

Purpose

Supporting the needs of government and regulators is a core objective of IAF and ILAC and their accreditation body members. This document sets out a number of ways to assist IAF and ILAC members develop, maintain and strengthen relationships with regulators at all levels. It also includes sample text that can be provided to regulators when specifying accreditation in regulation.

Introduction

In many economies, regulators may be national, state, provincial, and even municipal in their scope. They may be public authorities or represent private sector specifiers. Many regulators are already using accreditation effectively to support their regulatory and policy objectives. However there are some that are not aware of accreditation and are therefore at risk of creating duplicate or costly in-house systems. There are also regulators that do not possess sufficient information, which can lead to the incorrect application or specification of accreditation requirements.

Close cooperation between regulators and accreditation bodies (ABs) is essential to ensure that the service delivered by accreditation bodies and the accredited conformity assessment body community is meeting the needs and expectations of regulators.

It is acknowledged that cultural variations will exist from economy to economy in the way that accreditation bodies and regulators interact. However, this informative document includes a number of best practice principles that accreditation bodies can adopt (where appropriate) to increase the application or specification of accreditation by regulators.

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Further information

For further information about this publication, contact an accreditation body in your economy that is a member of IAF/ILAC. Please check our website for up-to-date information <http://iaf.nu/> or <http://www.ilac.org/>

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Introduction

Accreditation bodies (AB) have policies for the promotion of accreditation to various target groups, for example to raise the awareness of accreditation among potential clients (Conformity Assessment Bodies – CAB) and to increase awareness and understanding in the marketplace of the benefits of using services from accredited CABs.

Promotional activities will best meet their objectives when they are developed to focus on the specific needs of the target group, whether that be manufacturers operating in the global market or public authorities responsible for legislation in the field of environmental issues, public health etc., or for trade issues.

In recent years, public authorities have increased their use of services from accredited CABs to improve the function of the marketplace or to replace or supplement public control activities with services from CABs. Most economies now have regulators that are using accreditation in areas such as medical testing, drinking water testing, and environmental compliance. There are also references to standards and accredited conformity assessment in most trade discussions.

This document sets out some suggestions to assist ABs in their promotional activities with public authorities with the aim in the medium/long term of facilitating the continued use of accreditation and extending the use of accreditation into new areas.

When developing promotional activities targeting public authorities ABs may consider the recommendations below, focusing on:

- Establishing personal contact with Regulators
- Developing promotional material for Regulators
- Formal involvement of Regulators in the accreditation structure
- Electronic Communication tools

Further, the document contains in Annex B a sample text to illustrate how regulators may refer to accreditation and the Global Arrangements in legislation or other legal texts.



Establishing Personal/Direct Contacts with Regulators

1 Establish a good central contact point

A strong relationship with a central coordinating point within the regulator can help greatly to improve communication as a whole. For example, a Government ‘sponsor’ can represent an AB’s interests to the wider department or to other parts of government and can often open doors that would otherwise remain closed to an AB. So, the ABs should aim to have a recognised sponsor within the regulator.

ABs that are part of Government may also be monitored by a specific department. It is advised to liaise with this department regularly both formally (such as quarterly reporting) and informally (keeping them informed of developments or potential issues).

2 Face to face meetings/seminars

Personal contact and face-to-face meetings are the most effective means of developing relationships and closer cooperation. This can be carried out by developing a programme to establish contacts within the policy areas of priority departments. This approach, however, requires time and resource to research contacts, attend meetings, and to carry out any follow-up activity.

Workshops and seminars within government departments are also effective ways of communicating the benefits of accreditation to a wider group of policy makers. A strong contact point within the sponsor department may be able to facilitate the organising of a workshop, or provide the relevant introductions to other departments.

Workshops can be arranged to take place over lunchtime or after hours so as to avoid too much disruption to the working day. The use of a meeting room within the department is desirable, however should this not be an option, a location should be found within walking distance. Collaboration with relevant partners can also provide a broader message and therefore a more attractive reason for policy makers to attend. Suitable partners could include the National Standards Body or the National Metrology System.



Establishing Personal/Direct Contacts with Regulators *continued*

3 Identify and develop contacts with ‘trade officials’

Government officials and regulators that work across sectors that involve trade should be targeted for direct interaction, as accredited conformity assessment can provide the confidence required for product acceptance and the removal of technical barriers to trade. Trade negotiators (for WTO TBT Chapters) will also provide good contact points. Although they may already be aware of IAF and ILAC, establishing a close relationship can help address specific trade concerns or expand use of the global accreditation arrangements. The WTO website lists contact details for each national economy <http://tbtims.wto.org/en/NationalEnquiryPoints/Search>

4 Exchange of information on latest standards, guidelines, interpretation etc.

Meetings between regulators and ABs vary between economies in terms of frequency and depth of engagement. In some countries there are regular meetings while in others, meetings are only convened to solve problems and questions identified by the parties.

ABs should ensure that arrangements are in place for regulators to keep them informed on the latest standards, guidelines or interpretations issued at national or international level. This is especially important when regulators are referring to accreditation in their legislation and the up-dated requirements will have an impact on the operation of the CABs. If resources allow, ABs could allocate a nominated contact for each technical area.

5 Consultations

Responding to government consultations is an important way of establishing contact and engaging with regulators in some economies. ABs should take the opportunity to respond to all relevant consultations or to follow up with the appropriate policy contacts.

For all regulators, contacts need to be refreshed and followed up at regular intervals as the message is rarely taken on board at the first attempt and individuals move on quite regularly. This means that the familiarisation process needs to start again with new incumbents.



Developing Promotional Material for Regulators

1 Develop promotional material for Regulators

Distributing promotional material in hard copy or in digital format can be a highly effective medium for refreshing the memory of those regulatory officials who are already aware of accreditation as well as providing general introductory information to those who are not.

In order to meet both these objectives, promotional material should combine basic introductory information about accreditation and the associated terminology with some element of news or case studies. Sometimes—if examples can be cited without causing undue offense—it can be powerful to include case studies where a regulator incurred unnecessary expense or encountered problems and increased risk because standards and accreditation either were not used at all or were not specified correctly in order to implement public policy successfully.

IAF and ILAC (and the Regional Co-operations) have created a series of promotional materials that can be used by ABs and conformity assessment bodies as they are, or adapted to suit the need. See Annex A for further details.



Formal Involvement of Regulators in the Accreditation Structure

1 Establish an Advisory Forum

The AB could consider setting up an Advisory Forum or Committee to establish a more formal structure when cooperating with regulators. This can provide a means of broadening contacts across government, and of developing a schedule of regular meetings.

Terms of Reference for this Committee may be:

“To define the overall administrative and technical requirements conformity assessment bodies shall meet and to advise the AB in assessing against these requirements”

An Advisory Committee as proposed may serve three functions:

- To be the co-ordination point between regulators and the AB. The AB should plan the work programme for the committee to facilitate increased confidence in the accreditation system with regulators;
- To inform regulators on the technical work and the peer evaluation system of the regional cooperation/IAF/ILAC to demonstrate that the accreditation system constitutes the professional technical community for assessment of conformity assessment bodies;
- To be a co-ordination forum between regulators who could benefit from sharing experience in implementation of legislation as well as exchange of experience in assessment, registration/ notification and designation of conformity assessment bodies.

Such a Committee should not deal with technical issues at sectoral level; the AB should have Technical Advisory Committees dealing with specific technical issues. Although, as an alternative, ABs may choose to include representatives from regulators in the advisory committee structure they already have directly in place for their accreditation activities.

Formal Involvement of Regulators in the Accreditation Structure *continued*

2 Involvement of Regulators in the assessment process/share information

An Advisory Committee may serve as an effective tool for the collection of information on the needs of regulators for increased understanding and acceptance of the IAF/ILAC arrangements, and dissemination of information on the actual peer evaluation process and system.

Accreditation bodies, with the appropriate assistance from IAF/ILAC and the regional cooperations, should ensure that regulators are well informed about the purpose and function of the peer evaluation process. Accreditation bodies should ensure that regulators are informed of the outcome of their peer evaluation according to the policies on the distribution of peer evaluation reports.

IAF and ILAC publish Annual Reports to publicise the effort and resource that is invested to maintain the integrity and consistency of the IAF MLA and ILAC MRA respectively through the peer evaluation process. ABs are encouraged to distribute these reports each year to their regulator contacts to reinforce the confidence that they can derive from the IAF MLA and ILAC MRA

The IAF report can be downloaded from the IAF website <http://www.iaf.nu/articles/Promotional/Documents/25> and the ILAC report is available on the ILAC website at <http://ilac.org/publications-and-resources/ilac-promotional-brochures/>

Finally, many ABs allow regulators to observe the activities carried out as part of a peer evaluation in order to demonstrate the robustness of the process. It should be noted that it is up to the AB and the peer evaluation team leader as to whether to allow regulators and others as observers during the peer evaluation.

3 Technical Committees

The technical expertise held within an AB can be supplemented by a number of Technical Advisory Committees which can be used to provide advice on technical matters related to the development and operation of accreditation.

The committees can provide a forum for input from various bodies and individuals with an interest in accreditation, for example regulatory bodies. Input can be sought on areas such as:

- The formulation and review of specific technical criteria to facilitate effective and consistent application of accreditation
- The acceptability of particular procedures as a basis for accreditation
- The identification of potential assessors and sources of assessors
- The impact of regional and other international initiatives

Electronic Communication Tools

1 Provide easy access to the Directory of CABs

Many regulators will visit an AB site to verify the validity of a certificate or test report, and to check the scope of accreditation. ABs should make the search facility prominent on their websites and easy to use.

2 Grow a subscriber base

Communications from IAF, ILAC and the Regions can be a valuable source of information that can be sent to national regulators and authorities. As well as reinforcing awareness levels, regular communications may pop up in the 'inbox' at a time when a regulator is seeking a solution to achieve their policy objectives. In this way, communications improve the chances of an AB's involvement with regulators at an early stage of policy development.

IAF and ILAC each produce an electronic newsletter which is published twice a year. The newsletters, which are distributed as emails, can be subscribed to by those wishing to receive future editions. IAF also sends out regular bulletins to communicate information that is relevant to national authorities and major stakeholders.

The latest versions of the newsletters can be found on the IAF and ILAC websites.

IAF – http://www.iaf.nu/articles/IAF_Newsletter/164

ILAC – <http://ilac.org/news-and-events/ilac-newsletter/>

To receive future communications, one simply clicks on the **subscribe/unsubscribe** link in the newsletter and enter your email address. ABs are encouraged to forward the newsletters to regulator contacts encouraging them to subscribe in this way.

Note: One can also subscribe by clicking the links shown below on the homepages of the IAF and ILAC websites.



ABs could encourage their Regulators to subscribe to receive email alerts from the ILAC website http://ilac.org/latest_ilac_news/

In this way, regulators will receive notifications automatically when a new document is published or there is a change in the status of the ILAC MRA.

Electronic Communication Tools *continued*

3 Optimise the AB website

The website is the most important communications tool for an AB. It provides information in different formats, to different target groups, and is accessible to those who may not be familiar with accreditation.

Information appropriate to regulators should be easily identifiable on the home page of the AB's website. From here, it should be made easy for the regulator to access all relevant promotional materials and to contact the relevant personnel for further information.

Desk-based research is likely to be one of the tools that a regulator will use to gain insight into a market sector. It is therefore important that information about accreditation is easy to find against relevant searches. There are some simple steps that an AB can follow to improve the visibility of the AB website, and therefore increase the number of visitors the site receives from search engines.

3.1 *Sharing Links*

Search engines look for links between websites to rank the authority of the content displayed on pages. Inbound links (links from a 3rd party website to the AB site) count as a 'vote' to the credibility of the information published on it. Greater weight is placed on the link if:

- The link comes from a well-respected site with a high page ranking of its own, particularly if it also has relevant content to the search term.
- The link's anchor text (the text which is clicked through to reach the target website) is well worded and relevant to the content of the site.

The IAF and ILAC websites (and regional cooperation websites) already provide links through to their AB membership. To ensure the greater visibility, ABs should also include clear links to the IAF, ILAC and regional cooperation websites. Publishing a link to the homepage is satisfactory, however greater value will be derived by including links to relevant parts of the IAF or ILAC website. An example web page for use by ABs is shown in Box 1.

Electronic Communication Tools *continued*

Box 1: Accreditation – an international network



Accreditation is an international network which is managed by the IAF, in the fields of management systems, products, services, personnel and other similar programmes of conformity assessment, and the ILAC, in the field of laboratory and inspection accreditation.

Accreditation bodies, which have been evaluated by competent peers, sign arrangements that enhance the acceptance of products and services across national borders, thereby creating a framework to support international trade through the removal of technical barriers. These arrangements are also used to enhance the confidence of results used within economies, particularly in the provision of healthcare, food, environmental and building services.

The purpose of these arrangements is to ensure mutual recognition of accredited services between signatories, and subsequently acceptance of accredited services in many markets based on one accreditation.

The current list of IAF signatory accreditation bodies is available on the IAF website.

The current list of ILAC signatory accreditation bodies is available from the ILAC website.

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Reference to Accreditation and the Global Arrangements in Legislative or other Legal Texts

Part of the discussion with regulators and specifiers who intend to refer to accreditation in legislation or specifications, should be:

- Which type of conformity assessment activity will be most appropriate for the specific conformity assessment service the regulator will introduce in the legislation?
- How shall the criteria be drafted/defined which the CAB and the end user (service provider, manufacturer etc.) shall meet?

The AB should be prepared to analyse the specific need of the regulator/specifier and come up with advice on the relevant standard for accreditation of CABs and how the conformity assessment activity to be performed by the CAB is to be defined.

If the conformity assessment activity provided by CABs in accordance with the relevant standard does not fully meet the needs or expectations of the Regulator/specifier, the AB should provide advice on introduction of additional requirements in the legislation/specification to ensure that all the requirements the CAB shall meet are defined and will be assessed by the AB during the accreditation process.

Annex B includes examples of how to accurately and fully specify the accreditation criteria and reference to the IAF and ILAC Arrangements. This text can be provided to Regulators/specifiers to assist them in their drafting of Regulation or specification.

Annex A – Promotional Materials for AB and Conformity Assessment Body use

IAF and ILAC have created a number of promotional tools which can be used or adapted to support ABs promote accreditation to regulators. Many of these documents have been translated into multiple languages. All the current materials are available for download from the IAF and ILAC websites.

Public Sector Assurance –

<http://www.publicsectorassurance.org/>

A website that showcases how accredited conformity assessment is used around the world by central government, local government and regulators to deliver positive benefit. It features case studies that illustrate the value of accreditation to government officials and regulators in delivering results in key policy areas. It also provides independent research and supporting information to demonstrate the tangible benefits of conformity assessment to the public sector.

Promotional Brochures

www.iaf.nu/articles/Promotional_Documents/300

ilac.org/publications-and-resources/ilac-promotional-brochures

Powerpoint Presentation Slides

(available on the IAF and ILAC intranets)

IAF / ILAC Promotional Videos

www.youtube.com/user/IAFandILAC

Annex B – Specifying Accreditation and the Global Arrangements

Specifying the IAF Multilateral Recognition Arrangement (MLA)

The following is an example for specifying accredited services for external certification bodies (management systems, products or persons). All four paragraphs are needed to ensure that a party requesting external certification has met the International Standard and IAF requirements for competence and are providing reliable certificates.

- “1. The certification body shall be accredited in accordance with the requirements of ISO/IEC 17021 – *Conformity assessment- Requirements for bodies providing audit and certification of management systems (for management systems certification)* or ISO/IEC 17065 – *Conformity assessment – Requirement for bodies certifying products, processes and services* or ISO/IEC 17024 – *Conformity assessment – General requirements for bodies operating certification of persons (for persons certification)*.
2. The certification body’s scope of accreditation to ISO/IEC 17021, ISO/IEC 17065 or ISO/IEC 17024 shall encompass the area that is required for certification.
3. The accreditation of a certification body shall be issued by an accreditation body (AB), operating in accordance with ISO/IEC 17011, *General requirements for accreditation bodies accrediting conformity assessment bodies* and signatory to the respective IAF Arrangement.
4. Additional requirements can be laid down by the regulator. The accreditation body shall evaluate compliance with these additional requirements.”

The first paragraph stipulates that the **certification body** be accredited to ISO/IEC 17021, ISO/IEC 17065 or ISO/IEC 17024, while the second paragraph requires that the area in which **certificates** are issued be listed on the certification body’s scope of accreditation. If this requirement is not met, the certification body could claim that it is ISO/IEC 17021, ISO/IEC 17065 or ISO/IEC 17024 compliant even though the CB is not actually accredited for the requested standards.

The third stipulates that the Accreditation Body (AB) be an IAF MLA signatory. Without this paragraph, the CB could be accredited by an AB that has inadequate or misleading credentials. There are ABs that claim to be in compliance with SO/IEC 17011. Holding IAF MLA signatory status indicates that the AB has been periodically peer-evaluated against the requirements of ISO/IEC 17011 and additional IAF requirements.

Annex B – Specifying Accreditation and the Global Arrangements *continued*

Specifying the ILAC Mutual Recognition Arrangement (ILAC Arrangement)

The following is an example for specifying accredited services from external testing and calibration laboratories or inspection bodies. All four paragraphs are needed to ensure that a party providing external testing, calibration, medical testing and inspection services has met the relevant International Standard and ILAC requirements for competence and are providing reliable data and reports.

- “1. The laboratory shall be accredited in accordance with the requirements of ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories* (for testing or calibration laboratory) or with ISO 15189, *Medical laboratories – Particular requirements for quality and competence (for medical laboratories)* or the inspection body shall be accredited in accordance with the requirements of ISO/IEC 17020, *General criteria for the operation of various types of bodies performing inspection*.
2. The testing (or calibration) laboratory’s scope of accreditation to ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories* shall encompass testing (or calibration) of (list the test method(s) or parameter(s) that are required for the testing or calibration work being required or specified). The same applies to scopes of medical laboratories and inspection bodies.
3. The accreditation of a testing, calibration or medical laboratory or inspection body shall be issued by an accreditation body (AB), operating in accordance with ISO/IEC 17011, *General requirements for accreditation bodies accrediting conformity assessment bodies* and signatory to the ILAC Arrangement.
4. Additional requirements can be laid down by the regulator (e.g. the lab must participate in specific PT programs). The accreditation body shall evaluate compliance with these additional requirements.”

The first paragraph stipulates that the **service provider** be accredited to ISO/IEC 17025, ISO 15189 or ISO/IEC 17020, while the second paragraph requires that the **tests, calibrations, or examinations** requested be listed on the scope of accreditation for the laboratory or inspection body’s scope of accreditation. If this requirement is not met, the laboratory could claim, for example, that it is ISO/IEC 17025 compliant even though it is not actually accredited for the tests or calibrations specifically required.

The third paragraph stipulates that the AB should be an ILAC MRA signatory. It emphasises the importance of purchasing conformity assessment services accredited by an AB with the appropriate credentials without which it is not possible to be confident that the laboratory or inspection body has been accredited by an AB competent to carry out the assessment. There are ABs that claim to be compliant with ISO 17011. Holding ILAC MRA signatory status indicates that the AB has been periodically peer-evaluated against the requirements of ISO/IEC 17011 and additional ILAC requirements.



About IAF

The International Accreditation Forum (IAF) is a global association of Accreditation Bodies, Certification Body Associations and other organisations involved in conformity assessment activities in a variety of fields including management systems, products, services and personnel.

IAF promotes the worldwide acceptance, of certificates of conformity issued by certification bodies accredited by an Accreditation Body Member, and seeks to add value for all stakeholders through its activities and programs.



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About ILAC

ILAC is the international authority on laboratory and inspection accreditation, with a membership consisting of accreditation bodies and affiliated organisations throughout the world. Its site at www.ilac.org can provide a range of information on laboratory and inspection accreditation, as well as the location of its members world-wide.

ILAC promotes the increased use and acceptance by industry as well as government of the results from accredited laboratories and inspection bodies, including results from accredited organisations in other countries. ILAC liaises with many international bodies and stakeholders to achieve shared objectives.



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