

## EUROLAB Policy Paper

# The role of laboratories in testing, inspection and certification

## About EUROLAB

EUROLAB aisbl is the European federation of national associations, grouping together accredited laboratories of first, second and third parties. It represents and voices the opinion of measurement, testing and analytical laboratories regarding economic, political and technical issues having a direct impact on laboratories' activities on the European scene and worldwide. EUROLAB aims to promote cost-effective testing, calibration and measurement services, for which the accuracy and quality assurance requirements are adjusted to the actual needs.

EUROLAB provides to its members an open and interactive platform for discussions and exchange of information and viewpoints. Moreover, it plays an important role on the European scene by addressing, voicing and influencing European legislation which is of its members' interests, such as consumer protection, occupational health and safety, product and environmental safety.

## 1. Introduction

Measurement and testing are of fundamental importance to science, technology and the economy. "There is no science without measurements, no quality without testing and no global market without standards." (1)

Measurement<sup>1</sup>, testing<sup>2</sup> and inspection<sup>3</sup> play an important role in healthcare, food safety, undisputed drinking water quality, consumer protection, improving safety at work, monitoring and minimizing environmental hazards, improving product safety, etc. They are also important for detection and prevention of a range of criminal and other illegal activities such as doping in sport, food adulteration, sale of fake and inferior products, etc. (1). It is easily seen that almost all aspects in consumers' daily life is affected, but the economy in large is also dependent on the providers of measurement, testing and inspection services. Conformity with the requirements on products and services is the key for smooth functioning of the European Single Market as well as for the protection of the health and safety of European citizens and reducing environmental impacts. In addition, only flawless products are able to compete in international markets. Therefore, the benefits of the single market can only fully unfold for all economic operators if the conformity of the products traded in the single market increases significantly and sustainably.

Every sector has its different measurement, testing and inspection needs: chemical analytics differs from electromagnetic compatibility testing, just as regular vehicle inspection differs from inspection of financial services. The measurement, testing and inspection sector is therefore a highly diversified and specialized

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<sup>1</sup> Measurement : process of experimentally obtaining one or more values that can reasonably be attributed to a quantity ISO/IEC GUIDE 99 (2.1)

<sup>2</sup> Testing : determination of one or more characteristics of an object of conformity assessment, according to a procedure ISO/IEC 17000 (4.2)

<sup>3</sup> Inspection : examination of a product design, product , process or installation and determination of its conformity with specific requirements or, on the basis of professional judgment, with general requirements ISO/IEC 17000 (4.3)

sector that depends on trust in the results that the service providers deliver to consumers, customers, authorities or the economy at large.

Most recently, the rules of the European Union for placing products on the market were revised in the so-called 2008 Goods Package. This includes:

- Regulation No. 764/2008/EC on procedures for the application of national technical guidelines for products that have lawfully been placed on the market in another member state
- Regulation No. 765/2008/EC on rules for accreditation and market surveillance related to the marketing of products
- Resolution No. 768/2008/EC on a common regulatory framework for the marketing of products

In this updated framework of the “Quality Infrastructure” the role of measurement and testing performed by laboratories has been further manifested.

## 2. The testing, inspection and certification (TIC) sector

Testing is a specialised service, where the ability of the laboratory performing the tests to achieve accurate test results is the crucial factor. This ability is mainly determined by the competence and experience of the personnel performing the tests, the quality and suitability of the test equipment, including accurate calibration, and the quality assurance system of the laboratory. With respect to the methodology of testing, the following aspects are crucial in order to achieve the right level of quality:

- The laboratory must be able to choose and apply the test method that provide a technically correct and reproducible answer to the problem.
- The testing must be performed efficiently, and in such a way that delivery times can be met and costs and charges minimized.
- The laboratory must be able to provide reliable results with accuracy appropriate to the needs.
- The testing laboratory must have the necessary expertise available to be able to assist in the evaluation of the test results and to provide other relevant technical services of an advisory nature. The expertise may be in another organisational unit.
- The reports and presentations of the results must be clear and complete, and the recipient must be able to understand and apply them correctly.

Activities related to testing, inspection and certification<sup>4</sup> often are performed by third parties, i.e. entities that are fully independent of the manufacturer of a tested product or system, the service provider of an inspected service, the organisation that is audited etc. and where the entity has no user interest on the object or service.

Some of these activities may also be performed by first parties themselves (e.g. manufacturer’s laboratories or internal audit departments) and second parties (e.g. manufacturer’s laboratories for testing bought-in components, retailers testing laboratories etc.). If these activities are performed by accredited laboratories, their impartiality has been proven by their accreditation<sup>5</sup> and is monitored during accreditation audits. The results of accredited first and second party TIC entities are equivalent to those of third parties. The role of first, second and third party laboratories is further described in the EUROLAB Position Paper “First, second and third party testing – how and when”<sup>6</sup>.

<sup>4</sup> Certification: third-party attestation related to products, processes, systems or persons ISO/IEC 17000 (5.5)

<sup>5</sup> Accreditation: third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks ISO/IEC 17000 (5.6)

<sup>6</sup> EUROLAB Position Paper ‘FIRST-, SECOND- AND THIRD-PARTY TESTING - HOW AND WHEN?’; No. 1/2000, May 2000, EL/01-01/00/380

Testing and inspection services support the quality and safety of products through product performance evaluations. For placing a product falling in the scope of a regulation on the market in nearly all countries a proof of conformity with the regulation is required. This proof may be drawn up by the manufacturer himself, based on verification of conformity in the form of test reports or by certification. Certification is a special form of these services, where an independent third party attests that a product conforms with given specifications or a service or a management system is performed or operated according to the specification laid down. Certification is based on test reports, inspection reports and audit reports. The certification body may run its own laboratories, employ its own inspectors or auditors or may rely on reports from external institutions of proven quality. Certification companies that operate internationally normally offer certificates that allow market access in many countries and so help manufacturers to act in the global market. In many markets the proof of conformity by the manufacturer itself is not recognized and a certificate by a third party is indispensable for market access.

Manufacturers and second parties have the choice of using the services offered by third party companies, individual or bundled services, or to establish their own service departments or testing laboratories. For companies it is for every requested service a case by case decision whether to establish their own expertise or to buy services provided on the market. Results of these services needed for other than internal purposes normally require that the service provider gives proof of his competence and the quality of the service provided. Normally this is done by accreditation through the national accreditation body (NAB) which is equally applicable to first, second and third party service providers.

Some manufacturers, mainly larger companies, have established such service entities that are operated independently from the product business lines, some of them are accredited and have so demonstrated their impartiality and competence within the accredited scope. They normally don't run as a profit centre and so seldom offer services on the market. Some legislation, e.g. in the medical devices area, even require from manufacturers that they operate internal production surveillance entities and test facilities in order to get licenced for the manufacture of such products. Examples of such types of laboratories are e.g. electrical safety tests according to international safety standards, electromagnetic compatibility test halls, radiation protection test centres, chemical purity laboratories for educts and finished products and the like. These service entities normally require a major investment and are used in larger companies for more than one business unit and run independently from the production process.

### Market segments and trends<sup>7</sup>

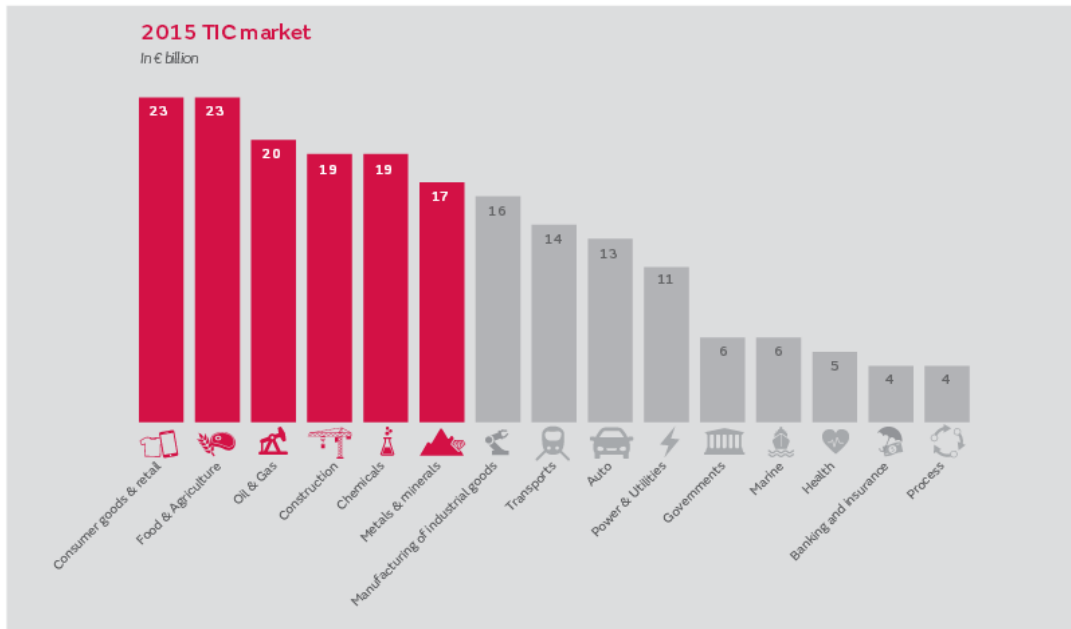
The TIC sector is characterized by a variety of segments, industries and technical niches which have different characteristics, drivers and growth stimuli.

**The Industrial sector** is mainly dominated by oil & gas, energy and transportation. **The building and construction sector** is a cyclical market with growing limitations in the western economies. Nevertheless, this sector is constantly developing thanks to the ongoing regulations focused on green and sustainable buildings. **The Consumer sector** includes testing, product inspection, process assessment and technical assistance for all types of products (e.g. electronics, toys and textiles). This sector is dominated by tighter regulations and the need to assure that all important criteria are properly and thoroughly evaluated. Thus there is an increased demand coming from the manufacturers' side for product testing services in order to reinforce the reputation and consumers' trust in their products. Both mid-market and larger players have been targeting consumer focused TIC companies.

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<sup>7</sup> Mergers Alliance, Global testing, Inspection and Certification, M&A updates, Summer 2012

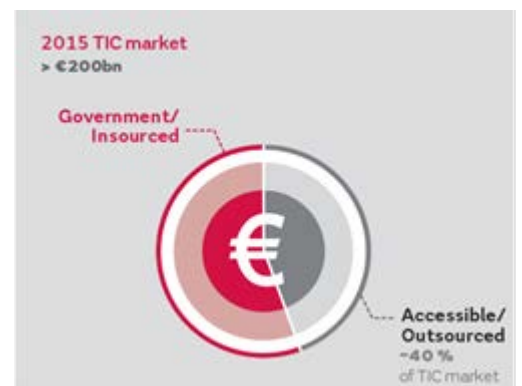
According to Bureau Veritas the estimated size of the TIC in 2015 was €200 billion, based on external macro-economic data such as investment volume per market, operational spending per market, the production value of goods and services, and the level of imports and exports. In the image below TIC was divided by sector, showing that the biggest markets are those relating to consumption, followed by oil & gas, construction, chemicals and mining.<sup>8</sup>



Source: IHS, Bureau Veritas estimates

The TIC market can be divided in two segments<sup>9</sup>:

- the accessible (outsourced) market where the private organisations or firms are the ones that provide the services and are specialised in testing, inspection and certification. The size of this market might vary according to factors such as the administrative organisation of the country, whether or not is industry focus or federal structure.
- the internal (insourced) market: the companies perform the TIC services as part of control and quality assurance; alongside with other public bodies and organisations that serve this market such as competition and port authorities, customs, industrial health and safety authorities.



Source : Bureau Veritas 2015 Registration Document

The figures and balance between these two markets can vary every year depending on the different policies implemented by the country's government and on the different practices used by the industry.

### 3. Challenges for the laboratories in a changing world

There are several major trends which have a considerable impact on overall technical and technological development and consequently on development in the field of measurement and testing: (2)

<sup>8</sup> Bureau Veritas Performance Perspective, 2015 Registration Document incorporating the Annual Financial Report, Chapter 1.4. The TIC industry, pages 12-13.

<sup>9</sup> Ibid

- The globalisation of world trade leads to a harmonisation of requirements and standards as well as to the development of global markets for products and services. This globalisation process also has repercussions on industrial and private testing laboratories.
- Small laboratories are being taken over by larger ones who are able to offer economies of scale. Larger organisations often merge and the past ten years has seen the rapid growth of global companies, which set up and operate laboratories in many countries. This trend is likely to continue to the point where the European laboratory community is very different in number and configuration to that of the present time.
- International agreements, such as GATT, WTO and mutual recognition agreements, dominated by the preoccupation of facilitating international trade, are aimed at avoiding unnecessary duplication of testing. Contrary to this, trade regions are trying to improve their competitiveness by increasing their exports and limiting their imports. In some cases, new barriers including technical ones to trade are thus created, e.g. by requiring that tests may only be performed by laboratories within the country.
- Local and regional networking of industry and service providers is taking place, the aim being to conquer international markets. As a result, the challenge for the laboratories is to get recognition/acceptance of their reports outside the national borders and thus increased visibility and impact.
- The quest of customers and society for improving the quality and safety of products is resulting in a greater awareness of the importance of market surveillance. Market surveillance is also a request of industry concerned with the fairness of competition between producers. This may infringe with the increased openness for free trade. In measurement and testing, there is a need to get comparable results in the determination of the characteristics irrespective of the organisation performing the market surveillance.
- The predictability of the technical development becomes more difficult as the time from designing a new product to marketing the final product is considerably shortened and industry is eager to create new markets.
- Besides these challenges in the geo-economic trade structure, technology is developing at high pace. Digitalization and trends based on it like Industry 4.0 make data and their communication the new business model. It has moved on from the state of being a new trend in industry and trade and is the new and fast growing market with new possibilities and threads. Data protection for safety, security and privacy reasons form a new challenge for testing, inspection and certification, requiring new methodologies and approaches to make this development a success story.

#### 4. Testing, inspection and certification support standardisation

Measurement, testing, and inspection all depend on and rely on standardisation. For comparability and therefore mutual acceptance of test results, a test must be performed against the same requirements using the same test method, specified in international standards. On the other hand, the competence of laboratories must be of the same level to achieve test results of equal quality and at comparable prices. These requirements are laid down in international standards also.

As a service provider, conformity assessment bodies themselves must meet differentiated specification standards that describe the state of the art with regard to the organisation and the competence of conformity assessment bodies. The ISO/IEC 17000 series of standards brings uniformity to conformity assessment and therefore makes a key contribution to the comparability and recognition of conformity assessment results. The same normative basis should be used to ensure a uniform level of competence throughout Europe in the course of accreditation.



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New standardization projects in the area of services can stimulate the European Single Market for services. Here, as the Commission rightly points out, there is still considerable need to catch up when it comes to a common understanding of what requirements the service provider has to meet cross-border. Services, which correspond to a conformity assessment or are of a similar nature to this, fundamentally require no new normative framework. Here, the laboratory community recommends the use of the existing ISO/IEC 17000 series of standards to ensure maximum consistency of the normative foundations.

Standardisation – market-oriented, organised and financed by the private sector:

The Commission rightly states in its communication that it "needs to be up to these challenges, producing timely and market-driven standards in an inclusive way and consolidating Europe's leadership in international standardisation." They should therefore standardize where the economic operators identify a corresponding need in the market. This applies in particular for the supporting role of standardisation in innovative sectors such as ICT. The private sector organisation and financing, as well as the national delegation principle, which states that every country is represented in Europe or internationally due to its national standardisation organisation and other players have no voting rights, provide a robust framework for this.

## 5. The European Conformity Assessment System

For more than 25 years, the "New Approach" has been in existence as a recognised set of rules for the marketing of products within the European internal market. Legislative harmonisation is limited to the essential requirements (performance or functional requirements) that products placed on the EU market must meet if they are to benefit from free movement. Products falling within the scope of the New Approach directives or regulations may basically only be put into circulation if they bear the CE marking. The party responsible for putting the products into circulation is the manufacturer. By applying the CE marking to his products, he declares that they are in compliance with the relevant legal provisions, and in particular with its essential health, safety and environmental requirements. The technical specifications for products meeting the essential requirements are laid down in harmonised standards which have to offer a guaranteed level of protection with regard to the essential requirements. Regulation (EU) No 1025/2012 on European Standardisation gives the Commission the possibility of inviting, after consultation with the Member States, the European standardisation organisations to draw up harmonised standards and it establishes procedures to assess and to object to harmonised standards.

On the basis of ISO/IEC standards, the EU consolidated conformity assessment procedures and the rules for their selection and use in directives (the modules). The modules are set out in a manner to favour their selection from the lightest ("internal control of production") for simple products or products not necessarily presenting serious risks, moving to the most comprehensive (full quality assurance with EU-design examination), where the risks are more severe or the products/technologies more complex. In order to face up to modern manufacturing processes, the modules foresee both product conformity assessment processes and quality management assessment.

Depending on the risk potential of the products, either the manufacturer alone is responsible for the conformity assessment procedure, or a notified body must be involved. A notified body is an independent inspection and certification body, which reviews the conformity assessment as performed by the manufacturer and testifies to its correctness based on unified evaluation criteria. The independence and competence of the notified body is guaranteed by means of national notification (normally mandated through accreditation) in the individual EU Member State; designation and surveillance of Notified Bodies is performed by the relevant state authorities.

The overall system of the New Approach with its corresponding EC directives or regulations and the conformity assessment procedures embedded in them has proven its worth. In order to continuously improve and to further develop health and consumer protection in Europe a focus should be placed on enforcement and harmonised application of the set of rules. With respect to the conformity assessment procedures, the role of the Notified Bodies within the overall system as independent control and surveillance bodies has to be maintained, and a European-wide equal level of competences should be assured accordingly. Well designed and applied processes and procedures lead to effective inspection and control of products and installations thus ensuring their compliance.

EUROLAB proposes the following improvements:

- Augmenting the current Notified Bodies system by promoting the European accreditation system.
- More influence of the accredited organisations and the opportunity to provide feedback on the general accreditation procedures and the interpretation of requirements is requested in those countries where this requirement of the European Regulation on National Accreditation Bodies (NABs) has not yet been sufficiently implemented.
- Accreditation processes should be as easy and flexible as possible, faster and more cost-effective. NABs should use market-oriented approaches, e.g. concerning the definition of accreditation scopes. There should be close collaboration with the notifying authorities.
- Additional expectations concern: more experienced assessors, feedback on complaints, suitable scopes of notified bodies in the NANDO database, and more transparent notification processes.
- Inclusion of Notified Bodies in the information flow of market surveillance authorities.

**6. Accreditation improves the robustness and the comparability of testing, inspection and certification activities**

A harmonised and credible accreditation system is of great importance for the laboratory sector. Accreditation is the method of ensuring competence in delivering conformity assessment activities. Such a system must be based on harmonised requirements and their application, be transparent, impartial efficient and authoritative. The accrediting process is based on a reliable and systematic approach to determine the competence of a laboratory, inspection or certification body.

Laboratory accreditation attests the technical competency of a laboratory to perform specific tests, types of tests or calibrations. When it comes to testing, accreditation attests that test results are obtained according to valid methods and procedures that comply with precise standards. When it comes to calibration, accreditation guarantees the laboratory capacity to carry out calibrations and metrological verifications in a certain domain and with specified uncertainties.



An example: How Accreditation impacts our every day's life in an office (UKAS)

Using accredited laboratories also facilitates trade and economic growth. The accrediting process is based on a reliable and systematic approach to determine the competence of a laboratory, an approach that has been accepted and implemented across borders. But at the same time, accreditation needs to enable a fair competition among accredited laboratories on a global market. This will be compromised if the application and interpretation of the necessary requirements and competences of assessors varies between national accreditation bodies.

An inquiry conducted by EUROLAB members reflecting the practices of EA<sup>10</sup> members noted an inconsistency and variation of the average time interval between the following on-site visit after the first surveillance of between 15 months and two years. Increasing the frequency of surveillance visits did not result in any improvement of the overall quality of laboratory work – but it did cause additional costs for those laboratories (and consequently for their customers). Another potential concern is the need for better coordination among accreditation bodies when it comes to cross-frontier accreditation and assessment. The original idea of this policy was to reduce the administrative burden for conformity assessment bodies and manufacturers that are active and have laboratories in several countries but – at least in Europe - the opposite happened and the system is now so bureaucratic that few conformity assessment bodies use it. Instead most multinational entities continue to have their local entities accredited by local Accreditation Bodies, resulting in multiple accreditations from various Accreditation Bodies, even though these local entities work under the supervision of the head office and under the same quality system and management. The same happens to accredited manufacturers laboratories that need a multitude of accreditations when serving the global market.

<sup>10</sup> The **European co-operation for Accreditation** or **EA** is an association of national accreditation bodies in Europe that are officially recognised by their national Governments



## 7. The European system of testing, inspection and certification must be competitive worldwide

EUROLAB distributed to its National Members a questionnaire on *Accreditation and Notification. Views and experiences of EUROLAB members*, which was meant to reflect the situation in the country and the views and needs of the national laboratory community (3). From the results of this inquiry the EUROLAB community could draw its own conclusions both at the national and the European level:

- An influential involvement in the general policies of the NAB which is required both in the European Regulation and in ISO/IEC 17011 is of great importance for EUROLAB members. For this purpose, the EUROLAB organisation strongly supports an effective representation in the relevant technical committees which should permit the participation of as many as possible active members.
- EUROLAB aisbl as a representative of the European laboratory community is continuously improving and strengthening its representation at all levels of EA through the active participation of EUROLAB representatives in the various committees and working groups of EA, ILAC, IAF and of the national accreditation bodies. This participation allows the laboratory sector to monitor developments at an early stage and to work towards a common approach, while at the same time upholding the good relations between accreditation, conformity assessment bodies and independent laboratories.
- EUROLAB highly supports the idea that voting rights for stakeholders, as they are already the custom in IAF and some national accreditation bodies, should also be introduced in EA and ILAC, to give all involved parties greater influence. In addition, a greater role should be given to stakeholder committees such as the EA Advisory Board (EAAB). Structures should be put in place ensuring that stakeholders can have de facto impact on the accreditation organisations' decisions and policies.

As an overall conclusion the expectations of the EUROLAB community, generally refer to a better harmonisation of accreditation and notification procedures throughout the European Economic Area in order to ensure a level playing field for the CABs and laboratories. Concerning what is expected of the different parties (NABs, notifying authorities, EA, European Commission) it should be kept in mind that due to the diverse experiences in the individual countries not all expectations are common in all countries. Whenever possible the setting of accreditation rules and guidance should be a top-down process, i.e. the documents are developed on an international level and are then transposed into the European / regional and national system. This will ensure a level playing field on a global scale.

## 8. EUROLAB profile

EUROLAB was created in Brussels on April 27, 1990 on the basis of a memorandum of understanding, signed by delegations representing at that time the private and public laboratories of 17 out of the 19 countries of the EEC and EFTA. Since October 1998 EUROLAB is a legal entity in the form of an international association under Belgian law (A.I.S.B.L. - Association Internationale Scientifique sans But Lucratif) setting it as the European Federation of National Associations of Measurement, Testing and Analytical Laboratories.

### Objectives

- Representation by formulating and voicing the opinion of European laboratories regarding political and technical issues having a direct impact on their activity, both on the European scene and worldwide.
- Coordination by interfacing with all European organisations having activities of interest to the laboratory community, and striving to avoid duplication of efforts and activities.

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- Action by providing adequate means for exchange of information and experience, such as the publication of our Position Papers, Technical Reports, Newsletter, Seminars, and Working Groups etc.
- Promoting cost-effective testing, calibration and measurement services, for which the accuracy and quality assurance requirements should be adjusted to actual needs.

### Mid-term Policy

EUROLAB's mid-term policy aims to:

- Support EUROLAB members' interests – interfacing with accreditors – and to help them in technical, regulatory and quality management matters, aiming at simplification and international harmonisation of regulations concerning competence and performance of laboratories.
- Be the major EUROPEAN multisectorial forum for laboratory and conformity assessment services, making product certification and technical evaluation more visible in EUROPE.
- Become a major EUROPEAN focus point for laboratory intercomparisons and proficiency testing.
- Act as important partner of the EC, EFTA and the standardization institutes, participating in international organisations such as EA, ILAC and developing links with other relevant communities worldwide.
- Use the EUROLAB network for public relations, and the provision of EUROLAB members' expertise to customers for the benefit of the European economy and society.

EUROLAB is cooperating with other organisations including:

- CEOC International (Confederation of Inspection and Certification Bodies) which is the European trade association that represents 30 independent inspection and certification organisations in 19 countries, and IFIA (International Federation of Inspection Agencies) which is a trade association that represents more than 50 of the world's leading international testing, inspection and certification companies. Already EUROLAB through its MoU with CEOC and collaboration with IFIA in arranging annual Safety Seminars and publishing joint position papers, is doing much to promote recognition of the importance of the TIC sector.
- EURAMET (The European Association of National Metrology Institutes) is a Regional Metrology Organisation (RMO) of Europe. Through this co-operation EUROLAB aims to develop joint projects related to technical procedures and issues that are of interest to the applied metrology and calibration community. More active cooperation between EUROLAB and EURAMET raises new possibilities for metrological and calibration laboratories in the areas of innovation and research, finding new solutions for industry.
- UILI (The Union Internationale des Laboratoires Indépendants) which is the worldwide organisation for testing and calibration laboratories, and for scientific consultants, and with NCSLI in the United States of America which is a professional, member-based organisation aimed at enhancing the understanding, application and advancement of measurement science across a broad range of disciplines. EUROLAB acknowledges the importance of collaborating with international organisations in order to extend its global reach, support its international position while giving a stronger 'global' voice.

## 9. Conclusions

Measurement and testing underpins the welfare of a modern society and touches almost every part of daily life from ensuring the safety and effectiveness of healthcare diagnostics and treatments, ensuring consistency of international standards and air quality monitoring, security and sustainability of our food supply to products safety. Measurement also plays a fundamental part in the innovation process. To develop new and improved products and processes, companies are looking for: improvements in quality or performance, reductions in waste, use of new materials or techniques.<sup>11</sup>

The goal of EUROLAB and its members is to be recognised as the voice of safety, compliance and quality in Europe and world-wide. But in order to achieve this goal continuous laboratory self-assessment is required. The laboratory community must be valued for its contribution to the improvement of quality and reliability of testing, and its role for making sure that the liberalisation of trade is not detrimental to health, safety and environmental protection.

EUROLAB considers it fundamental to convince EU officials, politicians and the business community that the measurement and testing industry adds value, protects consumer interests, guarantees the compliance of products placed on the market with relevant legislation and standards, but does not impose costs on business which would damage European competitiveness.

EUROLAB will focus on finding solutions to the wide range of challenges and will continue to be the effective voice of the European laboratory community.

## 10. Literature

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<sup>11</sup> Measurements in daily life, The National Measurement System, <http://www.npl.co.uk/upload/pdf/measurement-matters.pdf>