

The role of laboratories in the international development of accreditation

A. S. Ribeiro¹, J. Gust², A. Vilhena¹, J. Wilson³

¹*Affiliation National Laboratory for Civil Engineering, Lisbon, Portugal, asribeiro@lnec.pt, avilhena@lnec.pt, (+351) 218443000*

²*Fluke Calibration, Everett WA, USA, jeff.gust@flukecal.com, +1 (425) 293 6035*

³*National Laboratory Association, Pretoria, South Africa, jgpwilson@xsinet.co.za, +27(83)6520770*

Abstract – Laboratories are the larger group of stakeholders of ILAC, the international organization for accreditation. The impact of laboratory activities as independent entities that ensure safety and quality of products and services is growing and becoming a key issue in many fields. New challenges of globalization and international trade, technology developments and increasing expectations of citizens and consumers requires a robust implementation of accreditation to promote the fair competition and the sustainability of laboratories. For this purpose, harmonization and consistency of accreditation is a major task to be achieved through cooperation of all stakeholders.

Keywords – Accreditation, Laboratory, Conformity Assessment, Testing.

I. INTRODUCTION

There are many reasons for understanding the importance of accreditation for the economy. One of the most relevant is that global markets require a growing level of confidence in goods and services. Trade operations are supported in trust regarding the quality of goods and services provided by suppliers and agents of the transactions (namely, buyers and sellers) [1].

To provide the assurance of goods and services, a quality infrastructure is needed, bringing an added value for the citizens and consumers through the development and use of tools able to fulfil the expectation of safety and quality of life. Quality infrastructure is [2] “*The system comprising the organizations (public and private) together with the policies, relevant legal and regulatory framework, and practices needed to support and enhance the quality, safety and environmental soundness of goods, services and processes.*”.

According to the BIPM [2] “*The quality infrastructure is required for the effective operation of domestic markets, and its international recognition is*

important to enable access to foreign markets. It is a critical element in promoting and sustaining economic development, as well as environmental and social wellbeing.” considering that it relies on five domains:

- metrology;
- standardization;
- accreditation;
- conformity assessment; and
- market surveillance in regulated areas.

The relationship between conformity assessment and accreditation has a large impact on the global economy as conformity assessment is a way of ensuring that the suppliers adhere consistently to the standard. This means that they can be relied on and accreditation is a reinforcement of conformity assessment using external, independent entities (National Accreditation Bodies, NAB) that validate competence of Conformity Assessment Bodies (CAB) with services such as, calibration, testing, inspection and certification.

Accreditation of CAB’s is implemented by using system standards suitable to recognize, at international level, competence of conformity assessment providers. In the case of laboratories, ISO/IEC 17025 [3] is the reference and in the case of Inspection Bodies, ISO/IEC 17020 [4] supports the accreditation. The framework of these standards is called the ISO Casco toolbox (Fig. 1).

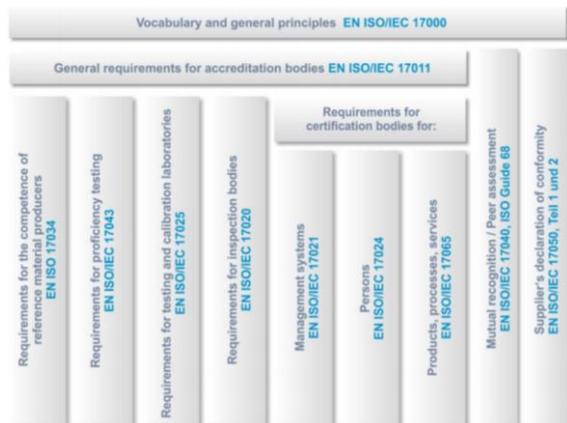


Fig. 1. ISO Casco Toolbox (Credits: ISO)

The recent revision of ISO/IEC 17025, introduced relevant changes, namely, a new vision of harmonization with other system standards (ISO 9000 and others), higher focus of the client, the interpretation of sampling activities, the implementation of decision rules associated with statements of conformance, the concept of impartiality, highlight of the process-based approach, risk-based thinking and flexible structure of organizations.

II. NEW TRENDS

Today laboratories face the same challenges as many organizations, overwhelmed by the growing development of technologies, products, materials, services which create new expectations that require innovation as new tool applied to conformity assessment. The dynamic and sometimes unpredictable world of today, described by the acronym VUCA (volatility, uncertainty, complexity and ambiguity), requires strong leadership, vision and knowledge to face daily shifts in economy, trade and international relations.

This development is strongly related to the digital transformation, being in the spotlight of government strategies worldwide. At European level, the digital single market (dsm) [5] – see Fig. 2 – is expected to have a huge impact on economic growth, boosting jobs, competition, investment and innovation [6].



Fig. 2. EU Digital Single Market Strategy, in [6]

To achieve the goals related to the digital economy,

smart cities concept [6], data-driven Society, reshape of communication and businesses through 5G, artificial intelligence, and many other challenges means that laboratories need to be involved in the digital transition and to be able to adapt to many daily changes that happen.

Urban development and smart cities are key concepts for the understanding of the relations to be established between digital technologies, disruptive innovation and society environment [7,8].

Performing conformity assessment in this new framework is becoming a dynamic challenge that will need flexibility, responsibility, knowledge (scientific and technical) with more specialized and competence in new fields (e.g., data science and data management, artificial intelligence, nano and bio materials, large sensor networks using big data approaches and quantum computing).

III. ILAC FORUM AND THE ROLE OF ILAC LABORATORY COMMITTEE

ILAC (International Laboratory Accreditation Cooperation) was created in 1977 in Copenhagen “with the aim of developing international cooperation for facilitating trade by promotion of the acceptance of accredited test and calibration results”, being the international organization for accreditation. It includes the accreditation bodies operating in accordance with ISO/IEC 17011, able to support the accreditation of entities such as, conformity assessment bodies (CABs, using ISO/IEC 17025 [3]), medical laboratories (using ISO 15189 [9]) and inspection bodies (using ISO/IEC 17020 [4]).

The main added value is given by the Mutual Recognition Arrangement (ILAC MRA) and the evolution of accreditation of CABs in recent years (Figure 3) shows an increasing interest due to globalization as a way to stand out from competitors.

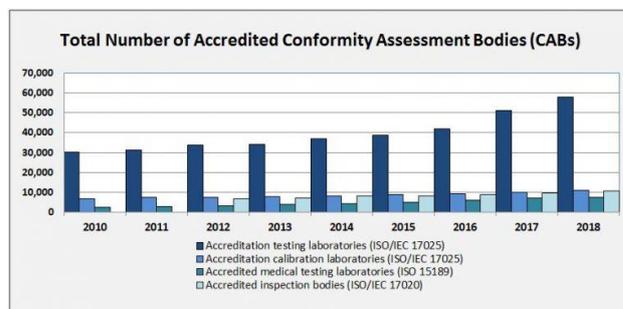


Fig. 3. Evolution of accredited CABs worldwide (2010 – 2018), in <https://ilac.org/about-ilac/facts-and-figures/>

This mutual recognition gives a unique approach that allows the recognition of competence of laboratory activities providers from the signatory Countries, based on mutual evaluation and acceptance of the national laboratory accreditation systems. The Global network of services rely on this system which expect that they can assure safety and quality of life to citizens and consumers by testing, inspection and certification (TIC).

The TIC Sector market is a large contributor to the economy (see Figure 4), as mentioned in [10] *“It provides greater consumer protection, safer products and industrial installations, reduces compliance costs for SMEs and increases brand reputations and consumers’ trust and confidence in a product by ensuring that products, infrastructures and processes meet the required standards and regulations in terms of quality, health and safety, environmental protection and social responsibility and can, therefore, also be a facilitator to international trade”*.

According with ILAC *“in 2018, almost 76,500 laboratories and over 10,500 inspection bodies were accredited by ILAC MRA Signatories”*. This gives a special role to laboratories as stakeholders in the ILAC organization, recognized by including in its structure the Laboratory Committee, which provides a platform for interaction with the laboratory community.

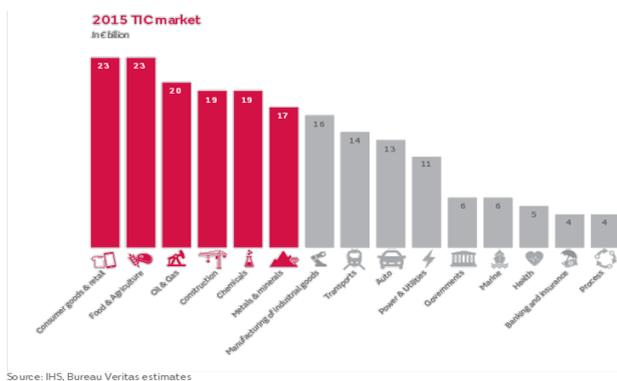


Fig. 4. 2015 TIC market (SGS Report)

IV. CONCERNS, EXPECTATIONS AND CHALLENGES OF LABORATORIES: THE 2017 INTERNATIONAL SURVEY

As described above, accreditation is essential for modern trade which requires harmonization and consistency in the application of its rules worldwide to have a fair and balanced competition. However, in some circumstances, different practices are found at national and regional levels. To support the development of ILAC strategy, the ILAC Laboratory Committee decided in 2017 to develop an international survey on harmonization and consistency of accreditation to provide a global view of the concerns, expectations and challenges of

Laboratories and Conformity Assessment Bodies. 421 responses from 35 countries and economies were received, allowing an analysis divided in three parts:

- characterization and validation of the sample of participants;
- accreditation performance analysis; and
- satisfaction analysis regarding the services provided by AB's and improvement analysis.

Results are found in the ILAC LC report [11] and include the analysis of the following issues identified by stakeholders of the ILAC Laboratory Committee regarding the lack of consistency observed: Scope definition; Cycle and frequency of assessment; Quality of Assessment; Translation barriers; Non uniform interpretation of ISO 17025 at national level by Accreditation Bodies; Accreditation Body policies; Use of PT/ILC and similar quality control tools in assessment; and Lack of recognition of ILAC Mutual Recognition Arrangement.

The main conditions to measure the impact of the survey were [11]:

- number of replies should be statistical relevant;
- ideally geographical representation by countries and by regions;
- cover a wide range of activities;
- represent a range of small, medium and large companies and institutions;
- cover a range of small to large number of accreditation parameters (both testing methods and calibration parameters);
- capture respondents experience regarding accreditation process.

A critical issue regarding the development of the survey was how the sampling of laboratories that participated in the survey would represent the whole community and their activities.

The distribution of laboratories by activities showed that a large spectrum of domains were included, although there were higher participation in some fields, namely, agro-food, environment and metrology. Figure 5 shows the distribution of replies obtained by activity.

Another relevant feature of the survey was to develop a performance analysis of ABs, considering the main conditions for accreditation, namely, time to get accreditation; use of extra requirements for accreditation; cooperation with stakeholders; impact of quality control tools; surveillance time interval; and cycle of accreditation.

Finally, a section of the survey aimed to establish a procedure to evaluate the degree of satisfaction of the laboratories regarding the accreditation process in different aspects, such as:

- Quality and competence of the auditors;
- Quality of the interpretation guides;

- Accreditation process;
- Complaints procedure.

The classification obtained regarding aspects to be improved and best performed aspects of accreditation are presented in fig. 6 and Fig 7, respectively.

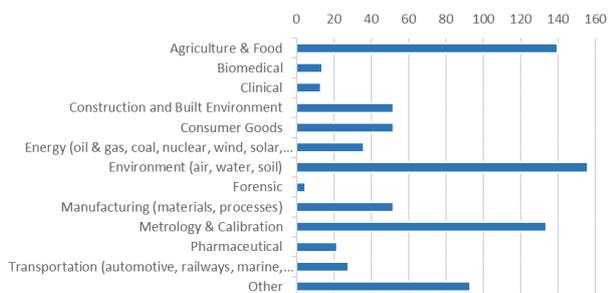


Fig. 5. Distribution of replies by types of activities [11]

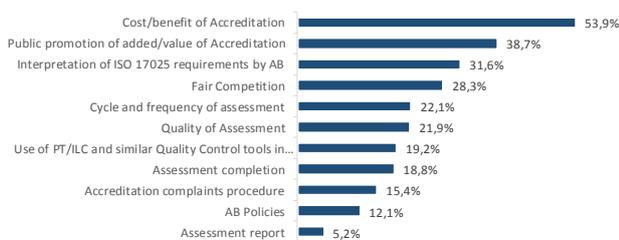


Fig. 6. Major aspects of accreditation needed to be improved in countries and economies [11]

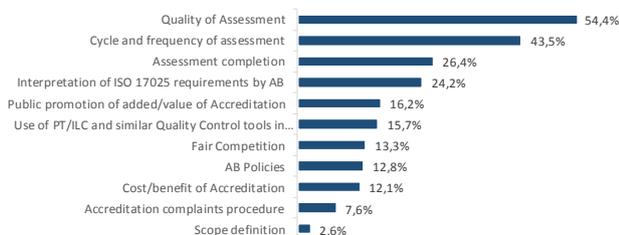


Fig. 7. Best performance aspect of accreditation in countries and economies [11]

V. CONCLUSIONS AND OUTLOOK

Accreditation plays a fundamental role in the economy and is expected to be an engine of economic development on a fair trade basis. In order to achieve this objective, it is necessary to ensure that the application and assessment to the standard requirements of ISO/IEC 17025 which is the reference standard for Laboratory accreditation, is applied worldwide in a balanced, harmonized and consistent manner.

The collaboration of the laboratory community for this purpose is necessary and the role of entities such as ILAC Laboratory Committee is particularly relevant, as demonstrated by the action of promoting a survey to this community in order to understand the current state of

implementation of accreditation, and its positive aspects and opportunities for improvement.

This approach has also enabled an independent evaluation of NAB’s performance as a way of supporting the evolution of accreditation and its recognition in the international context.

VI. ACKNOWLEDGMENTS

To the members of ILAC Laboratory Committee, co-authors of the 2017 International survey on harmonization and consistency of Accreditation. A global view of Laboratories and Conformity Assessment Bodies concerns, expectations and challenges.

To the laboratories and other stakeholders, national and international laboratory and conformity assessment bodies associations and international organizations that supported and contributed for this study.

REFERENCES

- [1] **Frenz, M.:** The Economics of Accreditation, Marion Frenz, Ray Lambert, UKAS, March 2013
- [2] **2017 definition Quality Infrastructure,** INetQI, adopted by BIPM, IAF, IEC, ILAC, ISO, ITC, ITU, OIML, UNECE, UNIDO and the World Bank.
- [3] **ISO/IEC 17025:2017** General requirements for the competence of testing and calibration laboratories, ISO, Geneva, Switzerland.
- [4] **ISO/IEC 17020:2012** Conformity assessment -- Requirements for the operation of various types of bodies performing inspection, ISO, Geneva, Switzerland.
- [5] **A Digital Single Market Strategy for Europe.** Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, 6 May 2015, Brussels, Belgium,
- [6] **European Commission Digital Strategy – a digitally transformed, user-focused and data-driven Commission,** European Commission, 21 Nov. 2018, Brussels, Belgium.
- [7] **Smart Cities. How rapid advances in technology are reshaping our economy and society,** Deloitte Report, Vers. 1.0, Nov. 2015.
- [8] **Digital Agenda for the EU. Digital transition action plan.** EC, 28 Jun. 2018, Brussels, Belgium.
- [9] **ISO 15189:2012 Medical Laboratories- requirements for quality and competence.** ISO, Geneva, Switzerland.
- [10] **White Paper: Trends & Challenges for the third party TIC Sector, and its implications for CEOC International,** September 2015, CEOC International, Brussels, Belgium.
- [11] **2017 International survey on harmonization and consistency of Accreditation. A global view of Laboratories and Conformity Assessment Bodies concerns, expectations and challenges.** ILAC Laboratory Committee report, April 2018.