted in 2005 and revised in 2009. The intention was to optimise resource allocation and utilisation and to avoid duplication of work between regions and the global level. The principles set out in P12 are:



- a. Regions shall inform ILAC and other regions of any new relevant work item planned which may have an impact internationally and invite participation from other regions or groups to the work item. Notification of new work items should be done via the regional and ILAC Secretariats;
- b. The region will develop the work item and share outcomes by reporting progress to the relevant ILAC Committee;
- c. ILAC may decide to invite the region to transfer the work item into an ILAC work item with the region taking the lead. Criteria for transferring a work item into an ILAC work item are:
  - i. Significant international importance and a direct impact on the ILAC Arrangement
  - ii. The expected outcome of the work item has an impact on recognition or acceptance of accreditation and the ILAC Arrangement.

The revision of the document in 2009 was done to introduce more flexibility in the application of the principles and to be less binding (as the principles in the 2005 version were not being followed by the regions).

## **V. GENERAL CONCLUSIONS**

### **Resource constraints**

The persisting global economic crisis places a strain on everyone's ability to afford to participate as the current global accreditation system demands. Affordability ranging from participation in the working groups, participation in peer evaluations, attending the various meeting and annual general assemblies of both the regional and global level structures has been strained and is likely to continue to be strained for the foreseeable future. IAF and ILAC need effective and efficient operations aimed at minimizing costs while still maintaining participation at all levels of the international accreditation infrastructure.

For IAF and ILAC to cope with the increasing demand for resources, there needs to be better use of the resources in the regions. If sufficient and qualified resources are to be allocated to issues of global impact, one pre-condition is that these issues are only dealt with at one level and not in parallel at both regional and global level.

One issue must, however, be dealt with at the global level – the global strategy for development of accreditation. The global approach to accreditation and consensus on the global strategy is essential as the strategy will define the frame or policy for future accreditation activities; any development at the technical level at either global or regional level must be agreed within this frame/policy.

Leadership to have a shared vision for accreditation amongst the cooperations of members is therefore a strategic issue at the global level. The structure and operation of IAF and ILAC must accommodate members and stakeholders to be engaged in the development of the strategy to ensure that the ownership is anchored with the members and that the vision is shared, understood and applied by the members.

### **Towards harmonization between the global and regional levels**

Harmonization of the global and regional work can best be done when there is a common and agreed understanding of the separation of activities and responsibilities between the two levels as described in Annex B. In order to manage the implementation of a separation between the two levels, it will be essential for there to be full support from the regions to implement the approach in managing the work

in the region - having in mind the need to consider whether the global level shall be involved when a new work item is considered or decided.

Therefore, regions shall be prepared to present for discussion at the global level, in a timely and efficient way, any technical (related to an accreditation or peer evaluation activity) or liaison issue, which may have global impact. This obligation for the regions is what today is the content and intention of ILAC P12; however, the procedure is currently not well implemented.

It may be claimed that regions already report the key activities in the region to the relevant committee in IAF and ILAC, and also present issues for discussion at the global level. However, if real harmonization of work is to take place, the process has to be managed by the top level of both the regional and global levels, i.e. the Executive Committees and the Secretariats. If the responsibility is held at the individual committees level, it is more likely that other aspects may influence the decision, for example, the committee may resist transferring “good and interesting” issues to the global level and may only ask the global level to deal with issues of “less importance” or where “resources are lacking” at regional level.

The effective implementation of this “division of work” will further require that the resources are available at the global level to deal with requests from regions on issues which may have an impact at the global level. The global resources must serve two purposes:

- i. To analyse, recommend and decide if a work item shall be dealt with at the global or regional level;
- ii. In cases where the issue is “global”, resources must be available to complete the task (for example, establishing a global TF or agreeing a region to complete a global task for all to take over as the preferred way of doing things).

In both cases, regions (i.e. the individual accreditation bodies that comprise the region) will be responsible for delivering the resources to the global level, so support from the regions is essential for a successful change of operation at the global level.

### **Models for Implementation**

There are two models for the implementation of the transfer of activities (analysis of technical issues) to regions, either (or a combination of):

- i. Delegate an issue to a region prepared to take on the task (model X), or
- ii. Form a global TF of representatives from the regions (model Y).

Both models will require a deliberate decision at the global level that:

- i. A specific issue recognised by members, by a region or at the global level shall be analysed,
- ii. Qualified and sufficient resources are available to carry out the analysis needed, and
- iii. The result of the analysis will have a global impact on accreditations delivered by the member accreditation bodies.

The initial analysis of specific issues must carefully investigate if the issue brought forward is of importance for the confidence and trust in the global system *or* if the issue shall be considered and solved at the regional level allowing the regions to have a slightly different approach to handling technical issues.

Only issues having an impact on the confidence in the global system *and where* different handling of the issue at regional level will have a negative impact on the global system should be dealt with at the global level.

An analysis concluding that an issue needs to be solved at the global level will further require that a decision shall be taken on the model for handling the issue: delegating a task to one region or to a TF established of competent resources from several (or all) regions.

If model X is preferred,

- i. A region may choose to use its existing (committee) structure and
- ii. Other regions should appoint contact persons to follow the work progressing allowing other regions to provide input and views to the analysis performed and solutions proposed.

If model Y is preferred,

- i. A specific TF shall be established and endorsed at the global level, composed of competent persons nominated by the regions and
- ii. Each region may appoint a mirror group or use its existing (committee) structure to follow the work progressing allowing regions to support its member of the TF.

The outcome of the work performed by either a region or a TF should be a recommendation to the global system for final consideration and adoption, including monitoring of its implementation.

### **Obligations of members and regions**

Whether the global structure should contain a more specific description of obligations to be met by members and regions (or to split the obligations between members and regions) needs to be clear. The compliance of regions and members with adopted global policies and requirements is currently evaluated during the peer evaluation activities, i.e. at four yearly intervals.

Many global decisions have, however, a direct impact on the operation of regions, their MLAs and the accreditation activity of the members and a four yearly frequency for follow-up activities may not be appropriate or sufficient. Therefore, on specific decisions, regions may need to be requested to report to the global level within a fixed time frame. Any global decision where regions are obliged to report to the global level must specify the purpose of the reporting and the deadlines to be met by the regions.

Furthermore, consideration should be given to the peer evaluation of regions to be supplemented by an obligation to report yearly on key activities in the region. This reporting should at least be on issues where global decisions have a direct impact on the work of regions, and vice versa. The responsibility for monitoring the regions and their reporting might be shared by the MLA/Arrangement Management Group and the Executives of IAF/ILAC.

## **VI. OTHER CONSIDERATIONS**

In considering the harmonisation aspects, a number of more general points emerged.

### **The values and role of the global system**

The global system should continue to have the values already established: *active involvement by members, democracy and decision making by consensus* but the global structure and the function of the system may be changed slightly. Careful consideration should be given to the on-going fact that the resources for work at the global level are contributed voluntarily by the members.

The structural question of whether to continue with the present approach of the global associations being built on individual member accreditation bodies and stakeholders or to transfer (more or less) into an “umbrella” association coordinating the work of regions, has not been considered by the TFG. However, there may be a need to discuss in the future if the added value of all members meeting at the

global level is proportional to the actual expense of hosting events and gathering all the members. It may be a lot cheaper and more efficient if representatives for regions met at the global level and the position of members were agreed and decided in the regions.

In the meantime, IAF and ILAC should continue as associations of members from economies around the world. As long as accreditation is a service based on standards used on a voluntary basis (i.e. no global law or regulation making it mandatory for conformity assessment bodies to be accredited or for end-users to require conformity attestations to be issued by accredited conformity assessment bodies), the strength of the system is founded and dependent on the commitment of accreditation bodies and conformity assessment bodies to comply with the agreed requirements. The values mentioned are closely linked to association built on membership of individual members.

At the same time, some regional cooperations are becoming more and more an integral part of the region's Developmental Agenda and there is a requirement for accreditation bodies to be more involved in the regulatory environment. These developments hold new challenges to IAF/ILAC's values such as:

- The ability to achieve a consensus vote, in cases where the priorities and objectives differ between regions;
- The potential for block voting based on regional affiliation; and
- How to prioritise work items at the international level.

The development of the global system therefore needs to be coordinated with, or at least mindful of, the regional development. The challenge is to ensure that the regulatory use of accreditation is in harmony with the global accreditation rules and, at the same time, for the global system to be flexible enough so that in some areas the use of accreditation in regions (by regulators) may be slightly different from the global approach (although it must never be in conflict with the global rules).

The global rules should act as the common denominator of the rules in all regions. They should have enough "strength" to ensure each other reliable enough to conclude an MLA/MRA. The more detailed the rules, the more difficult to enforce and the slower the process. The way we manoeuvre today is perhaps often more based on a level of mistrust (we look for hidden agendas, etc.) than a truly rational process.

The role and function of IAF and ILAC should be to focus on the activities listed as key activities at the global level, as stated in Annex B:

- i. Leadership and vision, including ownership for the development and philosophy of accreditation;
- ii. Ensure equivalence of outcomes through implementation of ISO/IEC 17011 and conformity assessment standards;
- iii. Managing the development and expansion of the global Arrangements into new activities;
- iv. Support to developing countries/unaffiliated bodies/regions;
- v. Liaison activities: working with international organizations or groupings of international organizations of strategic importance;
- vi. Promotion and Communication: a strategic objective to ensure that the leadership and vision for the development and philosophy of accreditation is visible and known to relevant external parties and internally among members.

The tasks and operation of the global associations will remain unchanged with regard to the:

- i. Development of the vision for accreditation and the strategy;
- ii. Management of the global arrangements (administration of the peer evaluation activities and the decision making on signatory status);

- iii. Support to developing countries / economies / regions. It may however be worth considering whether the actual support to the development of regions should be transferred to regions that are already recognised regions of IAF/ILAC as the technical knowledge and experience in operating a region lies with the other regions and not with IAF/ILAC;
- iv. Liaison activities: management of the liaison activities shall continue as a global activity including preparation of a global position to issues relevant to the global accreditation system. The persons conducting the actual liaison activity may be from the regions to optimise the utilization of resources available for liaison activities;
- v. Promotion and Communication: if promotion and communication is recognized as a strategic activity in relation to both external parties and internally, then these activities should be enhanced with regard to issues handled under the responsibility of the ILAC and IAF CMC/MCC and resources allocated to the work.

The main deliverables of the global system are the Arrangements, relying on the work of the Recognised Regions, including initiatives started at the regional level. The huge achievement of IAF and ILAC so far to gain trust and credibility of the Arrangements in the marketplace may enable a redefinition of the purpose of the Arrangements from being an agreement between the signatories to accept and promote certificates and reports issued by CABs accredited by signatories to the Arrangement, into a cooperation between accreditation bodies (and stakeholders) accrediting CABs which the marketplace can have confidence in and rely on in its decision-making process. It may be possible for further tasks with regard to “ensuring equivalence of outcomes through the implementation of ISO/IEC 17011 and conformity assessment standards” can be delegated to the Recognised Regions having in mind that the coordination at the global level is needed to ensure that global acceptance of reports and certificates issued by CABs under the global Arrangements.

The model for handling issues related to ensuring the equivalence of outcomes may however be changed. As discussed above, technical work related to the interpretation of standards and development of global mandatory or informative documents should focus only on issues having a global impact and on confidence in the global system, allowing the regions to make “regional” interpretations of the accreditation criteria thereby serving the needs or demands of the “local” market. This may legitimately allow some variation in the application of the accreditation requirements but will be justified by a more efficient and effective service to the local/regional market.

Whilst adopting an outward-looking approach, IAF/ILAC should consider if it is appropriately positioned to respond to market-driven changes, whether in the regulated sector or the voluntary field. This may require making provision for accreditation based on technical regulations as we acknowledge the move towards accreditation becoming a tool to assist in the protection of health, safety and the environment (regulatory areas) – globally, regionally and nationally. A discussion may be necessary on how far an accreditation body can go in taking on responsibilities for other activities and how these other activities are promoted and provided whilst ensuring that the confidence the marketplace has in the accreditation body is not harmed or damaged.

The IAF and ILAC Arrangements are also gaining increasing recognition amongst sector scheme owners e.g. WADA, IEC, FDA etc. each with their own rules of engagement and sets of requirements.

These developments hold new challenges such as:

- IAF and ILAC participation in the working of these groups;
- IAF/ILAC’s and their members’ ability to accommodate the different requirements of these groups;
- IAF and ILAC members’ ability to influence the requirements, e.g. GLOBALG.A.P., FDA, etc.