

Standards, Conformity Assessment, and Accreditation: the Pillars of Assurance in the Global Marketplace.

by Jon Murthy

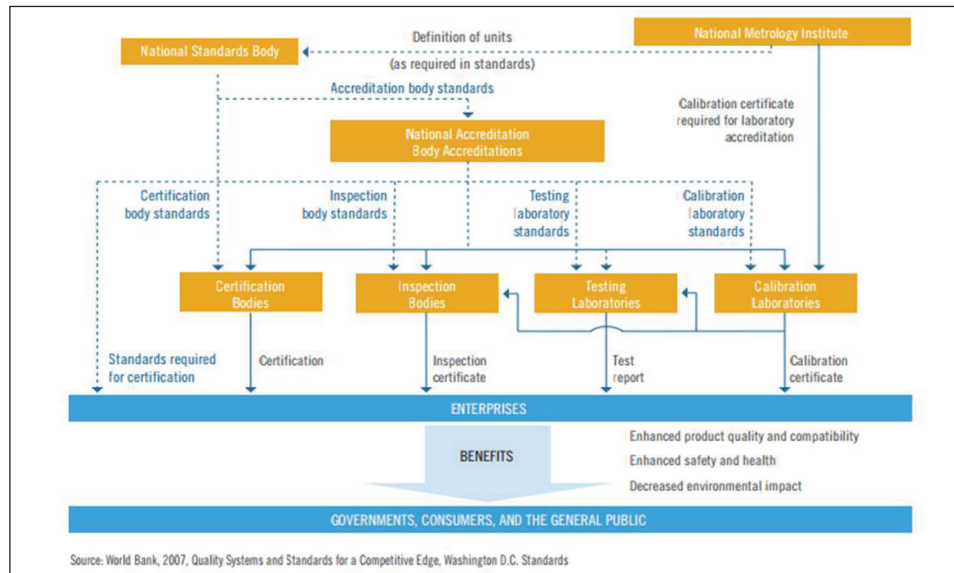
While the term “standard” can mean different things to different people, dependent on geography, age, and industry, a standard is in essence an agreed way of doing something. Whether that “something” is producing an item, delivering a service, or managing a process, standards provide a reliable basis for creating shared expectations. New standards are developed when industry

or government recognizes the need for one; whether it is to protect employees or consumers by regulating an industrial process or standardizing a new type of product. By distilling collective expertise into an agreed modus operandi, standards help to stimulate innovation, increase efficiency, reduce duplication, and make everyone’s life easier and safer.

Consequently, standards form the cornerstone of economies across the world, simultaneously facilitating trade while increasing consumer protection. It follows that as industries adopt a more global outlook, the need for compatibility of standards between measurements from international economies becomes crucial. However, in order for a standard to be effective, it must be easy to recognize whether a product, service, or process conforms to that standard. It is all very well for an organization to say that it conforms to certain standards, but the key question is—can it prove it?

Demonstrating Competence

The process of conformity assessment provides an unbiased way to show whether the product/service/system meets the relevant requirements. Third party conformity assessment bodies (CABs) cover all industry sectors and activities; from calibration, medical and testing laboratories, to inspection (the



examination of a design, product, service, process, or installation to ensure operational safety) bodies, to bodies that certify management systems, products, and persons.

Every industry sector relies on certification, inspection, testing, or measurement services to promote health and safety and the overall quality control of products, services, processes, and systems. Confidence in the competence of CABs is paramount if the results of their assessments are to be used by regulators, manufacturers, and end-users. Most organizations do not have the internal resources or expertise to effectively evaluate the competence of CABs, so they will look to accreditation processes to provide the necessary assurance.

Accreditation is internationally recognized as a robust independent declaration of an organization’s competence, the validity and suitability of its methods, the appropriateness of its equipment and facilities, and ongoing assurance through its internal quality control. In many economies there is a sole national accreditation body (NAB). Its role is to assess whether CABs are meeting a required standard of performance. Put simply, if CABs are the watchmen, then the NAB watches the watchmen. Economies in Europe have single ABs, while some economies such as the US, Canada, and Korea have multiple ABs. It

to environmental impact and construction. Currently there are thousands of different standards and specific tests that are accredited. In some industries accreditation is a legal requirement, while in others it is becoming the expected norm. Regardless of whether it is a legal requirement or not, an increasing number of organizations, in both the public and private sectors, are specifying accredited services as a precondition to tendering for contracts. Being accredited or using accredited services can therefore open doors to market sectors that were previously closed, increasing the potential for new business.

Often mistakenly used interchangeably, “accreditation” and “certification” perform entirely different roles in the quality assurance process. In essence, certification relates to the assessment of a product or service, whereas accreditation includes assessments of the technical competence, capabilities and independence/integrity of the organization which performs that certification.

Global Benefits, Delivered Locally

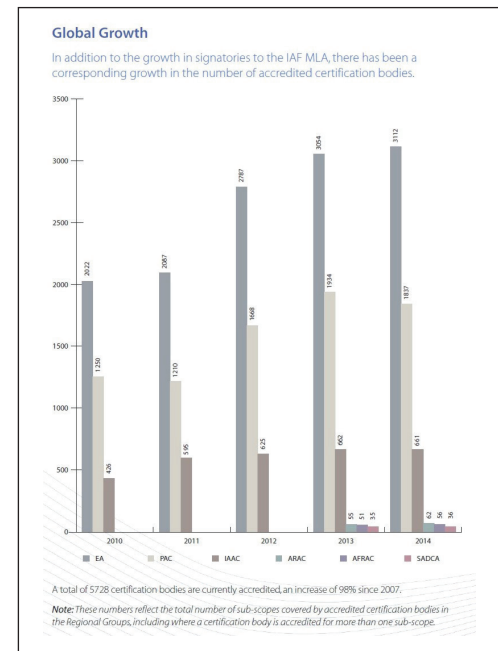
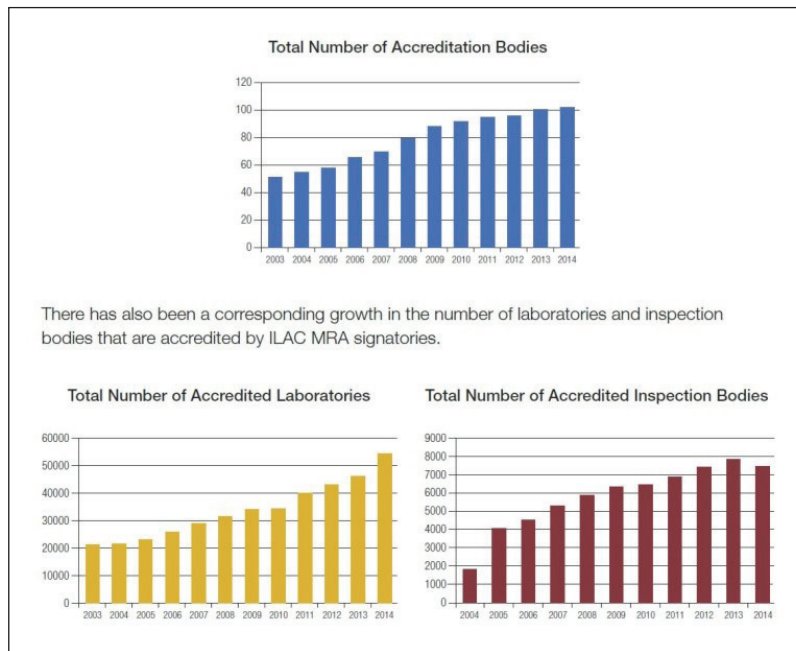
Today’s economy is a global marketplace, where international trade is vital. To support and facilitate this trade, a system is needed that allows organizations to have confidence that the imported goods and

may be that each AB covers a particular discipline such as testing, or it may be government policy to have multiple ABs. If they are signatories to the ILAC/IAF Arrangement, they are all deemed to be competent.

One of the key strengths of accreditation is that it can be applied to almost any industry sector and business situation, from food safety and product testing

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services meet performance and quality expectations that are found in standards. Just as standards need to operate internationally, so do certification and accreditation.

The International Laboratory Accreditation Cooperation (ILAC) is the international authority on laboratory and inspection body accreditation. The International Accreditation Forum (IAF) performs a similar role regarding accreditation of management systems, product, and personnel certification bodies. Together, ILAC and IAF form a global network of NABs and key stakeholders that helps to harmonize the work of CABs and accreditation bodies across the globe, and maintains international standards from one NAB to the next. These international standards, from the ISO CASCO toolkit, include the following:

- ISO/IEC 17025:2005 *General requirements for the competence of testing and calibration laboratories*
- ISO 15189:2012 *Medical Laboratories – Requirements for quality and competence*
- ISO/IEC 17020:2012 *Conformity assessment – Requirements for the operation of various types of bodies performing inspection*
- ISO/IEC 17065:2012 *General requirements for bodies operating product certification systems*
- ISO 14065:2013 *Greenhouse gases – Requirements for greenhouse gas validation and verification bodies for use in accreditation or other forms of recognition*

- ISO/IEC 17024:2012 *General requirements for bodies operating certification of persons*
- ISO/IEC 17043:2010 *Conformity assessment – General requirements for proficiency testing*
- ISO/IEC 17021-1:2015 *Conformity assessment – Requirements for bodies providing audit and certification of management systems*

Both ILAC and IAF have seen a steady and significant increase in membership and the number of accredited CABs.

Thanks to a combination of multilateral mutual recognition arrangements (ILAC's Mutual Recognition Arrangement [MRA] and IAF's Multilateral Recognition Arrangement [MLA]), accreditation equivalence is recognized in over ninety economies across the world. This "accredited once, accepted everywhere" approach helps to develop international trade by facilitating the acceptance of goods and services across national borders and lowering technical barriers to trade (TBTs).

The positive role of accreditation in reducing TBTs has been formally recognized in Article Six of the World Trade Organization's Agreement on Technical Barriers to Trade. Similarly, recognition is given in the recent Trans-Pacific Partnership trade agreement. Involving twelve leading Pacific Rim countries, the agreement aims to promote economic growth; support the creation and retention of jobs; enhance innovation, productivity, and

competitiveness; raise living standards; and promote transparency, good governance, and enhanced labor and environmental protection.

Just as duplication of equivalent schemes leads to inefficiencies in national markets, the same is true internationally. Before the introduction of the MRA/MLA, goods and services were often assessed by a recognized authority in the importing country. At best this led to an unnecessary duplication of already satisfactorily completed testing, but usually resulted in unnecessary delays at the point of entry—a potential deal-breaker for time-critical services and perishable goods. Not only is this costly for the exporter, but the importer, too, suffers through increased costs and damage to its reputation. A key to lowering these technical barriers to international trade is the existence of international recognition agreements for the work of accredited CABs. The MLA and MRA provide assurance that CABs in different economies are operating to the same internationally accepted standards.

Summary

Together, standards, certification, and accreditation form the pillars of assurance for governments, businesses, and end-users alike. The ever-increasing demands on governments to do more for consumer protection with limited resources have made a growing reliance on accredited conformity assessment necessary. This allows regulators to focus their resources on ensuring that regulatory objectives are appropriate for the market

needs and effectively mitigate risk. Governments also use accreditation to support their regulatory efforts in health, safety, environmental protection, fraud prevention, or market fairness, and therefore accreditation also serves as a risk management tool. Examples of this can be seen across the globe; from supporting imports/exports in Egypt and the steel industry in India, to underpinning safety in the US toy and power plant industries, to facilitating trade, market regulation, and international recognition in the Pacific Rim.

For industry, the system of standards, certification, and accreditation can help businesses deal with increasingly complex international supply chains, stricter standards and safety regulation, and an increased awareness of product liability risk. Whether it is facilitating reduced spending on regula-

tory compliance with clean air regulations in the US, increasing average profitability in Spain, investment yields in Japan, and return on assets in Denmark, standards, conformity assessment, and accreditation can have a positive impact on the bottom line as well. Additional information on ILAC is available at www.ilac.org, and on IAF at www.iaf.nu.

Author

Jon Murthy is the head of marketing for the UK Accreditation Body (UKAS). Prior to joining UKAS, Jon worked in a number of positions in BBC World Service, BBC OBs, BBC Technology, and BBC Vecta. Having completed a BBC-sponsored MBA, Jon's last role involved commercializing the Corporation's technical intellectual property, which resulted in technology spin outs that

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The ILAC Mutual Recognition Arrangement

Background

The International Laboratory Accreditation Cooperation (ILAC) first started as a conference in 1977 with the aim of developing international cooperation for facilitating trade by promotion of the acceptance of accredited test and calibration results. In 1996, ILAC became a formal cooperation with a charter to establish a network of mutual recognition agreements among accreditation bodies that would fulfil this aim. The ILAC Mutual Recognition Arrangement (often referred to as the ILAC Arrangement) is the culmination of twenty-two years of intensive work.

On November 2, 2000, thirty-six laboratory accreditation bodies, full members of the International Laboratory Accreditation Cooperation (ILAC), from twenty-eight economies worldwide, signed an arrangement in Washington, DC to promote the acceptance of technical test and calibration data for exported goods.

The Arrangement came into effect on January 31, 2001 and was extended in October of 2012 to include the accreditation of inspection bodies. The ILAC Arrangement provides significant technical underpinning to international trade. The key to the Arrangement is the global network of accredited testing and calibration laboratories and inspection bodies that are assessed and recognized as being competent by ILAC Arrangement signatory



accreditation bodies. The signatories have, in turn, been peer-reviewed and shown to meet ILAC's criteria for competence. Now that the ILAC Arrangement is in place, governments can take advantage of it to further develop or enhance trade agreements. The ultimate aim is increased use and acceptance by industry as well as government of the results from accredited laboratories and inspection bodies, including results from facilities in other countries. In this way, the free-trade goal of "a product tested or inspected once and accepted everywhere" can be realized.

Foundation

The aim of the ILAC Arrangement is to develop a global network of accredited

testing, calibration, and inspection facilities that can be relied on to provide accurate data and results.

The ILAC Arrangement provides technical underpinning to international trade by promoting cross-border stakeholder confidence and acceptance of accredited laboratory data and inspection results. Until the advent of the ILAC Arrangement, there had been no multilateral mutual recognition agreement in laboratory or inspection accreditation. That had been a hindrance for some types of international trade, particularly those products that have had to undergo retesting, recalibration or reinspection upon entry to importing countries. The ILAC Arrangement now facilitates this trade.

The principal elements for establishing confidence among the participating systems within ILAC are listed below. These elements are designed to ensure conformance with the requirements in order to establish and maintain mutual confidence in the technical competence of ILAC members and their accredited laboratories and inspection bodies. The elements are:

- Exchange of information on the development and operation of ILAC member accreditation schemes;
- Participation in the work and decision-making of the ILAC General Assembly and ILAC committees where applicable;

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- Participation in international inter-laboratory comparisons and proficiency testing programs;
- Participation in the work of ILAC expert groups and task forces held to discuss problems related to testing, calibration, and inspection in various technical fields;
- Evaluations of applicants and re-evaluations of signatories to this Arrangement are conducted in accordance with the relevant ILAC and regional cooperation documents;
- Observations of applicant bodies' and signatories' assessments of their laboratories and inspection bodies to determine if these facilities meet the requirements of the current version of ISO/IEC 17025 or ISO 15189 (for medical testing laboratories) or ISO/IEC 17020; and
- Confidence in the metrology institutes of the signatory economies to which traceability is claimed by accredited facilities and support for the measurement comparison activities of the International Bureau of Weights and Measures (BIPM) and/or regional metrology organizations.

How Does the ILAC Arrangement Work?

The ILAC Arrangement is based on the results of an intensive evaluation of each body carried out by peers and in accordance with the relevant rules and procedures contained in several ILAC publications.

Each accreditation body signatory to the Arrangement agrees to abide by its terms and conditions and by the ILAC evaluation procedures and shall:

- Maintain conformance with the current version of ISO/IEC 17011, related ILAC guidance documents, and a few, but important, supplementary requirements; and
- Ensure that all accredited laboratories and inspection bodies comply with ISO/IEC 17025 or ISO 15189 (for medical testing laboratories) or ISO/IEC 17020 and related ILAC policy and guidance documents.

The ILAC Arrangement builds upon existing or developing regional arrangements established around the world. The bodies participating in these regional arrangements are responsible for maintaining the necessary confidence in accreditation bodies from their region that are signatories

to the ILAC Arrangement. Each recognized regional cooperation body must abide by the procedures defined in ILAC requirements documents. The European cooperation for Accreditation (EA), the Asia Pacific Laboratory Accreditation Cooperation (APLAC), and the Inter-American Accreditation Cooperation (IAAC) are the current ILAC-recognized regions with acceptable mutual recognition arrangements (MRAs) and evaluation procedures. The Southern African Development Community in Accreditation (SADCA), the African Accreditation Cooperation (AFRAC), and the Arab Accreditation Cooperation (ARAC) are currently developing their MRA evaluation processes before requesting recognition and approval by ILAC. Accreditation bodies that cannot be affiliated with a recognized region may apply directly to ILAC for evaluation and recognition.

The evaluation of an accreditation body to establish its qualifications to be a signatory involves a team of peers (generally senior staff of experienced accreditation bodies). Evaluations include time spent at the headquarters office of the applicant body to determine compliance with ISO/IEC 17011. Additionally, the evaluators witness the performance of the applicant's assessors during actual assessments/reassessments to determine if the laboratories and inspection bodies are in compliance with ISO/IEC 17025 or ISO 15189 (for medical testing laboratories) or ISO/IEC 17020 and that there is sufficient depth of examination to determine competence.

In order to maintain the value and meaning of the ILAC Arrangement, the signatories agree to notify each other about any significant changes in the status or operation of the accreditation body. Issues of significance include changes in name or legal/corporate status; new agreements negotiated with other accreditation bodies or the revision, suspension, or termination of any such agreements; changes in key senior staff or the organizational structure; or significant changes in the operations of the body. Each signatory to the ILAC Arrangement must also designate a liaison officer to afford a consistent channel of communication between the accreditation bodies.

Future Steps

Now that the ILAC Arrangement is in place, the next crucial step is for govern-

ments and industries to take advantage of this arrangement. Governments can use it to further develop or enhance trade agreements. Another important step that is already underway involves government acceptance of the results from accredited laboratories and inspection bodies. Regulatory agencies around the world now accept the results from testing and calibration laboratories and inspection bodies that are accredited by accreditation bodies that are signatories to the ILAC Arrangement, without direct government review, including results from facilities in other countries.

Many specifiers, like government agencies, have come to appreciate the importance of credible accreditation programs that are based on internationally recognized standards. With restricted budgets, many government agencies can no longer do it all themselves; increasingly, they must rely on third-party laboratories or inspection bodies to support their regulatory efforts. When they do so, they need a fair and meaningful basis for identifying qualified providers. Accreditation provides that and the ILAC Arrangement provides a means for recognition of acceptable accreditation bodies.

Industry users of test and calibration data and inspection results similarly can take advantage of the ILAC Arrangement. Users will have greater confidence in the accuracy of the report they are purchasing, particularly if they are conscious of the scope of the laboratory or inspection body's accreditation, because it has been generated by a competent facility. Manufacturers also gain efficiency because of accreditation; instead of their own on-site assessments, they can defer to the assessments of competent accreditation authorities that are ILAC Arrangement signatories.

The ILAC Arrangement builds confidence among accreditation bodies and their ability to determine a facility's competence to perform testing, calibrations, measurements, or inspections. Confidence facilitates the acceptance of testing, calibration, and inspection results between countries when the results can be demonstrated to come from accredited facilities. This ultimately helps to reduce some technical barriers to trade. Through the ILAC Arrangement, the foundation for realizing the ideal of having products "tested or inspected once and accepted everywhere" has been established.

The International Accreditation Forum

Background

Accreditation assures users of the competence and impartiality of conformity assessment bodies (CABs). The International Accreditation Forum (IAF) is the world association for national accreditation bodies (NABs) and other bodies interested in conformity assessment services. Its *raison d'être* is to oversee development of a single, recognized international program of conformity assessment in a number of key areas, including products, services, personnel, and management systems. Accreditation reduces risks for businesses and their customers by assuring them that CABs are competent to carry out the work they undertake within their scope of accreditation, meaning that the certificates issued by accredited CABs can be relied upon.

The IAF was formed in 1993 following a meeting between "Organisations that Accredited Quality System Registrars and Certification programs" from the US, Canada, Mexico, Japan, Australia/New Zealand, the Netherlands, and the UK. From these relatively small beginnings, that membership has grown to seventy-four signatories reaching into all four corners of the globe.

The purpose of that initial meeting was to establish a program for accreditation bodies dealing with conformity assessment, whereby accreditations granted by one IAF Multilateral Recognition Arrangement (MLA) signatory are recognized in each and every other signatory's country. Based on the principle of equivalent outcome acknowledgement, the MLA both reduces costs and adds value to the accreditation bodies, industry, and ultimately consumers. It also makes a significant contribution to the world economy by eliminating technical barriers to trade, providing freedom of movement for goods internationally.

Having a product or service assessed for each new market would be an expensive and time-consuming process for businesses. Similarly, it would be extremely difficult for a company to remain competitive if it had to adapt its product or service to meet different standards in each international target territory. As is the case with standards, the MLA simplifies the operations of international companies as it promotes equivalence recognition, thereby eliminating the unnecessary



repetition of multiple conformity assessment activities for each product or service.

Structure and Scope

The criteria for the MLA can be divided into five levels and consists of two scopes, all of which must be satisfied before membership is granted. Level 1 refers to the mandatory criteria that apply to all NABs, as set out in ISO/IEC 17011:2004 *Requirements for accreditation bodies accrediting conformity assessment bodies*. The "main" scope refers to a combination of a Level 2 activity (e.g., product certification) and the corresponding Level 3 documentation (e.g., ISO/IEC Guide 65:2006 *General requirements for bodies operating product certification systems*). Similarly, the "sub" scope of the MLA represents a combination of the relevant Level 4 conformity assessment documentation (e.g., ISO 9001:2015 *Quality Management Systems*) and where appropriate the Level 5 scheme specific requirements (e.g. ISO TS 22003:2013 *Requirements for bodies providing audit and certification of food safety management systems*). Attestations made by CABs at both the main and sub scope levels are considered to be equivalent. Using the example above, the MLA facilitates international trade for a company that holds an ISO TS 22003 food safety certificate from a CAB that has been accredited by an IAF MLA member NAB, as that certificate is recognized as meeting national requirements in each and every other MLA member country.

Practicing what it preaches regarding reducing unnecessary duplication and equivalence recognition, the IAF has granted special recognition to three regional accreditation groups. The European cooperation for Accreditation (EA), the Pacific Accreditation Cooperation (PAC), and the

InterAmerican Accreditation Cooperation (IAAC) each has its own MLA that operates between its group members. The result is that IAF members that are signatories to these regional MLAs are automatically accepted into the IAF MLA.

Peer Assessment

The value of the MLA can only be realized if each member can demonstrate that its accreditation programs are implemented in line with IAF guidelines and operated in a consistent and equivalent way. Peer assessment plays a crucial part in both maintaining professional standards within industry sectors and in ensuring equivalence across international borders. The same is true of the IAF MLA, as member NABs are only allowed to sign the MLA following a successful completion of a stringent and rigorous peer assessment of their organization. The assessment is undertaken by an appointed peer evaluation team, tasked with confirming that the applicant member complies fully with both the relevant IAF documents, as well as international standards. Far from being a one-time affair, formal monitoring and re-evaluations are conducted on a regular basis. This ensures that both the operational competence and the consistency of implementation of accreditation systems are maintained. In turn, this helps to increase the influence of the IAF MLA among regulators, and allows greater confidence to be placed in the effectiveness of the MLA by those using accredited services.

In order to ensure that the various ISO/IEC guidelines are implemented in an equivalent way, the IAF issues its own guidance documents, based on the practical experience of NABs in applying the ISO/IEC guides. Members of the MLA are required to adopt the IAF guides into their operations, as they represent the agreed best practice in implementing ISO/IEC guides.

Future Development

The ultimate aim of the IAF is that every NAB in every country across the world will be able to sign up to its MLA. To help it realize this ambition, the IAF provides extensive technical assistance to NABs in developing economies. The technical know-how is also supported by financial

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assistance for emerging NABs, particularly to pay for staff training courses. In addition to helping to bring a developing NAB up to the required operating level, the IAF also enables the NAB's voice to be heard by allowing it to participate in IAF meetings and ensuring it is represented on the IAF board.

Running parallel to this, the IAF is continually promoting the wider acceptance of accreditation and the MLA among both regulators and end-users. Similarly, it is working with key stakeholders to ensure that the MLA itself meets the needs of, and remains relevant to, a constantly evolving worldwide economy. By striving to achieve all these key goals, the IAF is working toward creating a truly "certified once, accepted everywhere" marketplace for organizations across the globe.



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