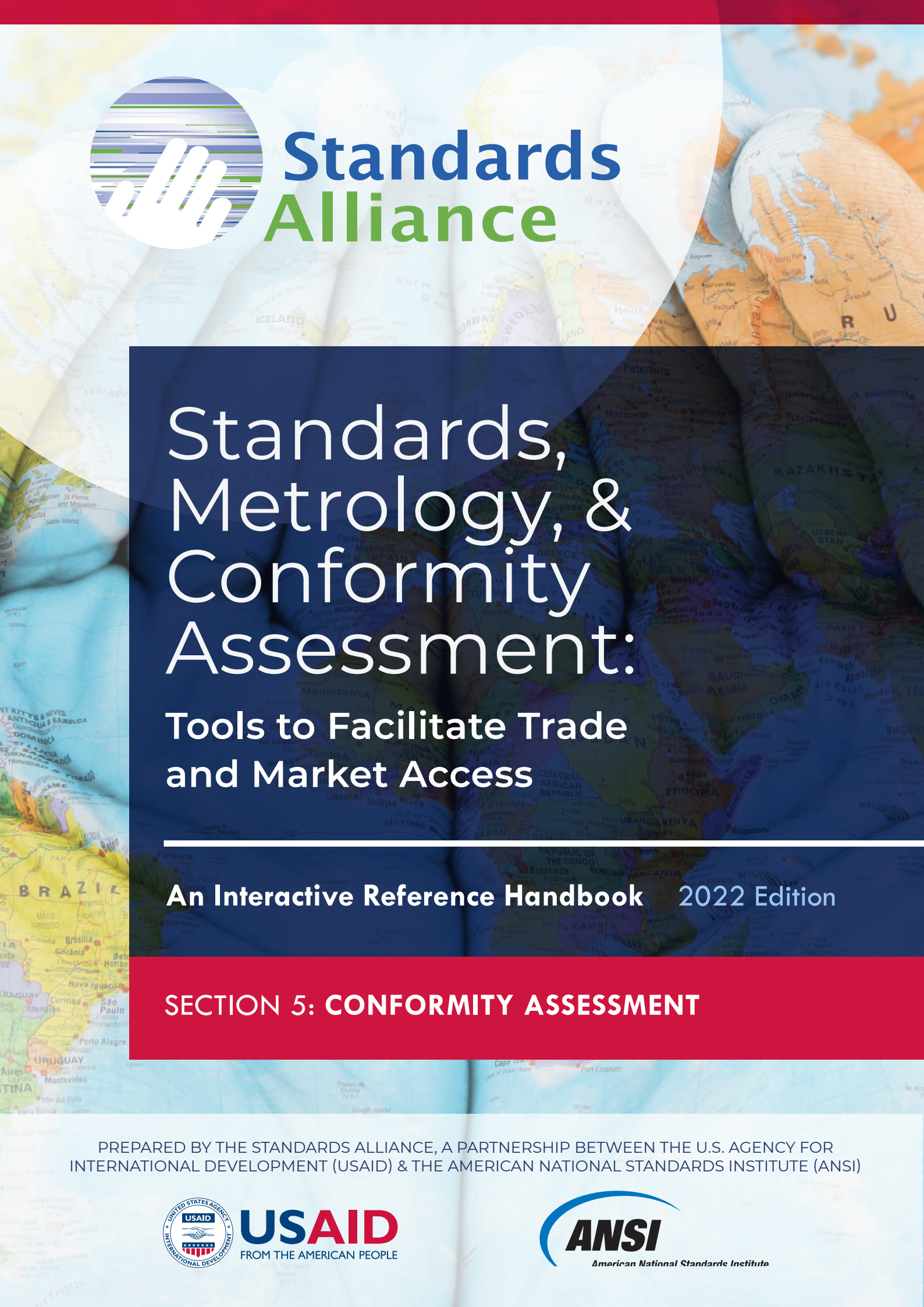

Standards Alliance

Standards, Metrology, & Conformity Assessment:

Tools to Facilitate Trade and Market Access

An Interactive Reference Handbook 2022 Edition

SECTION 5: **CONFORMITY ASSESSMENT**

PREPARED BY THE STANDARDS ALLIANCE, A PARTNERSHIP BETWEEN THE U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT (USAID) & THE AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)

USAID FROM THE AMERICAN PEOPLE

ANSI American National Standards Institute

SECTION 5

CONFORMITY ASSESSMENT

What is conformity assessment? Conformity assessment is the term given to techniques and activities that ensure a product, process, service, management system, person or organization fulfils specified requirements. The International Standard ISO/IEC 17000, *Conformity assessment—Vocabulary and general principles,* defines conformity assessment as the: "Demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled."

Standards and conformity assessment (CA) are intertwined. Each supports the other, influencing nearly every aspect of society. Whereas **standards** set important specifications for products, systems, and personnel; **conformity assessment** activities ensure those requirements are followed. Said another way, CA demonstrates specifications to a product, process, system, person, or organization are met.

CA activities provide numerous benefits across society, which help to safeguard human health and safety as well as our environment. Additionally, CA supports consumer and business confidence while also creating more predictable international trade.

Conformity assessment activities include sampling and testing, inspection, supplier's declaration of conformity, certification, and management system assessment. It also includes accreditation of the competence of those activities by a third party and recognition (usually by a government agency) of an accreditation program's capability.[1]

Conformity assessment can be voluntary or mandatory depending on the level of risk. When voluntary, it can provide useful information to a buyer and help substantiate advertising and labeling claims. When mandatory, it supports policy objectives, verifies compliance, and/or identifies needed corrective actions.

Conformity assessment has become increasingly relevant as nations seek to participate in the international trading system. When a country accepts products from a foreign market, for instance, the need to verify product claims, quality, and safety is paramount. To support effective product verification and testing, the World Trade Organization (WTO) outlines the foundational principles of CA to balance regulated public protection and support healthy competition.

The benefits of conformity assessment activities are unlocked through cooperation among international conformity assessment

[1] American National Standards Institute (2011). United States Conformity Assessment Principles. Retrieved from https://share.ansi.org/shared%20documents/news%20and%20publications/brochures/uscap%202011.pdf

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bodies (CABs) and/or accreditation bodies (ABs). Referred to as mutual recognition, this process involves international trading partners agreeing to adhere to similar or equivalent CA procedures or to recognize each other's CA results. Mutual recognition helps avoid added time and monetary costs of duplicative testing. Together, CA and mutual recognition promote market access, support consumer confidence, and decrease barriers to trade.

THE PRINCIPAL COMPONENTS OF CONFORMITY ASSESSMENT

CA centers on the verification process, which is performed using various procedures. The most common components of CA include:

Certification

Certification is a third party, written assurance that a product, service, process, person, organization, or system conforms to specific requirements. Many certification variants exist. For example, product certification may consist of initial testing of a product combined with assessment of the supplier's quality management system. This may be followed by surveillance to further assess the supplier's quality management system, plus testing of samples from the factory and/or the open market.

Who can perform certification? There are a variety of certification bodies that perform quality services across the globe; however, the best method to ensure that certification is accurate and consistent is to work with accredited certification bodies. This process includes the verification, or accreditation, of a certification body by a recognized accreditation body confirming that the certification body is qualified to perform internationally accepted certification. Another option for recognizing certification bodies is through bilateral trade agreements.

Testing

Testing is likely the most common form of CA. Testing may be undertaken by a manufacturer, user, or CAB. It is often accompanied by certification, which allows the product or service to advertise its certified compliance with a specific technical standard. Testing itself can include a variety of verification practices including quantitative methods (measurement and calibration) as well as qualitative methods.

While metrology is not generally considered a conformity assessment (CA) activity, CA relies on metrology to perform laboratory accreditation, testing, and product certification.

Inspection

Inspection bodies examine a wide range of products, materials, processes, work procedures, and services, in the public and private sectors. The goal of inspection is to reduce risks for the buyer, owner, user, or end consumer of the product or service being inspected.

General requirements for the operation of various types of inspection bodies is described in the International Standard ISO/IEC 17020, *Requirements for the operation of various types of bodies performing inspection,* developed by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

Verifying Conformity

There are three internationally recognized and accepted methods for verifying conformity. These are referred to as first, second, and third party assessment or

verification. Typically, these are chosen based on the risk associated with the product or service (with the highest risk items requiring third party assessment).

- **First party/self-assessment (usually by the supplier)** – A supplier's declaration of conformity (sDoc) is widely used in commercial transactions. This document states a supplier's assurance that products or services meet relevant technical specifications. These can be used to increase brand reputation in competitive markets and can decrease testing burdens on local governments. An sDoc can put additional liabilities on the supplier if products are found not to meet declared specifications. Overall, sDoc is time and cost efficient, and does not require a producer to disclose proprietary or commercially sensitive information.
- **Second party assessment (usually by the buyer)** – Includes inspectors commissioned by customers to assess manufacturers' premises. This provides a detailed indication of a product being manufactured in accordance with specified requirements.
- **Third party assessment (usually by independent persons or bodies)** – Generally considered the strictest and most thorough approach to CA. Third parties may be involved at all stages of ensuring compliance, individually or combined, of the verification process.

WHO CHECKS THE CHECKERS?

Accreditation

The terms accreditation and certification are often confused, but these should not be used interchangeably. Accreditation is the formal recognition by a specialized body verifying the competence of a certification body to provide specified services. Certificates issued by accredited certification bodies may be perceived as having increased validity.

Accreditation is third party attestation related to a conformity assessment body (CAB), conveying formal demonstration of the CAB's competence to carry out specific conformity assessment activities.[2]

CABs may want to demonstrate reliability and distinguish themselves from competitors by having an impartial evaluation of their competence based upon internationally recognized criteria. This process of evaluation is called an accreditation.

Accreditation confirms the quality and reliability of test data and provides assurance of the competence and independence of a CAB to carry out specific CA tasks. This process provides a framework to establish mutual recognition of CABs through internationally accepted principles. Mutually recognized CABs help minimize testing and certification duplication, reduce costs, decrease barriers to trade, and shorten delays to market access.

DEFINITIONS OF KEY CONFORMITY ASSESSMENT CONCEPTS

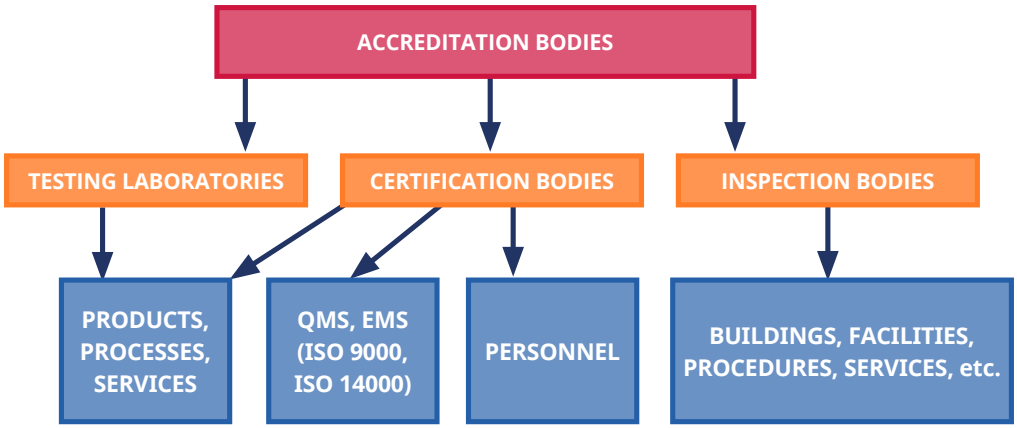
Accreditation: Formal evaluation and notice of a conformity assessment body's competence to carry out conformity assessment tasks, such as certification or testing

Certification: Third party, written assurance that a product, service, process, person, organization, or system meets specific requirements

First, Second, and Third Party Assessment: The three accepted methods for verifying conformity. First party assessment (also called self-assessment) is a supplier's own declaration of conformity. Second party assessment is evaluation by inspectors who have been commissioned by buyers. Third party assessment, considered the strictest, is evaluation conducted by independent bodies.

[2] International Organization for Standardization (2021). Certification & Conformity. https://www.iso.org/conformity-assessment.html

Conformity Assessment Activities and Processes



Inspection: Examination of products, materials, processes, work procedures, and services to determine conformity to specific requirements

Recognition: Formal evaluation and notice of an accreditation body's competence to carry out specific tasks, such as accreditation of testing laboratories and inspection, certification, and registration bodies

Sampling: Evaluation and testing of a sample of a product to determine conformity to specific requirements

Supplier's Declaration of Conformity (SDOC): Written assurance by a supplier that confirms conformity to specific requirements

Testing: The use of a specified technical procedure (test method) to determine one or more characteristics of a product, material, procedure, or service

CONFORMITY ASSESSMENT TOOLS TO SUPPORT PUBLIC POLICY

Conformity Assessment in Regulation

When using CA in regulation, a variety of interrelated considerations should be respected and many can be applied more than once during regulatory development process. For example, risk management helps identify which products should be subject to CA or decide which techniques (audit, test, or inspection) should apply based on product risk.

In regulation, government authorities ensure products and services meet national safety, health, and environmental requirements and provide assurances to prevent fraud or market manipulation. In the private sector, many production sectors have established CA systems and approval processes to enable comparability and ensure open competition.

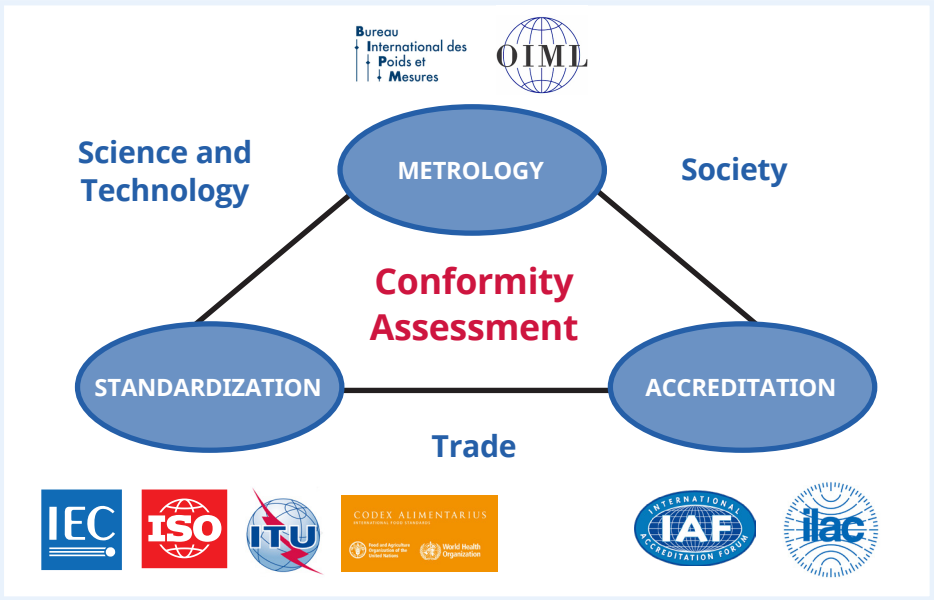
A prerequisite for fair trade is that a product or service accepted in one market must be accepted (or treated equally) in other markets without additional restrictions or duplicative testing, inspection, and certification.[3] This principle is foundational to both ISO/IEC 17011, *Requirements for accreditation bodies accrediting conformity assessment bodies,* as well as the WTO GATT Article 3 provisions regarding national treatment.[4]

MARKS OF CONFORMITY

A mark of conformity is a symbol found on a product or information documents about a product, process, or service that indicates it has been verified by a certification body to comply with relevant standards or regulations. There are many different marks of conformity

[3] International Organization for Standardization (2004). ISO/IEC 17011:2004, Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies. Retrieved from https://www.iso.org/standard/29332.html
[4] World Trade Organization (1994). The General Agreement on Tariffs and Trade (GATT 1947). Retrieved from https://www.wto.org/english/docs_e/legal_e/gatt47_01_e.htm

A Conformity Assessment Model



that correspond to a product standard or technical regulation and demonstrate the marked product adheres to the relevant standard or technical regulation.

Marks of conformity play a major role in consumer safety and international trade. Before 1990, certification was fundamentally concerned with consumer safety of products; today, certification also addresses environmental practices and can evaluate processes and services in addition to products. Products and documents that display an authorized mark of conformity (also called a certification mark) indicate that they have met certain safety, health, or environmental standards. Officials and consumers consider marks of conformity a sign that a product is safe to use and that the interests of the consumer are protected.

Marks on products or on information documents about products, processes, or services take many forms:

- Marks that identify or describe products, processes or services and their characteristics. These are not marks of conformity.
- Marks that indicate compliance with a specification, code of practice, management system or product or service standard. These marks of conformity are normally based on CA by an independent certification, accreditation, or inspection body, or placed on the product by the supplier through self-declaration of compliance.

Some marks not based on CA include the trademarks or brand names of the supplier, nutritional labeling, safety or handling warnings, claims of the absence of particular ingredients (often related to some eco-labeling programs, or alerts to diet-sensitive consumers), or details on the method of production. While it is possible for some of these labeling claims to be verified by CA, such labeling is usually done without a formal, structured CA process and therefore are not considered marks of conformity.

Marks can convey important messages about a product or service, but are the messages understood by consumers? Common questions include:

- Does a mark attest to the safety of a particular product, or its impact on the environment, or its durability and performance?
- Does a mark represent a claim that the product or service supplier operates under a management system complying with particular standards or codes of practice?
- Who owns the mark appearing on a product or accompanying a service?
- Does the mark belong to the supplier or an independent CAB?

- Why do some products have many different marks?
- Will the marks provide access for a product or service to a particular market, or will it result in acceptance of the product or service by a regulatory body?
- Where can a consumer find out more about the significance of a particular mark?
- Who is liable if a marked product fails?

While consumers may not fully understand the significance of every mark of conformity, the marks provide some information and/or a pathway to gain more information about the products they purchase.

Marks of Conformity: General Requirements

In order to obtain a conformity mark for a product, the manufacturer may be required to undergo a comprehensive product-testing program. Samples of the product are tested to nationally or internationally recognized standards and must be reasonably free from foreseeable risk of fire, electric shock, and related hazards. The certifying body may periodically, and without notice, visit each manufacturer's production facility to counter check that products continue to adhere to safety requirements. Even after the initial product evaluation, the certification body will continue to check samples of the product.

The Declaration of Conformity

A product conformity mark is not intended to include detailed technical information, but information must appear on a document called a declaration (certificate) of conformity that enables the inspector to trace the product back to the manufacturer or the authorized representative established in the exporting country. This is sometimes known as the manufacturer's declaration, and the manufacturer, authorized representative, or importer must be able to provide it at any time, along with the product's technical file.

Minimum Requirements for the Declaration of Conformity

- Product identification – model, serial number, etc.
- Names and numbers of the standards used to verify compliance
- Name of the independent testing laboratory authorized to perform CA
- Signature of the manufacturer or authorized representative
- The manufacturer's name and address

Note: For CE Marking, the European Directives complied with must be listed.

QUALITY MANAGEMENT SYSTEM STANDARDS[5]

What Is a Management System?

A management system describes the set of procedures an organization needs to follow to meet its objectives. Some small organizations may use informal rather than official management systems; however, the larger the organization, the more likely that procedures need to be recorded to ensure roles are clearly defined. This process of systemizing how things are done is known as a management system.

Quality Management Principles

Quality management principles are a set of fundamental beliefs, norms, rules, and values that can be used as a basis for quality management.[6] Management system standards provide a model to set up and operate a management system. These can be applied to any organization, large or small, regardless the product, service, or sector of activity.

Quality Management Systems and Conformity Assessment

An organization's management system, like a product or service, can be evaluated using

[5] International Organization for Standardization (2021). Certification & Conformity. https://www.iso.org/conformity-assessment.html
[6] International Organization for Standardization (2021). Certification & Conformity. https://www.iso.org/conformity-assessment.html

conformity assessment to determine if it follows relevant standards. Assurance that an organization adheres to management standards provides national and international stakeholders confidence that the organization's operations follow accepted practices.

Certification to ISO 9001, *Quality management systems,* is likely the most well-known example of conformity assessment of management systems, as more than one million organizations in 170 counties have been certified to ISO 9001. This standard is a benchmark for quality systems and supports a framework to enhance and assure an organization's ability to satisfy quality requirements. Using quality management systems like ISO 9001 helps ensure customers get consistent, high-quality products and services. This process provides consumers with confidence and attracts business.[7]

It is important to note that ISO itself does not perform QMS certification, nor does it issue certificates of conformity to ISO 9001 or any other standard. Rather, independent, international certification bodies perform QMS certification.

In addition to quality management, many other branches of management are guided by standards. Additional examples include:

- API Specification Q2, *Quality Management for Service Supply Organizations for the Petroleum and Natural Gas Industry*
- AS9100, for the aerospace industry
- ASTM E1578 – 06, *Standard Guide for Laboratory Information Management Systems*
- IEEE 2030.11-2021, IEEE Guide for Distributed Energy Resources Management Systems
- ISO 50001, *Energy Management*
- ISO 22000, *Food Safety Management*
- ISO/IEC 27001, *Information Security Management*

Management System Certification Standards

SECTOR	STANDARD
General	ISO 9001:2015
Environmental	ISO 14000:2015
Food Safety	HACCP, ISO 22000:2005
Information Security	ISO/IEC 27001:2103
IT Service Management	ISO/IEC 2000-1:2011
Medical	ISO 13485:2016
Supply Chain Security	ISO 28000:2007
Petroleum & Gas	ISO 29001:2010
Energy	ISO 50001:2011

INTERNATIONAL BEST PRACTICES – CONFORMITY ASSESSMENT

There are significant similarities in many national CA systems; however, no single national approach to CA is considered preeminent. Rather, best practices for CA are based on a common set of principles aimed at facilitating trade and supporting the health and safety of a nation's citizens, environmental protection, and good regulatory practice.

The following are basic international principles for CA:

- CA should safeguard public health, safety, and the environment.
- CA should be based on relevant international standards, agreements, and protocols, and should avoid undue national bias.
- CA should avoid creating unnecessary obstacles to trade by upholding the WTO TBT Agreement. See more on the TBT Agreement below.
- Information regarding CA requirements, accreditation procedures, and results should be made publicly available.
- CA procedures should be conducted with regard to confidentiality while ensuring full disclosure of CA results to regulatory authorities.

[7] International Organization for Standardization (2021). ISO 9000 Family. https://www.iso.org/iso-9001-quality-management.html

- CA is generally voluntary, but certain local or market demands may necessitate CA requirements in regulation.
- CA should operate in an explicit, credible, and transparent manner and should be accessible, equitable, and provide fair treatment to all users.

The following are some of the most common conformity assessment elements used globally:

Using qualified inspectors, auditors, and assessors: Technical competence, qualifications, and integrity of inspectors, auditors, and assessors are major requirements of implementing a successful conformity assessment system. Most inspectors and auditors have special training, experience, and international recognized credentials. One example of an international certification body is the United Kingdom-based International Register of Certificated Auditors (IRCA). IRCA is the first and largest international certification body for auditors and inspectors and has certified more than 11,500 auditors/inspectors in over 105 countries.

WTO compliance: Economies that have officially stated their intention to accede to the WTO, and those that have already completed the accession process, have had to develop or revise laws governing mandatory inspection and certification to bring them into compliance with the WTO Technical Barriers to Trade (TBT) Agreement and the Sanitary and Phytosanitary Measures (SPS) Agreement. The relevant WTO agreements for CA include:

- WTO Agreement on Technical Barriers to Trade (TBT Agreement)
- WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement)
- WTO General Agreement on Trade in Services (Services Agreement)
- WTO Agreement on Preshipment Inspection (Pre-shipment Inspection Agreement)
- WTO Agreement on Trade Facilitation (Trade Facilitation Agreement)

Inspection and certification bodies use harmonized international standards, procedures, and guides: One commonly used standard for inspection bodies is ISO/IEC 17020, Requirements for the operation of various types of bodies performing inspection.

Laboratory testing activities: In order to ensure acceptability of test results performed by testing and calibration laboratories internationally, it is essential that the international standard determining the competence of the laboratories (ISO/IEC 17025, *Testing and calibration laboratories)* is implemented. Many countries have formally adopted this standard as a national standard, including the U.S., Canada, Mexico, Laos, Myanmar, Vietnam, Egypt, the EU, and others.

Authoritative Agencies: The government agency responsible for inspection and enforcement of conformity is determined by a mutual agreement between agencies and is usually based on the agencies' primary responsibility. For example, agricultural products would be the responsibility of the Ministry of Agriculture; medical devices and drugs would be under the Ministry of Health; and aircraft, automobiles, etc. would be under the Ministry of Transportation. There are instances where there appears to be overlapping authority, and in these few cases, it is important that the agencies resolve who has the ultimate and sole authority.

CONFORMITY ASSESSMENT AND THE WTO TBT PROVISIONS

The WTO TBT Agreement obligates members to avoid unnecessary obstacles to trade. This obligation also applies to CA procedures. For CA, barriers to trade may include overly strict or time-consuming procedures that do not serve a necessary function in the assessment of product compliance with the domestic

Adopting International Standards and Procedures: Whenever possible, international best practice is to consider adoption of existing international standards rather than developing new and potentially duplicative standards or procedures.

regulations (Articles 5.2.3 and 5.2.6).[8]

As for standards and technical regulations, the WTO TBT Agreement also provides clear guidance on internationally accepted, best practices for conformity assessment. The key provisions of these sections of the TBT Agreement are listed below. [9]

- CA procedures are not prepared, adopted, or applied with a view to or with the effect of creating unnecessary obstacles to international trade.
- Members shall ensure that results of CA procedures of other Members are accepted, even when those procedures differ from their own, provided those procedures offer an assurance of conformity with applicable technical regulations.
- CA procedures shall not be more strict or be applied more strictly than is necessary.
- CA procedures shall give the importing member country adequate confidence that products conform, taking account of the risks non-conformity would create.
- The Most Favored Nation and national treatment provisions apply to CA procedures. CA shall be applied to products from WTO Members "in a manner no less favorable than that accorded to like products of national origin and to like products originating in any other country" (Article 5.1.1). Members are required to maintain confidentiality regarding CA results for imported products to ensure commercial interests are not infringed.
- Members shall ensure government bodies use relevant international guides or recommendations, or the relevant parts of them, as a basis for CA procedures. Exceptions can be made for issues of national security; prevention of deceptive practices; protection of human health or safety, animal, or plant life or health, or the environment; fundamental climatic or other geographical factors; and fundamental technological or infrastructural problems.
- Members are required to actively participate, within the limits of their resources, in the preparation of guides and recommendations for CA procedures.
- When possible, Members must ensure results of CA procedures are accepted, even when those procedures differ from their own. The validity of CA results should be assessed based on whether results are satisfactory to confirm conformity to equivalent standards or technical regulations.

INTERNATIONAL RECOGNITION AND ACCEPTANCE OF CONFORMITY ASSESSMENT

The primary objective of conformity assessment is to give its users confidence that requirements applicable to products, services, systems, processes, and materials have been met. One of the reasons

[8] World Trade Organization (2021). Technical Information on Technical barriers to trade. Retrieved from https://www.wto.org/english/tratop_e/tbt_e/tbt_info_e.htm
[9] World Trade Organization (2021). Technical Information on Technical barriers to trade. Retrieved from https://www.wto.org/english/tratop_e/tbt_e/tbt_info_e.htm

why internationally traded goods and services are subject to repeated CA controls is a lack of confidence by users of CA in one country regarding the competence of bodies carrying out CA activities in other countries. Mutual recognition of accreditation and certification systems helps to mitigate excessively repeated CA procedures.

Mutual recognition of accreditation and certification systems facilitates access to international markets, providing the technical underpinning to international trade by promoting cross-border stakeholder confidence and acceptance of accredited test data and certified results.

"Certified Once, Accepted Everywhere"

The present international concept for accreditation is "Certified Once, Accepted Everywhere." This is made possible through a network of mutual recognition arrangements or agreements among international accreditation bodies. Accreditation is a valuable and neutral tool that facilitates trade by enabling organizations to independently demonstrate their competence in an internationally acceptable manner.

The accreditation community is structured at both the regional and international level. At the international level, the main organizations are the International Laboratory Accreditation Cooperation (ILAC) and International Accreditation Forum (IAF). These organizations, together with the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), promote the use and acceptance of international standards and CA activities as part of national trade policies.

International Laboratory Accreditation Cooperation (ILAC)

ILAC is the international organization for accreditation bodies operating in accordance with ISO/IEC 17011 and involved in the accreditation of conformity assessment bodies including calibration

A Roadmap to Mutual Recognition

Source: EN Industries LLC

laboratories (using ISO/IEC 17025), testing laboratories (using ISO/IEC 17025), medical testing laboratories (using ISO 15189), inspection bodies (using ISO/IEC 17020), proficiency testing providers (using ISO/IEC 17043) and reference material producers (using ISO 17034).

ILAC also manages international arrangements for calibration, testing, inspection, proficiency testing providers' accreditation, and in coordination with IAF in the fields of management systems, products, services, personnel, and other similar programs of CA.

ILAC provides a focus for:

- Developing and harmonizing laboratory and inspection accreditation practices.
- Promoting laboratory and inspection accreditation to industry, governments, regulators, and consumers.
- Assisting and supporting developing accreditation systems.
- Global recognition of laboratories and inspection facilities via the ILAC Arrangement, thus facilitating acceptance of test, inspection, and calibration data accompanying goods across national borders.

ILAC and the Mutual Recognition Arrangement

In 2000, the 36 full members of ILAC representing 28 economies signed the ILAC Mutual Recognition Arrangement (ILAC MRA) in Washington, DC, to promote mutual acceptance of technical test and calibration data. The ILAC MRA came into effect on January 31, 2001.

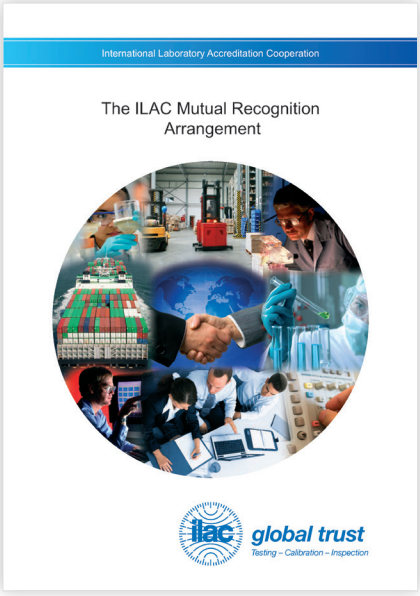
The ILAC MRA has been expanded three times since its establishment. These expansions added accreditation of inspection bodies (2012), accreditation of proficiency testing providers (2019), and accreditation of reference material producers (2020) to the ILAC MRA.

How does the ILAC Mutual Recognition Arrangement Work?[10]

According to the ILAC website, "[t]he ILAC MRA links the existing regional MRAs/MLAs of the Recognized Regional Cooperation Bodies. For the purposes of the ILAC MRA, and based on ILAC's evaluation and recognition of the regional MRAs/MLAs, ILAC delegates authority to its Recognized Regional Cooperation Bodies for the evaluation, surveillance, re-evaluation, and associated decision making relating to the signatory status of the accreditation bodies that are ILAC Full Members (ILAC MRA signatories).

The accreditation bodies that are signatories to the ILAC MRA have been peer evaluated in accordance with the requirements of ISO/IEC 17011 to demonstrate their competence. A full list of accreditation bodies that have signed the ILAC MRA can be found on ILAC MRA Signatory Search.

Using the signatory search and the accredited facilities directories, regulators and consumers can locate laboratories, inspection bodies, proficiency testing providers or reference material producers that are accredited for the specific calibrations, tests, inspections, provision of proficiency testing programs or production of reference material required, as well as the contact details of these facilities, thereby ensuring the service and results will be accepted under the ILAC MRA.



[10] ILAC (2021). ILAC MRA and Signatories. Retrieved from https://ilac.org/ilac-mra-and-signatories/

International Accreditation Forum (IAF)[11]

The IAF is an international association of CA ABs and bodies interested in CA. The forum supports the development of a single, international program for CA, thereby assuring accredited certificates to minimize business and consumer risk. The organization focuses on CA in the fields of management systems, products, services, personnel, and other similar programs.[12]

Practically, IAF functions in two main ways. First, it ensures its AB members only accredit competent bodies and are not subject to conflicts of interest. Second, it establishes MRAs, known as the IAF Multilateral Recognition Arrangements (MLA), between its members.

IAF Multilateral Recognition Arrangement

The IAF Multilateral Recognition Arrangement (MLA) aims to ensure mutual recognition of accredited certification between signatories to the MLA and, subsequently, international acceptance of accredited certification based on one accreditation. Accreditations granted by IAF MLA signatories are recognized worldwide based on their equivalent accreditation programs, therefore reducing costs and adding value to business and consumers. IAF's goal and motto is, "Certified once, accepted everywhere."

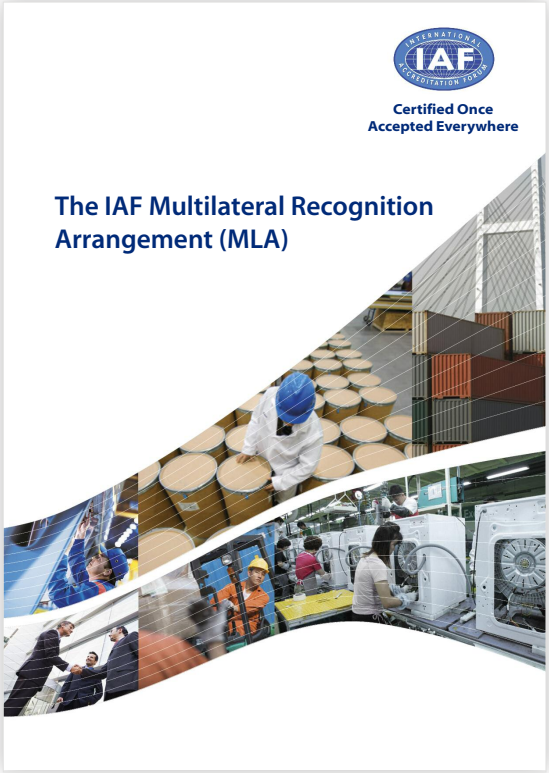
MLA Signatories

Following a stringent evaluation of AB operations by a peer evaluation team, IAF members are admitted to the MLA. The peer evaluation team is responsible for assessment of applicant member compliance with international standards and IAF guidelines.

Each IAF MLA signatory commits to:

- Maintain conformity with the current version of ISO/IEC 17011, Requirements for accreditation bodies accrediting conformity assessment bodies, and supplementary requirements documents.
- Recognize the competence and impartiality of accreditations of CABs by all other members of the MLA.

Three Regional Accreditation Groups (RAGs) have been granted special recognition to the MLA by the IAF: the European Co-operation for Accreditation (EA), the Inter-American Accreditation Cooperation (IAAC), and the Pacific Accreditation Cooperation (PAC). Membership to the IAF MLA is recognized as being satisfied by membership to any of the three RAG MLAs: EA MLA, IAAC MLA, and PAC MLA. IAF members who are signatories of RAG MLAs are automatically accepted into the IAF MLA.[13]



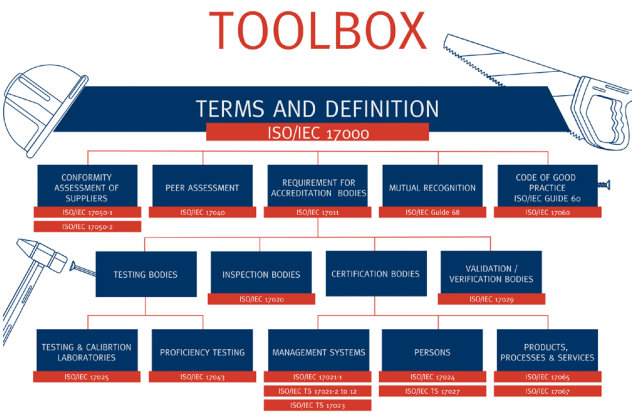
[11] IAF (2021). International Accreditation Forum. Retrieved from https://www.iaf.nu/
[12] IAF (2021). International Accreditation Forum. Retrieved from https://www.iaf.nu/
[13] IAF (2021). The Evaluation Process. Retrieved from https://iaf.nu/en/evaluation-process/

ADDITIONAL RESOURCES

The ISO–CASCO Toolbox[14]

In the realm of conformity assessment, ISO plays an important international role through its Committee on Conformity Assessment, CASCO. This committee works to develop guides and international standards for CA as joint ISO/IEC publications.

CASCO is among the largest committees in ISO, with 107 participating members, 35 observing members, and 18 international organizations that serve as liaison members. Liaison members include Bureau International des Poids et Mesures (BIPM), IAF, International Federation of Standards Users (IFAN), International Federation of Inspection Agencies (IFIA), International Certification Network (IQNet), ILAC, International Personnel Certification Association (IPC), and the Organisation Internationale de Métrologie Légale (OIML), among others.



Perhaps the most well-known output of the ISO CASCO is the CASCO Toolbox. The Toolbox provides a series of tools (standards) for managing compliance and creating clear public policy to support market access and protect consumers.

Using the CASCO Toolbox Benefits Many Stakeholders

From ISO: "For regulators, it provides a tool for managing compliance and providing an objective and defensible means to implement public policy and enforce national health, safety and environmental legislation. The CASCO toolbox provides a means for organisations to take responsibility for their own *compliance, and can reduce costs for governments when regulatory schemes utilise recognised private sector conformity assessment providers.

For manufacturers, wholesalers, retailers and service providers, they can make sure that their products and services meet specified requirements and deliver on customer expectations. Assessing their products and services in accordance with the CASCO toolbox helps them to meet the current best practice and avoid the financial costs and reputational damage of product failure in the market, including subsequent activities such as product recalls, product returns and destruction of unsuitable product.

Consumers also derive benefit from the CASCO toolbox because it provides them with a basis for selecting products or services in the market, including matters such as quality, price, safety, reliability, compatibility, interoperability, efficiency and effectiveness, and even the colour of a product. Consumers may have more confidence in products or services that are supported by a formal mark or certificate of conformity that attests to quality, safety or other desirable characteristics.

And finally, for traders, importers and exporters the CASCO toolbox are the recognised International Standards and Guides for conformity assessment procedures under the World Trade Organization Agreement on Technical Barriers to Trade (WTO/TBT Agreement). Application of the CASCO toolbox can be a basis for mutually accepting trading partners' products and services, and avoiding unnecessary barriers to trade."[15]

[14] ISO (2021). CASCO – Conformity Assessment Tools to Support Public Policy. Retrieved from https://casco.iso.org/toolbox.html
[15] ISO (2021). CASCO – Conformity Assessment Tools to Support Public Policy. Retrieved from https://casco.iso.org/toolbox.html

CONFORMITY ASSESSMENT REFERENCES

International Laboratory Accreditation Cooperation (ILAC)

www.ilac.org

The International Laboratory Accreditation Cooperation (ILAC) is an international cooperation of laboratory and inspection accreditation bodies. ILAC produces a series of publications, all of which can be viewed and downloaded via their website.

ILAC has created a series of promotional materials to support awareness and understanding of accreditation. They can be downloaded at ilac.org/publications-and-resources/ilac-promotional-brochures/. The series includes brochures on:

- The ILAC MRA
- Accredited Laboratories, Inspection Bodies, and Reference Material Producers
- Specifying Accreditation

ILAC offers additional documents available for download at ilac.org/publications-and-resources.

International Accreditation Forum (IAF)

www.iaf.nu

The International Accreditation Forum, Inc. (IAF) is the world association of Conformity Assessment Accreditation Bodies and other bodies interested in conformity assessment in the fields of quality management systems, products, services, and personnel. IAF produces reference documents and guides that can be viewed and downloaded via their website.

The South African National Accreditation System (SANAS)

www.sanas.co.za

The South African National Accreditation System (SANAS) is recognized by the South African government as the single National Accreditation Body that gives formal recognition that laboratories, Certification Bodies, Inspection Bodies, Proficiency Testing Scheme providers and Good Laboratory Practice (GLP) test facilities are competent to carry out specific tasks.

Southern African Development Community Accreditation (SADCA)

www.sadca.org

The Southern African Development Community Accreditation (SADCA), as a regional accreditation structure of SQAM (Standardization, Quality Assurance, Accreditation, and Metrology), was tasked with defining a suitable accreditation infrastructure, enabling organizations in the SADC Member States to access accreditation services from internationally recognized National Accreditation Bodies within their countries, or to from a regional accreditation service called SADCAS.

African Accreditation Cooperation (AFRAC)

www.intra-afrac.com

The African Accreditation Cooperation (AFRAC) is a cooperation of accreditation bodies, sub-regional accreditation cooperations, and stakeholders whose objective is to facilitate trade and contribute to the protection of health, safety, and the environment in Africa and thereby improve Africa's competitiveness.

Asia Pacific Accreditation Cooperation (APAC)

www.apac-accreditation.org

The Asia Pacific Accreditation Cooperation (APAC) was created in 2019 by the amalgamation of two former regional accreditation cooperations -- the Asia Pacific Laboratory Accreditation Cooperation (APLAC) and the Pacific Accreditation Cooperation (PAC). APAC manages and expands MRAs among accreditation bodies in the Asia Pacific Region. Members include accreditation bodies, accreditation focal points, and other stakeholders interested in accredited conformity assessment results.

The Inter-American Accreditation Cooperation (IAAC)

www.iaac.org.mx

The Inter-American Accreditation Cooperation (IAAC) is an association of accreditation bodies and other organizations interested in conformity assessment in the Americas. IAAC's mission is to promote cooperation among accreditation bodies and interested parties in the Americas, aiming at the development of conformity assessment structures to achieve the improvement of products, processes, and services.

The European Co-operation for Accreditation (EA)

www.european-accreditation.org

The European Co-operation for Accreditation (EA) was established in 1997 as a result from the merger of the European Accreditation of Certification (EAC) and the European Cooperation for Accreditation of Laboratories (EAL). EA is the European network of nationally recognized accreditation bodies based in the European geographical area.

United States Conformity Assessment Principles (USCAP)

www.ansi.org/uscap

The USCAP articulates the principles for U.S. conformity assessment activities that will allow consumers, buyers, sellers, regulators, and other interested parties to have confidence in the processes of providing conformity assessment, while avoiding the creation of unnecessary barriers to trade.

ISO Guide to Good Practice

www.iso.org/iso/casco_guide.pdf

This document was developed by ISO to assist regulators and market surveillance authorities. It is especially intended for developing regions, to design market surveillance systems that conform to modern good practice criteria and that make the best use of the "CASCO Toolbox" of International Standards and other deliverables that have been developed to support good regulatory practice.

ISO - Building Trust - The Conformity Assessment Toolbox

www.iso.org/iso/casco_building-trust.pdf

A comprehensive, user-friendly handbook covering all aspects of conformity assessment and its role in international trade, and will be useful for business managers, regulators and consumer representatives.